MTPConnect
MedTech and Pharma Growth Centre

MTPConnect REDI Initiative Skills Gap Analysis

Positioning the MTP workforce for post-pandemic prosperity

THIRD REPORT

OCTOBER 2021

REDI DEVELOPING AUSTRALIA'S MTP SECTOR WORKFORCE

Australian Government
Department of Industry, Science, Energy and Resources
Industry Growth Centres

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1. Context of the REDI Initiative Skills Gap Analysis Third Report

MTPConnect is delivering the Researcher Exchange and Development within Industry (REDI) initiative: a $32 million program supported by the Medical Research Future Fund (MRFF). The REDI initiative is focused on improving workforce skills and driving jobs growth across the medical technology, biotechnology and pharmaceutical (MTP) sector value chain, including all elements of the advanced medical products manufacturing ecosystem, such as research and development (R&D); preclinical and clinical development; production and manufacturing; logistics and distribution; and marketing, promotion and sales activities.[1]

This report is the third in a series of REDI skills gap reports by MTPConnect. The first, an interim report, published in November 2020, identified three skills gaps as near-term priorities for the sector, addressable within 12 to 18 months.[2] The second report identified a comprehensive set of 76 skills gaps, including 20 priority gaps that need to be addressed to drive continued sector growth.[3]

Building on the second report, this report highlights skills gaps in specific areas that have become more pronounced due to the COVID-19 pandemic, such as biosecurity, infectious disease resilience and advanced manufacturing. The REDI Skills Gap report series identifies 81 skills gaps, with detailed analysis provided on 24 of these. They represent a mixture of new and emerging gaps covering the full value chain from pre-production, production and post-production and focus the industry on the most important skills for building a resilient and competitive medical products manufacturing sector. These skills gaps will need to be addressed for Australia to build an MTP sector workforce that can deliver desired health outcomes for the community and, more broadly, support an economy that is more resilient to diseases and future biosecurity threats.

Overview of the methodology

This report has been informed through consultations with 30 sector stakeholders (Appendix 1) and secondary research completed throughout August 2021.

Structure of the report

The findings of the skills gap analysis are outlined in the following two chapters of this report. Chapter 2 presents a brief overview of the focus areas and identifies the priority skills gaps. Chapter 3 provides a detailed characterisation of these skills gaps; their impact, alignment with the sector priorities and megatrends and recommendations on how these skills gaps could be addressed.

1 MTPConnect, Researcher Exchange and Development within Industry (REDI) initiative, 2020
2 MTPConnect, REDI Program Skills Gap Analysis Interim Report, 2020
3 MTPConnect, REDI Initiative Skills Gap Analysis Second Report, 2021

2. Overview of the skills gaps

The COVID-19 pandemic has created an unprecedented health crisis. Since the emergence of SARS-CoV-2, the virus that causes COVID-19 in 2019, the pandemic has continued to have economic and health impacts worldwide. As at 10 October 2021, globally there have been 237 million recorded cases and 4.8 million deaths – and counting.[4] In Australia, as at 10 October 2021, there have been approximately 127,454 cases of COVID-19 and 1,432 deaths.[5]

Although the path to recovery from COVID-19 remains challenging, two key strategic actions that can better prepare Australia for any future diseases and/or pandemics were highlighted in the *COVID-19 Impact Report 2nd Edition* published by MTPConnect in October 2020:

- Develop advanced manufacturing capabilities that will enable the discovery and local production of novel vaccines (e.g. mRNA vaccines) and therapeutics.
- Invest in next-generation research and technologies that will build greater biosecurity capabilities and medical countermeasures, enabling better detection and response to future pandemic threats.

Progress is being made against each of these actions. Governments and industry organisations have taken several steps to strengthen Australia's infectious disease resilience capabilities, develop critical medical product manufacturing onshore and invest in developing and commercialising novel treatments. Highlights include:

- The Department of Health's Medical Research Future Fund, which reached its $20 billion maturity in July 2020, has announced funding of more than $200 million for the research and development of novel medical products in 2021. This includes $100 million to advanced manufacturing research under the Frontier Health and Medical Research Initiative, $80 million to support the commercialisation of novel drugs, medical devices and digital health technologies and $65 million for research projects through the Genomics Health Futures and Stem Cell Missions.[6]
- As part of the Australian Government's $1.3 billion Modern Manufacturing Initiative, the release of the Medical Products National Manufacturing Priority Road Map and the deployment of grant funding aims to drive innovation and build advanced manufacturing capabilities in areas such as mRNA vaccine manufacturing.[7] In conjunction with this federal initiative, states such as New South Wales, Victoria, South Australia, Western Australia and Queensland have also announced investments aimed at developing advanced vaccine manufacturing capabilities.[8,9,10,11,12]
- CSIRO is driving innovation in biosecurity and infectious disease resilience through the CSIRO Futures initiative, focusing on co-developing a national mission on infectious disease resilience. The mission aims to support the increase of health security for Australia and the Asia-Pacific region; increase sovereign supply chain capabilities; lessen the economic and social impact of future infectious disease outbreaks; and create opportunities for jobs and growth.[13]

4 World Health Organization (WHO), Coronavirus (COVID-19) Dashboard, as of 10 October 2021
5 Department of Health, Coronavirus (COVID-19) case numbers and statistics, as of 10 October 2021
6 Department of Health media releases, 2021
7 Department of Industry, Science, Energy and Resources (DISER), Make it Happen: *The Australian Government's Modern Manufacturing Strategy,* 2020
8 NSW Government media release, 'NSW looks to lead the way with mRNA vaccines, 2021
9 Matt Dennien, 'New $1.84b jobs fund to give Qld vaccine manufacturing a shot in the arm', *Brisbane Times*, 2021
10 Yara Murray-Atfield, 'Victoria announces $50m to fund mRNA COVID-19 vaccine production in Australia, paving way for Pfizer-style manufacturing', ABC News, 2021
11 David Ellis, "SA ready to lead COVID-19 vaccine production", University of Adelaide media release, 2021
12 Joe Spagnolo, "Health Minister Roger Cook's plan to manufacture COVID-19 Moderna vaccines in WA", The West Australian, 2021
13 CSIRO, *Infectious disease resilience: Co-developing a national Mission*, 2021

- The Defence Science and Technology (DST) Group is leading an initiative on strategic research to develop advanced defence capabilities through the Science, Technology and Research (STaR) Shots program. One STaR Shot focuses research efforts on enabling Defence to operate safely and effectively in contested Chemical, Biological, Radiological and Nuclear (CBRN) threat environments. To achieve this, DST aims to develop novel medical countermeasures, including fast and accurate detection of biomarkers and pathogens and modelling of processes and timings of disease emergence.[14]

Developing a sufficiently skilled workforce will be essential in ensuring the success of these strategic actions. Consequently, this third report investigates the critical workforce skills gaps that need to be addressed to support advanced medical products manufacturing and biosecurity capabilities. The areas explored include vaccine manufacturing, regenerative medicine, infectious disease resilience and medical countermeasures.

Identification of skills gaps

Four key skills gaps impacting these emerging priority areas have been identified, as illustrated below:

Theme	Key skills gaps	Description
Advanced manufacturing and supply chain	Shortage of Good Manufacturing Practice (GMP)- trained staff for advanced manufacturing	Capacity shortage of workers with practical knowledge of GMP standards to implement GMP-compliant processes in manufacturing settings for the medical products sector, including therapeutics and vaccines, such as regenerative medicine and mRNA vaccine technology
	Lack of process design expertise	Shortage of technical experts with an in-depth understanding of commercial-scale process design and the knowledge of regulatory requirements, both of which are important in designing efficient MTP manufacturing processes whilst maintaining the quality and safety of medical products
Business Operations	Lack of a commercialisation competency framework/resource for SMEs	Early-stage companies lack awareness of the range of different skills required at different stages along the development pathway to create and commercialise MTP products. Consequently, they do not take appropriate actions, such as collaborating with relevant subject matter experts, to address these skills gaps
Specialist and Technical Skills	Lack of in-silico (computational) skills for drug and vaccine development	Shortage of staff with computational skills for drug and vaccine development from pre-clinical to clinical phases, which would help reduce development costs and timelines

[14] Department of Defence, 'Eight STaR Shots will be established to focus strategic research and proactively develop new leap-ahead Defence capabilities', DST Strategy 2030, 2021

These four key skills gaps are related to broader gaps identified in the *REDI Initiative Skills Gap Analysis Second Report*, as outlined in the next chapter. However, they are highlighted in this report because they have relevance to the development of advanced manufacturing and biosecurity capabilities.

Five other skills gaps were also identified during our research (table below). The detailed descriptions of these gaps are excluded in this report because they were addressed in previous MTPConnect skills gaps reports.[15]

Other skills gaps identified	Description
Lack of expertise in supply chain planning	There is a lack of awareness of how to analyse and establish strong and resilient supply chains that consider a variety of different factors, such as the sourcing of Active Pharmaceutical Ingredients (APIs), fill/finish requirements for a drug or logistics requirements for regenerative medicine therapies. This also results in a lack of appropriate risk management and contingency planning in the supply chain.[16]
Lack of understanding of the regulatory process for MTP products, including genomics	Shortage of experts with a deep understanding of regulatory requirements to ensure pre-manufacturing and manufacturing activities are efficiently and correctly carried out to meet regulatory requirements. This is particularly the case in advanced and novel therapeutics, including genomics and regenerative medicine.
Lack of expertise in handling and analysing big data	Shortage of data analysts, system architects and data scientists who have the expertise in big data capture, interpretation and visualisation in the MTP sector. This is more pronounced in small and medium-sized enterprises (SMEs) and early-stage companies that do not have the resources to train and upskill their employees.[17,18]
Shortage of skilled project managers with MTP sector experience	Shortage of experienced project managers who have a sufficient understanding of regulatory requirements and are proficient in assessing safety of a novel drug/vaccine in the preclinical phase, defining target product profiles, data interpretation and devising appropriate risk-management strategies in the development to commercialisation cycle of novel therapies
Lack of trained bioinformaticians in genomics	Shortage of trained bioinformaticians to support genomics R&D with key skills, including data stewardship, analysis and interpretation

15 MTPConnect, *REDI Initiative Skills Gap Analysis Second Report*, 2021
16 Stakeholder consultation
17 MTPConnect, *REDI Initiative Skills Gap Analysis Second Report*, 2021
18 Stakeholder consultation

3. Characterisation of skills gaps

This chapter provides an in-depth characterisation of the four skills gaps in the themes identified in the Second Skills Gap Report. Each skills gap characterisation provides details of the skills and its context, why it exists, impact on the MTP sector and alignment to previous skills gaps reports, sector priorities and megatrends. Finally, potential solutions to address each skills gap are proposed.

Theme: Advanced manufacturing and supply chain

Skills gap #1: Shortage of GMP-trained staff for advanced manufacturing

Overview of the skill

GMP is a system of principles and procedures for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimise the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. It covers all aspects of production, from sourcing raw materials to manufacturing equipment to the personnel involved in the process. Most pharmaceutical and some medical technology manufacturing companies must be GMP compliant to minimise risk in the production process and ultimately to the patient using the product.[19,20]

Adherence to GMP standards in the advanced manufacturing of medical products such as novel vaccines, stem-cell and gene therapies is critical, for reasons which include:

- These novel products typically have very limited stability in terms of shelf life and temperature and are very sensitive to contamination. For example, mRNA can be degraded within seconds, so ensuring every raw material, solution and equipment used in the manufacturing adheres to GMP quality standards is critical.
- Regenerative medicines, which involve novel stem-cell and gene therapies, are customised to a single recipient. The collection and transport of the patient sample must be done in carefully controlled conditions, before it is transported to the manufacturing facility where the treatment is manufactured under strict GMP standards in small batches.[21] Once produced, the therapy is then transported back to the administration site for delivery to the patient. Ideally, the manufacturing site should be close to the site for patient sample collection and medicine distribution necessitating specialised handling and logistical requirements.[22]

Description of the skills gap

Stakeholder consultations have highlighted a shortage of competent GMP experts and workers for the advanced manufacturing of these novel medical products. Specifically, workers lack a combination of fundamental training in GMP principles and practical experience in implementing these principles in a commercial manufacturing setting.

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[19] Therapeutic Goods Administration (TGA), *Australian Regulatory Guidelines for Medical Devices (ARGMD)*, Section 14: Medical devices incorporating a medicine states that 'The manufacturing of a medicinal substance or Active Pharmaceutical Ingredient (API) that is incorporated into a medical device must be undertaken in accordance with an appropriate system for managing quality and is required to be in compliance with Good Manufacturing Practice (GMP), where appropriate' (p.229). The ARGMD is currently being reviewed and updated. The version referenced was released in May 2011, Version 1.1

[20] Therapeutic Goods Administration (TGA), Good manufacturing practice – an overview, accessed 30 August 2021

[21] Henriette Schubert, 'The challenges of personalized drugs – and some possible solutions', *Techtalk – powered by NNE*, 2021

[22] Stakeholder consultation

This is exacerbated by external factors such as the absence of formal training and qualification courses in undergraduate education. Without an appropriate level of training, employers are finding it challenging to hire people with the requisite skills or retrain the existing workforce to upskill them in GMP practices.[23] In addition, demand for GMP-trained workers has historically been limited, as there have only been a small number of GMP-licensed MTP manufacturing facilities in Australia.

Large pharmaceutical and medical technology companies tend to have in-house capabilities due to their global scale and knowledge management systems. However, Australian SMEs and early-stage companies lack these resources and consequently experience this shortage acutely. The use of in-house training programs by large pharma and medtech companies limits the workforce mobility. This increases training as part of on-boarding new workers as the worker's existing skills and competencies are harder to assess. Exacerbating this is the low uptake of national qualifications in Pharmaceutical Manufacturing. Support for GMP skill development in many cases is through consultant development of GMP systems, and then companies are left to perform the training of staff on-boarded after this time. This process has limitations, especially for SMEs and growing companies where resources for training are constrained.

Findings of the gap

Breadth of impact across the MTP value chain	Characteristics of skills gap	
Pre-production, Production, Post-Production	Well-known gap	Capability and Capacity gap

Impact of the gap

As highlighted in Chapter 2, the Australian Government is supporting the modern manufacturing of medical products, including the manufacturing of priority biopharmaceuticals in life-threatening infections, emergency and critical care, reproductive health and obstetric practices and mRNA vaccines locally.[24,25] Developing a sufficient number of GMP-competent experts and workers will be vital to achieving the government's ambition and expanding the production capability of novel medical products in Australia. An appropriately skilled workforce will boost Australia's sovereign supply chain capabilities and reputation in the global market as a manufacturer of advanced medical products.

Alignment with sector priorities and megatrends

This skills gap aligns with a number of gaps highlighted in the *REDI Initiative Skills Gap Analysis Second Report*, the MTP sector priorities and megatrends, as illustrated below.

[23] ibid.

[24] Department of Industry, Science, Energy and Resources (DISER), Make it Happen: *The Australian Government's Modern Manufacturing Strategy*, 2020

[25] Department of Industry, Science, Energy and Resources (DISER), *Sovereign Manufacturing Capability Plan: Tranche 1, Supply Chain Resilience Initiative (SCRI)*, accessed 15 September 2021

Related *REDI Initiative Skills Gap Analysis Second Report skills gaps*:

Skills gap	Description
Skills gap #1: Understanding of QMS and protocols	Capability gap in understanding and implementing quality assurance and control protocols, particularly relating to the manufacturing of therapeutics and devices, including Good Laboratory Practice (GLP), Good Clinical Practice (GCP), GMP guidelines and ISO standards
Skills gap #3: Manufacturing expertise in high-value therapeutics at a commercial scale	Shortage of local expertise required for the manufacture of high-value pharmaceuticals (e.g. biologics and cell therapies) at a commercial scale. This includes a lack of process engineers and a GMP/GLP/GCP-certified workforce

Sector Priority	Description
Priority 7: Support advanced manufacturing as a part of the broader Australian innovation system	Developing a competent GMP workforce will be critical to developing greater advanced manufacturing capability in Australia

Megatrend	Description
Precision healthcare	Developing and manufacturing precision healthcare products will require GMP expertise due to their technical complexity and evolving regulatory frameworks and requirements
Chronic burden[26]	The pressure of the chronic burden is driving the rise of novel therapies as a preventive measure and the demand for advanced manufacturing. Australia could focus on these high-value therapies and own an advantageous positioning as a leader in novel medical interventions
Developing markets	Australia can leverage its high-quality advanced manufacturing facilities for novel therapeutics to its densely populated neighbours and capitalise on their rapid growth to drive export revenue[27]
Global biosecurity	Developing alignment in the manufacturing standards and systems in the MTP sector with international best practices and establishing strong onshore advanced manufacturing capabilities will contribute to efforts to build resilience in response to biosecurity and infectious disease threats, as is being highlighted by the COVID-19 pandemic[28]

[26] Chronic burden refers to the pressure on health systems to manage chronic disease as we live longer than ever before. A fuller description can be found in MTPConnect's Sector Competitiveness Plan, 2020

[27] CSIRO, *Medical Technologies and Pharmaceuticals: A Roadmap for unlocking future growth opportunities for Australia*, 2017

[28] CSIRO, *Infectious disease resilience: Co-developing a national Mission*, 2021

Addressing the gap

The REDI initiative has already taken steps to address the lack of quality management systems and protocols. Building on these successes, additional opportunities exist to work with key GMP facilities and training providers to develop a training program that includes a mix of theory-based learning and immersive, practical training within a GMP-like facility. The training should be aimed at students in tertiary education, researchers in early-stage companies and SMEs and new recruits.

Skills gap #2: Lack of process design expertise

Overview of the skill

Process design is where the commercial manufacturing process is defined. It is the first stage in the product (drug) lifecycle, as described by US Food and Drug Administration (FDA) guidance on Process Validation.[29] It involves defining the product attributes to ensure quality, safety, recovery and efficacy. Its purpose is to design a consistent efficient process with effective process control to reduce variability. The goal is to deliver products that meet predefined standards and critical quality attributes – such as strength, purity, and potency.[30,31] It involves making use of product development information such as quality attributes, general manufacturing pathway and intended dosage form. A strategy for process control involves recognising sources of variability, collecting substantial supporting data to monitor and explain these variabilities and managing them by instituting appropriate measures, ensuring that the finished medical product is consistent and meets predefined standards. Effective process design should apply sound scientific methods and principles, making it a challenge for MTP companies accustomed to a heuristic or experimental-focused paradigm.[32,33]

Description of the skills gap

Stakeholder consultations have suggested there is a shortage of trained senior manufacturing staff, particularly those who have a combination of technical expertise in manufacturing processes and the process design skills and/or knowledge to build efficient, scaled-up processes that align with relevant quality standards. This is primarily an experience gap, as the current technicians and manufacturing staff workforce is limited to the relatively small number of manufacturing facilities across Australia that have not had sufficient exposure to process design.

[29] U.S. Food and Drug Administration, *Guidance for Industry Process Validation: General Principles and Practices*, U.S. Department of Health and Human Services, 2011
[30] ibid
[31] Sandra Wassink, 'Process Design & Risk Management — A Proactive Approach', *Pharmaceutical Online*, 2017
[32] Dana Barrasso, Debbie Hooper, Gavin Reynolds, Hervé Barjat, John Henderson, Mike Tobyn, 'Digital design for pharmaceutical product and process development', *European Pharmaceutical Review,* 2019
[33] PharmaOut, *FDA's PV Guidance: The Guidance, the Regulator and the Manufacturer*, 2011

As described in our *REDI Initiative Skills Gap Analysis Second Report*, the lack of commercial-scale manufacturing in Australia's MTP sector is a structural barrier that limits demand and career opportunities for process design experts. Employment opportunities for such highly skilled staff are typically restricted to the large MTP sector manufacturers.

Findings of the gap

Breadth of impact across the MTP value chain	Characteristics of skills gap	
Pre-production, Production, Post-Production	Recently Emerging gap	Experience gap

Impact of the gap

The lack of process design expertise leads to slower translation of research into commercial manufacturing, as work may need to be redone and processes re-engineered to build quality specifications and compliance with regulatory requirements. This skills gap also impacts start-ups, as they cannot find the right skill set to expand their operations.

An efficient process design will enhance the capability and speed of development and build flexibility in the manufacturing processes against evolving regulatory requirements. Having an adequate number of process design experts will be vital in achieving the target capabilities in advanced manufacturing of specialised medical products and therapeutics in Australia.

Alignment with sector priorities and megatrends

Process design expertise is particularly critical in advanced manufacturing, such as mRNA vaccines and regenerative medicine, where a combination of deep technical process experience, GMP requirements and an awareness of quality and regulatory standards is critical. It is also aligned with the *Skills gap #3: Manufacturing expertise in high-value therapeutics at a commercial scale,* identified in the *REDI Initiative Skills Gap Analysis Second Report*.

Process design expertise aligns with the following MTP sector priorities:

Sector Priority	Description
Priority 1: Align investment in knowledge priorities that meet current and future market needs	With the rising demand for precision medicine, gaining skills in process design will be crucial for the development and translation for commercial manufacturing of novel therapies in Australia
Priority 7: Support advanced manufacturing as a part of the broader Australian innovation system	Australia's reputation in advanced manufacturing and its opportunities for integration with global markets will rely on industry-wide excellence in quality management through efficient process design capabilities in advanced manufacturing

The following megatrends will drive the demand for process design expertise:

Megatrend	Description
Precision healthcare	Meeting quality and manufacturing standards is increasingly important in the context of demand for precision medicine solutions and its evolving regulatory frameworks
Developing markets	With strong process design expertise driving high-quality, consistent manufacturing of novel therapeutics such as stem cell/gene therapies, Australia could be a leading exporter in novel medical interventions to neighbouring high-population, high-growth countries
Global biosecurity	Developing a strong process design will boost manufacturing capabilities and build sovereign supply chain resilience in the face of biosecurity threats such as the COVID-19 pandemic

Addressing the gap

Specialised training for staff who have manufacturing expertise (e.g. cell culture, protein purification) could be developed to address this skills gap. This training would provide them with information on process validation, frameworks for process design including statistics – good experimental design, risk analysis, good documentation processes, regulatory requirements/pathways in the product lifecycle, control theory, and practical tips and pitfalls to be avoided. As a starting point to upskill workers in process design and development, common activities from production systems could be used. This includes six-sigma and lean techniques – such as root cause analysis, wishbone diagrams, kaizen and value-stream mapping – which can be developed across the workforce. This would provide foundational experiences which could be applied to larger process design/ development.

Theme: Business operations

Skills gap #3: Lack of a commercialisation competency framework/resource for SMEs

Overview of the skill

An important driver of successful innovation in the MTP sector is having a deep ecosystem with multiple early-stage companies. Collaborating with stakeholders across the sector and successfully commercialising technologies and research leads to the creation of a virtuous cycle of innovation and commercialisation, where researchers and start-ups can draw on the ecosystem and participate in knowledge sharing.

A wide range of skills is required to develop and commercialise an MTP innovation successfully. Examples of necessary skills include understanding market gaps and unmet consumer needs, design of clinical trials, health economics, regulatory and reimbursement requirements and product design and manufacturing protocols.

Description of the skills gap

Early-stage companies and SMEs often cannot obtain or access a range of different skills as they progress along the MTP value chain.[34] The skill sets required will be dependent on the nature of the technology being developed (i.e. vaccines, stem-cell, gene therapies, drugs and medtech) and the current stage of development. Stakeholder consultations have highlighted that spinouts, start-ups and emerging companies developing medical products lack a holistic framework that clearly articulates their workforce skills requirements at different stages along the commercialisation pathway.

Findings of the gap

Breadth of impact across the MTP value chain	Characteristics of skills gap	
Pre-production, Production, Post-Production	Recently Emerging gap	Capability gap

Impact of the gap

Having access to a clear framework of skills required to commercialise novel medical products successfully will help early-stage companies and SMEs recruit an appropriate workforce into the projects and identify training need if appropriate. This should lower costs and timeframes to commercialise products and ultimately result in more innovations reaching the market. For example, accessing the regulatory and/or clinical trials design skills at the appropriate time will minimise the need to redo experiments, save costs and maximise the chance for success.

Alignment with sector priorities and megatrends

This skill gap aligns with the gaps highlighted in the *REDI Initiative Skills Gap Analysis Second Report* and is comprehensive in nature, given that it relates to an overarching competency framework. Similarly, it is aligned with many of the megatrends and directly addresses the MTP sector priority relating to transforming the SME sub-sector:

Sector Priority	Description
Priority 3: Transform the SME sub-sector to support the growth of small companies into larger, more stable and successful companies	Developing start-ups and SMEs will position Australia as a hub for innovations in the MTP sector

[34] MTPConnect, *REDI Initiative Skills Gap Analysis Second Report*, 2021

Addressing the gap

A comprehensive competency framework across the different stages of the MTP value chain needs to be developed as a resource for early-stage companies and SMEs. This commercialisation competency framework will need to consider the different skill sets required for medical products including therapeutics, medical devices, diagnostics and digital health innovations.

Once the commercialisation competency framework is developed, training seminars/webinars would help interested early-stage companies and SMEs understand the competency framework and assess their skills gaps.

Theme: Specialist and technical skills

Skills gap #4: Lack of in-silico (computational) skills for drug and vaccine development

Overview of the skill

Computer-aided drug discovery/design methods have played an essential role in developing therapeutically important molecules. The first step in the drug discovery process involves searching for new drug molecules. Computational methods, known as in-silico experimentation, have been developed to identify promising drug candidates, aid in drug development, encompassing pre-clinical to clinical modelling of pharmacokinetics and pharmacodynamics.

In-silico skills can be relevant in all stages of drug and vaccine development, from preclinical discovery to late-stage clinical development. Through using in-silico in drug development, many compounds that could have side effects are eliminated. Only an effective lead molecule can be retained, resulting in minimising late-stage clinical trial failures and reducing investment needed for drug development.[35] In-silico experiments are also relevant in limiting the use of animal models in pharmacological research, aiding the rational design of novel and safe drug and vaccine candidates (and repositioning marketed drugs), supporting medicinal chemists and pharmacologists during their drug discovery process.[36]

The importance of in-silico skills such as computational modelling and simulation has gained widespread acceptance over the past two decades. In 2017, the FDA underscored the importance of computational tools in drug-development efficiency and as part of the drug review process. At the time, the FDA planned to convene workshops, publish additional guidance documents and develop policies that translated modelling approaches to regulatory review. The FDA also intended to grant meetings to sponsors who used modelling approaches to promote more collaboration on model-informed drug development issues.[37]

The growing importance of modelling and simulation is further underscored by the fact that the number of papers published on FDA-approved drug products involving physiologically based pharmacokinetic

[35] Hannah Balfour, '*In silico* trial successfully replicates human clinical research results', *European Pharmaceutical Review*, 2021
[36] Simone Brogi, Teodorico Castro Ramalho, Kamil Kuca, José L. Medina-Franco, Marian Valko, 'Editorial: *In silico* Methods for Drug Design and Discovery', *Frontiers in Chemis*try, 2020
[37] Kelly Gelinne, 'FDA Commissioner Emphasizes that Modeling & Simulation Can Increase Efficiency & Reduce Costs', *Nuventra Pharma Scien*ces, 2017

(PBPK) modelling rose 13-fold between 2012 and 2018, showing its increasing utilisation in drug development and approvals, indicative of faster regulatory approvals and go-to-market for drugs.

Description of the skills gap

Stakeholder consultations have revealed that a limited number of experts are trained in in-silico (computational) methods in the MTP sector. This skills gap relates to:

- Understanding the in-silico methods for drug design, such as molecular docking as a solution for identifying drug targets and efficacy predictions.[38,39] The molecular docking method has recently been exploited to repurpose drugs for different targets, including SARS-CoV-2.[40]
- Proficiency in using pharmacometrics tools, such as PBPK and physiologically based pharmacodynamic (PBPD) modelling packages.
- Proficiency in data visualisation techniques that complement in-silico computations.

This skills gap is more pronounced in SMEs and start-ups. Stakeholder consultations have revealed that large pharmaceutical and biotechnology companies are training their staff in in-silico drug development.

Findings of the gap

Breadth of impact across the MTP value chain	Characteristics of skills gap	
Pre-production, Production, Post-Production	Recently Emerging gap	Capacity and Capability gap

Impact of the gap

Developing greater workforce capacity in in-silico (computational) skills will help drive greater commercialisation outcomes across the MTP sector through faster drug discovery and optimised drug and vaccine development decisions. Eventually, this will enable patients to access innovative medical products and interventions faster and promote better health outcomes.

The scope of in-silico (computational) skills also extends to developing medical countermeasures and boosting Australia's defence industries capabilities in identifying novel drugs and interventions against potential biosecurity risks and infectious agents. For example, computational skills are critical for modelling and simulating the processes and risks involved when a new disease emerges in a community. It is also vital in studying the efficacy and risks of potential medical countermeasures to biological or chemical threats.

[38] Charlotte Di Salvo, 'A Critical Evaluation of the Advantages and Limitations of In Silico Methods in Clinical Research', *Proventa International*, 2021
[39] Stakeholder consultation
[40] Alfonso Trezza, Daniele Iovinelli, Annalisa Santucci, Filippo Prischi, Ottavia Spiga, 'An integrated drug repurposing strategy for the rapid identification of potential SARS-CoV-2 viral inhibitors', *Nature*, 2020

Alignment with sector priorities and megatrends

This skills gap aligns with gaps highlighted in the *REDI Initiative Skills Gap Analysis Second Report,* the MTP sector priorities and megatrends, as illustrated below.

Skills gap	Description
Skills gap #10: Understanding of and expertise in big data capture, management and analysis	Shortage of data scientists who can capture, curate and interpret large streams of (often unstructured) health data. This gap also extends to a lack of understanding among management around big data benefits and use cases, as well as a shortage of data 'influencers' who can demonstrate and communicate the value of analytics
Skills Gap #20: Shortage of pharmacologists and toxicologists with drug development expertise	Shortage of pharmacologists (who study drug interactions) and toxicologists (who study adverse effects) who understand and have expertise in the drug development pathway

In-silico (computational) skills align with the following MTP sector priorities:

Sector Priority	Description
Priority 1: Align investment in knowledge priorities that meet current and future market needs	Developing in-silico (computational) skills aligns with the sector need to acquire digital skills to drive efficiency in capturing and analysing data to supplement experimentation
Priority 5: Support the development of digital healthcare solutions, devices and data analytics	Developing modelling and simulation skills for drug discovery and novel molecule identification will lead to Australia building a strong capability in utilising digital tools to develop and manufacture MTP products

The following megatrends drive the demand for in-silico (computational) skills:

Megatrend	Description
Digital evolution	The digital enablement of the healthcare landscape is driving the use of modelling and simulation software that is changing how drug discovery is made, how data are captured and analysed to generate sophisticated insights and the selection of novel molecules for novel therapies and biosecurity needs
Precision healthcare	Discovering novel molecules is critical in precision medicine and the development of novel medical therapies and interventions
Chronic burden	The pressure of the chronic burden is driving the rise of novel therapies as a preventive measure and the discovery of novel drug molecules

Addressing the gap

Funding fellowships for PhD students and early-career postdoctoral researchers to be embedded within selected industry drug development and defence industry partners could be beneficial to bridge the skills gap. In such fellowships, the researchers or students will develop practical in-silico skills to study targets, vulnerabilities, generate simulations and evaluate novel pathways to regulatory approval for small molecules and biologics. Linking PhD students and early-career researchers to the industry through such fellowships will also demonstrate how to function in a synthetic environment and the commercially relevant research questions that require solutions.

4. Conclusion

The COVID-19 pandemic has highlighted Australia's need to accelerate its capacity and capabilities in advanced medical products (drugs, vaccines and devices) manufacturing and strengthen biosecurity capabilities. Catalysed by the Australian Government's Modern Manufacturing Strategy (MMS), state governments and industry organisations have undertaken a range of initiatives to achieve these goals, including investments in mRNA vaccine manufacturing. To support these initiatives, Australia's MTP sector will need to develop its workforce to have appropriate skills to drive growth across the manufacturing value chain and the sector.

This report has identified four key skills gaps that need to be addressed for Australia to develop greater advanced manufacturing and biosecurity capabilities – summarised below.

Theme	Key skills gaps	Description
Advanced manufacturing and supply chain	Shortage of Good Manufacturing Practice (GMP)- trained staff for advanced manufacturing	Capacity shortage of workers with practical knowledge of GMP standards to implement GMP-compliant processes in manufacturing settings for the medical products sector, including therapeutics and vaccines, such as regenerative medicine and mRNA vaccine technology
	Lack of process design expertise	Shortage of technical experts with an in-depth understanding of commercial-scale process design and the knowledge of regulatory requirements, both of which are important in designing efficient MTP manufacturing processes whilst maintaining the quality and safety of medical products
Business Operations	Lack of a commercialisation competency framework/resource for SMEs	Early-stage companies lack awareness of the range of different skills required at different stages along the development pathway to create and commercialise MTP products. Consequently, they do not take appropriate actions, such as collaborating with relevant subject matter experts, to address these skills gaps
Specialist and Technical Skills	Lack of in-silico (computational) skills for drug and vaccine development	Shortage of staff with computational skills for drug and vaccine development from pre-clinical to clinical phases, which would help reduce development costs and timelines

Developing these capabilities and building capacity will deliver a resilient, industry-ready workforce that can drive a globally competitive advanced medical products manufacturing sector. It will also enhance Australia's ability to respond to diseases and future pandemic shocks.

MTPConnect's REDI initiative is driving appropriate solutions to identify, analyse and address the sector's priority skills gaps and provide industry experiences and skills development for researchers, clinicians, MTP professionals and innovators.

Through this and the two previous reports of the REDI initiative's comprehensive skills gap analysis project, a broad set of skills gaps have been identified that need to be addressed to enable the Australian MTP sector to flourish.

Together, the reports provide a roadmap for action to develop the skills and capabilities needed to position the MTP workforce for post-pandemic prosperity. They are also supporting the deployment of new and targeted education and training programs which are helping to build an industry-ready workforce with the skills necessary to keep pace with a rapidly changing sector.

Appendices

Appendix 1: List of senior sector stakeholders consulted

This MTP sector skills gap assessment report was developed through targeted stakeholder consultations with several experts and senior sector executives. The perspectives shared by these stakeholders from industry associations, companies, research organisations and government representatives have informed key insights and recommendations within this report. MTPConnect would like to thank all those who shared their time and insights through these consultations. The list of stakeholders is shown in the table below.

Name	Organisation
Mark Grosser	23Strands
Steven Tipper	23Strands
Darryl Irwin	Agena Bioscience
Richard Rendell	Applied Precision Medicine
Jennifer Herz	Biointelect
Siân Slade	Biophoranta
Jennifer Hollands	Cell Therapies
Chris Still	Commonwealth Scientific and Industrial Research Organisation (CSIRO)
Michelle Baker	Commonwealth Scientific and Industrial Research Organisation (CSIRO)
Bevan Morton	Commonwealth Scientific and Industrial Research Organisation (CSIRO)
Anthea Moisi	Commonwealth Scientific and Industrial Research Organisation (CSIRO)
Denis Bauer	Commonwealth Scientific and Industrial Research Organisation (CSIRO)
Andrew Nash	Commonwealth Serum Laboratories (CSL)
Anthony Stowers	Commonwealth Serum Laboratories (CSL)
Claire Mason	Data61
Axel Bender	Department of Defence
Nicholas Fitzgerald	Department of Defence
Peter Shoubridge	Department of Defence
Alex Gibson	Department of Industry, Science, Energy and Resources (DISER)
Sam Waring	Department of Industry, Science, Energy and Resources (DISER)
Sebastian Brash	Department of Industry, Science, Energy and Resources (DISER)
James Griffin	Department of Industry, Science, Energy and Resources (DISER)
Leigh Farrell	Defence Materials Technology Centre (DMTC)
Felicia Pradera	Defence Materials Technology Centre (DMTC)
Nicholette Conway	Eli Lilly

Name	Organisation
Sue MacLeman	MTPConnect Board
Tim Cahill	Regenerative Medicine Catalyst Project Consortium
Stephen Richardson	Sanofi
Ric Sicurella	Takeda
Monica Ferrie	Victorian Clinical Genetics Services

Appendix 2: Glossary of terms

AMRAB	Australian Medical Research Advisory Board
API	Active Pharmaceutical Ingredient
CBRN	Chemical, biological, radiological and nuclear
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DMTC	Defence Materials Technology Centre
DST	Defence Science and Technology Group
FDA	U.S. Food and Drug Administration
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
in-silico	Computer experiments using computational methods/simulations
mRNA	Messenger ribonucleic acid
MRFF	Medical Research Future Fund
MTP	Medical technology, biotechnology and pharmaceutical
PBPD	Physiologically based pharmacodynamic
PBPK	Physiologically based pharmacokinetic
REDI	Researcher Exchange and Development within Industry
SME	Small and medium-sized enterprises
STaR	Science, Technology and Research

Appendix 3: References

Author(s), Organisation	Title	Year
Alfonso Trezza, Daniele Iovinelli, Annalisa Santucci, Filippo Prischi, Ottavia Spiga, *Nature*	An integrated drug repurposing strategy for the rapid identification of potential SARS CoV 2 viral inhibitors	2020
Charlotte Di Salvo, *Proventa International*	A Critical Evaluation of the Advantages and Limitations of In Silico Methods in Clinical Research	2021
CSIRO	Infectious disease resilience: Co-developing a national Mission	2021
CSIRO	Medical Technologies and Pharmaceuticals: A Roadmap for unlocking future growth opportunities for Australia	2017
Dana Barrasso, Debbie Hooper, Gavin Reynolds, Hervé Barjat, John Henderson, Mike Tobyn, *European Pharmaceutical Review*	Digital design for pharmaceutical product and process development	2019
David Ellis , *University of Adelaide*	SA ready to lead COVID-19 vaccine production	2021
Department of Defence	Eight STaR Shots will be established to focus strategic research and proactively develop new leap-ahead Defence capabilities, DST Strategy 2030	2021
Department of Health	Coronavirus (COVID-19) case numbers and statistics	2021
Department of Health	Medical Research Future Fund – Australian Medical Research and Innovation Priorities, 2020-2022	2020
Department of Industry, Science, Energy and Resources (DISER)	Make it Happen: The Australian Government's Modern Manufacturing Strategy	2020
Department of Industry, Science, Energy and Resources (DISER)	Sovereign Manufacturing Capability Plan: Tranche 1, Supply Chain Resilience Initiative (SCRI)	2020
Hannah Balfour, *European Pharmaceutical Review*	*In silico* trial successfully replicates human clinical research results	2021
Henriette Schubert, *Techtalk – powered by NNE*	The challenges of personalized drugs- and some possible solutions	2021
Joe Spagnolo, *The West Australian*	Health Minister Roger Cook's plan to manufacture COVID-19 Moderna vaccines in WA	2021
Kelly Gelinne, *Nuventra Pharma Sciences*	FDA Commissioner Emphasizes that Modeling & Simulation Can Increase Efficiency & Reduce Costs	2017
Matt Dennien, *Brisbane Times*	New $1.84b jobs fund to give Qld vaccine manufacturing a shot in the arm	2021
MTPConnect	Researcher Exchange and Development within Industry (REDI) initiative	2020
MTPConnect	REDI Program Skills Gap Analysis Interim Report	2020

Author(s), Organisation	Title	Year
MTPConnect	REDI Initiative Skills Gap Analysis Second Report	2021
NSW Government	NSW looks to lead the way with mRNA vaccines	2021
PharmaOut	FDA's PV Guidance: The Guidance, the Regulator and the Manufacturer	2011
Sandra Wassink, *Pharmaceutical Online*	Process Design & Risk Management — A Proactive Approach	2017
Simone Brogi, Teodorico Castro Ramalho, Kamil Kuca, José L. Medina-Franco, Marian Valko, *Frontiers in Chemistry*	Editorial: *In silico* Methods for Drug Design and Discovery	2020
Therapeutic Goods Administration (TGA)	Good manufacturing practice – an overview	2021
Therapeutic Goods Administration (TGA)	Australian Regulatory Guidelines for Medical Devices (ARGMD), Section 14: Medical devices incorporating a medicine	2011
U.S. Food and Drug Administration (FDA), U.S. Department of Health and Human Services	Guidance for Industry Process Validation: General Principles and Practices	2011
World Health Organization	Coronavirus (COVID-19) Dashboard	2021
Yara Murray-Atfield, ABC News	Victoria announces $50m to fund mRNA COVID-19 vaccine production in Australia, paving way for Pfizer-style manufacturing	2021

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