Data & AI Consultancy

Uncovering workforce and skills gaps in regenerative medicine

An analysis of current and future workforce and skills gaps within the regenerative medicine sector in Denmark and the Greater Copenhagen Region

JULY 2024

Disclaimer

This report presents an initial analysis of the skills demand and workforce gaps within the emerging field of regenerative medicine and advanced therapy medicinal products (ATMPs) in Denmark and the Greater Copenhagen Region. However, it is important to note that ADC does not claim that these insights are fully representative of the entire countries or industries in question. The findings presented are based on the data available and analysed at the time of the research and should be understood as indicative, rather than definitive, of the broader situation. They serve as a starting point for understanding the dynamics of this field and should be complemented with further studies for a more comprehensive understanding. Given the novelty of this sector, its competitive nature, and the inherent challenges of accessing proprietary knowledge, the scope of the analysis is necessarily limited.

Despite these limitations, the findings of this study are valuable. They provide a holistic view, crossing boundaries of different technologies in ATMPs, various types of workforce, labour market actors, and geographical locations. This approach, to ADC's knowledge, is novel in Denmark and the Greater Copenhagen Region and provides new insights that either have not been documented before or have only been assumed.

This report should therefore be seen as a stepping-stone towards a deeper understanding of the workforce and skills demand within regenerative medicine. While it may not provide a complete picture, it contributes to the collective knowledge base, serving as a catalyst for further research and discussion in this rapidly evolving field.

The analysis presented in this report is conducted in good faith. ADC cannot foresee future events, developments, or uncertainties. As such, any predictions or portrayals of future scenarios outlined in this report may be incorrect or incomplete. The actual outcomes and progressions may deviate from those projected or stated in this report. ADC does not guarantee or assure that any of the future scenarios described herein will be realised. The content of this report should not be relied upon as a guarantee or assurance of future events. ADC holds no responsibility for any damages incurred from decisions based on this report or any future predictions contained within, except where determined by applicable mandatory laws.

List of abbreviations

AI – Artificial Intelligence

AP – Academy Profession

AR – Augmented Reality

ATMP – Advanced Therapy Medicinal Product

CAGR – Compounded Annual Growth Rate

CAR-T – Chimeric Antigen Receptor T-cells

CDMO – Contract Development & Manufacturing Organisation

CMC – Chemistry, Manufacturing, and Controls

CMO – Contract Manufacturing Organisation

CRISPR – Clustered Regularly Interspaced Short Palindromic Repeats

CRO – Contract Research Organisation

CSO - Contract Service Organisation

CTA – Clinical Trial Application

CTMP – Cell Therapy Medicinal Product

DREAM – Danish Research Institute for Economic Analysis and Modelling

DTU - Technical University of Denmark

EMA – European Medicines Agency

EUROSTAT – Statistical Office of the European Union

FDA – Food and Drug Administration

FTE – Full Time Employee

GMP – Good Manufacturing Practice

GTMP – Gene Therapy Medicinal Product

HR – Human Resources

iPS cells – Induced Pluripotent Stem Cells

ISCED – International Standard Classification of Education

ISCO – International Standard Classification of Occupations

LIT - Labour Intelligence Tool

MSC Nordics – M S&C Nordics AB

QA – Quality Assurance

QC – Quality Control

RM – Regenerative Medicine

S&Es – Scientists & Engineers

SAP – Self Assembling Peptide

sCTMP – Somatic Cell Therapy Medicinal Product

SME – Small and Medium-sized Enterprise

SOP - Standard Operating Procedure

UNESCO – United Nations Educational, Scientific and Cultural Organisation

TCR-Sequencing – T-cell Receptor Sequencing

TEP – Tissue Engineered Product

VR – Virtual Reality

Key results

Regenerative Medicine (RM), driven by Advanced Therapy Medicinal Products (ATMPs), presents new opportunities for patient treatment. As this field grows, it requires a specialised workforce that surpasses the currently available talent, highlighting a need for education tailored to RM. This report offers insights into the current and future workforce and skills demand within RM and educational measures needed in Denmark and the Greater Copenhagen Region to bridge the most prevalent gaps.

The findings are primarily based on the opinions, experiences, and expectations of industry professionals and educational representatives. While these do not provide a complete overview, they offer valuable perspectives on the current and future challenges. However, these insights are subject to uncertainties and may not fully capture the extent of the skills gaps across the sector.

*The skills gaps are not listed in prioritised order.

Projections

The Danish RM industry is projected to demand up to 2.000 FTEs by 2035.

A deficit in talent supply of up to 600 FTEs is expected in RM in 2035, almost one-third of the demanded workforce.

The largest deficits are expected in candidates with master's and PhD degrees.

Industry growth and maturity are expected to increase the demand for candidates with shorter educations.

Workforce & skills demand

Of 27 surveyed representatives from the Nordic RM sector, 18 experience a skills gap.

Scientists & Engineers are perceived as having more prevalent and varied skills gaps, compared to technicians.

Profiles in biology, cell biology and engineering with the required skills for RM work are perceived as the hardest to find.

The sector requires more interdisciplinary talent with dual expertise in biology and manufacturing.

Current state

Scientists & Engineers primarily lack skills related to manufacturing, compliance, regulatory expertise and clinical application.

Prevalent skills gaps in S&Es*:

- Manufacturing and compliance skills: QA, QC, CTA, GMP, process and analytical development, ATMP production, bioprocessing.
- Drug approval knowledge including understanding regulatory requirements and submission processes.
- Clinical application skills including clinical knowledge, administration and dosage, and cell delivery devices.
- Translational research skills including value chain understanding and interdisciplinary skills in combining biology, engineering and clinical application.
- Specialised skills in cell and gene technologies.

Technicians primarily lack skills related to compliance, manufacturing and translational research.

Prevalent skills gaps in technicians*:

- Skills in GMP, QA and QC including analytical testing methods, protocols and handling procedures for stability testing.
- Translational research skills including value chain understanding and knowledge of cell biology.
- Manufacturing skills including process development and standardisation, scale up proficiency, bioreactors, and bioprocessing.
- Cleanroom behaviour and practices including gowning, aseptic working practices, and environmental monitoring.
- Hands-on experience to complement theoretical knowledge.

Future state

- Skills gaps linked to transitioning from pre-clinical to clinical stages will likely remain a long-term bottleneck.
- Skills in clinical application, commercialisation, and regulatory compliance are expected to grow in importance.
- As products advance to later-stage development, the demand for a larger workforce grows, highlighting the need for ATMP-related education to ease talent competition with other industries.
- Despite current lesser needs for process and manufacturing technicians due to product immaturity as well as less profound skills gaps in lab technicians, a shift towards large-scale manufacturing will likely require a larger, more skilled technician talent pool.

Potential educational measures to bridge the gap

- Educational programmes in ATMPs for biopharmaceutical profiles.
- Options for specialising in ATMP related skills as part of short-term educational programmes for technicians.
- Closer collaboration between industry and educational institutions through e.g. industry professionals as educators.
- Hands-on training accompanied by simulation training.
- Apprenticeships and internships to gain practical experience.
- Micro-credentials and other continuing education options.

Table of content

Introduction

Navigating new terrain requires a rethinking of the workforce

Regenerative medicine (RM), driven by Advanced Therapy Medicinal Products (ATMPs), is revolutionising healthcare by enabling the regeneration, repair, or replacement of damaged cells and tissues. As this field expands, it necessitates a workforce with specialised skills that currently exceeds the available talent, especially in the Nordic countries where ATMP development is still emerging. However, scant knowledge exists on the industry's specific workforce needs.

This analysis aims to define and understand the current and future workforce and skills demand within the RM sector compared to the talent supply specifically in Denmark and the Greater Copenhagen Region*. By identifying the existing skills gaps, the report seeks to inform and guide the establishment of targeted educational and strategic initiatives. The goal is to provide stakeholders with actionable insights for decision-making, ensuring a skilled and capable workforce aligned with the sector's evolving needs.

The methodology adopted for this analysis began with desk research to establish a foundational understanding of the current landscape. Desk research was complemented by an analysis of the Danish job market to discern prevailing skill trends and a projection of workforce demand and supply using data from Statistics Denmark. To refine these insights, a survey was sent to key industry professionals and educational representatives, followed by interviews with these representatives. Global industry representatives have been interviewed to put the results into perspective.

While each organisation has its own specific needs and challenges, this report focuses on the experiences shared by many. The findings of this analysis reveal experiences of notable skill shortages across various professional profiles, with the most acute gaps observed in manufacturing and compliance skills for Scientists and Engineers (S&Es). While skills gaps for technicians are currently experienced as less prevalent, their significance is expected to increase as the industry matures. Furthermore, a critical transition challenge is expected in the move from preclinical to clinical development, which requires interdisciplinary talents adept in both manufacturing and biology, alongside regulatory expertise. Moving forward, there is a projected need for skills in commercialisation and clinical application.

In response to these challenges, stakeholders underscore the importance of implementing diverse educational initiatives including specialised long and short-term ATMP-focused educational programs, innovative training methods, and internships and apprenticeships. Furthermore, there is a call for life-long learning opportunities for the existing talent pool.

*Encompassing the Capital Region and Region Zealand in eastern Denmark and Region Skåne and Region Halland in southern Sweden.

Thank you to the expert group of the analysis, who have contributed by providing guidance on the approach and results of the analysis and given insights from their own experiences of the workforce needs. The role of the expert group has been to ensure that the findings from this project align with the sector-specific knowledge that the industry and educational experts hold, and to ensure quality of the results generated throughout the project.

- **Johan Flygare**, Associate senior lecturer, Lund University, Division of Molecular Medicine and Gene Therapy
- **Thomas Hassing Ronøe Carlsen**, CEO, Novo Nordisk Foundation Cellerator
- **Anne Mette Nøhr**, Project Director, Novo Nordisk
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- **Inge Marie Svane**, Professor, MD, Director. Center for Cancer Immune Therapy, Department of Oncology, Copenhagen University Hospital, Herlev
- **Ditte Caroline Andersen**, Professor, Department for Clinical Biochemistry, Odense University Hospital and University of Southern Denmark

The methodological basis consists of six interconnected pillars

Desk research

Desk research was conducted with the objective of identifying existing knowledge and relevant data sources. During this research, studies on the skill needs within RM and ATMPs were identified, inspiring the approach in this analysis.

Furthermore, the desk research phase has provided a directory of concepts, and a preliminary understanding of the skill needs in the workforce.

Job post analysis

An analysis was conducted on the Danish job market to identify job postings relevant to RM. The analysis covered all job postings between January 2020 and October 2023, revealing 5.794 job postings relevant to RM or related fields out of a possible 1.191.337.

These job postings were analysed to identify the highest demand for skills and educational backgrounds. The results were used as background knowledge for the following survey and interviews.

Survey analysis

A survey was sent to companies, organisations and educational institutions assumed to be relevant to RM in the Nordics.

The survey was sent to 121 candidates. 36 completed the survey of which 25 were confirmed to work with RM and 2 expect to do so within 10 years, resulting in a response population of 27. Results should thus be interpreted with caution and should not be considered as fully representative or capturing the total extent of the sector's needs.

Projections

An analysis of the Danish labour market was conducted using data from Statistics Denmark.

The analysis is based on a general biotech and pharma workforce, since it is assumed that this workforce encompasses the RM workforce, which is not well defined.

The results are then interpolated to create inferences about trends for the RM workforce in Denmark towards 2035.

Interview analysis

To gain a deeper understanding of the workforce demand, interviews* were conducted with 21 industry representatives and 2 authority representatives.

Additionally, interviews were conducted with 16 educational institutions to understand how they currently supply skilled talent to the workforce. Some educational institutions we interviewed in dual roles as educators as well as employers.

Global ecosystem analysis

9 interviews were conducted with representatives from 6 different international ecosystems, including Germany, France, Japan, Singapore, the UK, and the USA.

The interviews focused on uncovering the initiatives that drive and complicate the success of these ecosystems, and identify trends, current skill needs, skills gaps, and educational initiatives to provide perspective to the Nordic ecosystem.

*Interview respondents overlap with survey respondents.

Field definitions

RM may be defined as "the process of replacing or regenerating human cells, tissues, or organs to restore or establish normal function"[1]. The analysis examines the skills demand within RM with a specific focus on ATMPs.

Most new RMs are classified by the European Medicines Agency (EMA) as being ATMPs, which are "engineered RMs encompassing cell-based therapies, gene therapies, and tissue-engineered therapies"[3]. The analysis adopts the EMAs definition of ATMPs as described on the upper right of this page. Consequently, this analysis does not include RMs such as bone marrow transplants, which are regulated as transplants rather than medicines[4]. See appendix A for a detailed definition.

The development life cycle for ATMPs is illustrated on the bottom right. While this process shares characteristics with conventional drug development, there are unique considerations and challenges. During the manufacturing of ATMPs, processes are often developed concurrently with clinical development, frequently involving small-scale production for early-stage clinical trials (phases I-II). Normally, when conventional drugs advance to later stage clinical development (phase III), development is relatively predictable as the drugs are synthesised through well-known chemical processes that can be controlled and standardised. However, in the manufacturing of ATMPs, e.g. autologous cell therapy, treatments are often personalised for individual patients, preventing a high degree of predictability and standardisation. Furthermore, traditional drugs are usually produced on a large scale for a broad patient group, rather than being personalised for individual patients. Given the often-personalised nature of ATMPs, the manufacturing process may need to be adapted for each patient, adding further complexity.

[1]Association for the Advancement of Blood & Biotherapies (2024): Regenerative Medicine
[2]Institute for Stem Cell & Regenerative Medicine (2024): What is regenerative medicine?
[3]Corbett et.al (2017): Innovative regenerative medicines in the EU: a better future in evidence?
[4]UK Parliament (2016): Written evidence submitted by the Medicines and Healthcare products Regulatory Agency.
[5]European Medicines Agency (2024): Advanced Therapy Medicinal Products: Overview.

EMAs definition of ATMPs:

"Gene therapy medicines (GTMPs): These contain genes that lead to a therapeutic, prophylactic or diagnostic effect. They work by inserting 'recombinant' genes into the body, usually to treat a variety of diseases, including genetic disorders, cancer or long-term diseases. A recombinant gene is a stretch of DNA that is created in the laboratory, bringing together DNA from different sources.

Somatic-cell therapy medicines (CTMPs/sCTMPs): These contain cells or tissues that have been manipulated to change their biological characteristics or cells or tissues not intended to be used for the same essential functions in the body. They can be used to cure, diagnose or prevent diseases.

Tissue-engineered medicines (TEPs): These contain cells or tissues that have been modified so they can be used to repair, regenerate or replace human tissue.

In addition, some ATMPs may contain one or more medical devices as an integral part of the medicine, which are referred to as **combined ATMPs**. An example of this is cells embedded in a biodegradable matrix or scaffold."[5]

ATMP Product development life cycle*

Research	Development	Commercialisation
• Discovery/idea • Exploration • Pre-clinical testing and safety • *In vivo* proof of concept	• Clinical trial application • Product manufacturing, GMP, CMC • Clinical trials I-III • Safety and efficacy data • Product filing	• Phase IV studies and pharmacovigilance • Marketing & price negotiations • Large scale production and clinical implementation

** The illustration of the process is created from knowledge gathered through review of material on the subject and interviews with industry professionals.*

Workforce definitions and terminology

The RM workforce largely reflects the broader life science workforce, encompassing a diverse range of roles spanning research and development, biomanufacturing, clinical care, and regulatory affairs[6].

In this report, the term "workforce" is defined in alignment with the UNESCO categorisation of "Scientific and Technical Personnel", falling under two main groups: "Technicians" and "Scientists & Engineers"[7] as defined by Eurostat. The definition excludes roles falling outside of these groups such as cleaning, general maintenance, and HR personnel, among others. This decision was made to focus the analysis on roles deemed essential for advancing ATMP development, while recognising the diversity of roles that collectively contribute to this development. While a larger number of groups could provide more detail to the analysis, it would also excessively complicate data collection.

S&Es and Technicians typically undergo different tertiary educational programmes with different durations – long-term university degrees versus short-term degrees at universities, university colleges, technical colleges, etc., respectively. Therefore, differentiating between the groups is crucial to understanding the specific educational initiatives needed for each. However, the demarcation between roles filled by different educational backgrounds is not always clear. Some technician roles may be filled by individuals with university degrees, or even PhDs, rather than those with a traditional technician background. Thus, in some cases, it is challenging to create a unified definition of the workforce from an educational perspective compared to an industry perspective.

At the start of the survey and before interviews, the representatives were made aware of the definitions to ensure clarity regarding the roles discussed and were asked to add their reflections on the definitions if relevant. However, this does not eliminate the risk of interviewees interpreting the discussed roles outside the agreed definitions, meaning minor variances might occur.

[6]US Government Accountability Office (2023): Regenerative Medicine and Advanced Therapies: Information on workforce and education.
[7]Eurostat Statistics Explained (2022): Glossary: Scientific and technical personnel.
[8]Eurostat Statistics Explained (2023): Glossary: International standard classification of education (ISCED)
[9]Eurostat Statistics Explained (2019): Glossary: Scientists and engineers

Eurostat definition of 'Technicians':

"The technicians and associate professionals group includes occupations whose main tasks require technical knowledge and experience in one or more fields of physical and life sciences, or social sciences and humanities. Technicians and associate professionals perform mostly technical and related tasks connected with research and the application of scientific or artistic concepts and operational methods, and government or business regulations. Most occupations in this major group require skills at the third ISCO-08 skill level, usually obtained as a result of studying at a higher educational institution following completion of secondary education for a period of 1 - 3 years (International standard classification of education (ISCED) 97 level 5B, ISCED 2011 level 5)."[8]

Eurostat definition of 'S&Es':

"S&Es refer to persons who, working in those capacities, use or create scientific knowledge and engineering and technological principles, i.e. persons with scientific or technological training who are engaged in professional work on science and technology activities, high-level administrators and personnel who direct the execution of science and technology activities. S&Es includes those who conduct research, improve or develop concepts, theories and operational methods and/or apply scientific knowledge relating to fields which are covered by one of the following occupations defined in the International standard classification of occupations (ISCO-08):

- 21 Science and engineering professionals;
- 22 Health professionals;
- 25 Information and communications technology professionals."[9]

The relevant workforce represents a range of educational backgrounds

The tables below show examples of the types of educational backgrounds that S&E and technician candidates working in the RM sector possess. Table 1 presents the educational programmes from which survey respondents report that they typically recruit. Table 2 presents the most frequently observed educations per educational level in the broader biotech and pharma industry workforce, assuming some overlap between this workforce and the RM workforce.

The educations can be mapped across the two tables. For technicians, the Academy Profession (AP) graduate programme in chemical and biotechnical science translates to laboratory technicians, production technology translates to operators and process technicians, and the bachelor's degree in biomedical laboratory science translates to biomedical technician. For S&Es, the educations align with demand, though the industry appears to focus slightly more on specialisations.

This information provides relevant insights into the educational baseline of the analysed workforce and can be used to guide any educational measures being initiated to bridge the experienced workforce skills gaps.

Table 1: Educational programmes that the surveyed industry professionals are most likely to recruit their RM workforce from (survey)

Scientists and engineers		Technicians
Medicine	Immunology, bio-, and molecular medicine	Laboratory technician
Biology	Cell, molecular, and human biology	Biomedical technician
Engineering	Biotechnology, bio-/chemical engineering	Operator
Chemistry	Chemistry and biochemistry	Process technician
Other	Pharmacy and biophysics	

Source: Open answer survey responses, N = 27.

Table 2: Most frequently observed educations per educational level in the biotech and pharma industry (2022)

	AP graduates		Bachelor's
1	Chemical & Biotechnical Science	1	Bio-/chemical engineering
2	Pharmaconomist	2	Biomedical laboratory scientist
3	Production technology	3	Nurse

	Master's		PhDs
1	Pharmaceutical Science	1	Medicine
2	Biotechnical Engineering	2	Technical Science
3	Biology and Molecular Biology	3	Natural Science

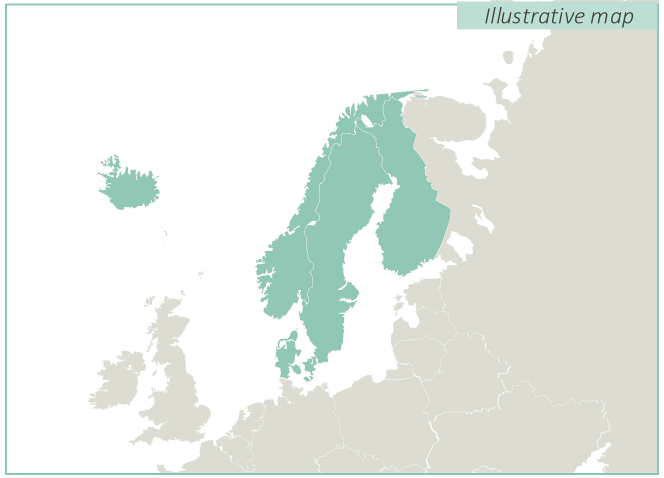
Source: ADC based on data from Statistics Denmark.

Countries in scope

Skills demand and supply

This report primarily aims to identify key skills gaps within the RM sector in Denmark and the Greater Copenhagen Region. Recognising that similar skill requirements may exist across the sector internationally, the analysis of skills demand is broadened to encompass all Nordic countries. However, the report does not include perspectives from Iceland due to recruitment challenges.

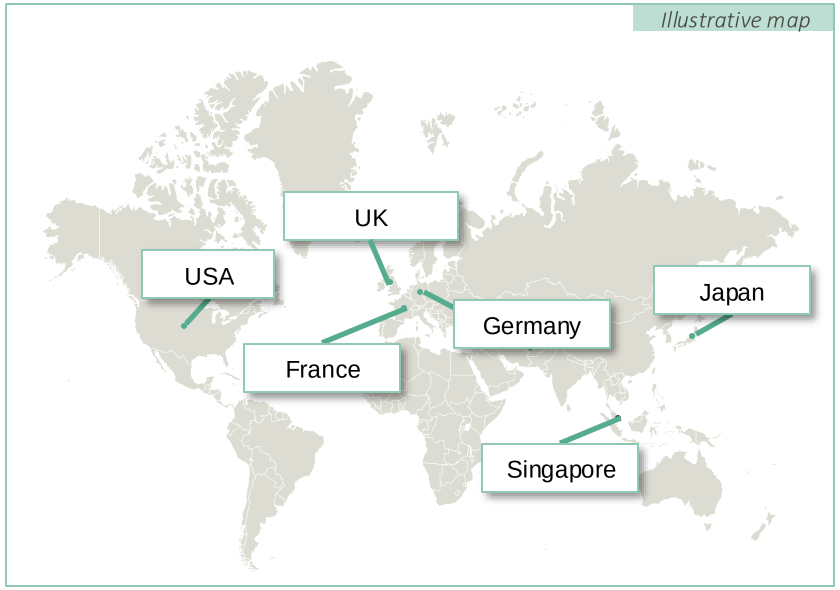
The qualitative analysis of workforce supply is restricted to Denmark and the Greater Copenhagen Region to ensure relevance of any suggested educational initiatives to this specific geographical region. Insights from educational actors in Denmark and the Greater Copenhagen Region present the efforts made to meet demand and any ongoing initiatives. The data used in the quantitative projections of the workforce and the job post analysis is solely focused on Denmark.



Global trends and perspectives

Although the main objective of the analysis is to understand the demand and supply in Denmark and the Greater Copenhagen Region, it is crucial to acknowledge the sector's rapid international development. Both industry and research institutes compete for skilled talent beyond national borders, meaning Denmark and the Greater Copenhagen Region should not be seen as an isolated ecosystem. Another objective is to understand the dynamics of evolving international ecosystems with more mature RM and ATMP sectors and how their developments could provide insights into the progress in Denmark and the Greater Copenhagen Region[10].

Nine leading experts from six international ecosystems have been interviewed for this purpose, including USA, UK, Germany, France, Singapore, and Japan. In this analysis, an ecosystem is defined as a structure of complementary and interdependent actors, companies, organisations, and policymakers working to pursue both individual and collective goals in a sector or geographical area. The aim of these interviews was to uncover a range of aspects related to workforce and skills demand, relevant educational initiatives, and the initiatives and framework conditions that either facilitate or hinder the success of these ecosystems.



[10] Alliance for Regenerative Medicine (2023): Workforce Report: Gap Analysis for the Cell and Gene Therapy Sector

Projections of Danish workforce demand and supply

The global biotech and pharma industries are expected to grow towards 2035, and RM can be an enabler of this growth

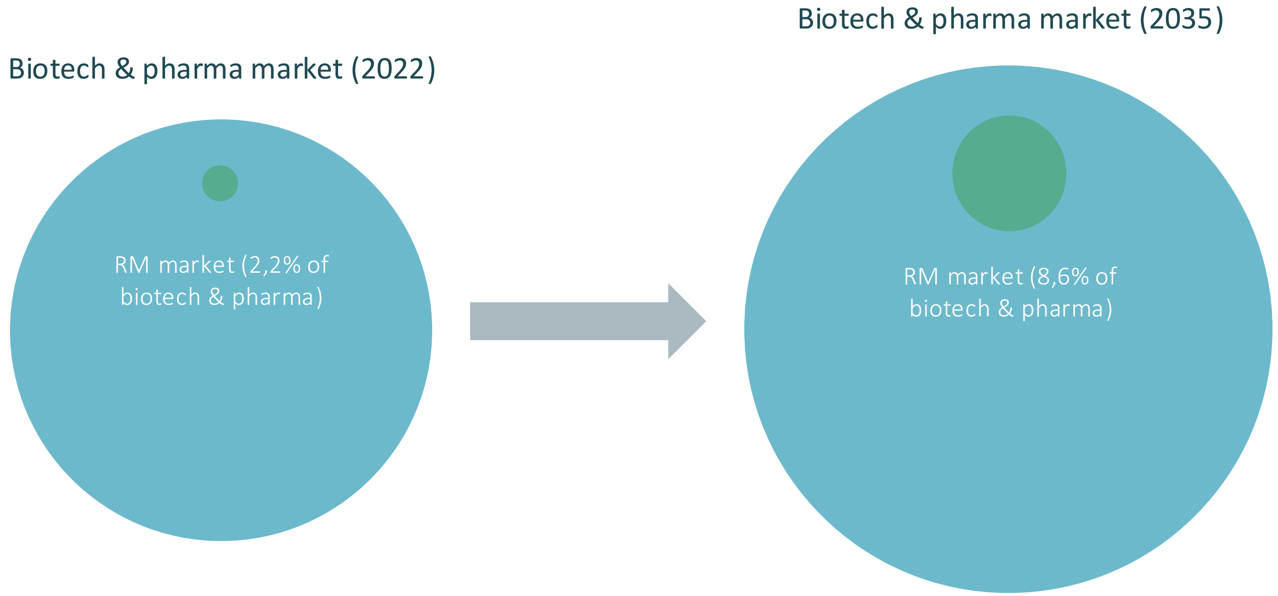
To analyse the development of the RM field, a literature review of projections from multiple analysis institutes was conducted (see methodology on page 56.). The review reveals that the global biotech and pharma industry is expected to grow at an average compounded annual growth rate (CAGR) of 9,2% until 2035, representing a high growth scenario in the analysis. Additionally, a conservative low growth scenario with a CAGR of 3,9% in biotech and pharma is presented. This scenario is based on findings from previous work by ADC[11].

The review shows that the global RM market was estimated to represent 2,2% of the pharma and biotech market in 2022. By 2035 it is expected to represent 8,6%, corresponding to a CAGR of 21,1%. As shown in table 3, this growth rate is assumed in both the low and high growth scenario for RM. Overall, the significant growth of the RM field indicates that it can be an enabler of the growth of the biotech and pharma industry, since RM is considered a sub-industry within biotech and pharma in the projections.

Table 3: Growth rates in scenarios

Industry	Low growth	High growth
Biotech and pharma	3,9% p.a.	9,2% p.a.
RM	21,1% p.a.	21,1% p.a.

Figure 1: Industry growth from 2022 to 2035 for global biotech & pharma and RM

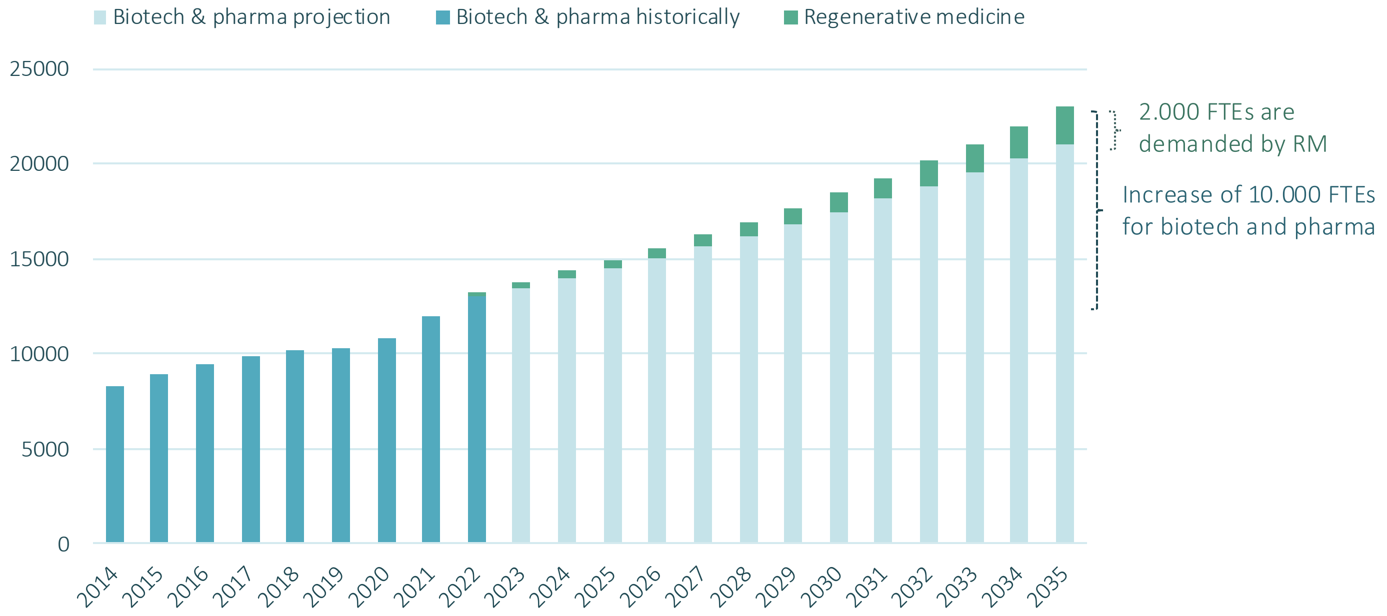


[11]Damvad (2020): Dansk life science frem mod 2030

Realising the growth potential of the biotech, pharma and RM industries requires a robust talent pool to recruit from

Figure 2 below illustrates the expected workforce demand in the Danish biotech, pharma and RM industries by 2035. The workforce demand in the biotech and pharma industry is projected to increase by 10.000 full time employees (FTEs), with 2.000 of these FTEs expected in the RM industry. The 2.000 FTEs corresponds to 8,6% of the total labour demand in the biotech and pharma industry. The findings highlight that the biotech, pharma and RM industries require a robust talent pool to realise the growth potential. Note that these projections do not include workforce demand from the public sector, such as educational institutions and hospitals.

Figure 2: Expected workforce demand in Danish biotech & pharma, and RM industries until 2035 (in high growth scenario)



Note: values are rounded to nearest 100

Analysing the workforce within RM requires simplifying assumptions

- Quantifying the workforce within RM is challenging due to it being a highly specialised and relatively new field.
- The granularity of the data from Statistics Denmark is inadequate to analyse the workforce within RM directly.
- Instead, the analysis is based on a curated list of educations and industries, deemed relevant for working with ATMPs (see methodology pages 52-54).
- Thus, the findings may reflect trends from a broader workforce than RM specifically.
- A more detailed description of the methodological considerations can be found on pages 50-56.

Competition for talent will increase for biotech, pharma and RM industries

The growing workforce demand towards 2035 might affect the Danish labour market in biotech, pharma and RM through increased competition for talent.

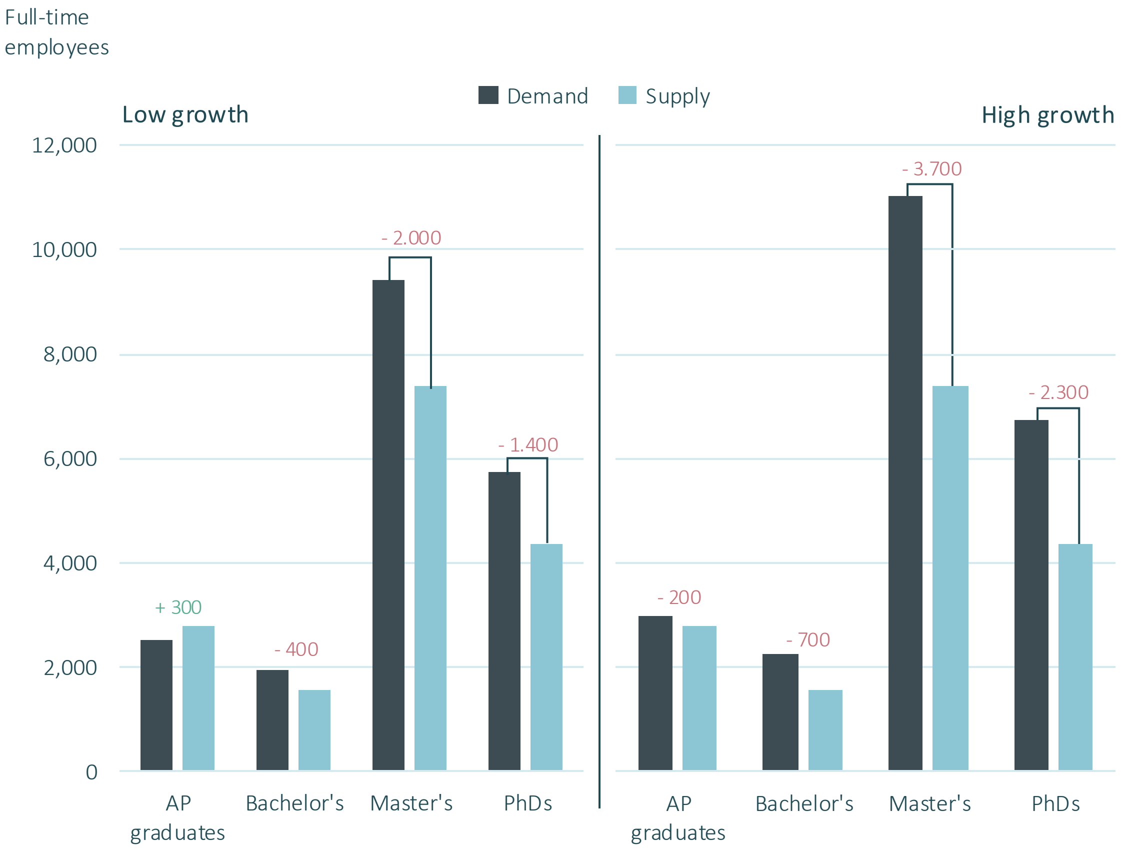
The graph to the right shows the expected workforce gap in the biotech and pharma industry per educational level by 2035. In a high-growth scenario, supply deficits of 3.700 master's, 2.300 PhDs, 700 bachelor's, and 200 AP graduate FTEs are expected. A low-growth scenario projects shortfalls of 2,000 master's, 1,400 PhDs, and 400 bachelor's FTEs, but a surplus of 300 AP graduate FTEs. Both scenarios reveal notable workforce shortages in the biotech and pharma industry, with a total expected shortfall of up to 6,900 FTEs across all educational levels by 2035 in the high growth scenario.

The corresponding expected supply deficit for RM is 8,6% of this, estimated to be up to 600 FTEs. The supply deficit is anticipated to be largest for master's and PhDs.

While 600 FTEs might not seem substantial, it is crucial given that the RM industry's total projected labour demand by 2035 is 2,000 FTEs. This suggests that nearly one-third of the demanded workforce may be unmet in a high-growth scenario. Additionally, the RM workforce gap is part of a larger labour shortage for biotech and pharma, as well as potential gaps in the public sector not accounted for in the analysis.

Overall, the results highlight significant challenges for the Danish RM industry. With no direct education for ATMPs in Denmark, employers must compete with biotech, pharma, and the public sector for talent. This greatly intensifies competition and may result in the ATMP sector struggling to attract the necessary skills, potentially inhibiting growth. To address this, the sector could refine its approach to attract the right profiles with the necessary skills without extensively recruiting from a broad range of backgrounds. This requires mapping the skills needed to sustain sector growth.

Figure 3: Expected gap between labour supply and demand per educational level within biotech and pharma by 2035



Source: ADC based on data from Statistics Denmark and DREAM.

Note: The values are rounded to nearest 100.

The workforce and skills demand in regenerative medicine

The surveyed population is predominantly active in Cell & Gene Therapy

Although the sample size of 27 respondents is relatively small, their responses represent a broader workforce. According to survey responses, 1.962 individuals currently make up the RM workforce in the surveyed organisations*. Some descriptive statistics on the organisations the survey respondents represent can be found in appendix B1 and B2.

Most survey respondents report working in cell therapy (CTMP) and gene therapy (GTMP), with fewer being involved in tissue therapy (TEP) or combination products. These results align with a 2021 report on the Nordic ATMP landscape, which indicates that CTMPs and GTMPs constitute 94% of existing ATMP companies, while TEPs account for 6%[12]. Among the survey respondents working with TEPs, only one company exclusively uses this technology. Consequently, the demand for skills is expected to be more reflective of the needs within the CTMP and GTMP sectors.

Within the product development lifecycle, most respondents are engaged in Research & Discovery and Development. There is no definitive pattern to the types of organisations that are more involved in the earlier stages compared to those who have advanced to the development stage. However, all educational institutions (10) are engaged in the pre-clinical phase. Six SMEs/biotech companies, three hospitals, two pharmaceutical companies, and two contract manufacturing companies are also active in Research & Discovery. This diversity is similarly observed in clinical development, as illustrated in figure 5. The development phase has a somewhat lower university representation, with five universities involved in development compared to 10 in research.

Two survey respondents work with commercialising RM-relevant products: one pharmaceutical company and one university. A subset of survey respondents work in clinical implementation and clinical care, largely represented by hospitals.

[12]MSC (2021): Nordic ATMP landscape and implications for the scale of an infrastructure for process development and manufacturing.
*Data is self-reported. The criteria for identifying RM relevant workforce may vary among respondents.

Figure 4: Which of the following areas does your organisation operate or have activities in?

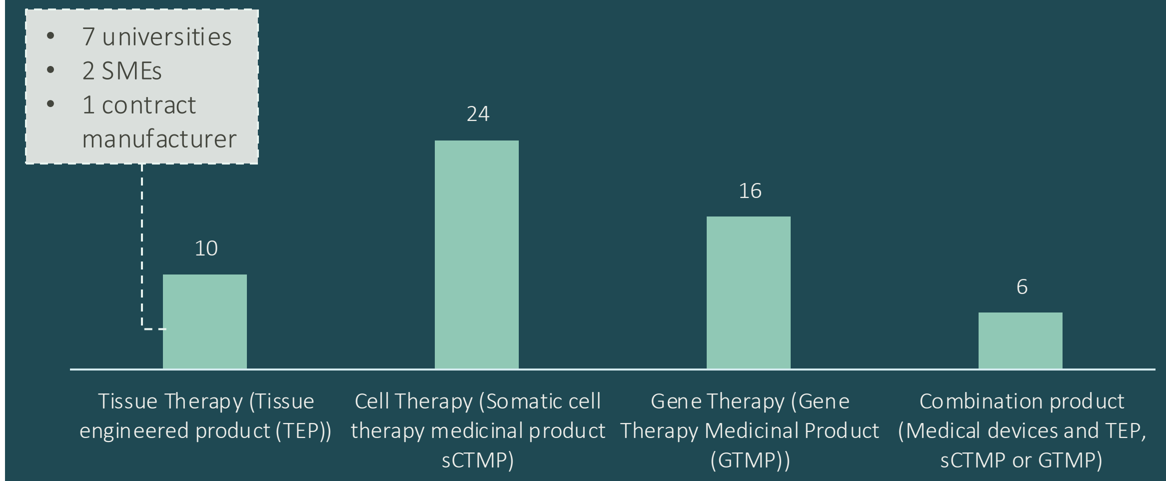
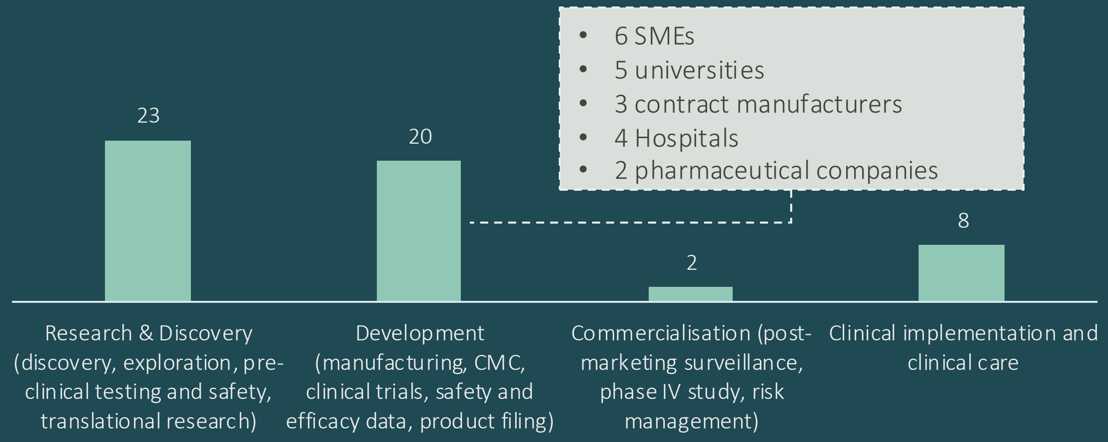


Figure 5: Which phase of RM does your organisation primarily operate in?



N = 27. Multiple answers could be chosen.

Experiences of current skills gaps within RM vary across survey and interviews

Survey and interview responses reveal variations in whether respondents currently experience a skills gap in RM. Of the surveyed organisations, 18 report experiencing a current skills gap.

Several factors influence the perceived availability of skilled personnel, such as company or department sizes, as smaller companies require fewer personnel. These may not experience a significant skills gap currently but may do so in the future. Smaller companies emphasise in interviews that, until now, they have managed to enhance the skills of their relatively small workforce to equip them for work with relevant technologies.

Moreover, many surveyed and interviewed companies recruit international talent, discovering that it is possible to find individuals with the necessary expertise, provided they have a global recruitment base. This reliance on international recruitment among respondents in the Nordics suggests a scarcity of available local talent proficient in RM technologies.

All survey respondents but one expect the field to grow over the next decade and 17 expect a future skills gap. Interview respondents expect that as products progress into phase 2 and 3, there will be a shortage of candidates and that the candidates will lack the skills for further product development.

"Cell therapy is still very explorative, so it all depends how the field evolves. If you project the number of projects that have been initiated the past 5 years, the field will develop significantly. We expect a large lack of workforce, which also reflects the need to scale the workforce now to prepare for the future."

- Contract Service Organisation

Figure 6: Do you currently experience a skills gap within RM and do you expect a skills gap in the future?

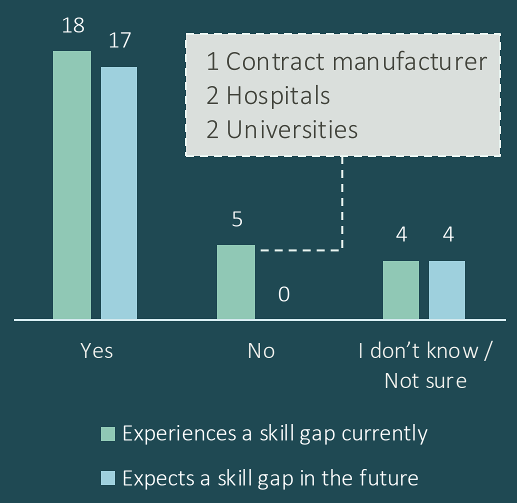
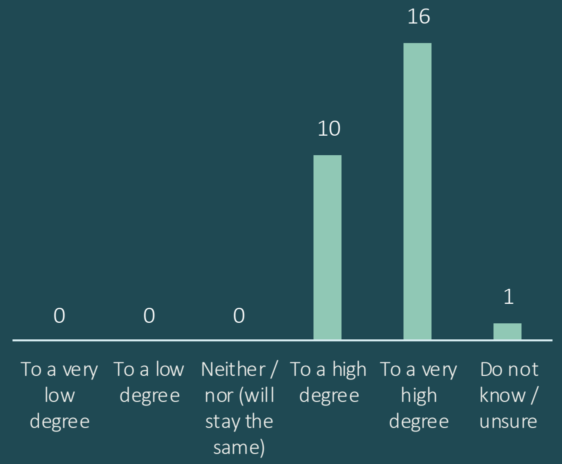


Figure 7: To which degree do you expect the field to grow over the next 10 years?



"We experience a lack of skills and people. We need scientific staff who can design the path into the clinic, and people with hands-on expertise, such as lab technicians, and operators. There are no disciplines where we experience easy access to talent."

- Contract Service Organisation

"The most talented candidates come from the US, Southern Europe, Australia etc. If we could only recruit from biotech companies or universities in Denmark or Sweden, then yes, we would have a big problem. But our recruitment base is practically global."

- SME/Biotech

N = 27. The survey was launched twice with minor variations in format. 6 respondents were not asked about the potential skills gap in the future, resulting in variation in response numbers.

Profile and skills demand analysis aids in identifying educational needs

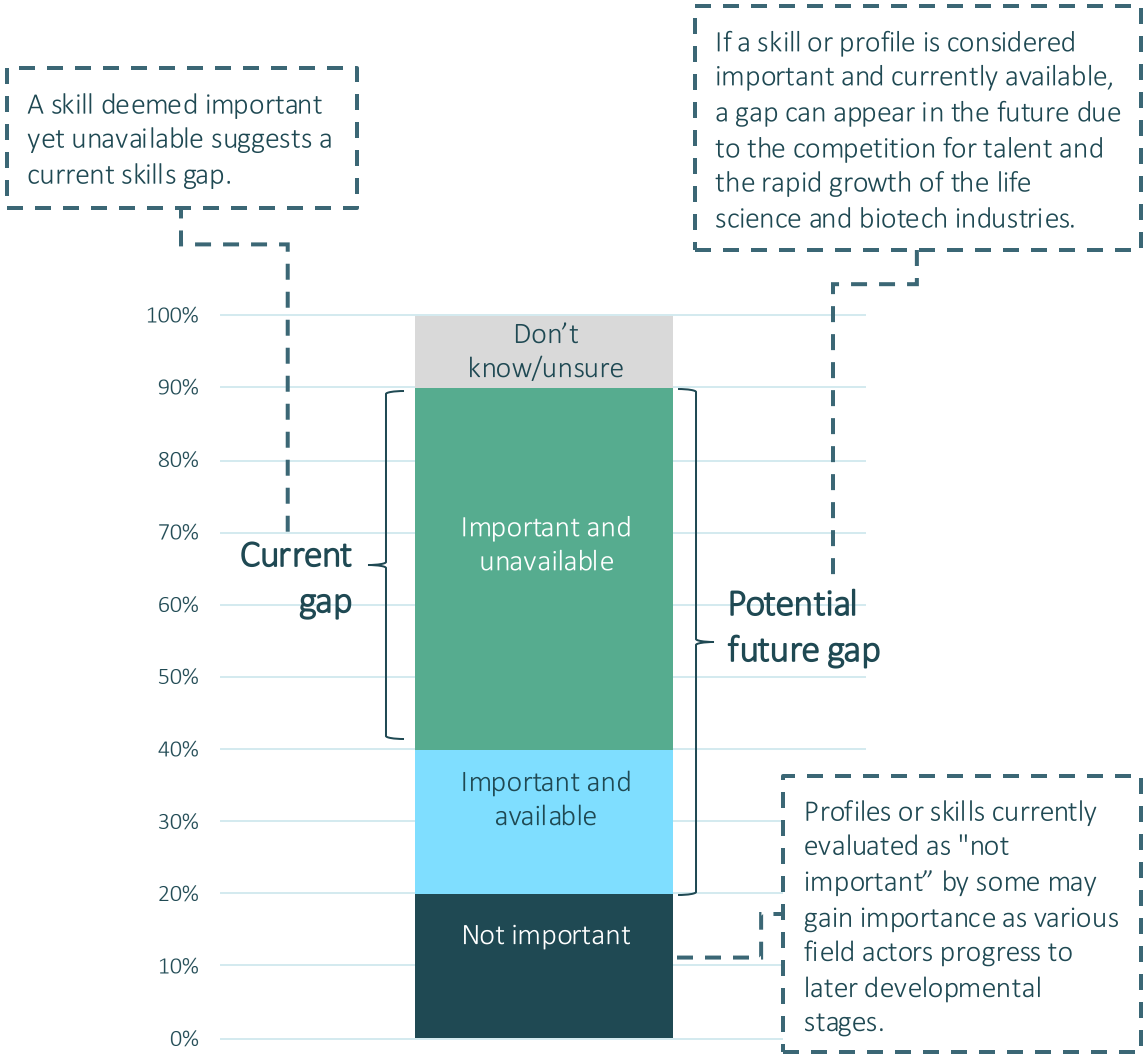
The following pages present 1) The significance and availability of a range of profiles with the necessary skills relevant to the RM workforce and 2) The most prevalent skills gaps experienced by respondents for S&Es and technicians working with RM.

Profiles: The list of profiles was created by considering the most frequently observed educations in the biotech and pharma industry as showed on page 10 coupled with a list of educational backgrounds retrieved through the job post analysis (appendix E9) and desk research on relevant analyses of the ATMP workforce. The resulting list of profiles and educational backgrounds was then grouped into the profile groups shown in figure 8 (next page).

Skills: The predefined skills list presented to survey respondents was created through a combination of in-demand skills retrieved from the job post analysis (appendix E6), desk research on relevant international analyses of the skills demand within RM and ATMP sectors, and input from the expert group. The resulting extensive skill list was divided into the categories presented on page 23. Survey respondents provided feedback on the same skill categories for both workforce groups (S&Es and technicians). To facilitate experiences of gaps in other skills, survey respondents had the option to highlight these experiences in the survey. The analysis focuses on specialised skills. A list of baseline skills retrieved from the job post analysis can be found in appendix E5.

Results from the analysis point to a multitude of skills gaps. Only the ones most often highlighted and emphasised as most critical are presented in the report. Other findings from the survey and interviews are presented in appendix B.

Guiding illustration on interpretation of survey results



Experience of importance and availability of profiles and skills

Respondents lack access to a broad set of skilled profiles needed for RM

Survey respondents were asked to evaluate the significance of a range of profiles to their RM workforce, and to indicate whether they experience that they can acquire profiles with the needed skills. The results are presented in figure 8. Survey respondents were able to complement the predefined list with additional relevant profiles. These are presented in table 4.

The following pages describe each profile group structured from most to fewest survey respondents highlighting a skills gap within each group.

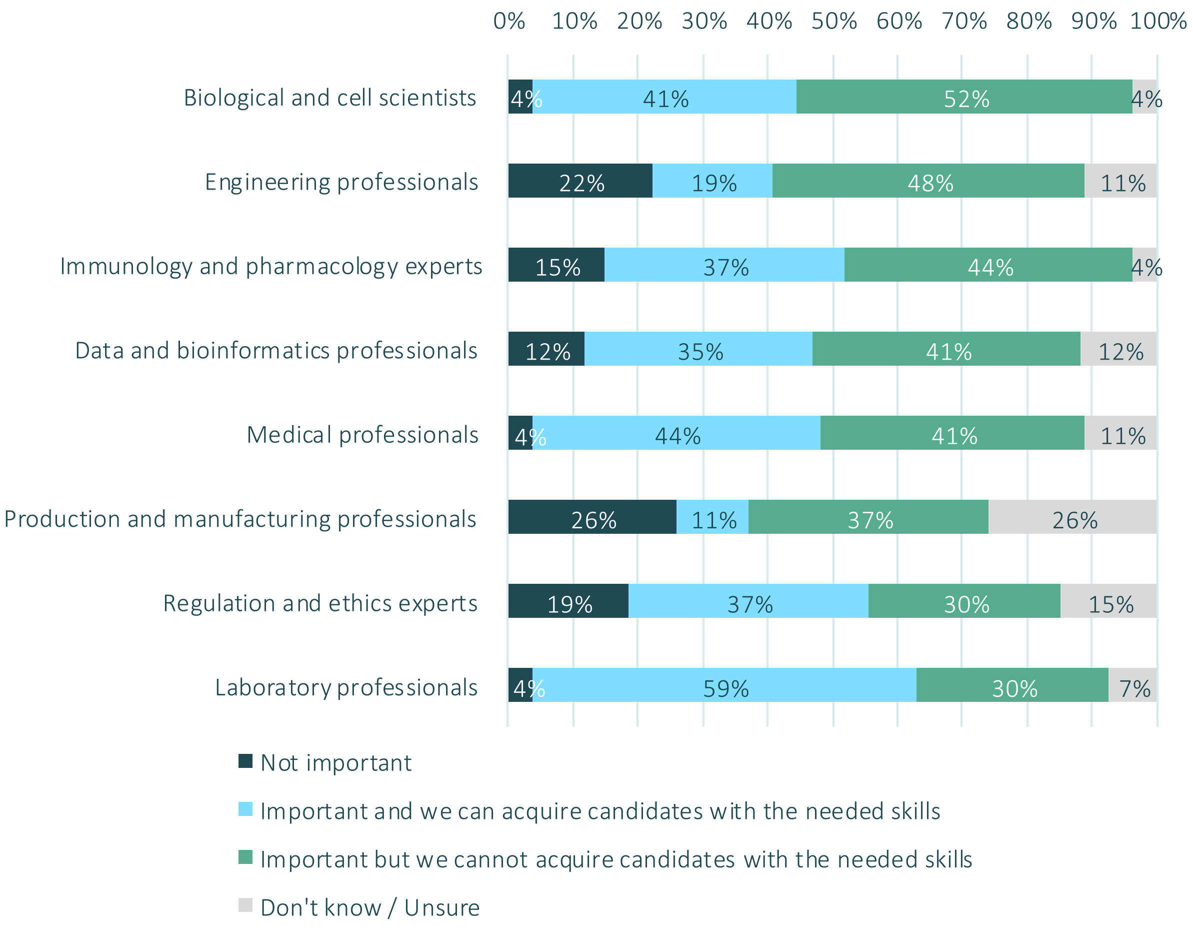
Table 4: If relevant, please list other profiles important for your RM workforce

(open answer)

Additional profiles highlighted*	
Quality Assurance (QA) and Quality Control (QC) personnel	Regulatory experts
Cell biology representatives	Profiles with a mix of biology, pharmacology and technology application
Lab-techs with cell and stem-cell knowledge	IT and automation profiles (including bioinformaticians, statisticians and data managers)
Specialists in analytical development (and documentation and safety of products)	Process development specialists (biotech engineers and process operators)

*Each of these additional profiles are mentioned by a total of 1-3 survey respondents.

Figure 8: How important and readily available are the following profiles to your RM workforce?



N = 27.

93% of survey respondents find **biological and cell scientists** important

52% experience a lack of access to **biological and cell scientists** with the necessary skills

Biological and cell scientists include stem cell biologists, cell scientists, molecular biologists, microbiologists, geneticists, biotechnologists, etc. The results may reflect a field that remains heavily research-oriented and in preclinical stages. The demand could also stem from the extensive requirement for biological knowledge throughout the development lifecycle.

67% of survey respondents find **engineering professionals** important

48% experience a lack of access to **engineering professionals** with the necessary skills

Engineering professionals include tissue engineers, bioengineers, biomedical engineers, and process engineers. While this number is smaller relative to the percentage requiring biological and cell scientists, it is noteworthy that almost half the survey respondents encounter difficulties in sourcing candidates with the necessary skills, indicating a skills gap within this group.

81% of survey respondents find **immunology and pharmacology experts** important

44% experience a lack of access to **immunology and pharmacology experts** with the necessary skills

Experts in immunology and pharmacology are essential for understanding how medicinal products interact with the human body and immune system, and for predicting and evaluating factors such as dosage, delivery methods, side effects, and therapeutic efficacy. They play a crucial role in preclinical and clinical testing phases, including interpreting trial results and adjusting therapy designs. Furthermore, they contribute to regulatory approval processes by providing evidence to demonstrate safety and efficacy.

76% of survey respondents find **data and bioinformatics professionals** important

41% experience a lack of access to **data and bioinformatics specialists** with the necessary skills

Data and bioinformatics professionals include data scientists, bioinformaticians, statisticians, and others that are responsible for managing and analysing the large volumes of complex data. Their analyses help inform decision-making and development strategies, contributing to the understanding of the safety and efficacy of ATMPs. Difficulties in sourcing these professionals with the right skill set may stem from the complexity of data generated by ATMP research/development coupled with the required understanding of biological data, comprehension of the regulatory landscape of ATMPs, a shortage of available talent due to high demand, and a lack of practical experience in handling and analysing biological data within a clinical or pharmaceutical context.

85% of survey respondents find **medical professionals** important

41% experience a lack of access to **medical professionals** with the necessary skills

Medical professionals include profiles such as medical doctors, clinical research scientists, pharmacists, and nurses, among others. Medical professionals are integral to the clinical application of ATMPs and to the understanding of the diseases and conditions these products aim to treat. Ensuring a steady supply of medical professionals equipped to work with ATMPs is essential not only for clinical development but also for the later stages when more products receive approval. Given the novelty of the ATMP field, there may be a limited number of professionals with direct experience in working with these products.

48% of survey respondents find **production and manufacturing professionals** important

37% experience a lack of access to **production and manufacturing professionals** with the necessary skills

This group encompasses roles like production technologists and process technicians/operators. Production and manufacturing professionals are generally not required until products advance to the clinical stages. Therefore, organisations with a strong research focus may not currently deem these professionals necessary. Among those who consider these roles relevant, only 11% believe these professionals possess the required skills.

89% of survey respondents find **laboratory professionals** important

30% experience a lack of access to **laboratory professionals** with the necessary skills

Laboratory professionals include roles such as biomedical laboratory scientists and laboratory technicians who carry out tests and analyses in the lab. They are primarily responsible for routine procedures and for ensuring the laboratory operates smoothly and efficiently. Several interviewees noted that laboratory professionals with experience or specialisations in other fields often possess the skills needed to work with ATMPs, given the similarity of tasks. This suggests that while laboratory professionals generally have the skills to work with ATMPs, there may still be gaps that need to be addressed.

67% of survey respondents find **regulation and ethics experts** important

30% experience a lack of access to **regulation and ethics experts** with the necessary skills

Regulation and ethics experts include regulatory affairs specialists and bioethicists who ensure that ATMPs are developed ethically and in compliance with regulations. The regulatory landscape for ATMPs is dynamic, evolving as new knowledge is acquired. As most pre-clinical development work is conducted in academia, the initial manufacturing choices often differ significantly from clinical development requirements. Academic staff may be less familiar with the regulatory requirements for Good Manufacturing Practice (GMP) in ATMP production[13]. This underscores the need for greater knowledge of regulatory requirements and production process development for ATMPs earlier in the product development life cycle compared to traditional drug development.

[13]Silva et.al (2022): ATMP development and pre-GMP environment in academia: a safety net for early cell and gene therapy development and manufacturing

Skills gaps are most prevalent and varied in S&Es

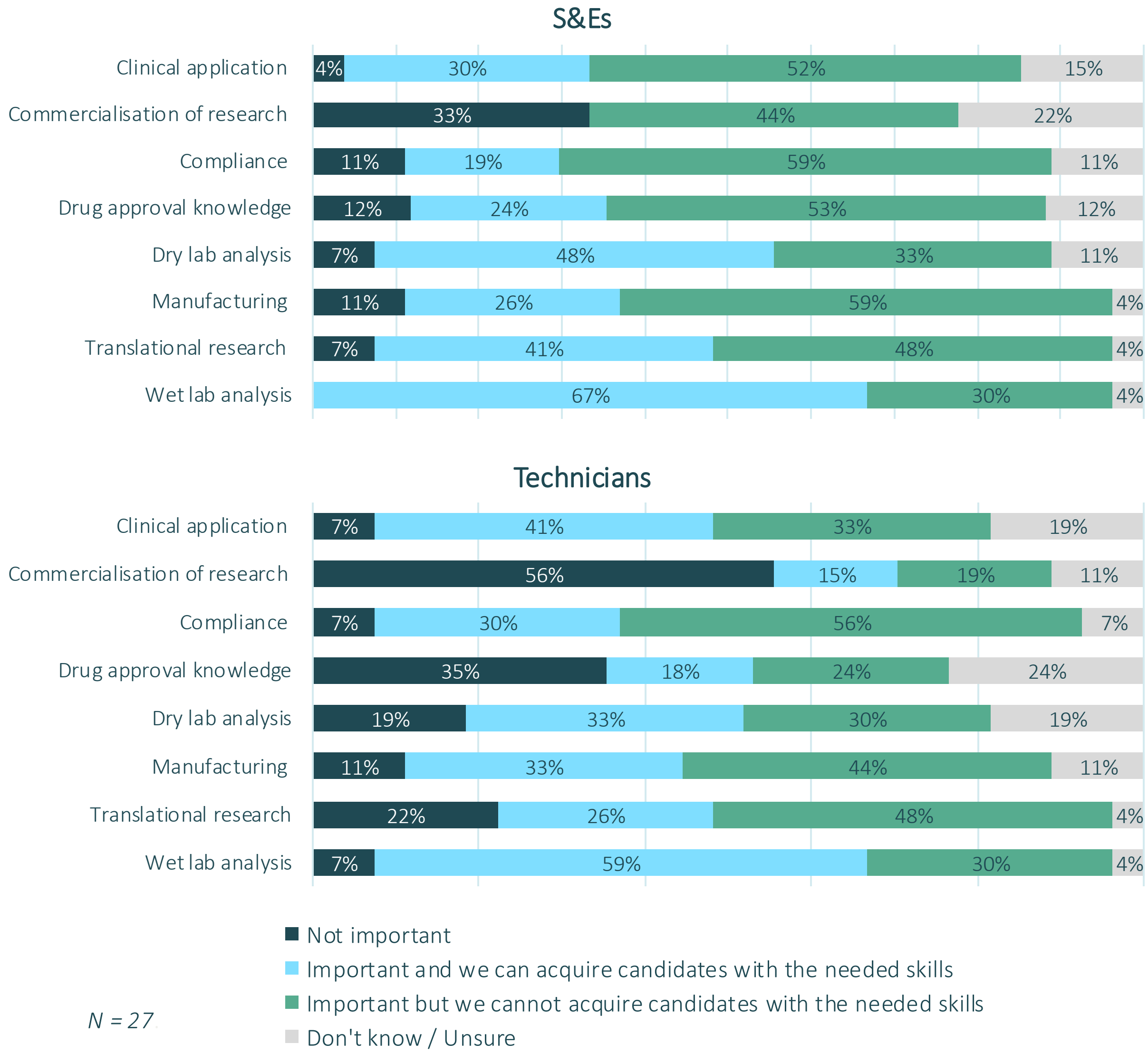
Moving from profiles to skills, the subsequent sections analyse the prevalent skills gaps within the two workforce sub-groups, focusing on the skill areas most frequently highlighted by survey and interview respondents. Figure 9 shows that most prevalent experienced skills gaps for S&Es include manufacturing, compliance, drug approval and clinical application skills. For technicians, the main skills gaps relate to compliance, translational research, and manufacturing skills. Fewer survey respondents experience skills gaps for the technicians compared to S&Es.

The analysis orders the skills gaps from most to least reported for each subgroup, with additional insights from interviews providing further nuances. Skills not featured in figure 9 are thus also discussed on the following pages.

The focus is on the most considerably highlighted skills gaps, leaving out certain skill sets like dry lab and wet lab analysis*, which only 30-33% of respondents highlighted as lacking across both workforce sub-groups. The footnote on this page explains these skills. Nevertheless, aspects of dry and wet lab skills are discussed indirectly in the analysis due to insights from interview responses, underlining that these skills should still be considered important and potentially lacking in the RM workforce.

While the analysis attempts to distinguish between the two workforce sub-groups from the perspective of educational level (as defined on page 9). It is important to acknowledge the fluid boundaries between the two from an industry perspective, making a rigid separation impractical. Respondents' varying perceptions and experiences complicate this clear division.

Figure 9: To which degree are the following skills relevant and available for your RM workforce?



N = 27

*Dry lab analysis include: Imaging, numerical analysis, computer simulation and modelling, bioinformatics.
*Wet lab analysis include: cell-based analysis, biochemical and molecular analysis, assays, PCR, PGE, ELISA, mass spectrometry, histochemistry, chromatography.

Respondents point to a deficiency in manufacturing and compliance skills for S&Es

59% of survey respondents experience a lack of **manufacturing** skills for S&Es

"I can imagine that there could be a challenge with those who have a clinical or research background; they may lack some basic production technology insight and knowledge."

- Authority/non-profit organisation

59% of survey respondents experience a lack of **compliance** skills for S&Es

"Maybe engineers and biologists are interested in an industry career. Then they would need courses in GMP. Offering at least one introductory course, around ten weeks or so, that would probably help a lot"

- Contract Service Organisation

Manufacturing skills include areas such as knowledge and understanding of ATMP production, operations management, bioprocessing, process development and scale-up, control and risk analysis, biocontamination, and sterile environments. Ensuring optimal manufacturing processes, which includes faster production times and increased cost savings while maintaining safety, is particularly critical given the high cost of producing ATMPs. This becomes even more important when scaling up production during later stages of clinical development. Interview respondents highlight that although candidates with relevant educational backgrounds often possess a manufacturing skillset that would work in production of synthetic pharmaceuticals, the biological nature of ATMPs require a more advanced knowledge of the specificities of manufacturing ATMPs.

Compliance skills, including GMP, Quality Control (QC), Quality Assurance (QA), and Clinical Trial Application (CTA), are essential for ensuring that pharmaceutical products are safe, effective, and of high quality. This includes analytical testing methods, understanding protocols, and handling procedures for stability testing. Respondents in both survey and interviews stress the need for more specialised QA and QC skills to evaluate product quality effectively. Additionally, GMP skills are highlighted as a crucial area for upskilling, which includes understanding quality systems, documentation, validation, and risk management, along with practical experience with these areas. Interview respondents stress the importance of staying updated on GMP regulations, new technologies, and best practices. Thus, these respondents see a need for continuing educational efforts.

Skills in manufacturing and compliance are often overlapping, as manufacturing processes need to be controlled according to quality standards to ensure compliance. More specific skill needs in these areas are highlighted on the following page.

S&Es lack skills in analytical and process development

Due to the experienced lack of compliance and manufacturing skills, interview respondents stress a particular need for S&Es with skills in analytical and process development relevant to ATMPs. According to the interview respondents, the novelty of the field means that the analyses and processes in most cases need to be developed from scratch, including the methods for validation. Furthermore, a lack of public knowledge sharing on manufacturing details results in lack of standardised processes.

Skills in process development include the ability to design the processes that bring medicinal products from research to clinical development, including the internal operational processes of a GMP facility. The design and control of the manufacturing process plays an important role ensuring that the quality of the products correlate with efficacy and safety standards. According to respondents, skills in process development and scaling are not taught in depth in traditional engineering courses.

Interview respondents also highlight a need for S&Es who are skilled in developing analytical methods to characterise and validate the biological products involved in ATMPs. According to respondents, one of the main responsibility areas for S&Es is designing and overseeing these analyses and processes, whereas the practical execution in many cases is the job of the technicians. Some respondents experience that while S&Es possess skills in conducting analyses from their education, including dry and wet lab analyses, there is a lack of access to individuals who can develop the more advanced analytical methods needed to ensure compliance.

Skills in development of processes and analytical methods

to ensure compliance is highlighted as important and lacking for S&Es

”The cell biologists we hire are very talented, but they cannot scale up, and they cannot run the processes.”

- Pharmaceutical company

"The biggest challenge is finding employees with sufficient analytical skills because we need analyses that can verify the studies, and they are not standard analyses, so they need to be developed.”

- SME/Biotech

Respondents experience gaps in drug approval knowledge and clinical application skills

53% of survey respondents experience a lack of drug approval knowledge for S&Es

52% of survey respondents experience a lack of clinical application skills for S&Es

“Small innovative companies working on something specific within cell therapy, trying to get something marketed, face a huge mountain they need to climb to get something approved. In the many years I have been in this field, there have only been more rules added, none have been removed. So, there is no doubt that it is a huge burden for them."

- Authority

Drug approval knowledge, fully presented to respondents as 'Understanding of drug approval processes and health technology assessments' includes knowledge of the Food and Drug Administration's (FDA) and EMA's submission processes, and regulatory knowledge. These skills are important for S&E professionals, with 53% of respondents identifying a shortage of S&E professionals with the necessary knowledge in drug approval. Interview respondents highlight that most S&Es have received a more traditional academic training, which in most cases does not include regulatory knowledge. One aspect is to be trained in the existing ATMP regulatory guidelines, while another aspect often stressed by interview respondents is skills in defining the quality standards that will inform these guidelines.

Clinical application encompasses a broad array of skills, including clinical knowledge, administration and dosage, cell delivery devices, understanding of stem cell concepts and application techniques, biomechanics, bioengineering, and biomaterials. More than half of the respondents (52%) reported a shortage of these skills in S&Es. Interview respondents highlight that in addition to an experienced current need for more skills in clinical application, these skill may be in even larger demand in the future, once products move to later stages of development. In clinical stages, interview respondents anticipate a need for clinical application experts who can organise the clinical trials and who understand the impact on patients.

Lack of translational and commercialisation skills present bottlenecks

48%

Of survey respondents experience a lack of translational research skills for S&Es

"To succeed, we need individuals with some form of translational experience who can build upon the classical units for managing clinical development: quality, regulatory affairs, and clinical development."

- SME/Biotech

Due to the complexity of ATMPs, many products get lost in what's known as the "valley of death" during the translation from the laboratory bench to development, manufacturing, and bedside application. Consequently, there is a pressing need for professionals who excel in bridging the potential gaps in the ATMP value chain.

Among interviewed industry representatives, employees with translational skills, including insights into the entire value chain of ATMP development, are highly sought after in recruitment processes. These professionals understand the preceding stages of the value chain and possess the foresight necessary for subsequent phases. Additionally, this enables professionals to ensure and support quality regulatory affairs and applications for clinical trials. Many interview respondents describe the need for translational research skills as a need for more interdisciplinary profiles that can combine knowledge of biology, engineering and clinical application while also understanding compliance and regulation.

44%

Of survey respondents deem skills in commercialisation of research important for S&Es. Of those respondents, all report these skills to be currently lacking.

"I believe the skills gaps for a long while will be in the development part where you mature your processes and produce clinical studies. Later, we will experience a demand for commercial skills, but that is not where we are currently experiencing a need."

- Contract Service Organisation

Commercialisation skills include the ability to identify commercial potential and a capacity to innovate. Skills in commercialisation of research may in some cases be closely connected to translational skills. Both include the ability to consider the entire value chain of ATMP development, being able to make informed decisions during early stages that will increase the chance of a product reaching commercialisation.

Less than half of the survey respondents deem commercialisation skills important for S&Es. Interview respondents emphasise that few ATMPs have matured enough for commercialisation to be relevant, which might result in a current lower demand for these skills. However, as products mature, interview respondents expect commercialisation skills to become increasingly important. Out of all survey respondents deeming commercialisation skills important for the S&Es working with RM, all experience these skills as currently lacking. Thus, following increased future growth and maturity in the field, commercialisation may present a growing skills gap.

The S&E workforce need specialised skills in cell and gene technologies

Although the S&E workforce is highly valued for their foundational knowledge in scientific studies and process design, industry representatives emphasise specific skills, technologies, and processes that this segment of the workforce should be acquainted with in order to work with ATMPs.

In general, interview respondents highlight that while for example basic cell culture techniques are taught in biology courses, the scale-up processes and large-scale bioreactors used in ATMP manufacturing require more specialised biological training.

Interview respondents list a multitude of specialised skills related to deep knowledge of, and experience with, cell and gene technologies. This exhibits a demand for very specialised S&Es. Interview respondents highlight these as difficult to recruit for mainly two reasons: 1) Low maturity of the ATMP field in Denmark means less S&Es have prior experience from the field, resulting in a need to recruit internationally, and 2) Few options for specialising in ATMPs during education.

The most frequently mentioned cell and gene technology skills and skill areas are listed on the right.

"We are looking for employees with 10 years of experience who are skilled in conducting assays, in vitro pharmacology, or in vivo pharmacology. They might not have prior experience with DNA technology, but they have worked extensively in drug development. They should also demonstrate the ability to quickly adapt to working with CRISPR-armed viruses and bacteria."

- Contract Service Organisation

Specialised skills in cell and gene technologies

Are emphasised as highly important for S&Es and difficult to access

- Stem-cell technologies and stem-cell cloning
- Chimeric Antigen Receptor T cells (CAR-T cells)
- Induced Pluripotent Stem cells (iPS cells)
- Assay expertise to measure and analyse the presence, concentration, activity, or effectiveness of a substance such as drug, enzyme, protein or biomolecule.
- Self-assembling peptides (SAPs)
- *In vitro* and *in vivo* pharmacology to understand interactions between product and living organism
- Gene editing technologies such as Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR)
- Human and mammalian cells

Technicians lack skills in compliance and translational research

56%

of survey respondents experience a lack of compliance skills for technicians

48%

of survey respondents experience a lack of translational research skills for technicians

"There is a general gap in GMP skills among production personnel. Those I know from the Contract Development & Manufacturing Organisation (CDMO) business struggle to find employees with QA and QC skills."

- Authority/non-profit organisation

Similarly to the S&E workforce, interview respondents stress the need for more GMP training for technicians. Furthermore, practical experience with QC and QA are also highlighted as lacking.

Compliance skills is one of the skill areas most frequently mentioned by interview respondents as lacking for technicians. Respondents stress that whereas technicians involved in production may have theoretical knowledge of GMP, practical experience in a GMP-environment is often lacking.

The same point is highlighted in relation to QC, where respondents stress the need for technicians proficient in specialised analytical testing methods as well as understanding of specific protocols and handlings procedures for stability testing and ensuring product robustness.

As was the case for S&Es, the survey respondents report a lack of access to technicians with translational research skills. However, more survey respondents overall deem these skills important for S&Es than for technicians (89% vs. 74%).

Interview respondents experience that few technicians hired for ATMP development possess a thorough understanding of which stage of the product development life cycle they are hired into, and how it connects to other stages of the life cycle, including understanding differences between clinical trial phases. This results in difficulties such as comprehending clinical applications of laboratory findings in early research phases or generally how to optimise their own value creation in the part of the life cycle they work in.

Interviews further reveal that this demand for translational skills among technicians may represent a multitude of unmet skill needs that all contribute to bridging laboratory research and clinical application. Especially technicians with process technical backgrounds play a pivotal role in bridging non-clinical and clinical work. These lack scale-up proficiency, GMP training and biological understanding (as described on the following pages) which are important skills when translating to a clinical environment. Translational skills may also include aspects of regulatory compliance, skills in developing and standardising processes and protocols, thus overlapping with the compliance skill category.

Technicians need to understand the intricacies of biology and cell-biology

The technician roles currently found in ATMP development mainly include professionals with two backgrounds: A process/QC background and a biological background. Adding to the predefined skills list in the survey, interview respondents emphasise that both need additional skills in biology.

Laboratory technicians, already equipped with a solid biological background, lack more advanced skills related to working with and producing cells, such as freezing, thawing, and feeding cells, doing cell counts, and subculturing (the process of transferring cells to new vessels to maintain culture continuously). According to interview respondents, working with ATMPs demands more specialised cell culturing skills and knowledge than what is currently obtainable through educational programmes for laboratory technicians.

For process technicians, the demand is more related to having some basic cell biology and microbiology knowledge. According to interview respondents, few process technicians possess biological understanding from their education. Some respondents choose to fulfil process technician roles with trained laboratory technicians due to the need for biological understanding. However, as more companies move to large-scale manufacturing, the need for skilled process technicians with biological skills are highlighted as highly important (see appendix B10).

This skills gap can lead some industry representatives to hire graduates to conduct tasks fit for technician roles rather than fulfilling those positions with ”actual” laboratory and process technicians. This is described as necessary because of the skills gap but at the same time less ideal, as academics are hard to retain in technician roles due to lower wages and repetitive work tasks that are less professionally fulfilling for graduates.

Laboratory technicians

Need skills in working with **cells and stem cells**

”For lab technicians, I believe we generally lack candidates with the right background. They are educated in other areas and other skills. Generally, they don’t have experience working with cells and stem cells. It’s easier with academics, they have broader profiles and are easier to recruit internationally.”

- Contract Research Organisation

Process technicians

Need basic knowledge of **cell biology and microbiology**

”Previously, we have hired process technicians with a background in craftsmanship. That works fine in more traditional production areas. But in cell therapies, it’s right on the edge of whether we can use a process technician or instead use a lab technician that has a background in natural sciences. When we get more production-oriented later, we would want someone with more biological understanding than a traditional process technician."

- Pharmaceutical company

Technicians need ATMP related manufacturing skills such as bioreactor operation, cryopreservation, and scale-up processes

44%

Of survey respondents experience a lack of manufacturing skills for technicians

"A couple of things come to mind that are typically neglected when considering processes, such as scalability, for instance, which is crucial regardless of techniques. Bioreactor harvest and chromatography scalability are not generally considered in education, but they are incredibly important within the industry for regulatory purposes. Regulatory aspects are also rapidly evolving."

- Authority

"The process operators receive some training in production, but there could be more focus on small-scale production. What they are trained for is primarily for hardcore large-scale, for the big factories. There is a significant difference between what is needed in the large factories and what we need in our smaller setup."

- Pharmaceutical company

Related to the points on the previous page, 77% of the survey respondents deem manufacturing skills important for technicians and 44% experience a lack of access to technicians with the necessary manufacturing skills.

Interview respondents emphasise that technicians working with ATMPs should have experience in working with bioreactors and understanding bioreactor principles as well as understanding the documentation and compliance aspects of bioreactor operation for regulatory purposes. Technicians should also be familiar with working in upstream and downstream bioprocessing and possess skills in flow cytometry tools.

Furthermore, technicians need skills in cryopreservation and logistics, which include techniques for thawing, freezing, and handling of cellular products during transportation and storing. Skills in cryopreservation are highlighted as important to ensure the long-term commercial viability of ATMPs.

In relation to bioreactor operation, scalability has been highlighted by industry representatives as a skill often overlooked when educating technicians. Technicians need more understanding of the nuances of scaling up processes from a laboratory to a production level. This can include maintaining cell viability and function when increasing volume and understanding factors that can affect cell growth and product quality.

Interview respondents highlight that these manufacturing skills are often developed in a more applied and practical setting which is currently difficult to obtain through available educational programmes.

Technicians need skills in cleanroom behaviour and hands-on experience

As part of a need for compliance and manufacturing skills, interview respondents highlight a need for technicians with skills in cleanroom behaviour and practices. This skillset includes gowning correctly, ability to work in sterile environments, aseptic working practices to avoid cross-contaminations, and environmental monitoring. While graduates may possess basic cleanroom skills, the high standards required in ATMP production can be a significant step up.

This skills demand is often highlighted by interview respondents in relation to a demand for technicians with hands-on experience. Interview respondents stress that a predominant focus on theoretical knowledge during education does not equip technicians with the necessary practical experience with the different working practices.

Hands-on experience is also emphasised in relation to other skill areas such as bioreactors, working with cell cultures, and skills related to quality and GMP processes, and general handling of laboratory equipment and working in laboratory settings.

Technicians with hands-on experience in the ATMP field are highlighted as a scarce resource, and interview respondents emphasise a potential to include more practical elements in educational curricula.

Skills in cleanroom behaviour and practices

including aseptic working practices is highlighted as important and lacking for technicians

Hands-on experience

in addition to theoretical knowledge is highlighted as important and lacking for technicians

"In terms of technicians, it's important that they have hands-on experience in the lab, understanding how cells are affected and influenced, and comprehending the protection of the product and how to avoid contamination. The process technicians need to understand the processes and how quality is ensured within them."

- Contract Service Organisation

A current need exists for biologists, cell scientists and engineers with manufacturing and compliance skills, but ATMP trained technicians may gain increasing importance

S&Es

Related profiles (with biggest gaps)

Most respondents in this analysis highlight multiple skills gaps for S&Es, and skills gaps are experienced across S&E related profiles. However, most prevalent skills gaps are identified in:

- Biological and cell scientists
- Engineering professionals

Most prevalent skills gaps

Manufacturing and compliance skills: QA, QC, CTA, GMP, process development and scale-up, analytical development, knowledge of ATMP production, bioprocessing

Drug approval knowledge including understanding regulatory requirements and submission processes.

Clinical application skills including clinical knowledge, adminstration and dosage, and cell delivery devices.

Translational research skills including value chain understanding and interdisciplinary skills in combining biology, engineering and clinical application.

Specialised cell and gene technology skills including proficiency in biochemical analysis, biotechnology and genetic engineering, pharmacology and biomaterials.

Technicians

Related profiles

Fewer respondents experience skills gaps in technician related profiles (excl. engineering professionals). However, assuming an increasing need for technicians when ATMP productions scale up, addressing skills gaps for the following profiles may be crucial:

- Production and manufacturing professionals
- Laboratory professionals
- Engineering professionals*

Most prevalent skills gaps

Compliance skills, especially GMP training, QC and QA skills, including analytical testing methods, understanding of protocols and handling procedures for stability testing.

Translational research skills including life cycle understanding and knowledge of cell biology.

Manufacturing skills including process development and standardisation, scale up proficiency, bioreactors, and bioprocessing

Skills in clean room behaviour and practices such as gowning, knowledge of sterile environments, aseptic working practices, and environmental monitoring.

Hands-on experience to complement theoretical knowledge of e.g. laboratory behaviour and GMP processing.

* Engineering professionals are included in the overview of technicians as it became evident from interviews that engineering professionals take on technician roles as well as S&E roles. In order to provide a better understanding of the skill needs and gaps, it is important to also consider candidates with engineering backgrounds in relation to the technician workforce.

Skills gaps in clinical development may constitute a current and future bottleneck

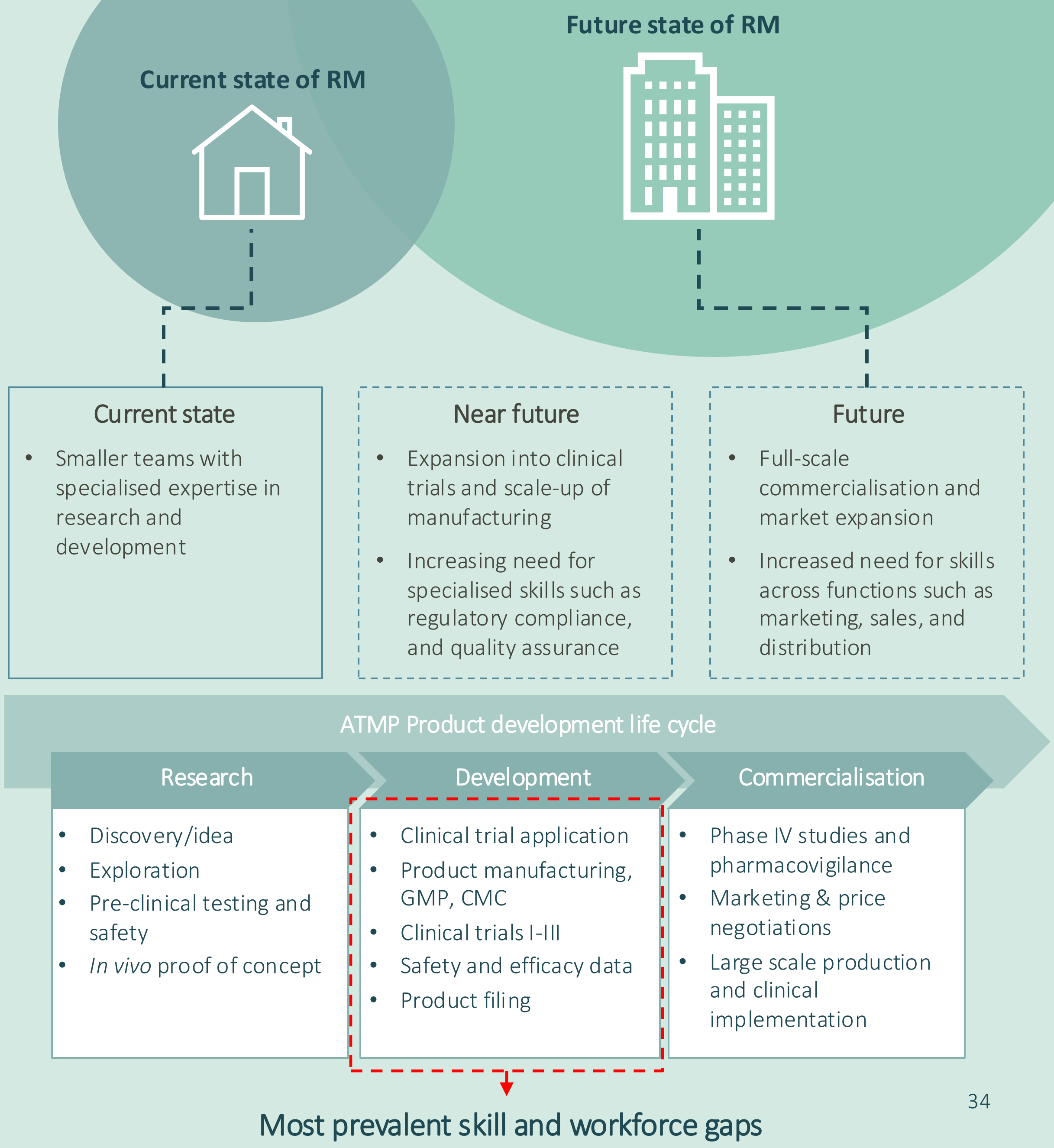
The most prevalent skills gaps are in the clinical development stage in ATMP production

The emphasis on skills in manufacturing, compliance, regulation, and translational research highlights a workforce gap in the clinical development stage. Organisations currently experience and forecast a skills gap in the transition from research to the development stage, which can also be interpreted as a reflection of the field's current maturity.

The skills gap in clinical development is also experienced as a challenge by global ecosystem representatives, especially combined with a growing gap in the number of manufacturing personnel equipped for working in RM. Representatives highlight a challenge with technician job positions in manufacturing, which often involve low pay, unfavourable working hours such as night shifts, and no options for working from home. These working conditions can deter students from pursuing a career in the field and contribute to high employee turnover as workers leave the industry. In addition, representatives echo the lack of candidates possessing both manufacturing relevant skills as well as skills in biology.

In a more distant future, products will move towards commercialisation. This will likely result in a surge in demand for application, pharmacovigilance, marketing, clinical implementation, and large-scale production expertise - all of which are essential for successfully bringing products to market and maximising their reach and impact. Thus, in addition to attending to current skills gaps, there is a need to consider how to avoid skills gaps in other areas in the future. This is however connected to higher risks, as no assurance of the field's growth and development can be asserted.

> *"The field is relatively young, so most companies and hiring personnel are either in the preclinical or early clinical phases. There are very few organisations in the late clinical or commercial phases. Consequently, the need for skills will evolve over time. With more companies emerging and obtaining a more mature profile, they will have more products in development, including those in later stages."*
>
> *- SME/Biotech*



Educational measures and initiatives

Several educational initiatives can be applied to specialise the workforce in RM

The survey and interview results indicate a need for educational measures to specialise the workforce via existing educations, continuing education and to some extent by creating new educations. The interviewees highlight needs for training students in RM skills, hands-on experience, and establishing new RM courses within existing education frameworks:

Equip educational institutions with industry experts: Employing educators from the industry can provide teachers and students with the industry-specialised knowledge they need to fit industry needs.

RM-specialisation tracks: Give students the opportunity to specialise in RM. These tracks can then be divided between students wanting academic and industry careers. These could be achieved through collaboration between university colleges and academies, that can provide skills in process analysis and manufacturing, and universities that can skill in biology.

Industry projects: Offering students opportunities to conduct projects and write theses while working in the industry gives them insights into workplace-specific intricacies and provides an inexpensive skilling and onboarding opportunity for the industry.

Promoting industry-based internships: Currently, Biomedical Laboratory Scientists often take internships in medical hospitals due to readily available positions. To guide these candidates towards industry positions, initiatives are needed to facilitate their transition.

On-going education: As the field is continuously developing, it is essential to ensure that the workforce is continuously upskilled in science, engineering and hands-on skills.

Manufacturing training facilities: Respondents stress a need for more manufacturing training facilities that can upskill candidates in manufacturing skills. Candidates come from diverse backgrounds, all of whom need to be trained to the same level.

Table 5: Which educational measures are needed to train the workforce to work with RM?	Technicians	S&Es
Increased hands on/practical experience during education	67%	63%
Increased specialisation in RM skills* during basic education**	59%	59%
Formalised workplace upskilling programmes/courses	59%	48%
RM relevant continuing education that builds on basic education	56%	48%
RM relevant courses in all existing basic educational programmes	48%	48%
New full educational programme focusing on RM skills	33%	48%

Technicians N = 18, and S&E N = 19. Only respondents who indicated that the workforce requires additional RM-specific training were presented with this question.

"If the academies were to implement regenerative medicine as a part of the educations it would most naturally be as an elective. Then students could choose to specialise in regenerative medicine during their last semester."

- Academy

"Continuous educational developments are needed as there will always be new advancements. Especially in a field as diverse as regenerative medicine, where there are many different types of treatments that can theoretically be developed."

- SME/Biotech

*The question sought to investigate ways to enhance the workforce's skill level in an open-ended manner, without focusing on or defining specific skills. Responses formed a basis for crafting interview questions and identifying skills for basic education. Therefore, "RM skills" refers to the needs highlighted in this analysis.

** In the survey 'basic education' relates to educational activities that act as the foundational stage that prepares individuals for more specialised and advanced education

A variety of educational initiatives in RM and ATMPs exist in Denmark and the Greater Copenhagen Region

Although there are some educational initiatives within RM in Denmark and the Greater Copenhagen Region, further RM-specific specialisation needs to be integrated in the educational programmes.

Aalborg University[14]**:** Aalborg University offers the course "Regenerative Medicine" as part of its Master's in Medicine, covering a spectrum of engineering concepts for cell-based therapies.

Technical University of Denmark (DTU)[15]**:** At DTU, the Cell and Drug Technologies research section plans to integrate research initiatives in RM into academic courses within the next five years, starting in 2024.

The University of Copenhagen: The University of Copenhagen is involved in research in RM and ATMPs, although these areas have yet to be incorporated into their course offerings.

Danish University Colleges: Currently, there is no specific educational focus on ATMPs and RM at Danish University Colleges. Educational representatives argue that basic methods indirectly cover the necessary skills. However, the representatives are open to developing new initiatives if there is a demand for educational programs and continuing education.

Pharmakon[16]**:** Pharmakon is a center for education and development in pharmaceutical practice. It offers customised courses for the life science industry, including GMP training that emphasises supporting the implementation of quality standards for regulatory compliance. However, these courses focus on the theoretical and regulatory aspects of GMP regulation with no opportunity for working hands-on with GMP.

Lund University[17]**:** Anchored in the Lund Stem Cell Center, five universities have developed The National ATMP Research School, offering six courses covering molecular biology and regulatory frameworks within the field. Lund University plans to develop programs at the bachelor's, master's, and PhD levels, as well as continuing education.

Despite the existence of various educational initiatives in Denmark and the Greater Copenhagen Region, these programmes could add significant value to the workforce if they offered specialisation in RM.

5 out of 9 surveyed educational representative are currently **developing RM-related electives or specialisation options** in existing educations.

"We have not had significant activities in production methods, human cells, and production activities until now. This will enable us to train more engineering students to gain hands-on experience."

- University

"We are developing programs from Bachelor's level up to PhD, and we aim to have educational programs for lab assistants and technicians as well. We are are trying to get a holistic view of the whole value chain."

- University

Pharmakon course examples in GMP

- Basic GMP
- Basic GMP for new operators
- EU GMP rules - requirements and interpretations
- Annual GMP
- GMP - latest news
- GMP for ATMPs

[14]Aalborg University (2024): AAU Modules, Regenerative medicine
[15]DTU Health Tech (2024): Cell and Drug Technologies
[16]Pharmakon (2024): GMP course overview
[17]Lund Stem Cell Center (2024): Program Overview.

International ecosystems have implemented upskilling opportunities for the workforce

Internationally, there is a preference for PhDs and post doctors. Ecosystems emphasise a strong research base as their greatest strength (see appendix D1). However, representatives highlight that this is unsustainable due to high costs, turnover risks, and a limited talent pool. They advocate for a diverse workforce across the entire educational spectrum.

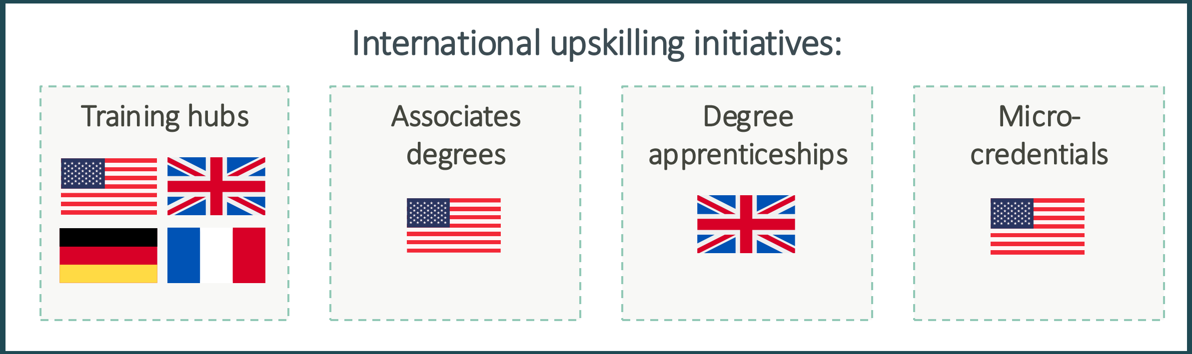
Generally, companies themselves take responsibility for upskilling their employees to tailor them to specific skills, often via onboarding courses, "on-the-job learning”, or mentorship programmes rather than formal training courses. However, several ecosystems offer alternative educational pathways in addition to conventional education:

Training hubs[18]: Clusters and facilities dedicated to upskilling employees in research and manufacturing for RM, often in collaboration with the industry.

Associate degrees[19]: These two-year undergraduate programmes provide foundational education and skills within a specific sector or area of expertise.

Degree apprenticeships[20]: These work-based higher education programmes combine academic study with on-the-job training, allowing apprentices to earn a university degree while working in a relevant industry and earning a salary.

Micro-credentials[21]: Is a way to upskill employees transitioning from adjacent industries. They certify the learning outcomes of short-term educational activities, proving that employees possess specific skills. In the Nordics, micro-credentials exist, but not within RM and ATMPs[22]. There are also varying understandings of what they entail, their extent, how they can be standardised internationally, and if the industry truly recognises their value.



”The industry often favours candidates with a college degree or a two-year associate's degree, as they can be more efficiently trained for the required skills, over those with a post-doc or a four-year degree, who may lack the hands-on experience needed to work with regenerative medicine. Although the industry still hire individuals from the latter group, there’s a gradual shift away from it. They can be perceived as expensive and volatile assets because it's not what they went to school for."

- USA

“Micro-credentials are a useful tool for quickly upskilling and reskilling existing talent. If the talent comes from adjacent industries, such as pharmaceuticals, biologics, and manufacturing, it is ideal because they are already familiar with the cleanroom style of working and working with bioreactors."

- USA

[18]UK Regenerative Medicine Platform (2024): Research hubs
[19]Associate Degree Online (2024): How to Get an Online Associate’s Degree in Biology
[20]Advanced Therapies Apprenticeship Community (2023): Become an Apprentice
[21]Workcred (2024): Credentials in Regenerative Medicine
[22]European Commission (2020): A European Approach to Micro-Credentials

Changes in workforce composition may increase demand for short-term education

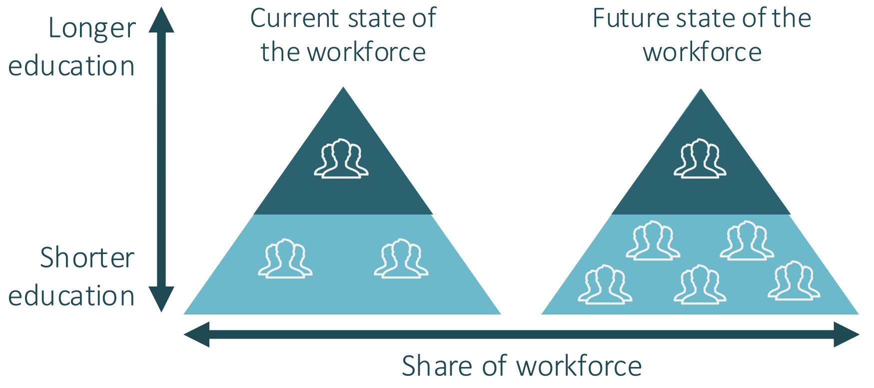
Based on experiences of international RM ecosystems, as the field matures and shifts from research to manufacturing, the demand for technicians and other employees with shorter educational backgrounds, such as AP graduates or bachelors, will increase significantly relative to highly educated employees such as researchers with PhDs.

This expectation contrasts with quantitative scenario projections, which anticipate a greater relative increase in demand for highly educated employees compared to technicians and those with shorter educational backgrounds. These projections assume that the current educational distribution will persist, reflecting historical hiring patterns dominated by highly educated individuals during the research phase. Additionally, the expected demand for AP graduates should be coupled with the results from the survey and interviews. Many AP graduates are not currently equipped with the necessary skillset to work within RM. The projected future demand for AP graduates may thus depend on the extent to which educational measures to equip candidates with RM relevant skills are applied to future educational programmes.

If the industry's expectations are met the growth rates for future demand will shift with a higher need for employees with shorter educational backgrounds, as suggested in the illustration to the right. This may enhance the deficit for the technician workforce.

Therefore, to sustain industry growth, the future workforce composition must include relatively more employees with shorter educational backgrounds.

Current and expected future composition of the workforce



"Once the industry starts producing products, the demand for technicians will increase. There are approximately 7.000 people working in RM in the UK. This number has doubled over the last five years. We anticipate another doubling in the next five years. These include technicians, lab technicians, analysts, and regulatory personnel, essential for manufacturing. Without them, investment in RM will be hindered."

- UK

Employers ask educational institutions for more practical and hands-on training

Survey and interview respondents stress the value of having hands-on experience with ATMPs in the workforce - especially within GMP. To address this challenge, collaboration between educational institutions and industry is essential to establish initiatives that align with industry needs.

Establishing GMP-approved production settings at educational institutions would be too costly and difficult to adapt to the industry's changing needs. Internships, however, provide students with opportunities to work directly in GMP-approved settings. Nevertheless, finding these internship positions can be a challenge, indicating a need for initiatives to create support initiatives for internships for those interested in careers in RM or ATMPs.

Use of Augmented Reality (AR) and Virtual Reality (VR) for Hands-on Training:

One potential alternative to cost and internship challenges is using VR and AR technologies to simulate real-life industry scenarios such as lab experiments, auditing, and GMP production settings and can provide candidates with inexpensive, preliminary exposure to GMP tasks and help them determine if such roles align with their career aspirations.

Interviewees recognise the potentials of using VR/AR and several ecosystems are exploring the use of AR and VR in manufacturing and lab settings to facilitate upskilling in GMP processes. One such initiative is the pilot AR/VR training programme for ATMP development, launched by British Cell and Gene Therapy Catapult and the University of Sheffield's Advanced Manufacturing Research Centre[23]. Part of the Advanced Therapies Skills Training Network initiative to address future skills demand, the pilot aims to familiarise users with process manufacturing technologies and equipment[24]. However, while VR and AR training can offer preliminary experiences, it should accompany and not replace physical hands-on experience and guidance from seasoned professionals.

[23]Advanced Therapies Skills Training Network (2024): CGT Catapult begins Virtual Reality training to help ensure future workforce needs.

[24]Cell and Gene Therapy Catapult (2021): Press release: FourPlus and Cell and Gene Therapy Catapult deliver cutting-edge VR training technology

"We are very present at educational institutions to foster collaboration. I don't think there's much more to it. We could start developing more specialised courses to offer more practice-oriented teaching, but that requires a broader skill set among the instructors at the institutions. One solution is to introduce research areas that align with industry needs so we can channel the skills via these research areas. The educational institutions need to generate interest in the subject areas we need, so students are directed.

- Pharmaceutical company

"Internships are important. Universities must guarantee internships for biomedical laboratory scientists, whereas laboratory technicians must find one themselves. However, since hospitals provide guaranteed internships, biomedical laboratory scientists often end up there. There is a need for more industry internships for both biomedical laboratory scientists and laboratory technicians"

- Academy

"We continue to explore VR and AR training. The prevailing belief is that while these methods will likely become more common, they will complement rather than replace physical training. I think it will significantly reduce training costs and investment needs, but eventually, some physical training will still be necessary."

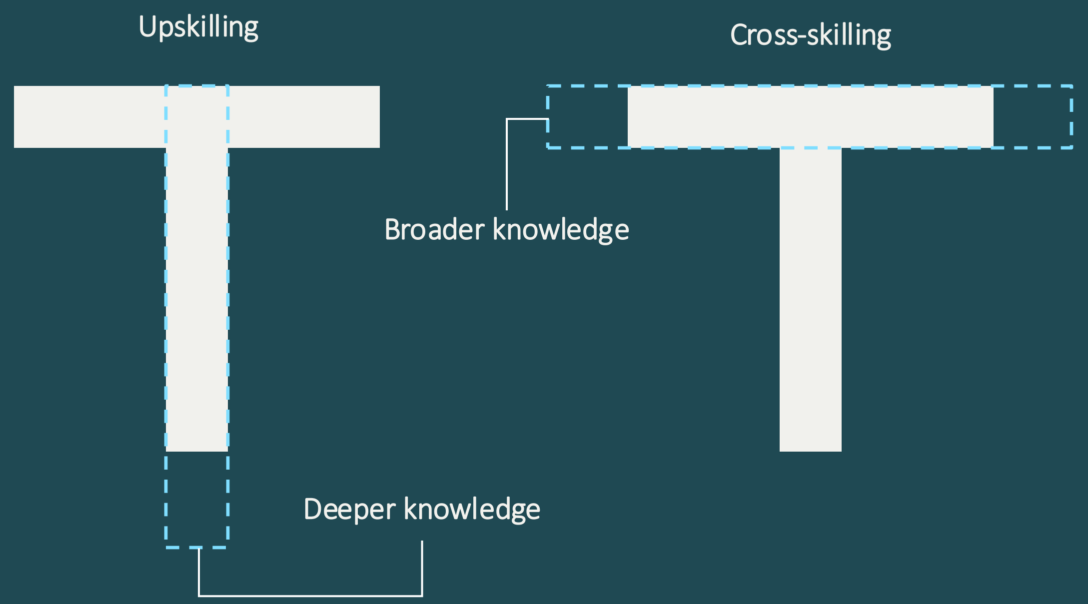
- UK

Education initiatives needed to cross-skill biopharmaceutical profiles in ATMPs

Most skills gaps highlighted in this report relate to the specificities of working with ATMPs compared to traditional drug development. There is thus a need to cross-skill candidates to also have knowledge and understanding of ATMPs, building upon an existing baseline of skills. For both technicians and S&Es interview respondents highlight needs for creating educational initiatives that can be integrated in or build upon existing relevant education. Such initiatives are being implemented in other countries.

The Atlantic Technological University in Ireland did launch a new Master of Science in ATMP Technology and Manufacturing in the academic year 2023-2024. The aim of the programme is to provide S&Es with a "comprehensive grounding in critical aspects of ATMP cell therapy and vector manufacturing and quality control/quality affairs". The programme was created in response to the expansion of the ATMP sector in Ireland and an identified need for structured educational offerings aimed to cross skill staff in existing biopharmaceutical science jobs[25]. The programme admits undergraduates from various S&E subjects relevant to the life sciences and candidates with alternative degrees who have prior experience in the ATMP industry.

In 2018, the UK established the Advanced Therapies Apprenticeship Community designed to train individuals in developing, manufacturing and delivering ATMPs[26]. The programme provides apprenticeship opportunities to a variety of talent ranging from manufacturing operatives to technical experts and researchers. Among a long list of apprenticeships, they offer programmes for science manufacturing technicians focusing on operating systems and equipment for ATMP production[27], and for laboratory technicians focusing on conducting laboratory work under highly regulated conditions and quality requirements[28].



"I would create an undergraduate/bachelor setup that is more broadly related to pharmaceutical development, where you use mammal cells. Then, I would establish master's programmes that are specific to cell therapy. I'm not considering gene therapy here, but I would adopt a similar approach to that"

- Contract Service Organisation

[25]ATU (2024): Master of Science in Advanced Therapy Medicinal Products (ATMP) Technology and Manufacturing.
[26]Advanced Therapies Apprenticeship Community (2024): Driving the ATMP workforce of tomorrow.
[27]Advanced Therapies Apprenticeship Community (2024): Science Manufacturing Technician Level 3.
[28]Advanced Therapies Apprenticeship Community (2024): Laboratory Technician Level 3.

Concluding remarks

Concluding remarks and future perspectives

To identify current and future skills demand in RM, desk research established a foundational understanding. This was complemented by analysing the Danish job market to identify skill trends and project workforce supply and demand using Statistics Denmark data. To refine these insights, surveys were sent to key industry professionals and educational representatives, followed by interviews with these. Global industry representatives were interviewed to provide international perspectives to the local findings.

While this report aims to provide a comprehensive analysis to the workforce and skills demand, details may be omitted due to the complexity of data collection and limitations in available data. Despite these limitations, the report offers novel insights into the RM ecosystem in Denmark and the Greater Copenhagen Region and serves as a stepping stone for deeper analyses.

Current gaps

Skills gaps exist across various professional profiles, particularly in manufacturing and compliance skills for S&Es. These gaps especially impact scalability and cost-effective manufacturing. Although the skills gaps for technicians are less prevalent, their importance is expected to grow significantly as the industry matures.

The transition from preclinical to clinical development will be a critical challenge, requiring interdisciplinary talents adept in manufacturing, biology, and regulatory expertise. Moreover, there is a growing need for skills in commercialisation and clinical application, areas currently experiencing shortages.

Many employers expect the workforce to possess advanced degrees, such as PhDs, along with extensive experience in the field. This creates a need for specialised educational activities so graduates can add immediate value to the workforce.

As such, employers express a need for initiatives that foster collaboration between educational institutions and industry. This includes implementing diverse educational programmes such as ATMP-specialised courses, innovative training methods, internships, apprenticeships, and continuing education opportunities.

Future gaps

As the field of RM matures, the composition of the workforce is expected to evolve significantly by 2035. There will be a growing demand for shorter educational programs and an increase in technicians to support manufacturing processes. Advances in automation and artificial intelligence promise to reduce costs and make manufacturing less labour-intensive. These technological advancements will also create new skill requirements, such as data scientists and data engineers specialized in biology and cell and gene therapies. Employees transitioning from manual tasks to automated processes will also need to acquire new data management skills.

The future workforce gaps in RM will depend on political initiatives, policies, and technological advancements. Addressing future skill shortages will require a collective effort from all relevant actors in the regenerative medicine ecosystem.

The success of RM will hinge on closing current and future workforce and skills gaps, supporting political initiatives to foster ecosystem growth, and leveraging technological advancements such as AI, augmented reality, and virtual reality.

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Methodology & appendix

Appendix table of content

Methodology

Survey and interview analysis

Interview and survey population analysis

Survey Analysis

A survey was distributed to companies and educational institutions relevant to regenerative medicine in Denmark and Sweden. Organisations were selected based on insights from desk research and input from the associated expert panel. Conducted between December 2023 and March 2024, the survey was sent to 121 organisations, with 36 completing it. Among the 36 respondents, 25 worked in organisations involved in RM and two expected to do so within the next 10 years, resulting in a response rate of 22,3%. Depending on the given sample size, generally, an acceptable survey response rate is between 5% and 30%. Although the response rate for the survey in this analysis falls within this range and is thus considered to be representative for the sample, more participants always yield more in-depth results. However, it is also important to note that the 27 respondents collectively represent 1962 employees working in RM.

The survey aimed to map the current availability of relevant skills, as defined during desk research, and to gain further insight into other relevant skills and gaps. Additionally, it sought to identify expectations for future skill needs and gaps. Topics covered in the survey included current and future workforce skill needs, gaps experienced within the medicinal product development value chain, key professions crucial to the workforce, and necessary initiatives to reduce future workforce gaps.

Throughout the survey period, respondents received multiple email reminders and phone calls to follow up on response status.

The survey has served as the foundation for identifying current and future workforce skill needs, with the results informing subsequent interviews.

Interview Analysis

To obtain a deeper understanding of workforce demand, 39 interviews were conducted between March and April 2024. These interviews included 21 company representatives and 2 authority representatives, aimed at comprehending their skill and workforce demands. Additionally, interviews were conducted with 16 educational institutions to understand how they currently supply skilled employees to the workforce.

The interviews followed a semi-structured interview guide, with three separate guides tailored to target each population group. These guides provided a framework for the interviews while allowing flexibility to explore insights further, including themes such as current experienced skills gaps, the need for specialisation versus educational level, the importance of hands-on experience, and future trends within the Nordic ecosystem.

Conducted via Microsoft Teams, the interviews lasted between 45 and 60 minutes and were recorded for transcription. Subsequently, the interviews were thematically analysed to identify overlapping trends and skills gaps across industry and educational representatives. All quotes were translated into English and refined for clarity and coherence. Insights from the interviews were supplemented with desk research, particularly focusing on specific initiatives or resources mentioned during the interviews.

Methodology

Projections

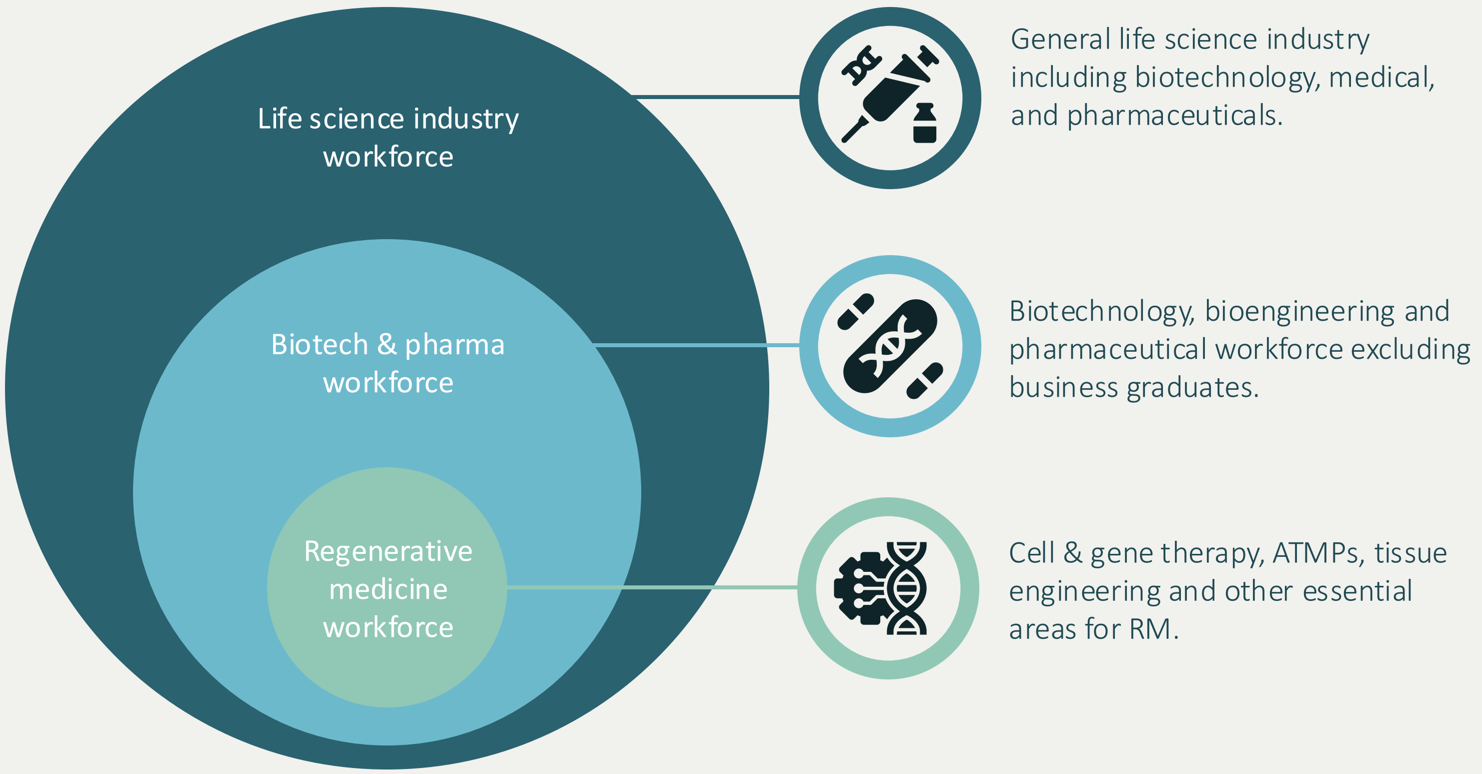
Analysing the workforce requires simplifications

The highly specialised and relatively new field of regenerative medicine (RM) poses challenges in quantifying its workforce. The analysis and case projections are rooted in microdata obtained from the registers of Statistics Denmark and projections made by the DREAM group. However, the granular nature of this data is inadequate to analyse the workforce in RM exclusively.

As there are no direct educational paths or defined industry codes for RM or ATMPs, ADC has made certain simplifying assumptions to realistically model a workforce. The labour force observed in the analysis is derived from a curated list of educations and industry lines, adhering to the Danish statistical classification of economic activities (NACE). The analysis excludes the public sector or educational backgrounds with a focus on business, management, or administration.

It's important to note that the analysis extends beyond just the workforce in RM, as illustrated in the accompanying figure. Hence, the results should not be seen as exclusive to RM but rather as a reflection of a broader workforce that encompasses this field. As a result, trends specific to RM may not necessarily align with the findings.

Regenerative medicine is assumed to be encapsulated by other well-defined areas



Methodological considerations

The projection model from DREAM does not adjust for the individual connection to labour market. This is accounted for by scaling the workforce within each five-year age group, between the ages 20-75, and educational level with the average employment rate between 2016-2021.

The demand of labour follows two scenarios. One where the growth of the labour market within each educational level follows the historic rates between 2016 and 2022. In the high-growth scenario the growth rates for each educational level are taking from the report "Dansk life science frem mod 2030". From 2030 to 2035 the growth rates in both scenarios are adjusted according to the projections for the relevant fields made by the DREAM group in the Education Projection from September 2023.

The labour force within regenerative medicine is based on a list of education codes (see next slide) and selected line of industries from the Danish system of statistical classification of economic activities (NACE). Hence, the analysis does not examine the public sector.

The line of industries are:

211000	Fremstilling af farmaceutiske råvarer
212000	Fremstilling af farmaceutiske præparater
325000	Fremstilling af medicinske og dentale instrumenter samt udstyr hertil
721100	Forskning og eksperimentel udvikling indenfor bioteknologi

Assumptions in the model

- The average employment rates for each age group and educational level in 2035 will be the same as the average between 2016-2021.
- The retirement age will increase to 69 by 2035, but individual who are 75 years old are included, since it is assumed that the number of seniors on labour market will increase in the future.
- The share of the labour force that works within the field of RM for each educational level will grow with the historic rates toward 2030. From 2030-2035 these shares will grow at rates from the DREAM groups educational projections.
- The ratio between the employees within RM to the total workforce in Denmark within each educational level in 2035 will be equal to the average between 2016-2022.
- Demand is forecasted based on the number of full-time employees in 2022, while the demand is forecasted based on the total number of individuals available in the labour force.

The analysis is based on a selected list of educations from Statistics Denmark that are deemed important for the field of regenerative medicine (1:2)

Educations	AUDD-code
Bioteknologi, cand.polyt	3000 / 8333
Biokemi, bach.	3045 / 8050
Biomedicinsk teknik, cand.scient.med.	3049 / 7195
Biosystemteknologi, cand.scient.tech.	3050
Bioteknologi, master	3051
Molekylærbiologi, cand.scient.	3058 / 8202
Lægemiddelvidenskab, cand.scient.	3137 / 7430
Kemi, cand.scient.	3139
Anvendt kemi, cand.polyt.	3140
Medicin og teknologi, cand.polyt.	3141 / 8332
Biomedicinsk informatik, cand.scient.	3155
Sundhedsinnovation, cand.merc.(sund.)	3207
Laboratorieteknologi, prof.bach.	3274
Lægemiddelregistrering, master	3309
Biosystemteknologi, cand.polyt.	3344
Kvantitativ biologi og sygdomsmodellering, cand.polyt.	3354
Akademiuddannelse i proces-, laboratorie- og fødevareteknologi	3841
Procesteknolog, kemisk-bioteknologisk	4029
Laborant	4036
Laboratorietekniker, biologi	4049
Laboratorietekniker, kemi	4050
Biokemi, cand.scient.	4208 / 8090
Procesoperatør med speciale i pharma og fødevareingrediens	4567
Laboratorietekniker	5061
Bioanalytiker, prof.bach.	5159
Klinisk biomekanik, bach.	5165
Sygeplejerske, prof.bach.	5166
Farmakonom	5177
Laboratorie-, fødevare- og procestekn. (overbygning), prof.bach.	5210 / 5459
Kemiteknik, cand.polyt.	5240
Bioinformatik og systembiologi, cand.polyt.	5241
Kemi og bioteknologi, cand.scient.tech.	5245
Klinisk biomekanik, cand.manu.	5265
Kemiteknologi, ing.prof.bach.	5270
Kemi og bioteknologi, cand.polyt.	5273 / 5544
Kemi- og bioteknologi, ing.prof.bach.	5275
Kemiteknik og International Business, ing.prof.bach.	5282
Kemi, teknikumingeniør	5330
Kemi, ingeniør prof.bach.	5339
Kemi, akademiingeniør	5355
Kemi, cand.polyt.	5363 / 8092
Teknisk videnskab, ph.d.	5399
Farmaceut, cand.pharm.	5425 / 7425
Bioteknologi, ing.prof.bach.	5429 / 7933
Medicinalbiologi, cand.scient.	6119 / 6127
Molekylærbiologi, kombination (RUC)	6129
Biologi, kombination (RUC)	6130
Almen biologi, cand.scient.	6131
Kemi, kombination (RUC)	6138
Medicin, c.med.	7170
Medicin, bach.	7172
Biomedicine, cand.scient.	7174
Humanbiologi, c.scient.	7175
Sundhedsvidenskab, ph.d.	7180
Folkesundhedsvidenskab, cand.scient.san.publ.	7185 / 7187
Klinisk videnskab og teknologi, c.scient.	7188
Immunologi og inflammation, cand.scient	7314
Lægemiddelvidenskab, bach.	7415
Farmaci, bach.	7420
Farmaceutisk videnskab (cand.scient.pharm.)	7424 / 7426
Medicin med industriel speciale, bach.	7920
Kemiteknologi, ing.bach.	7922 / 8140
Bæredygtig bioteknologi, ing.bach.	7924
Sundheds- og velfærdsteknologi (teknisk videnskab), ing.bach.	7928
Medicin og teknologi, ing.bach.	7932
Life Science og Teknologi, ing.bach.	7964

The analysis is based on a selected list of educations from Statistics Denmark that are deemed important for the field of regenerative medicine (2:2)

Educations	AUDD-code
Medicin med industriel specialisering, cand.scient.med.	7995
Naturvidenskab, ph.d.	8000
Kemi (komb. HUM), cand.scient.	8014
Medicinalkemi, bach.	8040
Sundhedsteknologi, ing.bach.	8042
Biofysik, bach.	8045
Bioengineering, cand.polyt.	8046
Biofysik, c.scient.	8095
Biologi, bach.	8139
Molekylærbiologi, bach.	8149
Molekylær biomedicin /Molekylær medicin, bach.	8150
Medicinalkemi, c.scient.	8151
Bioteknologi (NAT), bach.	8152
Biomedicin, bach.	8155
Biokemi og molekylær biologi, bach.	8156
Biologi, industribach.	8169
Engineering (Biomaterial Engineering for Medicine), cand.polyt.	8174
Biologi, cand.scient.	8200 / 8226
Molekylær biomedicin /Molekylær medicin, cand.scient.	8205
Biochemistry and Molecular Biology, cand.scient.	8227
Bioteknologi (NAT), cand.scient.	8231 / 8270

Bioinformatik, cand.scient.	8233
Bioteknologi, ing.bach.	8265
Nanobioscience, bach.	8291
Nanoscience, cand.scient.	8295
Nanobioscience, c.scient.	8296
Biomedicinsk teknologi, cand.polyt.	8312
Erhvervsøkonomi og bioentrepreneurskab, cand.merc.(bio)	8319
Sundhedsteknologi, cand.polyt.	8327
Farmateknologi, cand.polyt.	8328
Bæredygtig bioteknologi, cand.polyt.	8346
Biosystemteknologi, cand.polyt.	8351
Kemisk og biokemisk teknologi, cand.polyt.	8358
Nanobioteknologi, cand.polyt.	8370
Medicinsk bioteknologi, cand.polyt.	8371
Teknologisk diplomuddannelse i bio- og procestekn. og kemi	8359
Klinisk sygepleje, master	8882
Industriel lægemiddeludvikling, master	8883
Kvalitetssikret lægemiddelanvendelse, master	8884
Pharmaceutical regulatory affairs, master	8891
Bioteknologi, master	8899
Health care IT, master	8909
Exam. pharm.	9465

Step-by-step illustration of the model

Supply

Based on data from Statistics Denmark the current number of people in the labour force in 2022 within each age group and educational level for both the regenerative medicine field and the total labour force in Denmark are found.

Based on data from the DREAM group the total labour force for each age group within each level of education in 2035 is calculated.

The total available labour force in Denmark is adjusted with the proposed connection to the labour market for the ages between 20-75, based on the average employment rate for each age group within each educational level between 2016-2021.

Lastly, the supply of the labour in the regenerative medicine field is calculated by scaling the total labour force within each age group and educational level by the fraction of the RM workforce of the total workforce from 2022.

Demand

Based on data from Statistics Denmark the current number of full-time employees (FTEs) in the labour force in 2021 within each age group and educational level for the RM field are found.

The yearly average growth rates for each educational level with the field of regenerative medicine is calculated from 2014-2022

The historic calculated growth rates, growth rates from the DREAM groups education projections, and "Dansk Life Science frem mod 2030" are used to calculated the expected demand within each educational level for two different scenarios.

The balance between expected supply and demand of the RM workforce are compared within each educational level in 2035

Literature for quantifying regenerative medicine from market size

Regenerative medicine:

- Fortune Business insights, USD 28,6 billion in 2022 => USD 197 billion in 2030 (28,2% CAGR)
- Presedence research USD 22,2 billion in 2022 => USD 174,7 billion in 2032 (22,8% CAGR)
- Global market insights USD 52,3 billion in 2022 => USD 329 billion in 2032 (20,4% CAGR)
- Future market insights USD 13,4 billion in 2023 => USD 73 billion in 2033 (18,5% CAGR)
- Imarc group USD 22,2 billion in 2023 => USD 116,1 billion in 2033 (19,6% CAGR)
- Data horizzon research USD 18,3 billion in 2022 => USD 100,9 billion in 2032 (18,7% CAGR)
- Verified market research USD 39,9 billion in 2022 => USD 179,8 billion in 2030 (17,9% CAGR)
- Acumen research consulting USD 21,6 billion in 2022 => USD 204,1 billion in 2032 (22,7% CAGR)

Biotech

- Presedence research USD 1.224 billion in 2022 => USD 3.210 billion in 2030 (12,8% CAGR)
- Grand view research USD 1.370 billion in 2022 => USD 3.880 billion in 2030 (14% CAGR)
- Acumen research consulting USD 430,6 billion in 2022 => USD 1.345 billion in 2030 (15,5% CAGR)
- Vantage Market Research USD 1.094,6 billion in 2022 => USD 2.772 billion in 2030 (14,2% CAGR)
- Straits research USD 729 billion in 2022 => USD 2.200 billion in 2030 (14,8% CAGR)
- Emergen research USD 1.370 billion in 2022 => USD 5.010 billion in 2032 (14,8% CAGR)
- Coherent Market Insights USD 820,4 billion in 2023 => USD 1.850 billion in 2030 (12,3% CAGR)
- Market Research Community USD 900,9 billion in 2022 => USD 1.849 billion in 2030 (9,4% CAGR)

Pharma

- Acumen Research Consulting, USD 1.500 billion in 2022 => USD 2.800 billion in 2032 (6,4% CAGR)
- Fortune Business Insights, USD 1.585 billion in 2021 => USD 2.401 billion in 2029 (6,1% CAGR)
- Fact and Factors, USD 1.482 billion in 2021 => USD 2.309 billion in 2030 (5,7% CAGR)
- The Business Research Company, USD 1.738 billion in 2023 => USD 3.206 billion in 2030 (8,5% CAGR)
- Grand View Research USD 1.482 billion in 2022 => USD 2.363,2 billion in 2030 (6,1% CAGR)
- Presedence research USD 1.200 billion in 2022 => USD 1.780 billion in 2032 (4,1% CAGR)

- Skyquest, USD 222,4 billion in 2022 => USD 353 billion in 2030 (5,9% CAGR)
- Business Research Insights, USD 484 billion in 2021 => USD 1.518 billion in 2030 (11,8% CAGR)

Methodology

Job post analysis

LIT gives us access to analyse 3,9 million job posts in the Danish labour market

Labour Intelligence Tool (LIT) is a platform developed by the Danish company, Tembi, previously a branch under ADC. LIT contains close to 3.9 million job postings from the job database "Jobindex" dating back to 2008. A sample of job posts has been retrieved, from which the current demand for specific skills has been identified relating to RM.

The analysis focused on job posts in the period from January 2020 to October 2023. To extract insights from the unstructured text in the job posts, all identified job posts underwent pre-processing through LIT's machine learning and natural language processing algorithm. This pre-processing automatically detects and extracts employers, educational requirements, skill requirements etc. from job posts, making it possible to analyse the data on an aggregated level.

Through a qualitative assessment, the identified skills retrieved in the sample have been categorised into two groups: specialised skills and baseline skills. In this report, specialised skills are defined as skills that are specific and unique to the job type in question, and which does not go across a broad range of jobs. Baseline skills encompass common, non-specialised skills that cut across a broad range of job types. In cases where identified skills have been assessed to be the same or similar, such as the case for the skill "dansk" and "Danish", these skills have been combined to a single entity.

3,9 million Danish job postings since 2008 have been continuously gathered

Job posts in the period January 2020 to October 2023 are isolated

AI detects and extracts data such as employer, skill requirements etc. that are relevant to RM

Highlighted skills are qualitatively assessed to be baseline or specialised skills

A thorough literature review created the basis for a search using keywords

Conducting a search in LIT using only the keywords 'regenerative medicine' yielded 49 job posts in the sample. Subsequently, a literature review was conducted to identify keywords that reflect the current demands for skills within RM. The objective was to expand the list of keywords for a more comprehensive search. The literature review uncovered various papers that have analysed the skill and workforce gap in regenerative medicine and its related scientific fields, offering different perspectives. After reviewing the papers, four key articles were selected to provide a list of keywords to be used in the search in LIT. These papers include analysis within RM, biomanufacturing, and cell and gene therapy.

The keywords chosen for the search query relates to key skills identified in the literature. Further, the keywords were tested in LIT and their results qualitatively inspected. The keywords used in the final search query showed results that related to skills and procedures also identified in the literature review, thus strengthening the sample. The selected keywords aim to sample workforce demand across the value chain in ATMP development. Thus, broader terms, such as “patient selection”, have also been included to capture e.g., translational medicine. Generic keywords, such as «manufacturing», that would largely increase the sample but provided more noise in the data were excluded.

The identified papers and the subsequent keywords extracted from the papers are highlighted on the right. Conducting a LIT-search using these keywords resulted in a dataset revealing 5.794 job posts within the sample, out of a total of 1.191.337 job posts spanning from January 1st, 2020, to October 1st, 2023. An example of a retrieved job post can be found in appendix E11.

Selected papers

- Carrese, J. (2021). Labor Market Analysis for Cell and Gene Therapy Technician Workforce. The national Institute for Innovation in Manufacturing Biopharmaceuticals.
- Green, G. M., Read, R. H., Lee, S., Tubon, T., Hunsberger, J. G., Atala, A. (2021). Recommendations for workforce development in regenerative medicine biomanufacturing. Stem cells translational medicine, 10(10), 1365–1371.
- Candarlioglu, P. L., Dal Negro, G., Hughes, D., Balkwill, F., Harris, K., Screen, H., et al. (2022). Organ-on-a-chip: Current gaps and future directions. Biochemical Society Transactions, 50(2), 665-673.
- Fekete, N., Walker, R., Pike, N. (2023). Workforce Report: Gap Analysis for the Cell and Gene Therapy Sector. Alliance for Regenerative Medicine.

Extracted keywords

"cell therapy", "gene therapy", "immunotherapy", "cell biology", "regenerative medicine", "stem cells", "viral vector", "T-Cell therapies", "advanced therapy", "mammalian cell culture", "mammalian tissue culture", "stem cell concepts", "stem cell applications", "bioprocessing operations", "bioprinting", "downstream processing", "upstream processing", "Biomechanics", "chromatography", "tissue-engineering", "3D bioprinting", "organoid technology", "synthetic biology", "patient selection", "trial design", "drug development", "biomarkers", "micro-fabrication", "organ on chip", "flow cytometry"

Available job posts and preprocessing algorithm cause limitations to the analysis

It's important to acknowledge that LIT exclusively includes job posts from Jobindex, representing the Danish job market. Consequently, the findings do not fully capture the skills demand entirely across Denmark and the Greater Copenhagen Region. Additionally, this review excludes job posts from individual company websites and other databases such as LinkedIn, unless these are also posted on Jobindex. Therefore, it is advised to interpret the results in combination with other data sources.

By using a keyword search query in LIT that returns aggregated data, it is not possible to identify which job posts are explicitly related to RM or locate data’s corresponding job posts. The data retrieved represent indications from related scientific fields of the target population. Thus, the findings of this LIT-analysis does not comprehensively depict the full demand of skills within regenerative medicine.

While the keywords employed for the search in LIT have been recognised as being relevant to RM, it is important to note that the job postings extracted from LIT, and consequently the results provided in this section, cannot be guaranteed to precisely align with job posts specifically related to regenerative medicine. However, the job posts obtained through LIT articulate a similar demand for skills.

The analysis should therefore be understood as an analysis of a sample group that relates to the target population.

The identified skills have been contextualised through supplementary data sources, such as surveys and interviews conducted with people currently employed within RM. These sources confirm the pattern identified in this analysis.

Appendix A

Defining regenerative medicine and ATMPs

Appendix A1: Definition of Regenerative Medicine

Regenerative Medicine is a multidisciplinary field of medical research and practice that may be defined as "the process of replacing or "regenerating" human cells, tissues or organs to restore or establish normal function"[1]. The promise of RM is to revolutionise medical care for a variety of diseases by fixing the root causes[2].

This analysis examines the skills demand within regenerative medicine with a specific emphasis on the development of ATMPs (defined on the following page). The only exception is the projections of Danish workforce demand and supply where assumptions are based on expected growth in the global RM market specifically.

ATMPs are therapeutic products applied within the field of regenerative medicine. The term 'regenerative medicines' is often used as an umbrella term for ATMPs or synonymously with ATMPs. Furthermore, research highlights that new regenerative medicines are classed by the EMA as being ATMPs which are "engineered regenerative medicines encompassing cell-based therapies (often using stem cells or progenitor cells to produce tissue), gene therapies and tissue-engineered therapies"[3]. Therefore, focusing on ATMPs can provide a robust insight into the skills demand within regenerative medicine.

The decision to scope the analysis around ATMPs is supported by the following reasons:

1) Advancing the field of regenerative medicine requires specific skills to develop and work with ATMPs.
2) The field of RM is multifaceted with varying definitions, hence focusing on ATMPs can streamline the analysis and yield tangible insights.
3) The term 'ATMPs' facilitates a common language among diverse stakeholders and countries, enhancing the productivity of the analysis.

This focus on ATMPs implies that the analysis does not include other regenerative medicines, such as bone marrow transplants, which are regulated as transplants rather than medicines[4]. This distinction is critical to consider when interpreting the findings.

In this report, the terms 'ATMPs' and 'regenerative medicine(s)' are occasionally used interchangeably, acknowledging the nuances between them[5].

[1]Association for the Advancement of Blood & Biotherapies: Regenerative Medicine
[2]Institute for Stem Cell & Regenerative Medicine: What is regenerative medicine?
[3]Corbett et.al (2017): Innovative regenerative medicines in the EU: a better future in evidence?
[4]UK Parliament (2016): Written evidence submitted by the Medicines and Healthcare products Regulatory Agency.
[5]European Medicines Agency: Advanced Therapy Medicinal Products: Overview.

Appendix A2: Definition of Advanced Therapy Medicinal Products (ATMPs)

This report applies EMA's definition of ATMPs (I) :

ATMPs can be classified into three main types:

Gene therapy medicines (GTMPs)

These contain genes that lead to a therapeutic, prophylactic or diagnostic effect. They work by inserting 'recombinant' genes into the body, usually to treat a variety of diseases, including genetic disorders, cancer or long-term diseases. A recombinant gene is a stretch of DNA that is created in the laboratory, bringing together DNA from different sources.

Somatic-cell therapy medicines (CTMPs/sCTMPs)

These contain cells or tissues that have been manipulated to change their biological characteristics or cells or tissues not intended to be used for the same essential functions in the body. They can be used to cure, diagnose or prevent diseases.

Tissue-engineered medicines (TEPs)

These contain cells or tissues that have been modified so they can be used to repair, regenerate or replace human tissue.

In addition, some ATMPs may contain one or more medical devices as an integral part of the medicine, which are referred to as **combined ATMPs**. An example of this is cells embedded in a biodegradable matrix or scaffold.

While the terms 'ATMPs' and 'regenerative medicine' are used throughout the report, the workforce challenges and skills gaps identified may be applicable beyond the ATMP or regenerative medicine area, extending to other areas of the life science and biotech sector. Each of the respondents might face unique recruitment challenges, but this report concentrates on the commonalities across multiple respondents.

Appendix A3: Definition of the ATMP development life cycle

The product development lifecycle for ATMPs involves several stages, from initial discovery to post-market surveillance. The illustration of the process as seen below is created from knowledge gathered through review of material on the subject and interviews with stakeholders. While the product development lifecycle for ATMPs shares similarities with traditional drug development, it carries unique considerations and challenges that are important to highlight in order to contextualise the insights presented in this report.

In the context of ATMPs, manufacturing processes are often developed concurrently with clinical development. This is also true for conventional drug development, but the processes can be more standardised in comparison to ATMPs. During clinical trials, manufacturing processes are developed and optimised to ensure that the ATMP can be produced consistently and safely. This often involves small-scale production for early-stage clinical trials (phase I-II).

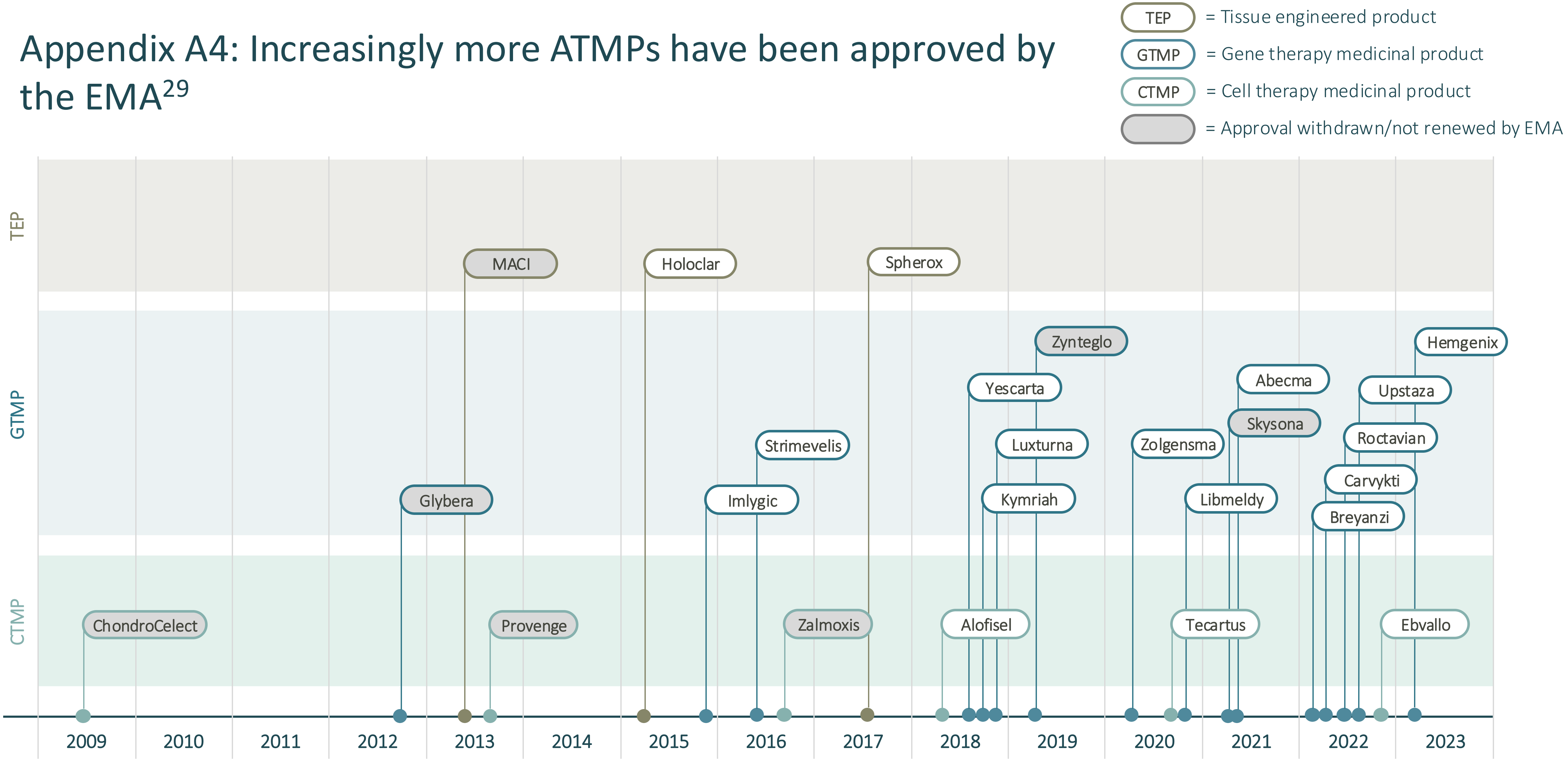
As the product advances to later stages of clinical development (phase III), the manufacturing process also needs to be scaled up. This involves ensuring that the product can be made at a larger scale without compromising safety, efficacy, or quality. All critical aspects of manufacturing need to meet stringent regulatory standards. In this part of the development, traditional drugs are typically less complex and more predictable in their manufacturing process. They are often synthesised through chemical processes, which are more easily controlled and standardised than the biological processes used in ATMP manufacturing.

Furthermore, traditional drugs are usually produced on a large scale for a broad patient group, rather than being personalised for individual patients. Given the often-personalised nature of ATMPs, the manufacturing process may need to be adapted for each patient. This adds an additional layer of complexity to the manufacturing process during clinical development.

Product development life cycle

Research	Development	Commercialisation
• Discovery/idea • Exploration • Pre-clinical testing and safety • *In vivo* proof of concept	• Product manufacturing, GMP, CMC • Clinical trials I-III • Safety and efficacy data • Product filing • Clinical trial application	• Phase IV studies and pharmacovigilance • Marketing & price negotiations • Large scale production and clinical implementation

Appendix A4: Increasingly more ATMPs have been approved by the EMA[29]



Appendix B

Survey and interview analysis

Appendix B1: The survey results represents 27 respondents that work or will work in RM

The survey population in this study consisted of a total of 121 organisations identified as working with RM, identified through preliminary desk research. Of the 121 organisations, 36 completed the survey. Of the 36 respondents, 25 confirmed they work with RM and two respondents replied that their organisation does not currently work in RM but plans to within the next 10 years. These respondents make up the population of the survey. This results in a response rate of 22.3% within the target respondent group. The 9 respondents that did not work in companies that operate in RM or were unsure have been excluded from the survey.

Most of the respondents work at organisations that are either academic institutions or small or medium-sized companies. Most of the respondents work in organisations with between 1-9 or 10-49 employees that work with RM.

The respondents within the population primarily work in Denmark and Sweden and retain high-level positions in their organisations.

121 organisations were invited to the survey
36 organisations completed the survey
11 organisations did not finish the survey
74 did not participate in the survey

25 organisations work with RM
2 expect to work with RM ≤10 years
8 do not work with RM
1 was unsure if they work with RM

The population of the survey consists of 27 respondents

15 work in Denmark
10 work in Sweden
2 work in Norway
1 works in the Netherlands

10 participants work in academic institutions
7 work in a small or medium sized enterprise
5 work in a hospital
3 work in a CMO / CDMO
2 work in a pharmaceutical company

8 are C-level employees
8 are heads of a department
7 are professors
2 are directors
1 is an expert
1 is a vice-president

10 work in organisations with 1-9 employees in RM.
10 work in organisations with 10-49 employees in RM.
4 work in organisations with 50-249 employees in RM.
3 work in organisations with over 250 employees in RM.

Appendix B2: The surveyed organisations represent nearly 2.000 employees working with RM

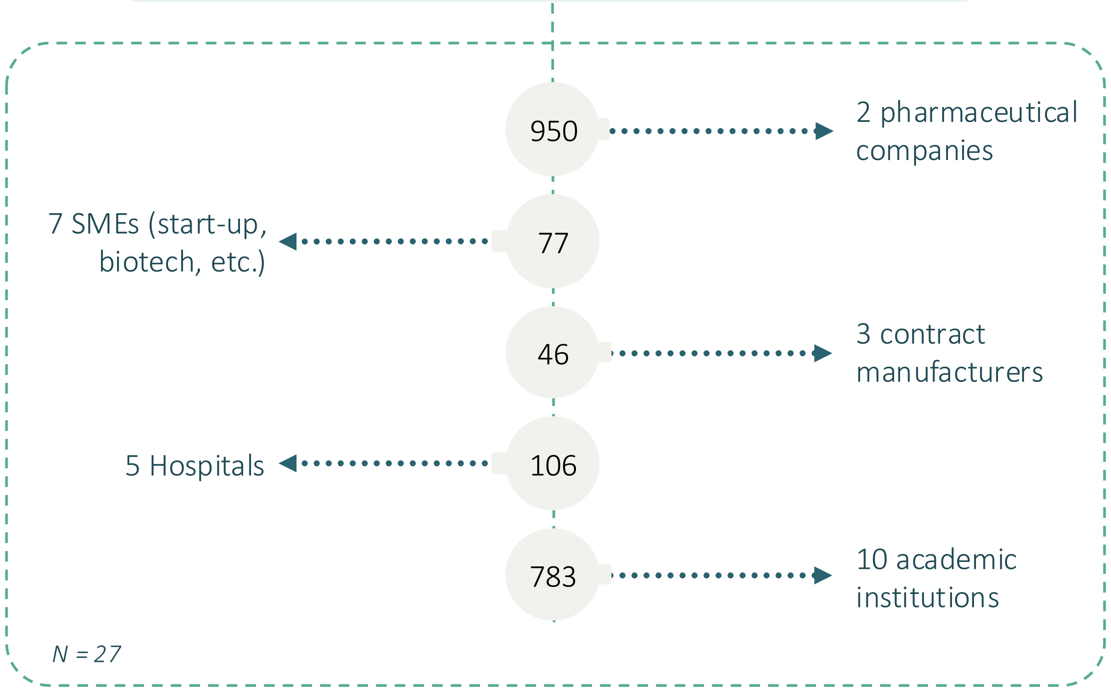
As the survey population consists of a sample size of 27 respondents, any conclusions about skills gaps in RM should be considered with some uncertainty. Nevertheless, there is substantial value in understanding the sector's experiences and expectations related to workforce requirements.

Although the sample size is relatively small, their responses represent a broader workforce. According to survey responses, 1.962 individuals currently make up the RM workforce in the surveyed organisations*.

The survey responses indicate that the RM workforce exists across various types of organisations, including academic institutions, hospitals, small and middle-sized enterprises (SMEs) working with biotech, contract manufacturers, and large pharmaceutical companies.

The numbers presented here seem to deviate significantly from the projections. However, the projections focus only on the Danish private sector, while the numbers presented here include the public sector, employees from other countries working for multinational pharmaceutical companies, and academic institutions outside of Denmark.

Figure 10: Distribution of 1.962 self-reported employees working with RM in the surveyed organisations:



*The data is self-reported and the inclusion criteria for identifying the RM relevant workforce may vary among respondents.

Appendix B3: Respondents value long educations for S&Es and hands-on experience for technicians

Survey and interview respondents largely expect their employees to possess advanced degrees, such as PhDs or postdoctoral qualifications.

This is especially the case for those in S&E roles, as they are expected to design and lead research initiatives and processes, work independently, demonstrate analytical critical thinking skills. These roles often require deep subject matter knowledge, typically found in individuals with PhD and postdoctoral experience. Conversely, the technician workforce is not expected to have the same level of education. Instead, technicians are valued more for their hands-on skills than for extensive academic qualifications.

Additionally, survey respondents highlight that current opportunities for gaining experience in RM or ATMPs primarily require previous work experience in these fields, thereby excluding recent graduates from entering the workforce.

Survey results show that one-third of respondents believe the technician workforce, and over half believe the S&E workforce, cannot obtain necessary specialised RM skills through existing educational programs. As a result, respondents emphasise the importance of workplace upskilling for most candidates. Respondents highlight that if educational programs offered specialized training, it could potentially reduce the necessity for workplace upskilling. The results show that while technicians can largely be equipped with the necessary skills through their basic education, S&E personnel are in greater need of continuous and workplace-specific upskilling.

56% of respondents state that the technician workforce, and 63% state that the S&E workforce, require experience working with RM or ATMPs before they have the necessary skills.

N = 27

37% of respondents state that the technician workforce, and 52% state that the S&E workforce, **cannot gain necessary** specialised RM skills through **existing** educational programs.

N = 27

48% of respondents state that upskilling the technician workforce, and 26% state that upskilling the S&E workforce, would become **unnecessary** if they received RM-specific training in their education.

N = 27

"To excel in our field, one must possess a considerable degree of specialisation. When it comes to technicians and operators, I prioritise specialisation over general education. However, in roles such as process development, the balance shifts. Here, a broader educational background becomes more valuable. For scientists, a PhD is typically a requirement."

- SME/Biotech

Appendix B4 : Upskilling is currently required for most candidates before they have the necessary skills

Does the workforce need upskilling or training?

A significant portion of survey respondents, 81% for scientists and engineers and 78% for technicians, believe that additional training, upskilling, and/or certification are essential for these groups to acquire the necessary skills for working in the field of RM.

Does the workforce need prior experience working with GMP?

60% of respondents respond that scientists and engineers, and 52% respond that technicians, need prior experience in working with GMP to acquire the necessary skills for working with RM.

Figure 11: The workforce needs upskilling/training/certificates before it has the needed skills

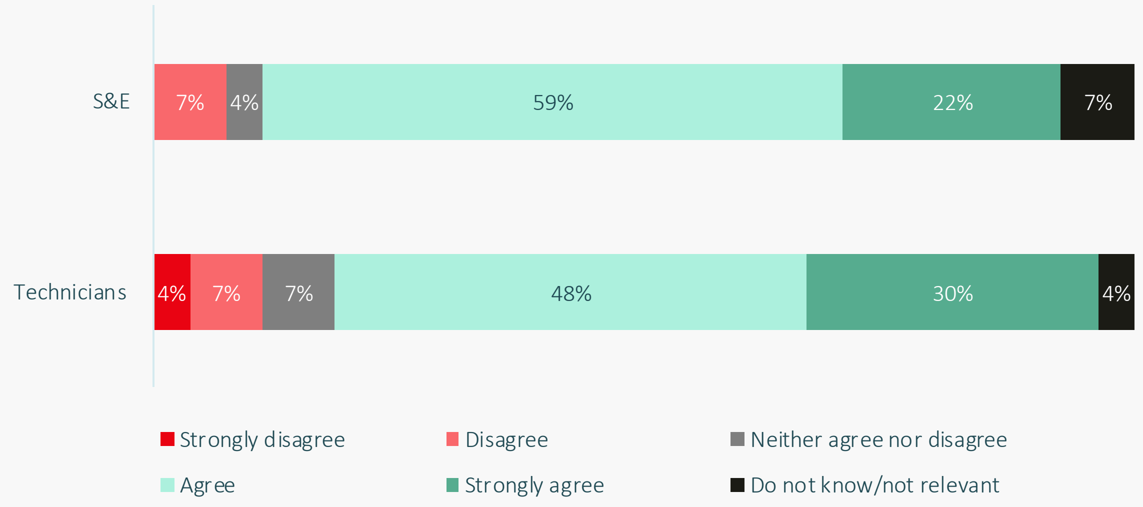
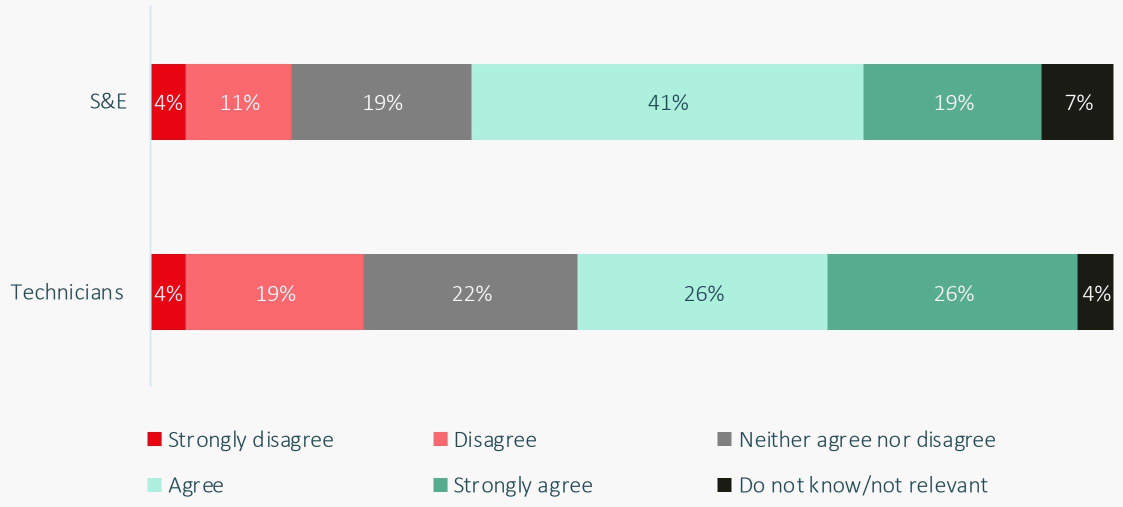


Figure 12: The workforce needs prior experience working with GMP before it has the needed skills



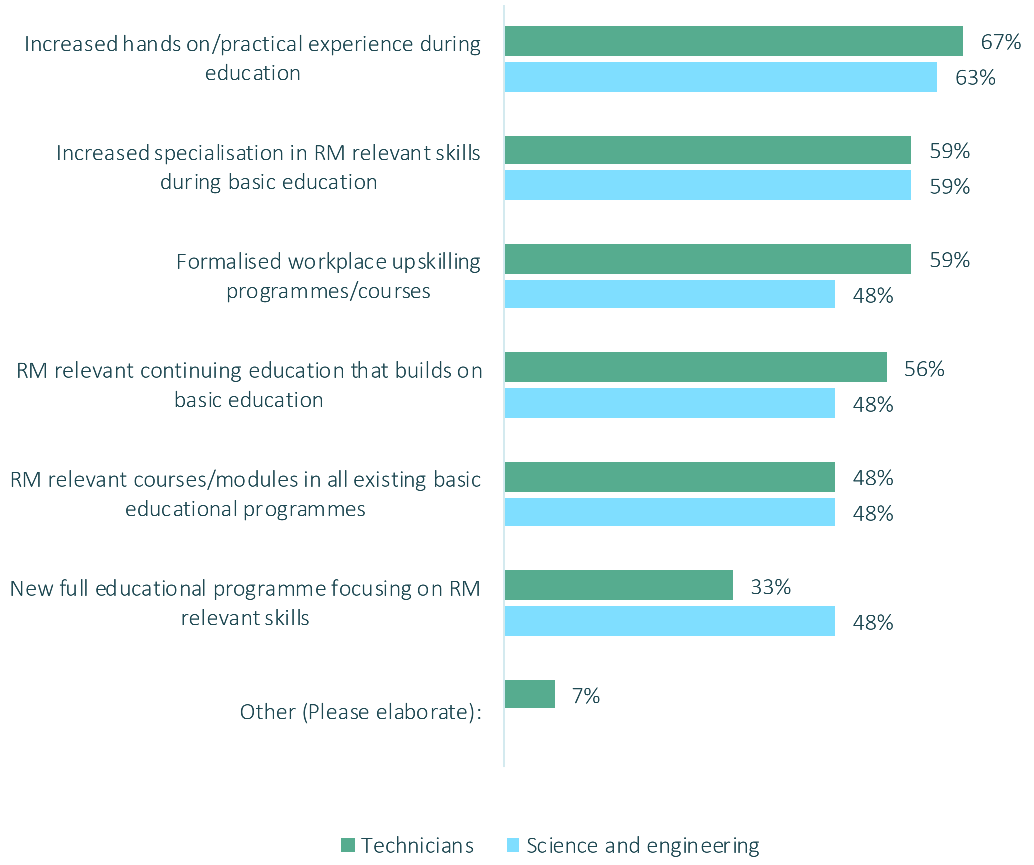
Appendix B5 : Multiple educational measures are necessary to train the RM workforce

According to the survey respondents, enhancing hands-on or practical experience during education is necessary for both technicians and the S&E workforce. This is followed by the need for increased specialisation in RM relevant skills during basic education. Furthermore, establishing formal workplace upskilling programs or courses is seen as a critical educational step for training technicians and slightly less so for the S&E workforce (however, 48% of respondents still deem this necessary).

The results underscore the significance of strategies such as RM-relevant continuing education that extends basic education, along with the incorporation of RM-relevant courses or modules into existing basic technician and S&E education programs.

The introduction of entirely new educational programs is seen as the least crucial educational strategy for training the technician workforce, while more respondents consider this relevant for the S&E workforce. This suggests that the industry views upskilling technicians as more critical than completely overhauling existing educational pathways. It might also indicate that the S&E workforce requires more in-depth knowledge and a wider range of specialised RM-specific skills, which could only be acquired through longer educational programs.

Figure 13: In your opinion, which educational measures are needed to train the workforce to work with RM?



Technicians N = 18 & Science and engineering N = 19
Only respondents who indicated that the workforce requires additional RM-specific training in their educational curriculum were presented with this question.

Appendix B6: More initiatives are in the educational pipeline

5 institutions have already developed or are currently developing new specialisation options relevant to RM as part of existing educational programmes. These may be the same 5 institutions that reply that they have developed or are currently developing electives related to RM.

3 have already or are currently developing specific educational programmes related to RM and/or curricula that include papers or articles about RM.

2 have already developed or are currently developing mandatory courses related to RM as part of existing educational programmes.

Finally, 3 reply that they are currently not working with implementing educational activities related to RM, and do not expect to do so in the near future.

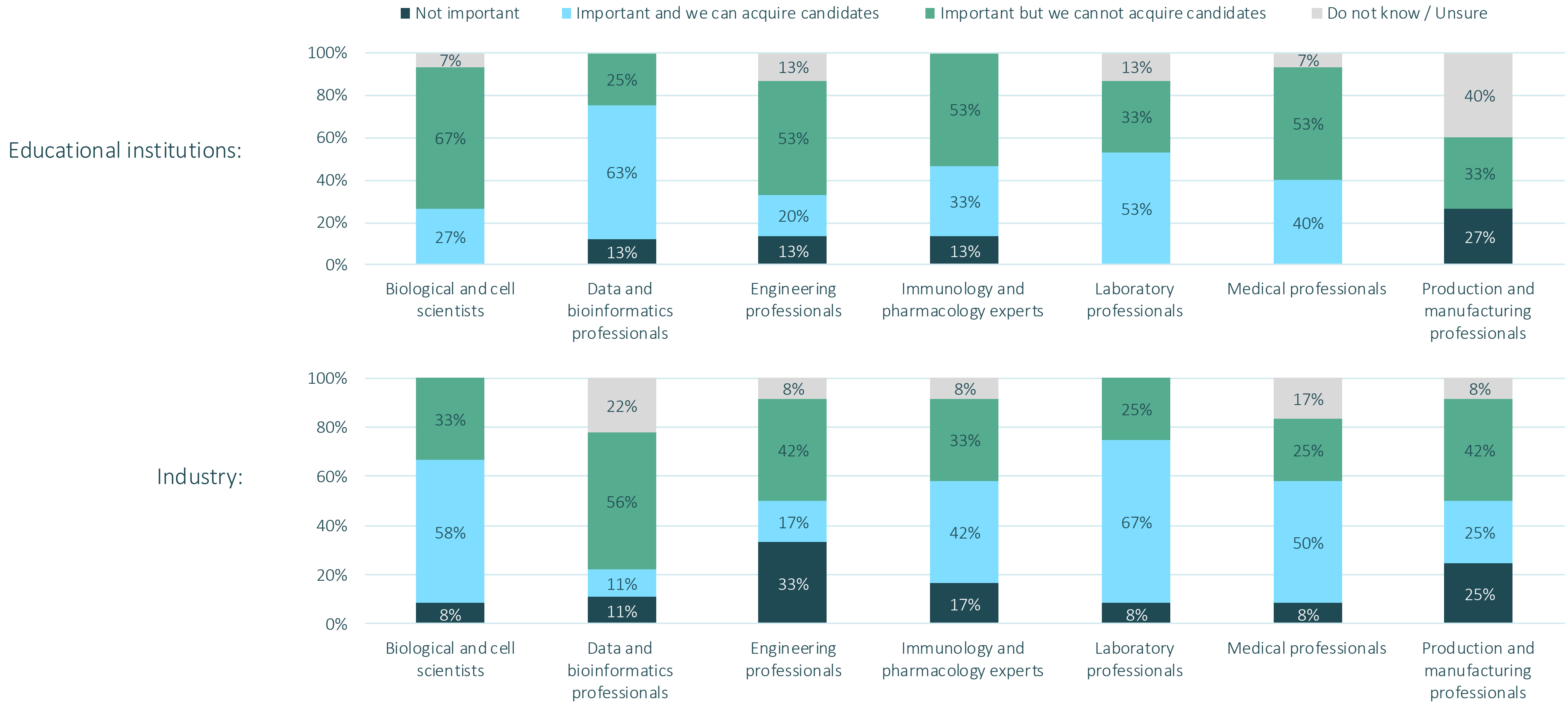
The results indicate that educational initiatives are underway which may help accommodate some of the potential future skills gaps highlighted in this report to some extent. The following pages elaborate on some of the potential initiatives highlighted by both industry actors and educational institutions.

Figure 14: How does your academic institution currently work with implementing educational activities related to RM?

N=9.
Only respondents who indicated that they were employed at educational institutions were presented with this question.

Appendix B7: How important and readily available are the following profiles to your RM workforce?

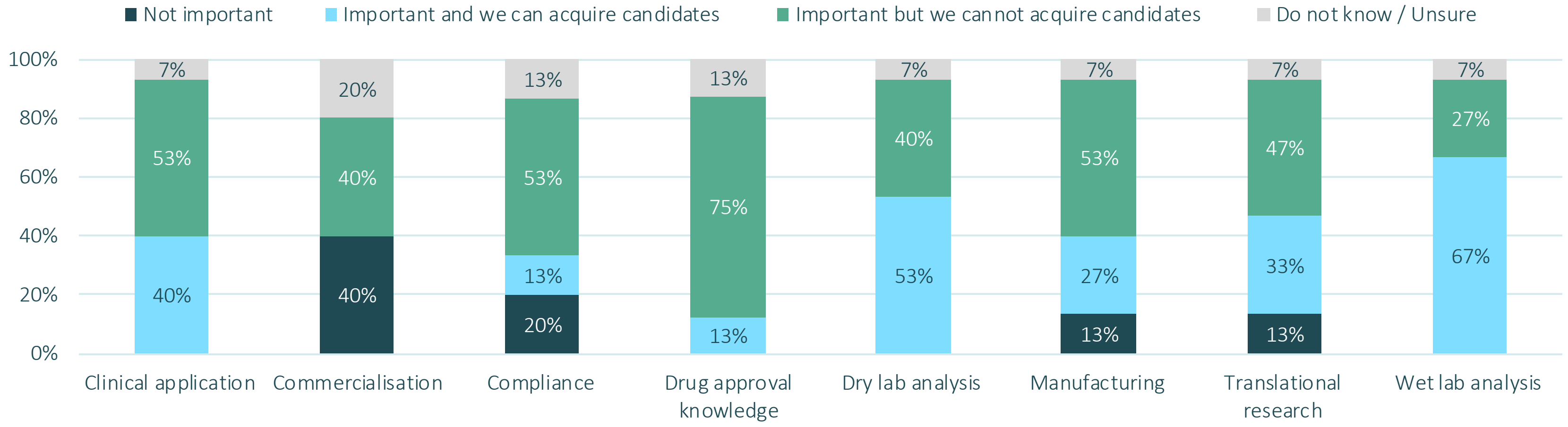
Figure 15: How important and readily available are the following profiles to your RM workforce?



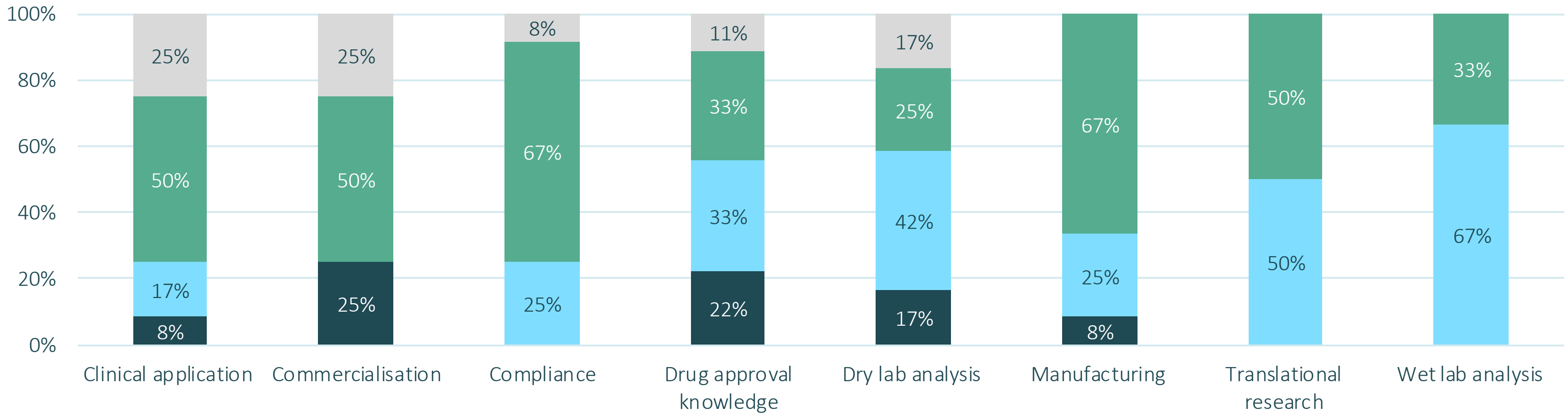
Appendix B8: Acquiring candidates with the required skills across various areas is challenging

Figure 16: To which degree are the following skills relevant and available for your science and engineering workforce within RM?

Educational institutions:

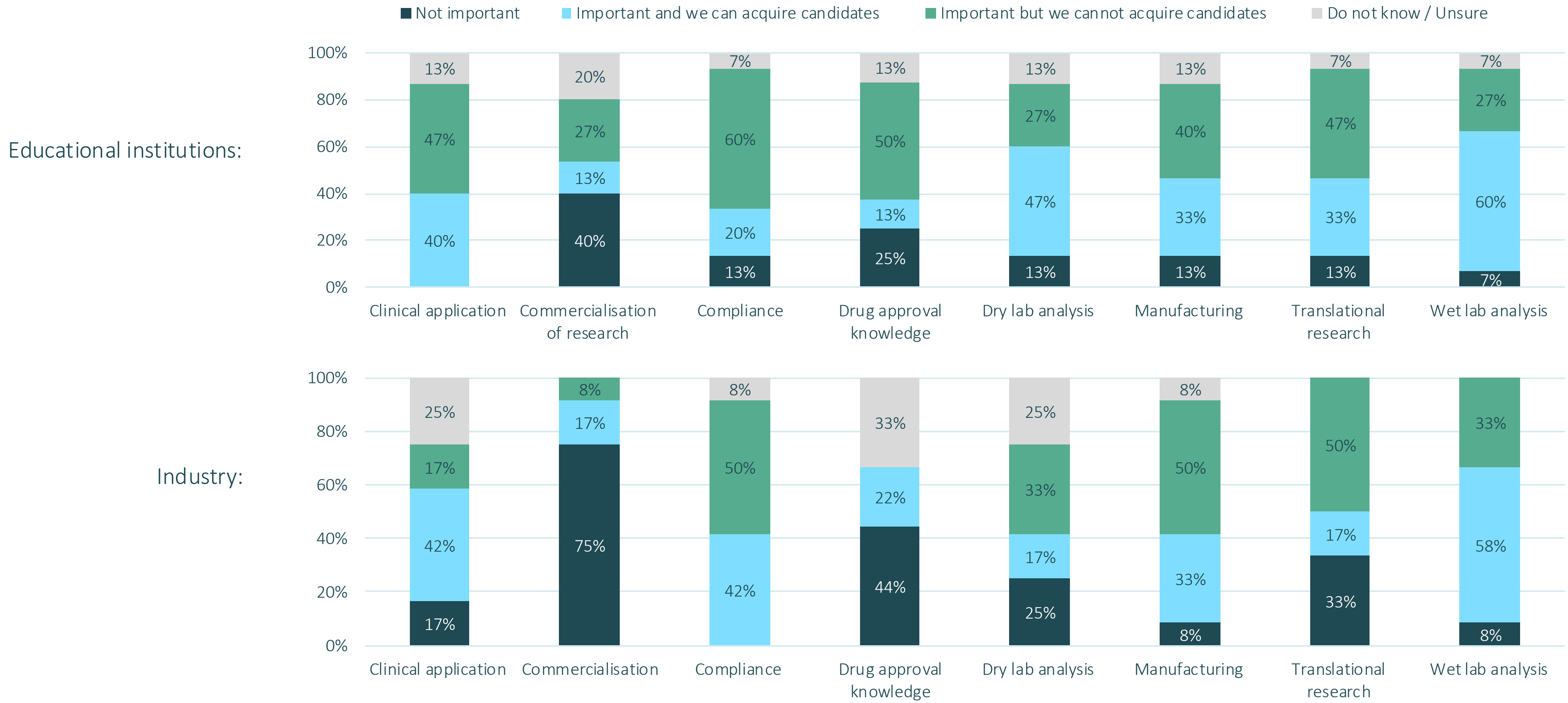


Industry:



Appendix B9: Acquiring candidates with the required skills across various areas is challenging

Figure 17: To which degree are the following skills relevant and available for your technician workforce when working within RM?



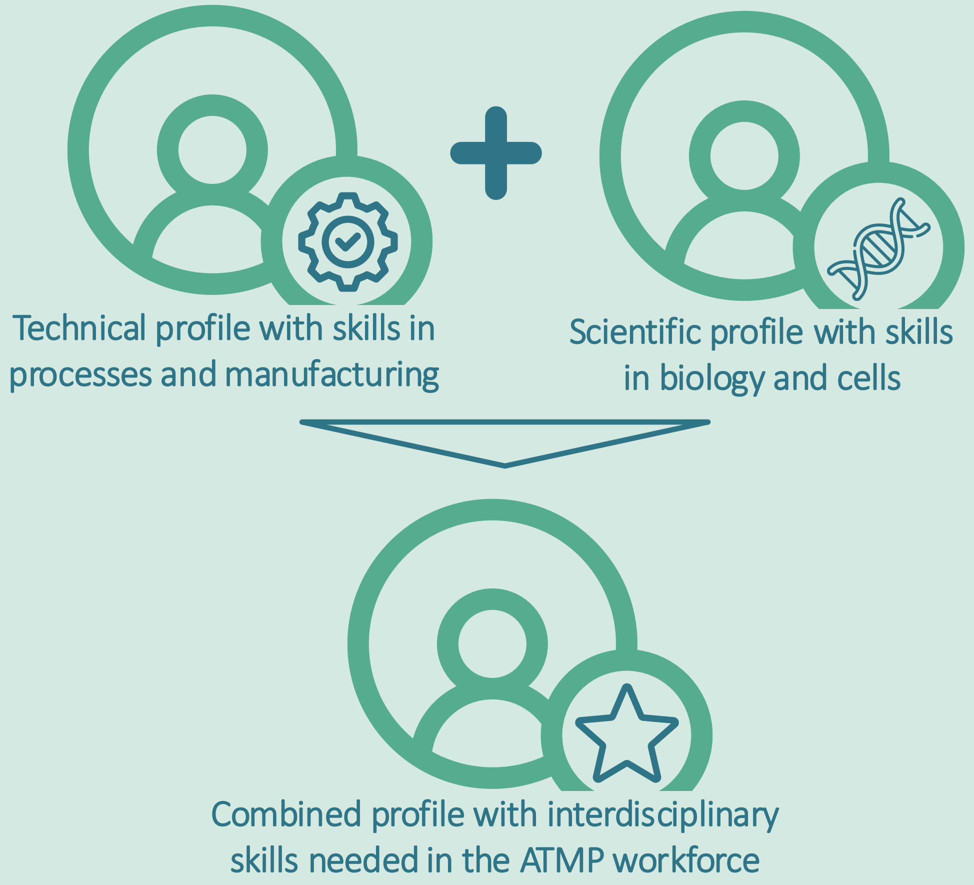
Appendix B10: Interdisciplinary profiles and skillsets are needed now and in the future

There is a notable emphasis on the shortfall in compliance and manufacturing skills, which includes a crucial need for translational capabilities from non-clinical to clinical settings. Similarly, there is a significant demand for skilled biologists and stem cell scientists, alongside technical expertise in biology and cellular operations.

These requirements highlight a pressing need for interdisciplinary talents. While it might be an overgeneralisation, there is a recurring theme of technically skilled candidates lacking biological expertise, and vice versa. The difficulty in sourcing individuals who possess dual expertise in process development and biology is a key point raised by interview respondents. As a result, employers are investing considerable time and resources in integrating biology and cell therapy profiles with Chemistry, Manufacturing, and Controls (CMC) profiles who possess manufacturing and compliance skills to cultivate the "ideal" candidates. This demand is anticipated by multiple interview respondents to become increasingly critical in the future, as a greater amount of products progress to later stages of development.

Interview respondents are divided on whether it is more feasible to train technical professionals in biological sciences or to equip biologists with technical skills. This decision heavily depends on the required depth of knowledge and skills in each specific context.

Cross-training technical and manufacturing professionals in biology and cellular biology may address some of the current demand for biological and cell scientists. Nevertheless, the need for highly skilled scientists in biology is expected to persist in the field, as these roles are deemed essential to the RM workforce.



“One thing is to develop the products – that demands biologists and cell biologists who know this field in detail. But in the future, we need people with a combination of process understanding and biological understanding, because we need both. I need those that are anchored in the biology, but I also need those that are anchored in the biotech process part of things”

- Pharmaceutical company

Appendix C

Projections

Appendix C1: The most frequently observed educational backgrounds are related to pharmacy, medicine, and laboratory activities

When examining the educational backgrounds of the biotech and pharma workforce, the data from Statistics Denmark only allows us to observe a broader range of educations. This is because there are no specific programs to graduate with a Bachelor's or Master's degree in RM in Denmark. A possible exception could be a PhD program with a dissertation on, for instance, tissue engineering, or stem cell therapy. However, with the general classification in the data these are still just observed as PhDs in medicine. Therefore, with input from the job post analysis and desk research, a list of educations that are potentially relevant for working within the field of RM has been curated.

The table on the right presents the share of the most frequent highest achieved educations for each educational level. The sum of shares for each level may not add up to one hundred percent due to discretionary considerations.

Across the non-PhD educational levels, the most frequently observed educations are AP graduates in Chemical and Biotechnical Science (Laborant), Master's degree in Pharmaceutical Sciences, Master of Science in Biotechnical Engineering, and Master's degrees in Biology and Molecular Biology.

Table 6: Most frequent highest achieved educations per educational level (2022)

AP graduates

1	Chemical & Biotechnical Science (Laborant)	77 %
2	Pharmaconomist	14 %
3	Production technology	9 %

N = 3.180

Bachelor's

1	Chemical & biochemical engineer	28 %
2	Biomedical laboratory scientist (Bioanalytiker)	27 %
3	Nurse	24 %
4	Pharmaceutical science BSc	7 %
5	Biology & molecular biology BSc	5 %

N = 1.688

Master's

1	Pharmaceutical Science	41 %
2	Biotechnical Engineering	14 %
3	Biology and Molecular Biology	14 %
4	Chemistry and Biochemistry	11 %
5	Medical Engineering	7 %

N = 5.846

PhDs

1	Medicine	48 %
2	Technical Science	27 %
3	Natural Science	25 %

N = 3.041

Source: ADC based on data from Statistics Denmark.

Appendix C2: With the expected growth in the biotech, pharma, and regenerative medicine industries, the workforce may become even more specialised by 2035

Based on the literature review of multiple projections of relevant industries, this report presents two scenarios for the pharma and biotech industries referencing previous ADC work on how the revenue of the general life science industry will develop. A high growth scenario, which predicts a 9,2 % CAGR, matching global expectations from the literature review, and a more conservative low growth scenario with a CAGR of 3,9 %.

These scenarios are used to find the growth rates for each educational level from 2022 to 2030. From 2030 to 2035 the growth rates for each educational level in both scenarios are adjusted according to the projections for the relevant fields made by the DREAM group in the Education Projection from September 2023.

The expected annual growth rates for higher educational levels are larger than for lower skilled labour, matching the historic development. The growth rates might seem similar for the two scenarios. However, since the results are compounded over 13 years, even small changes in the growth rates can lead to large discrepancies in the end results.

It is important to note that these projections are made under the assumption of ceteris paribus and do not account for any technology shocks that might affect the productivity of the labour force differently. Additionally, they only evaluate whether the expected supply attributable to the observed workforce can meet the expected demand. The model accounts for structural changes like increasing the retirement age and the increase of foreign labour, but not competition for skilled labour between similar industries. In the end, potential imbalances between labour demand and supply could, in the worst case, result in the industry not realising the full potential and thus not realising the expected growth rates.

Table 7: Expected growth rates per educational level toward 2035

	Low growth	High growth
AP graduates	-1,6 % p.a.	-0,3 % p.a.
BSc level	2,2 % p.a.	3,5 % p.a.
MSc level	3,9 % p.a.	5,2 % p.a.
PhDs	5,2 % p.a.	6,5 % p.a.

Source: ADC based on data from Statistics Denmark and the DREAM group.

Appendix C3: The observed biotech and pharma workforce is becoming more educated

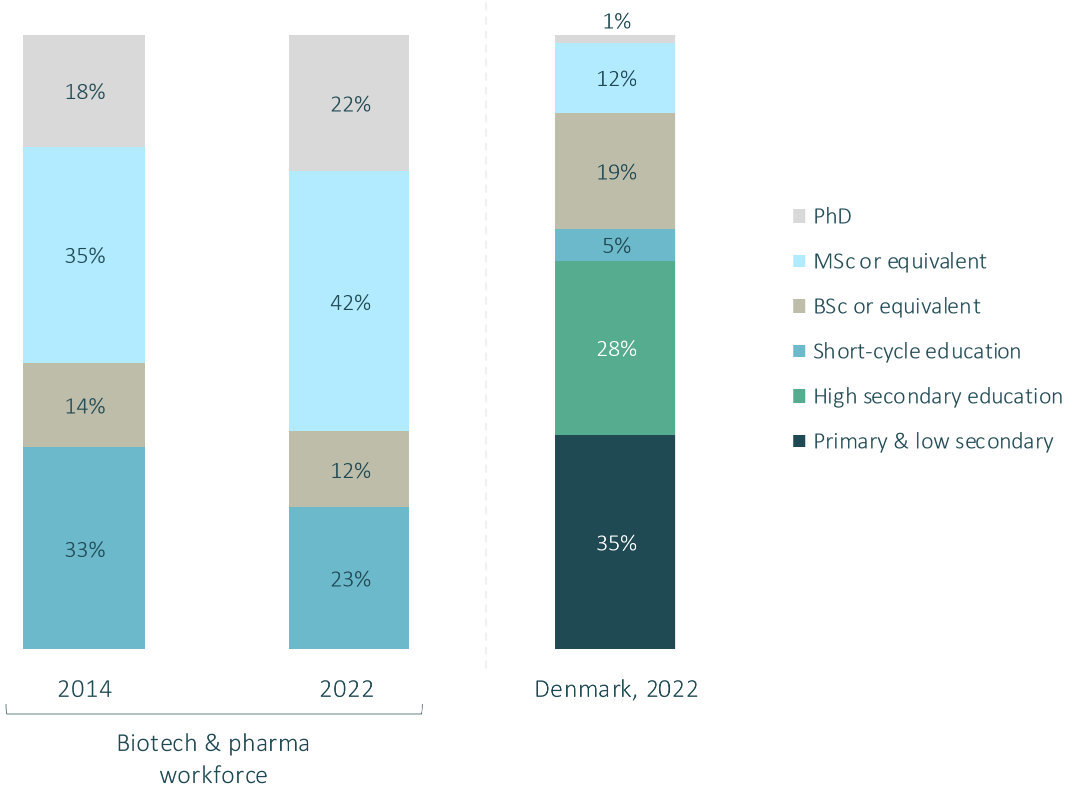
The general level of education in the observed Danish workforce has increased in the period between 2014 and 2022.

The number of full-time employees with a PhD or long-term higher education (MSc or equivalent) has increased with 22% and 20%, respectively. In the same period, the number of full-time employees with a short-cycle education has decreased by 30 %.

While the significant relative increase in highly skilled labour aligns with general trends in the Danish labour market, it's noteworthy that such labour makes up 64% of the total observed workforce.

It is important to note that the lack of lower skilled labour in the observed workforce can in part be explained by the curated list of educations that are included in the analysis.

Figure 18: Highest completed educational level in the Danish biotech and pharma workforce



Source: ADC based on data from Statistics Denmark.

Appendix D

Global ecosystem analysis

Appendix D1: Ecosystems highlight the strong research base as their biggest strength

All ecosystems emphasise the strength of their academic networks. They highlight the importance of establishing a robust research base, comprising of skilled researchers, funding opportunities for innovative projects, effective collaborations with hospitals, and infrastructure to transform early-stage innovations into start-ups.

The strong emphasis on nurturing a solid research base may be attributed to the fact that RM is still in its early developmental stages, with ongoing research and limited manufacturing activity.

Additionally, a strong ecosystem heavily depends on its ability to efficiently foster and support collaboration among start-ups, mid-sized companies, large pharmaceutical firms, educational institutions, and regulators on an ongoing basis.

One such initiative is the British Cell and Gene Therapy Catapult which is an independent innovation organisation advancing cell and gene therapies. Part of Innovate UK's Catapult Network, it collaborates with industry, government, and academia to turn ideas into products and services. The catapult drives innovation, attracts investments, supports skill developments, and help shape policy by leveraging research and overcoming industry barriers[30].

Furthermore, some ecosystems highlight their commitment to continuously upskilling the workforce through various initiatives and the presence of cluster organisations dedicated to enhancing the skills of industry hires. They also point out high talent availability, as seen in the US, along with favourable investment opportunities, and the presence of the entire medicinal product development value chain encompassing research, manufacturing, and clinical testing and implementation.

”In most of the biotechnology sector, we have a strong and recognised academic research ecosystem that is strengthened by several networks of small labs that share knowledge among each other"

- France

”There is a tendency for other organisations to view the Cell and Gene Therapy Catapult as an excellent source for recruiting talent. While this indirectly contributes to upskilling the workforce, it presents an interesting organisational challenge for us, as it can be quite frustrating. However, we acknowledge that companies hiring our candidates is part of the role we must play. We bring people into our organisation, where they learn a great deal, and then often move on to roles in the industry."

- UK

”The main strength lies in the availability of talent and their education level. Investments and existing combinations of developers and manufacturers are also notable. Manufacturing isn't always carried out where innovation occurs. The types of talent vary, with innovators and academics from universities and colleges in the main hubs differing from those involved in manufacturing, necessitating a distinct mindset and talent pool."

- USA

[30] Cell and Gene Therapy Catapult (2024): About us

Appendix D2: Lack of structured and long-term national funding inhibits development

A well-functioning ecosystem requires accessible funding opportunities for researchers and start-ups. While multiple life science ecosystems, such as those in the USA, are ripe with opportunities for both public and private funding, such as more than $8,5 billion funded from the government, this is not the case for ecosystems in other parts of the world.

In Singapore public and private funding opportunities, especially within stem cell therapies, used to be plentiful[31]. However, public funding opportunities have since ceased, leading private investors to pursue other publicly backed investment opportunities. This has led to decreased funding opportunities as research areas within regenerative medicine have to compete with other research areas for funding. In France, there is a lack of focus on RM by the government, resulting in stagnation in the private investment landscape.

In Japan, it is generally difficult to receive funding from large pharmaceutical companies due to the high costs of developing treatments with RM, uncertainties regarding their effectiveness, and safety concerns. Similarly in Germany, investment challenges arise in the phases where research initiatives are translated into start-ups. Investors associate investments in early-stage start-ups as too risky and with long timelines for returns on their investments. This is especially prevalent in the RM field, where additional uncertainties surround regulation and applicability.

The lack of investments in research, start-ups, and established companies acts as a major barrier for organisations working with RM, hindering their ability to mature the ecosystems they are a part of and to attract a sustainable workforce with the necessary skills to work within RM. Alleviating these investment barriers by creating long-term, structured, and robust investment schemes will support these companies in maturing their organisations and research efforts.

[31]Consortium for Clinical Research and Innovation, Singapore (CRIS)(2023): New national facility boosts Singapore's cell and gene therapy capabilities.

”Funding is obviously an important factor in the ecosystem. All researchers and companies need funding, whether its state driven, or company driven funding, there's all kinds of investors, of course, investing locally or company-wide.”

- USA

”Stem cell research was well supported in the early 2000s. Therefore, we also set up a stem cell consortium where hundreds of millions of dollars were invested for research. Once the hype died, funding dried up, and people pivoted to other areas.

- Singapore

"We do not have smaller venture companies. Instead, we need to collaborate with larger pharmaceutical companies. However, it is often difficult to find such companies that want to invest. This is because they see regenerative medicine as more expensive and have many safety concerns."

- Japan

”Acquiring seed funding, especially in high-risk areas like regenerative medicine, is tough. Most investors shy away due to lengthy development timelines."

- Germany

”The state has focused less on regenerative medicine. Because of lacking financing, the workforce is less skilled. The private investors follow the national strategy. If the French state isn't focusing on the field, they are less interested in investing because they want to make a return."

- France

Appendix D3: Political mis-prioritisation and collaboration act as barriers in ecosystems

The international ecosystems highlight initiatives, trends, and strengths, but like the Nordic ecosystem they also face barriers such as lack of political prioritisation, navigating regulatory frameworks, and inadequate collaboration.

Political prioritisation: A lack of political prioritisation hampers ecosystems' ability to create translational environments where industry and educational institutions collaborate. Singapore and France lack political support, with Singapore having shifted focus from RM and France yet to prioritise building strong ecosystems in this field.

Navigating regulatory Frameworks: Regulatory frameworks for medicinal products are strict and complex, particularly for RM. Both private companies and regulatory bodies lack necessary experience and skills, complicating clinical trials and market access. This is in large part due to the different nature of ATMPs compared to conventional products, making approval processes unfamiliar and complicated.

Infrastructure for collaboration: An insufficient infrastructure for collaboration hinders translational research and restricts possible synergies in the ecosystems. Ecosystems like Japan, USA, UK, and Germany lack infrastructure for collaboration across the value chain. Japan needs government encouragement for industry collaboration with educational institutions. The UK lacks support in transitioning products from early-stage innovation to translational research. In the USA, challenges exist in bringing clinically approved products to treatment centres for clinical applications.

"Imagine a cell therapy that restores pancreatic function, eliminating the need for insulin. The potential lifetime value of such treatment is immense, yet the healthcare system fails to recognise it, disregarding the long-term health problems, including chronic illnesses and amputations."

- UK

"Each state in Germany issues production licenses independently. This decentralisation results in inconsistencies, adding complexity. Germany's tendency to strive for stringent regulations can make the process even more challenging compared to other European countries like Italy, France, and Nordic nations."

- Germany

"Our funding opportunities have provided stable funding for academic researchers, enabling transition from lab to translational research, including studies for human trials. We offer funding from $8 million to $15 million. Applications are reviewed within two months, with approval granted the following month."

- USA

Appendix D4: Advancements in AI and automation necessitate change in ecosystems

Given the rapid developments in RM and its expanding applications, automation and the use of AI are seen as inevitable developments.

Implementation of Automation and AI:

Automation will enhance accessibility to regenerative medicinal products by increasing production capacity and reducing costs. However, the implementation of AI and automation in regenerative medicine necessitates development of new skills within the ecosystems, although unknown currently. Some ecosystems anticipate that the transformation driven by automation and AI will be led by experienced young professionals. Consequently, there will be ongoing needs for upskilling to meet new skill requirements, such as those in bioinformatics, accompanying the implementation of AI and automation.

"AI will have a role in the future, as evidenced by its current use in development. It enables effective modelling of complex cellular systems. Digitisation and automation in manufacturing are already underway. The shortage of skills in bioinformatics is a concern and we may see increased demand for automation engineers and individuals involved in reactor operations."

- UK

"The demand for treatments exceeds the capacity of current facilities. Automation not only expands access to patients but also reduces costs. Achieving efficient automation requires interdisciplinary teams working in collaborative lab settings."

- Germany

"In automated environments, digital proficiency is essential, though quality control remains paramount. In manual processes, individuals bear full responsibility. In automated systems, while machines may provide feedback, interpreting data, and making decisions are key tasks. Managing, understanding, and processing extensive data becomes necessary. Cell therapies demand a thorough understanding of their nature, implications, and potential pitfalls."

- USA

Appendix E

Job post analysis

Job post analysis

Appendix E1: The target sample follows the same trends as the rest of the job market

There are no noteworthy differences in the frequency of job postings within the sampled job posts within RM compared to the total number of job posts on JobIndex. While certain periods show heightened activity in RM job postings, such as from October 2020 to January 2021, the fluctuations are not deemed to be large enough to draw any conclusions.

A similar pattern is observed in the count of employers during the same timeframe, with the number remaining relatively consistent throughout the period.

Figure 19: Number of job posts over time

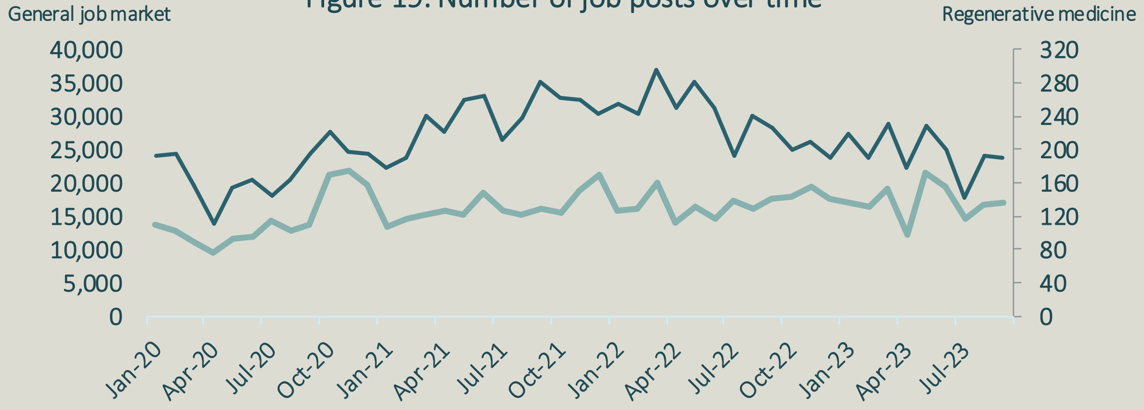
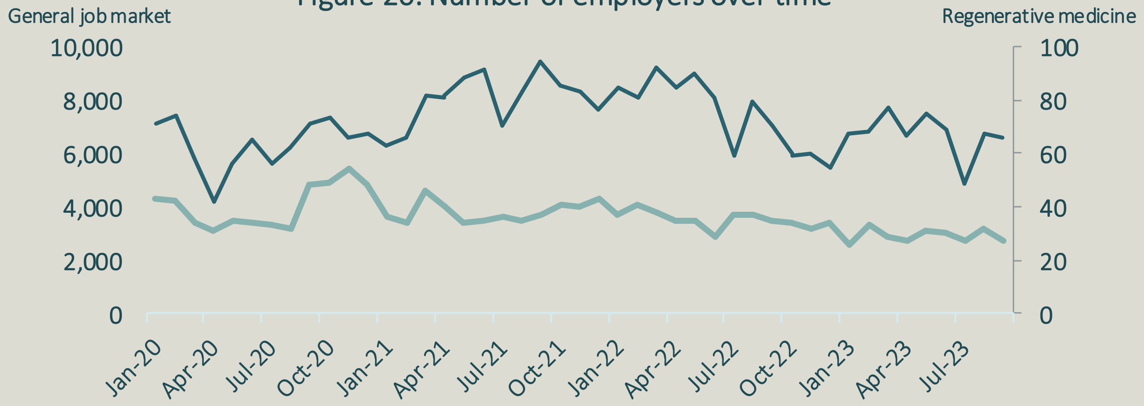


Figure 20: Number of employers over time



General job market ■ Sampled jobs regenerative medicine ■

Note: Data is based on Tembi Labour Intelligence Tool (LIT)
The graphs show job posts in Denmark in the period Jan. 2020 to Oct. 2023.
Graph 1: The graph shows the number of total job posts in the period Jan. 2020 to Oct. 2023 compared to the sampled job posts within regenerative medicine.
Graph 2: The graph shows the number of total employers in the period Jan. 2020 to Oct. 2023 compared to the sampled employers within RM.

Appendix E2: The sampled jobs are looking to fill research and technician positions

Positions described as postdoc or PhD positions are predominant in the sample. Specifically, 271 job posts (4.6% of the total) look to fill a postdoc role. Similarly, 264 job posts (4.5% of the total) seek candidates for a PhD position. Additionally, 154 job posts (2.6% of the total) pertain to Associate/Assistant professor roles, which can be expected to primarily relate to job posts from universities.

Given the prominence of Danish universities as major contributors to the job posts within this sample, it is unsurprising that titles such as postdoc, PhD, and professor rank highest.

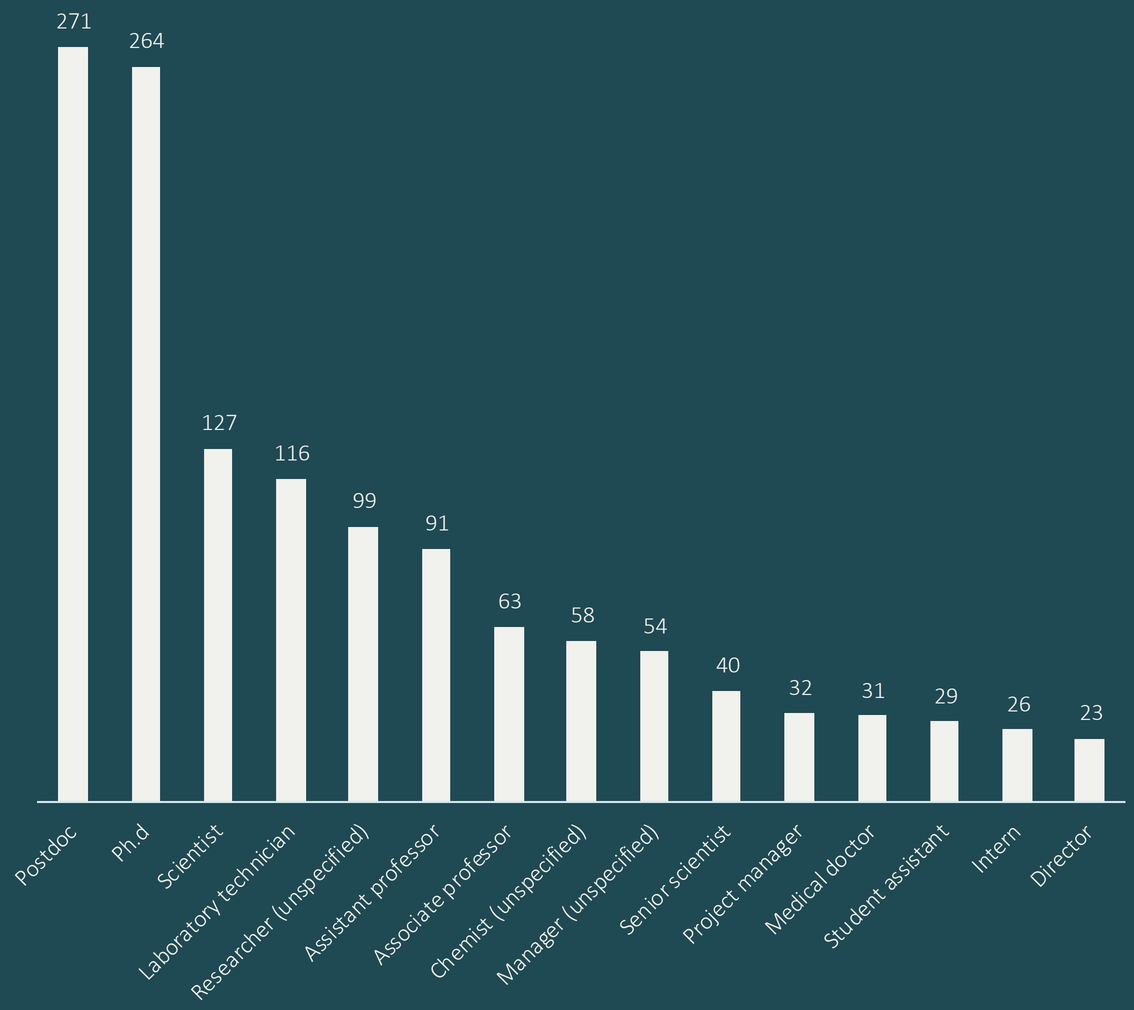
Moreover, 58 job posts (1,0% of total) target candidates for roles as chemists, highlighting a demand for specific technical expertise. Additionally, 116 job posts (2,0% of the total) focus on recruiting laboratory technicians, underlining the significance of practical skills in laboratory settings.

In the managerial realm, a collective 86 job posts (1.5% of the total) are directed towards applicants for either managerial or project management roles. This indicates a demand for individuals with leadership and organisational capabilities.

Furthermore, a smaller percentage, 31 job posts (0.5% of the total), explicitly seek medical doctors, emphasising the integration of clinical expertise within the sampled job posts.

In summary, the analysis indicates that the job posts within the sample align with positions in research, laboratory work, project and traditional management, and clinical expertise, which resembles multiple stages of the value chain within RM.

Figure 21: Top 15 job titles within sample group



Note: Data is based on Tembi Labour Intelligence Tool (LIT)
The graph shows job posts in Denmark in the period Jan. 2020 to Oct. 2023.
The graph shows a total of 1.349 matches on the sampled 5.794 job posts retrieved based on keyword search. The full list can be found in appendix E.

Appendix E3: Employers want a systematic and well-coordinated workforce…

Employers within the sample are especially looking for a workforce skilled within coordination, planning, analysis and IT.

The 1.511 (26,1% of total) mentions of basic knowledge within *analysis* and *IT* indicate that the market needs an analytical and technical workforce, while the 1.672 (28,9% of total) mentions of *coordination* and *planning* reflect the importance of systematic and well-coordinated approaches needed to produce ATMPs.

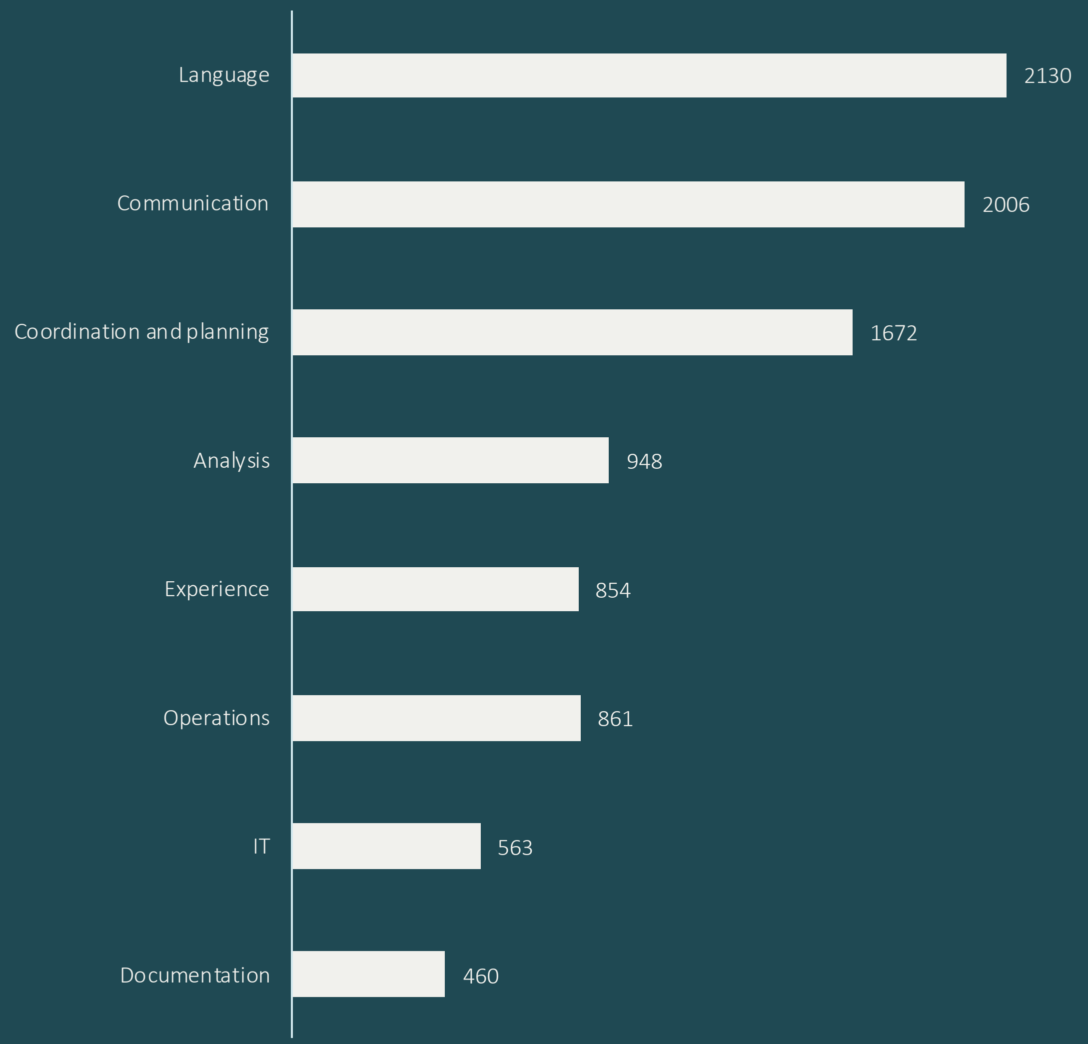
In addition, *language* and *communication* are the top requested skills for the target population. *Language* and *communication* are mentioned in 4.136 (71,4%) of the retrieved posts. These are recognised as "soft skills" and are found in high demand for all job posts available on LIT.

Previous *experience* is mentioned in 854 (14,7%) of the job posts, but it is not specified if it is experience from education or previous work. 861 (14,9%) of total job posts mention skills related to *operations*, and 460 (7,9%) mention skills within *documentation* of procedures and results.

Basic skills for the sample group may still demand a profound understanding and substantial experience with the tools and processes requested, as regenerative medicine is a highly specialised field.

An expanded view of the main categories can be found on the next slide. Full lists of each skill group can be found in Appendix E5.

Figure 22: Top baseline skills



Note: Data is based on Tembi Labour Intelligence Tool (LIT)
The graph shows job posts in Denmark in the period Jan. 2020 to Oct. 2023.
The graph shows a total of 9.281 matches on the sampled 5.794 job posts retrieved based on keyword search.

Appendix E4: ...and communi-cation and planning skills

Communication skills extend beyond linguistic abilities to include conveying knowledge through mentoring, presentations, networking and teaching. These skills are needed in all phases of the value chain.

From coordination and planning, there is a demand for leaders, project managers, stakeholder management and trainings.

Expanding further into the domains of analysis and IT, skills such as data analysis, analytical methods, IT-systems expertise, and proficiency in Microsoft Office tools are highlighted. These skills are e.g., used in result analysis, evaluations, documentation of findings, and engineering.

Development, implementation, maintenance and support are important operations that can be found across the value chain, but perhaps especially in manufacturing of ATMPs. Relevant applicants should be familiar with Standard Operating Procedures (SOPs). Operations might require specialised knowledge within the ATMP realm and could be considered both a baseline and specialised skill.

IT:
- IT (140)
- Excel (107)
- MS Office (96)
- Systems (55)
- IT-systems (53)
- Technical (47)
- PowerPoint (34)
- Word (31)

Communication:
- Communication (534)
- Communication skills (467)
- Communicate (322)
- Teach (191)
- Communicator (104)
- Presentation (101)
- Mentoring (63)
- Formulation (46)
- Presentation skills (46)
- Agile (32)
- Coaching (51)
- Networking (49)

Operations:
- Development (283)
- Processes (85)
- Maintenance (127)
- Support (55)
- Implementation (70)
- SOPs (105)
- Execution (51)
- Test (85)

Analysis:
- Analysis (293)
- Analytical skills (115)
- Data analysis (114)
- Analytical (110)
- Data (95)
- Analytical methods (89)
- Analytics (47)
- Deviations (85)

Coordination and Planning:
- Stakeholders (302)
- Planning (252)
- Project Management (213)
- Stakeholder management (111)
- Coordinating (142)
- Coordination (96)
- Leadership (82)
- Management (81)
- Manager (54)
- Project planning (49)
- Organizational skills (39)
- People management (36)
- Problem solving (34)
- Leads (42)
- Training (139)

Note: Data is based on Tembi Labour Intelligence Tool (LIT)
The graph shows job posts in Denmark in the period Jan. 2020 to Oct. 2023.
The graph shows a total of 8.382 matches on the sampled 5.794 job posts retrieved based on keyword search.

Appendix E5: Lists of baseline skills

The table below shows the categorisation of all retrieved baseline skills identified through the LIT analysis. The skills are sorted into eight main categories: Analysis, Communication, Language, Experience, Coordinating and Planning, IT, Operations and Documentation.

For each category, there are lists of skills found in 5.794 job posts. The number in parenthesis shows the number of job posts out of the total that mentioned the specific skill. LIT avoids double counting, such that it does not count a mention for «analytical» if «analytical methods» is previously identified.

Analysis:

- Analysis (293)
- Analytical skills (115)
- Data analysis (114)
- Analytical (110)
- Data (95)
- Analytical methods (89)
- Analytics (47)
- Deviations (85)

Communication:

- Communication (534)
- Communication skills (467)
- Communicate (322)
- Teach (191)
- Communicator (104)
- Presentation (101)
- Mentoring (63)
- Formulation (46)
- Presentation skills (46)
- Agile (32)
- Coaching (51)
- Networking (49)

Language:

- English (1.581)
- Danish (549)

Experience:

- Research experience (80)
- Experience (254)
- Laboratory (53)
- Scientific background (33)
- Research (339)
- Scientific (95)

Coordination and planning:

- Planning (252)
- Stakeholder management (111)
- Coordinating (142)
- Coordination (96)
- Leadership (82)
- Management (81)
- Manager (54)
- Project planning (49)
- Organisational skills (39)
- People management (36)
- Problem solving (34)
- Stakeholders (302)
- Leads (42)
- Training (139)

IT:

- IT (140)
- Excel (107)
- MS Office (96)
- Systems (55)
- IT-systems (53)
- Technical (47)
- PowerPoint (34)
- Word (31)

Operations:

- Development (283)
- Processes (85)
- Maintenance (127)
- Support (55)
- Implementation (70)
- SOPs (105)

Documentation:

- Reporting (150)
- Review (78)
- Documentaiton (194)
- Document (38)

Appendix E6: List of specialised skills

The three first tables show the raw data retrieved for specialised skills.

The last table shows the categorisations made for the analysis. The skills that are similar in purpose or because of abbreviations have been combined.

gmp	321
clinical	221
project management	213
process development	186
drug development	179
clinical trials	158
molecular biology	145
python	132
r	130
optimisation	130
pharmaceutical industry	129
elisa	121
hplc	112
bioinformatics	111
manufacturing	109
cell biology	104
clinical development	101
validation	95
automation	93
lean	91
publication	91
regulatory	89
pharmaceutical	86
compliance	85
flow cytometry	83
immunology	83
monitoring	83
characterisation	82
mass spectrometry	81
sap	78
programmering	76
chromatography	73
machine learning	73
capa	72
developer	70
medical	69
biomarkers	68
cell culture	67
cmc	67
strategy	67

audits	66
proteomics	66
crispr	65
design	65
qc	65
api	64
gcp	63
biochemistry	62
cgmp	62
lc-ms	62
supervision	62
engineering	61
ms project	61
celler	60
data management	59
qpcr	59
microbiology	58
qa	57
assays	56
biology	56
protocols	55
r&d	55
troubleshooting	52
ai	51
fermentation	51
pcr	50
stem cell biology	50
risk assessment	49
biotechnology	47
clinical research	47
glp	47
lims	47
purification	46
statistics	46
analytical chemistry	45
fda	45
marketing	45
rna	45

drug	44
matlab	44
proteiner	44
biologics	43
data science	43
flowcytometri	43
modellering	43
analytical development	42
image	42
data transfer	42
quality control	42
process optimization	40
alk	39
biotech	39
quality assurance	39
allergy immunotherapy	38
metabolomics	38
ich	37
metabolic engineering	37
microbial	37
process validation	37
downstream processer	36
business understanding	35
medical devices	35
oncology	35
protein chemistry	35
inspection	35
manufacturing processes	35
optimising	33
procurement	32
cmc development	32
commercial	32
immunoassays	32
controlling	31
emas	31
trial management	31
diabetes	31
big data	30

Combinations for Analysis	
optimisation, total	**203**
optimisation	130
optimising	33
process optimisation	40
monitoring, total	**221**
montoring	93
inspection	35
controlling	31
supervision	62
Manufacturing, total	**144**
Manufacturing	109
manufacturing processes	35
cmc, total	**99**
cmc	67
cmc development	32
cell biology, total	**154**
cell biology	104
stem cell biology	50
Validation, total	**132**
validation	95
process validation	37
Biotechnology, total	**86**
biotechnology	47
biotech	39
qa, total	**96**
qa	57
quality assurance	39

Appendix E7: Categorisation of top 25 employers

The table shows the categorisation of the top 25 companies and institutions retrieved from the job posts, and the number of job posts from the sample they are responsible for.

From the top 25 retrieved employers, each company has been looked up to identify them as either medicinal/pharmaceutical, biotech, university or consultancy.

Recruitment companies (Unique Human Capital and QTC Recruitment) are considered consultancy firms.

Employer	# job posts	Category
Novo Nordisk	1.788	medicinal/pharma
ALK-Abelló A/S	581	medicinal/pharma
Danmarks Tekniske Universitet	444	university
KU - sund - panum kbh n	337	university
Aarhus Universitet	263	university
Lundbeck	156	medicinal/pharma
Syddansk Universitet	140	medicinal/pharma
Fujifilm Diosynth Biotechnologies	129	biotech
Region hovedstaden	124	public
KU - science bio - bric	75	university
Leo Pharma	74	medicinal/pharma
AGC Biologics A/S	67	biotech
KU - science - nbi	62	university
KU - science - plen	60	university
Aalborg Universitet	57	university
Ferring Pharmaceuticals A/S	55	medicinal/pharma
KU - sund - kbh ø	52	university
Nordic Bioscience A/S	49	biotech
Unique Human Capital	48	consultancy
Zealand Pharma A/S	40	biotech
Klifo A/S	38	consultancy
Gubra Aps	37	biotech
QTC Recruitment	36	consultancy
KU - science - bio	32	university
ku-sund-metabolismecentret	32	university

Appendix E8: List of top 200 employers

Novo Nordisk	1.788
ALK-Abelló A/S	581
Danmarks Tekniske Universitet	444
KU - sund - panum kbh n	337
Aarhus Universitet	263
Lundbeck	156
Syddansk Universitet	140
Fujifilm Diosynth Biotechnologies	129
Region hovedstaden	124
KU - science bio – bric	75
Leo Pharma	74
AGC Biologics A/S	67
KU - science – nbi	62
KU - science – plen	60
Aalborg Universitet	57
Ferring Pharmaceuticals A/S	55
KU - sund - kbh ø	52
Nordic Bioscience A/S	49
Unique Human Capital	48
Zealand Pharma A/S	40
Klifo A/S	38
Gubra Aps	37
QTC Recruitment	36
KU - science – bio	32
ku-sund-metabolismecentret	32
chr. hansen a/s	24
immudex aps	24
kræftens bekæmpelse	23
ku sund mærsk tårnet	23
københavns universitet	23
ku - sund – ivs	21
bioporto diagnostics a/s	18
ku - sund - ikvh - fr. Berg	17
ku-center for sundhed og samfund	17
region syddanmark	17
novo nordisk a/s	15
samplix aps	15
bioneer a/s	14
align technology	13
evaxion biotech aps	13

ku - science - bio snm	13
minerva imaging aps	13
river stone biotech aps	13
visiopharm a/s	13
dragonfly therapeutics cph aps	12
ku - science - nex	12
roskilde universitet	12
symphogen a/s	12
nnit	11
radiometer medical aps	11
taconic biosciences a/s	11
talents2work aps	11
bioinnovation institute	10
genmab	10
bavarian nordic a/s	9
chemometec a/s	9
novozymes a/s	9
arla foods ingredients group p/s	8
pokeacell aps	8
region nordjylland	8
ssi	8
aj vaccines a/s	7
fmc corporation	7
visiopharm	7
alphalyse a/s	6
biosyntia aps	6
cbio a/s	6
y-mabs therapeutics a/s	6
academic work	5
agilent technologies denmark	5
arla foods ingredients group p/s,	5
cerebriu	5
cp kelco	5
datalogisk institut, københavns universitet	5
moment	5
muna therapeutics aps	5
nbcd a/s	5
octarine	5
qlife aps	5
region midtjylland	5

statens serum institut	5
vaccibody	5
arla foods amba	4
bacthera denmark a/s	4
biomar a/s	4
bioporto a/s	4
ecco sko a/s	4
evaxion biotech a/s	4
expres2ion biotechnologies	4
fmc	4
harboes bryggeri a/s	4
inprother aps	4
intomics a/s	4
iqvia	4
ku	4
ku - science -food og nexs	4
ku - sund - iph	4
ku - sund - teilum - kbh ø	4
novo nordisk fonden	4
nykode a/s	4
ppd	4
qlife	4
quanterix	4
scantox a/s	4
snipr biome aps	4
storbjerg search & selection	4
aak denmark a/s	3
aalborg universitet københavn	3
arla foods	3
biomar group	3
cysbio aps	3
cytiva	3
fertin pharma	3
fujifilm diosynth biotechnologies holdings denmark aps	3
iff	3
larix a/s	3
leo pharma a/s	3
novartis	3
orphazyme a/s	3
oslo universitetssykehus hf	3

pharmacosmos a/s	3
pleaz	3
professionshøjskolen absalon	3
science-community.org network	3
unikum therapeutics aps	3
university of southern denmark	3
waters corporation	3
abzu	2
adecco.dk	2
algiecel	2
aligntech	2
ascendis pharma	2
bioomix aps	2
bioxpedia a/s	2
blusense diagnostics aps	2
ceptur therapeutics aps	2
chromologics	2
clintec	2
colofact aps	2
coloplast a/s	2
compass human resources group a/s	2
convatec, infusion care	2
copenhagen	2
cordes biotech a/s	2
covance	2
edwards lifesciences	2
eurofins miljø a/s	2
evosep	2
fondenes videnscenter	2
gsk	2
immunaware aps	2
johnson & johnson family of companies	2
ku - science - taastrup	2
ku - sund - institut for folkesundhed - kbh k	2
lunds universitet	2
lægemiddelstyrelsen	2
medpace	2
merck kgaa	2
nordic bioscience a/s | herlev | dk	2
nordic bioscience clinical development a/s	2

octarine bio aps	2
oticon medical	2
perkinelmer	2
qiagen	2
randstad a/s	2
region sjælland	2
savara aps	2
sciex	2
stipe therapeutics aps	2
syneos health	2
thermo fisher scientific	2
unilabs a/s	2
vaccibody as	2
wolterjohannsen	2
aarhus university	1
agilent technologies	1
akerhus universitetssykehus	1
aloop therapeutics aps	1
amgen	1
anybody technology a/s	1
arla foods ingredients	1
artisan bio aps	1
asics denmark a/s	1
astellas pharma a/s	1
biorigin aps	1
biosyntia	1
bloch & buus aps	1
bristol myers squibb	1
cambrex karlskoga ab	1
celvivo aps	1
centaflow a/s	1
cerebriu a/s	1
ceremedy aps	1
charles river	1
clinigma aps	1
corteva agriscience	1
curia	1
danaher	1
danish cancer society	1

Appendix E9: Lists of educations

The table shows all educations retrieved grouped, and number of job posts mentioning each education. The upper labels are the defined education used for analysis and its corresponding total number of mentions.

Engineering	337
engineering (unspecified)	172
electrical engineering	9
mechanical engineer	27
chemical engineer	60
biomedical engineering	31
process engineer	4
bioengineering	3
software engineering	3
engineer background	2
biochemical engineering	2
engineering degree	22
environmental engineering	2

Natural sciences (unspecified)	168
science	69
Natural sciences education	15
natural sciences	50
scientist	19
Natural sciences background	8
scientific	4
Natural science academic education	3

Business	105
business administration	30
business	26
logistics	3
finance	21
marketing	11
supply chain management	6
business intelligence	3
commercial	3
hr	2

Biology	277
biology (unspecified)	206
human biology	29
Medical Laboratory Technologist	13
microbiology	15
cell biology	8
molecular biology	6

Pharmaceutical sciences	233
pharmacy	99
pharmaceutical sciences	29
pharmacist	48
pharmacology	20
pharma	37

Technician	42
process technician	15
technician	7
automation technician	3
electrical technician	3
Process operator	14

Medicine	139
medicine	63
medical	23
molecular medicine	4
medical degree	3
aud	4
biomedicine	42

Technical education	20
industrial electrician	3
artisanal background	2
technology	9
mechanical	6

Laboratory technician	116
laboratory technician	96
educated laborant	20

Biotechnology	16
biotechnology	12
biotech	4

Veterinary	20
veterinary medicine	11
veterinary science	9

Chemistry	139
chemistry	113
chemist	26

Life Sciences (unspecified)	178
life science	153
life sciences	16
food science	9

Bioinformatics	44
bioinformatics	38
biostatistics	3
informatics	3

Biochemistry	211
biochemistry	195
biochemist	6
biochemistry	4
proteomics	6

Mathematics	33
mathematics	15
applied mathematics	2
statistics	16

Appendix E10: Lists of job titles

The table shows requested job titles within the sample, with the number of mentions out of 5794 retrieved job posts.

Postdoc, Total:	**271**
Postdoc	230
postdoctoral fellow	16
Postdoctoral researcher	22
postdoctoral position	3
Ph.d, Total:	**264**
phd candidate	3
Ph.d.	261
Laboratory technician, Total:	**116**
Laboratory technician	100
laboratory	8
lab technician	5
analysis laboratory technician	3
Researcher (unspecified), Total:	**99**
Researchers	75
researcher	3
Research scientist	21
Assistant professor, Total:	**91**
Assistant professor	80
assistant professorship	11
Associate professor, Total:	**63**
Associate professor	50
associate professorship	13

Chemist (unspecified), Total:	**58**
Chemist	58
Manager, Total:	**54**
Manager	30
management	3
lead	3
leder	8
group lead	4
leadership	3
team leader	3
Medical doctor, Total:	**31**
Medical doctor	24
md	7
Student assistant, Total:	**29**
student assistant	18
student	11
Intern, Total:	**26**
intern	17
internship	9
Medical Laboratory Technologist, Total:	**21**
Medical Laboratory Technologist	18
Microbiologic laboratory technician	3

Clinical research associate, Total:	**20**
clinical research associate	8
cra	12
Laboratory assistant, Total:	**18**
laboratory assistant	18
Academician, Total:	**18**
academician	10
Academic staff member	8
QA specialist, Total:	**16**
qa professional	6
qa specialist	6
qa officer	4
QA, Total:	**14**
qa	9
qa employee	5
Subject matter expert, Total:	**13**
subject matter expert	6
sme	7
Microbiologist, Total:	**12**
microbiologist	12
Laboratory manager, Total:	**8**
lab manager	5
laboratory manager	3
Biostatistician, Total:	**4**
biostatistical specialist	2
biostatistics	2

Appendix E11: Example of job post within the target sample

Postdoc position in green implantable electronics for regenerative medicine

The Department of Biological and Chemical Engineering, Aarhus University, invites qualified applicants for a 2-year postdoc position offering applicants to join the research on green implantable electronics for regenerative medicine at the research group Nanofiber Technology and Cellular Engineering.

Expected start date and duration of employment

This is a 2–year position from 1st August 2023 or as soon possible.

Job description

Regenerative medicine is paving the way to generate functionality of biological tissues via imitating cellular, biochemical, and mechanical cues that can be integrated by employing materials science and bioengineering methods. In this regard, Bioelectricity is a quintessential characteristic of living organisms and has a crucial role in physiological and medical sciences. The rapidly increasing demand for electronic medical devices come at a time when environmental and interplanetary pollution are at an all-time high. It is becoming ever-more necessary to consider the sustainability and life-cycle of emerging electronics. The project aims to apply innovative electrospinning technology to explore novel synthesis of bio-sourced polymeric nanogenerators based on conversion of mechanical energy to electric energy as implantable electronics for regenerative medicine.

You will be contributing to optimizing the electrospinning parameters, characterizing the piezoelectric/triboelectric response under ultrasound stimulation, assaying biocompatibility by in vitro culturing neural and cardiac cells via colorimetric assays, immunocytochemical staining and confocal imaging.
You will be in close collaboration with biophysicists to examine electrophysiology using patch clamp and multi electrode array. You will also be involved in supervision of bachelor and master thesis projects.

Your profile

Applicants should hold a PhD in biomaterials, stem cell biology, tissue engineering, biofabrication, material engineering or related disciplines

Qualifications:

- Experience in electrospinning and nanomaterials characterizations or similar.
- Experience in biofabrication for cardiac and neural tissue engineering applications.
- Good skills in communication of research results internationally as evidenced by publications in excellent peer-reviewed journals.
- Experience in supervising students and teaching at a high academic level.

Source: Aarhus University, Jobindex
https://www.jobindexarkiv.dk/cgi/showarchive.cgi?tid=r11453832

where it all adds up

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