WORKFORCE & CAPACITY SUMMIT

Addressing capacity and capability in the Medical Technologies, Biotech and Pharmaceutical (MTP) sector

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ENDORSING ORGANISATIONS

The following industry organisations endorse the contents of this White Paper.

AusBiotech AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

Medicines Australia Better health through research and innovation

MTAA Medical Technology ASSOCIATION OF AUSTRALIA

Acknowledgement of Country

ARCS acknowledges the traditional owners of the land on which we meet and work.
We pay our respects to Elders past, present and emerging.

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ARCS AUSTRALIA®

ARCS Australia is a national, membership association representing professionals engaged in the MTP industry. Our membership is made up of individuals working in clinical research, regulatory affairs, health economics, pharmacovigilance, medical affairs and other disciplines related to the development and quality use of therapeutic goods.

ARCS Australia members are based in industry, academia, medical research institutes, government, and hospitals and other clinical settings.

ARCS Australia provides education, career pathways, professional development, networking opportunities and advocacy.

ARCS Australia is an education affiliate of MTP Connect, the federally funded growth centre for the MedTech, Biotech and Pharmaceutical sectors. This affiliation acknowledges our unique role in providing professional education to the sector.

Through its members, ARCS Australia has a broad and effective reach throughout the health sector and provides a neutral forum to develop and foster consensus on policies and initiatives to develop and grow the therapeutics sector for the benefit of all Australians.

WORKFORCE & CAPACITY SUMMIT

The scale of the MTP industry and its continuing growth presents great opportunity for the nation, but also increasingly faces severe challenges in training, recruitment, and retention of skilled workers.

Given the workforce and capacity challenges facing the industry, ARCS Australia convened the Workforce and Capacity Summit. The summit was held over four days in November 2021 and was attended by just over industry 100 experts. These included representatives from manufacturers, sponsors, research institutions, research and development consultancies, training organisations, hospitals as well as individuals from state and federal governments and industry peak bodies.

The sector has attracted multiple recent reviews, especially into the drivers for manufacturing, appropriate regulatory and governance frameworks and improving translational research and development. There is no intention for this White Paper to recapitulate those prior reviews or to attempt a detailed analysis of wider industry policy. The focus of the summit was on workforce capacity issues and how to address the obvious challenges arising to allow the therapeutics sector to continue to flourish benefitting the nation.

FOREWORD

Australia is highly regarded internationally, for the quality of its medical research and scientific and engineering innovation. Nowhere is this more apparent than in the research, development and manufacturing of therapeutic goods.

There is an immense opportunity to capture the fruits of that innovation in a vibrant, research–based manufacturing industry with growing exports. This will bring opportunities for substantial, skilled employment and retain more of the value of the nation's innovative research and development.

This vision can only be realised if industry development is supported by the required infrastructure to recruit and develop the skilled workforce on which it depends. Failure to do so risks declining quality standards, major hurdles to growth and loss of value overseas. The industry is, therefore, at a crossroads.

The development of therapeutics requires many and varied skills and infrastructure. Skills shortages exist across the sector and are particularly acute in the two key areas of clinical research and GMP manufacturing.

As the leading professional body for professionals in the MTP industry, it is incumbent upon ARCS Australia to provide the necessary leadership to directly address these challenges to develop the workforce of the future for our industry and for the good of all Australians.

In commending this White Paper to you, it is important to acknowledge the many individuals and organisations who have contributed selflessly to the deliberations of the summit and to the preparation of the final text. I thank you all.

Dr Shanny L Dyer
Chief Executive Officer, ARCS Australia

EXECUTIVE SUMMARY

Australia's medical technology, biotechnology and pharmaceuticals industry is the largest sector by value of manufactured exports. It supports a rapidly growing clinical research sector, which offers advanced access to the latest breakthrough therapies to as many as 95,000 Australians each year. These activities combined contribute around $9 billion to the economy each year and employ approx. 80,000 skilled workers.

The rapid growth of the sector is causing increasingly severe shortages of skilled workers, especially in clinical trial operations and pharmaceutical manufacturing.

The COVID–19 pandemic mobility restrictions exacerbated skill shortages. The pandemic also exposed a lack of sovereign capacity for manufacturing of essential medicines, especially vaccines, and vulnerability of reliance on international supply chains for access to key medicines and pharmaceutical ingredients.

The ARCS Australia Workforce and Capacity Summit was convened to examine the challenges facing the industry and to recommend solutions. The summit was attended by more than 100 industry experts representing the full range of industry stakeholders.

The summit identified a number of opportunities to develop the workforce and accelerate the growth of the industry. These included:

- Greater engagement with tertiary education providers, to raise awareness of the sector and opportunities it offers for graduates, and integration of appropriate content into current curricula.
- Development of a more robust and standardised professional framework, including recognised competency frameworks and professional standards which support careers and nationally standardised training programs to support and grow the local workforce capacity.
- Effective and efficient visa pathways to address short–term needs which that cannot be met locally and increased the awareness of these pathways within the sector.
- Leveraging the strategic opportunity to support developing nations in our region, especially in SE Asia and the Pacific.

RECOMMENDATIONS

1. Overwhelmingly, the participants called for the establishment of robust and comprehensive national competency standards for the key professions that service the MTP industry. These standards should align with those already established in Australia and overseas and provide the elements of nationally consistent training programs.

2. As the peak professional body for the MTP sector, industry endorsed ARCS to lead the development of a national training curriculum for the key professions, linked to the competency frameworks, and to engage with all stakeholders to facilitate its adoption.

3. The MTP industry sector should develop a stronger and more coordinated outreach via its peak bodies to tertiary institutions to increase awareness of the sector and the existing and emerging career opportunities. Furthermore, this outreach should extend to the provision of training (including micro–credentialling) that will facilitate the development of 'job–ready' entrants.

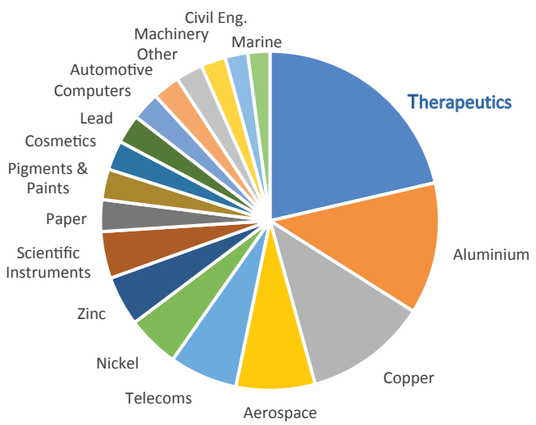
4. ARCS and its industry partners should take a more active role to engage with government policy in order to realise the economic development and employment opportunities identified by this summit in the areas of:
   a. Targeted manufacturing support specifically for mRNA, APIs and commercial fill and finish
   b. A range of ecosystem support policies including: tax incentives, workforce and training policy and visa and immigration policy

THE AUSTRALIAN MTP INDUSTRY

Excellence in Manufacturing and Research and Development

The Australian MTP industry develops, manufactures, and supplies medicines, other pharmaceutical products, biologics and blood products, medical devices and diagnostics and is Australia's largest exporter of manufactured goods. The sector employs more than 70,000 workers[1] and each year exports more than 7 billion dollars' worth of locally manufactured goods – around 14% of all Australian manufactured exports.[2]

Therapeutics is Australia's largest manufactured export sector



$7.2

billion dollars annually

13.5%

of all manufactured exports

Pharmaceutical Products & Medicines	$5.58 bn
Medical Devices	$1.65 bn

Data from Commonwealth Department of Foreign Affairs and Trade. *Trade and Investment at a glance, 2020.*
https://www.dfat.gov.au/publications/trade–and–investment/trade–and–investment–glance–2020#manufactures–sector

Australia is comprehensively integrated into the global MTP industry. In addition to local manufacturing, Australia imports a very substantial proportion of the therapeutics it consumes. As a small market, the nation is vulnerable to international supply chain constraints, particularly given its remoteness from the major manufacturing centres in Europe, North America and China and the small size of the local market (around 1.5% of the global market). The global companies active in Australia contribute substantially to the national innovation economy, funding local research and development including a vibrant clinical trials industry.

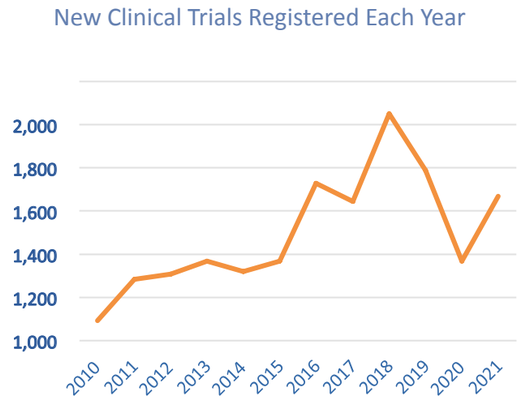
Australia has a well–deserved international reputation for excellence in medical research and a world–class health system. The regulation of clinical trials in Australia is efficient – with most trials being notified to TGA via the Clinical Trial Notification (CTN) scheme. This environment is driving robust growth in the clinical trials sector. Owing to the relatively small population, clinical trials in Australia tend to be early stage (Phase I/II) which require smaller numbers of enrolled patients. However, a proportion of trials are Phase III/IV, typically involving Australian centres as part of global multi–centre trials.

The number of clinical trials conducted is growing strongly. New trial registrations doubled in the period 2010–2018. Trial activity decreased temporarily over 2019–20 with the onset of the COVID–19 pandemic, but growth has since resumed and is rapidly returning to pre–COVID–19 levels.

In addition to their value in developing new therapies and diagnostics, clinical trials are a substantial contributor to the Australian economy. Clinical trials provide skilled employment for more than 8,000 Australians and contributed approximately $1.4 billion to the economy through direct expenditure and investment in 2019, with a long–term annual growth rate of 6.5%. More than 95,000 Australians participate in clinical trials each year,[3] benefitting from advanced access to the latest breakthrough therapies.

1. https://www.medicinesaustralia.com.au/wp–content/uploads/2020/11/MTPC_Workplace_Skills_Report_FINAL.pdf
2. Commonwealth Department of Foreign Affairs and Trade. Trade and Investment at a glance, 2020. https://www.dfat.gov.au/publications/trade–and–investment/trade–and–investment–glance–2020#manufactures–sector
3. Australia's Clinical Trials Sector, MTP Connect, 2021. https://www.mtpconnect.org.au/reports/clinicaltrialsreports2021

Clinical Trials –a growing contributor to the Australian Economy



$1.4

billion dollars annually

6.5%

Annual growth rate 2015–19

Australia's Clinical Trials Sector, MTP Connect, 2021.
https://www.mtpconnect.org.au/reports/clinicaltrialsreports2021

The very success of the sector and the rapid growth it enjoys brings with it the challenge of an acute shortage of skilled workers, particularly in clinical trials operations. Shortages also exist in other specialist areas including key technical skills in manufacturing and in the areas of regulatory and medical affairs and pharmacovigilance (drug safety monitoring).

These roles require a wide range of scientific and management skills necessary to conduct research, design and implement clinical trials, carry out product development and establish and operate conduct manufacturing operations in a technically complex and rigorously regulated industry.

The emergence of the COVID–19 pandemic in 2019 exposed and highlighted three critical challenges to this nationally vital industry.

- A chronic shortage of appropriately skilled workers, which is exacerbated by the rapid growth of the industry and becoming an inhibitor of further growth.
- A lack of sovereign capacity to produce essential medicines, particularly vaccines.
- The nation is highly dependent on global supply chains and, as a small market in global terms, acutely vulnerable to disruptions of those supply chains.

The shortage of a skilled workforce in particular has become critical across the sector, exacerbated by the restrictions on international travel due to the pandemic.

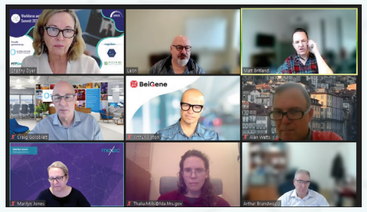
However, the pandemic has only exposed a problem which has been there for some time. The MTP Connect Workforce Skill Report[4] has confirmed the skills shortage across the sector. This shortage is creating risks for our sector as staff are completing activities and functions for which they do not have the experience, nor the competency. The skills shortage has also fostered a "buy" rather than "build" approach in some parts of the ecosystem, introducing inefficiencies and adding costs to doing business in Australia.

4. https://www.mtpconnect.org.au/reports/mtp–workforce–skills

THE SUMMIT STRUCTURE

The summit was organised into the following workforce streams.

- Clinical Trials
- Regulatory Affairs
- Pharmacovigilance
- Medical Affairs
- mRNA Manufacturing



Each of these workforce streams convened in parallel over two days with summary of findings discussed at a general plenary.

The discussions were supported by a qualitative survey conducted among participants, prior to the summit which provided information reflective of the current circumstances and practices across the sector. The survey was limited to one per workforce stream per organisation. Key findings of the survey are detailed in the following discussion.

The following summarises the deliberations of the summit and the issues raised in the different workforce streams.

CLINICAL TRIALS

The clinical trials sector is growing at a compound annual growth rate of 5% in dollar terms reaching $1.4 billion in 2019.[7] This growth is driven by a global growth in trial activity and by Australia increasing its share of early–stage Phase I/II trials while maintaining its share of later–stage trials.

33% of clinical trials staff are employed on work visas with 12.5% of firms having more than 20 positions filled by visa holders.

This rapid growth has resulted in an acute shortage of skilled clinical operations personnel. Participants in this workforce stream reported an extremely challenging recruitment environment with a heavy reliance on overseas workers.

- 71% anticipated headcount growth of >5% in the coming year
- 66% were not confident of meeting that growth needed from the domestic workforce
- 71% believed that the ability to recruit locally has become more difficult since the onset of COVID–19
- 33% already employ some staff on work visas with 12.5% having more than 20 positions filled by visa holders
- 71% believed current visa offerings to be fit for purpose.

Organisations are investing heavily in training, especially of junior recruits, with 44% of organisations having internship programs in place, and a further 22% developing such programs, and 78% currently employing interns or trainees.

Formal competency frameworks are an area of active development, with over half (57%) having frameworks in place and a further 26% actively developing such frameworks. There was strong concern that inconsistent training approaches between organisations were a burden on the sector.

There is an urgent need for standardised industry training which is recognised across the sector and transferable.

Flexible working arrangements are ubiquitous, with almost all organisations (96%) offering remote working, and close to 80% of organisations actively considering international hires for remote working roles.

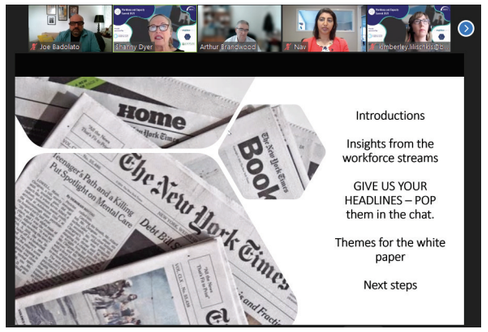
Digitalisation is having a substantial impact, with 61% of organisations reporting major impacts on the workforce requirements.

Regional activities are increasing with half (51%) of all organisations anticipating increased activities in support of the Asia Pacific region in the next 2 years.

7. MTPConnect: Australia's Clinical trials Sector. https://www.mtpconnect.org.au/reports/clinicaltrialsreports2021

COVID–19 has had a significant short–term impact, with the number of trials down by 13% in early 2020. However, this appears a temporary, global impact, and numbers are recovering, including new trial activities in the areas of COVID–19 vaccines, diagnostics and therapies.

Discussion in this workforce stream was around several clear themes.



- **A need to raise awareness of the sector amongst university graduates**

  There was strong support for integration of clinical trials educational content into relevant university and TAFE programs as a means of raising awareness of employment opportunities and preparing graduates to enter the sector. There were also calls for greater coordinated outreach activities such as supporting university careers fairs and seminars, which were seen as effective ways of recruiting new entrants into the sector.

- **Harmonised competency and training frameworks**

  The ad hoc approach to training across the clinical trials sector is a significant obstacle to a harmonised assessment of role competency and equitable remuneration. There is currently a siloed approach with training programs being organisation specific. Those smaller organisations that don't have the resources to have their own training programs would benefit from a national approach.

  It was noted that several competency and training frameworks already exist overseas and that these could be easily adapted for the Australian context.

  It was noted that some third–party training is already being offered and this was a welcome development. However, it was also argued that the scale of current offerings is inadequate and there is a need for substantial increases in both the range and depth of training available, including offering more bespoke and in–depth training for more senior personnel.

  There was broad consensus on the need for nationally agreed approaches to both competency frameworks and professional training. ARCS Australia, as the pre–eminent professional body for the sector, was seen as the appropriate organisation to lead the development of this framework.

- **Improving current migration frameworks**

  There were calls for improvement of current visa and residency pathways with concerns over challenges to international hiring around inconsistent assessment processes at different stages of the professional journey and inadequate definitions among the prioritised occupations lists. It was also argued that to achieve improvements, the industry needed to better engage via industry bodies with the Federal Government in this area. There was also concern about inadequate understanding of the currently available migration pathways, which in turn results in their underutilisation.

  For recruitment of international graduates, there needs to be a more thoughtful approach to "selling" the destination, emphasising the attractive points of difference of the Australian work environment.

  The increasing significance of Asia Pacific operations was acknowledged, and appropriate relocation arrangements were considered necessary.

- **Challenges in staff retention**

  There were serious concerns expressed over increasingly commonplace predatory recruitment activities, with substantial sign–on benefits and other inducements to poach staff from competing organisations. This is resulting in a disincentive to invest in training, as trainees were frequently lost shortly after completing training. However, this was also seen as a reflection of the changing labour market and a need for organisations to review salary scales and working conditions, and to consider approaches such as subsidised training conditionally linked to retention clauses in contracts.

REGULATORY AFFAIRS

The small local market in Australia means that Australian manufacturers must from the outset seek international markets for their products. Australia is also a substantial importer of therapeutics and 43% of respondents worked for organisations headquartered overseas with operations in multiple jurisdictions. This means that regulatory affairs professionals must have expertise in regulatory requirements not just of Australia but for those of the major export markets, especially Europe, North America, and East Asia. 43% of organisations anticipated growing activities in the Asia Pacific over the coming 24 months.

29% of organisations were not confident of meeting recruitment needs locally and 43% anticipated regulatory work to be taken offshore in the coming two years.

In addition, the breadth and complexity of the regulatory role in businesses as they develop and/or bring on new products for the markets, can mean that the appropriate skills cannot often be found in the one person. For SMEs this can mean that they either bring in regulatory consultants or risk making costly mistakes.

Continuing growth in the industry combined with a shortage of qualified regulatory affairs staff presents a current recruitment challenge.

- Growth in regulatory workforces reflected the overall growth of the industry generally with 57% of organisations expecting growth in headcount over the coming two years.
- 29% of organisations were not confident that their staffing needs could be met from local recruitment and 57% reporting that the COVID–19 pandemic had made the challenge more difficult.

Perhaps surprisingly, given the need for international regulatory knowledge, there was negligible use of international recruitment in the regulatory affairs sector, with no significant use of visas reported.

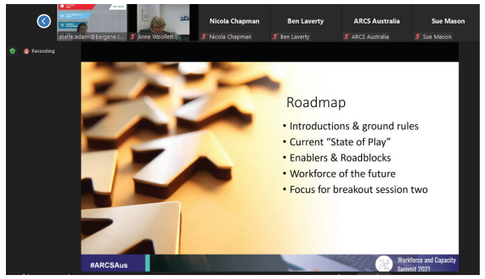
Training and competency are developing areas in regulatory affairs.

- 29% of organisations reported they have competency frameworks for regulatory affairs professionals and 14% are working to develop them.
- 29% employ between 1 and 5 interns or junior trainees each year.

The impact of digitalisation was reflected in work practices.

- 71% of organisations supported remote working in regulatory affairs (the majority of roles being suitable for remote working).
- 43% anticipated some of the work currently conducted in Australia may be taken offshore within the next two years. Conversely there is negligible use of offshore hiring of remote regulatory workers by Australian organisations or business units.

The nature of regulatory affairs means that it is particularly suited to remote or home working. However, participants cautioned that there remains the need for regulatory affairs officers to engage frequently with other parts of their organisation, particularly production, sales and marketing, and product development and that face–to–face engagement was still an essential part of internal relationships. The ease of remote working also means that there was a higher likelihood that work may be conducted cooperatively across international boundaries.



The TGA did not participate in the summit, but several respondents expressed concern that the shortage of regulatory skills in Australia was having an adverse effect on the national regulator in recruiting appropriately skilled staff to conduct regulatory reviews. This was seen as a significant weakness in the Australian regulatory framework.

Discussion in this workforce stream focused on the following themes.

- **Professional standards and training**

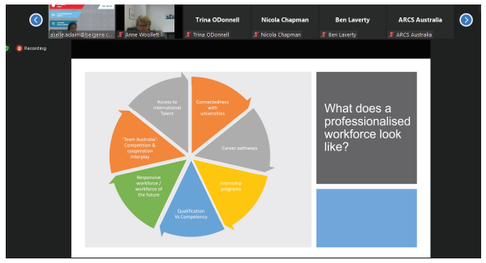
  The lack of clear professional standards in regulatory affairs was seen as a very significant weakness and threat. In the absence of clear competency standards, organisations struggle with recruiting, potential applicants are discouraged from entering the profession and smaller organisations found it difficult to identify and select the right regulatory service providers. Regulatory services in Australia are characterised by the presence of a very large number of small operators, mostly sole traders of highly variable competence.

  There was again broad consensus from this workforce stream for ARCS Australia to lead the establishment of a professional framework to drive an increase in professional standards and provide greater certainty to organisations in recruitment and acquisition of regulatory services. Again, it was noted that there are existing competency standards developed internationally and that these should be easily adapted for local use.

  A participant involved in the provision of university courses in regulatory affairs observed that, should there be national competency frameworks established, they would immediately be able to tailor their teaching materials to address those standards. Participants involved in delivery of regulatory training pointed out the challenge of devising training syllabus in the absence of objective competency standards outside that of individual companies. They remarked that development of such a national competency framework would result in a rapid adaptation of current tertiary and professional development training offers and likely stimulate additional provision of training to address the standards.

"Should there be national competency frameworks established, then I would immediately be able to tailor my university teaching materials to address those standards."

UNIVERSITY LECTURER



- **Impacts of digitalisation**

  Digitalisation has had a profound impact on the practice of regulatory affairs.

  - The advent of electronic records and documentation are now ubiquitous and have transformed regulatory practice. Electronic records management has introduced considerable efficiencies and shifted the emphasis from labour intensive document preparation to those skills necessary to engage effectively with regulators to drive the dialogue around product safety and performance.
  - The advent of "digital health" has also brought requirements for new regulatory skill sets, particularly in the regulation of software. This includes embedded software in electromedical devices, as well as standalone software applications, particularly those used in diagnostics and in patient management and record keeping, where new regulatory concerns including privacy come to the fore. The burgeoning field of artificial intelligence is seen as a particular challenge.
  - The explosion in medical software and relative ease and speed of software development compared to hardware devices has lowered the barriers to entry for start-ups in the medical services space, with many small organisations developing medical software. This has resulted in an emerging group of small organisations that is largely regulatory naïve and in need of support.

- **Awareness of the role of regulatory affairs**

Participants agreed that there was a need for greater awareness of regulatory affairs. Although a critical role in the supply of regulated marketplaces, there was little awareness of the function amongst graduates and the very broad–based career opportunities it presented by regulatory affairs. Participants echoed calls in other streams for greater coordinated industry outreach and for greater inclusion of regulatory content in relevant tertiary training.

PHARMACCOVIGILANCE

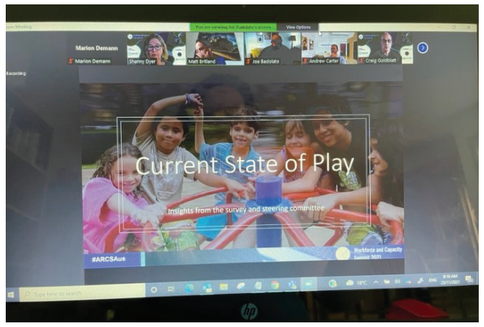
Pharmacovigilance is a specialist area involved in the monitoring of patient and user feedback on drug safety and interactions. The participants in this workforce stream reported similar concerns expressed in the regulatory and medical affairs workforce streams, with a particular emphasis on professional standards.

Skills shortages were less acute although this may be partly because of the smaller numbers, and more specialist role of the pharmacovigilance function and the flexibility offered through suitability for remote working.

- Only 12.5% of respondents were concerned about sufficient availability of local workers> However, recruitment of new staff was still being impacted (similar to other workforce streams).
- 25% of organisations reported operating traineeships or intern programs.

88% of organisations stated it was likely that pharmacovigilance activities will be offshored in the coming 2 years and 75% anticipated an increase in activity in the Asia Pacific region.

Pharmacovigilance has a formal requirement for organisations to employ a designated Qualified Person in Pharmacovigilance (QPPV). However, only 37% of organisations reported having a formal competency framework for this role. This was an obvious concern, and the pharmacovigilance workforce stream echoed the strong calls for establishment of independent national competency frameworks.



The impact of digitalisation on those working in pharmacovigilance was similar to that seen in the practice of other information–centric roles such as broader regulatory affairs.

- 63% of organisations reported major impacts of digitalisation on practice of pharmacovigilance.
- Most pharmacovigilance roles were suited to remote working and 63% of organisations supported remote working.
- 29% of organisations had actively considered hiring remote workers offshore.

Internationalisation, facilitated by remote working, was also evident.

- 88% of organisations stated it was likely that pharmacovigilance activities will be offshored in the coming 2 years and 75% anticipated an increase in activity in Asia Pacific. This presents a potential risk in that Australian pharmacovigilance signals and associated decision making may be diluted in a centralised operation based overseas.

MEDICAL AFFAIRS

The medical affairs role is central to the continuing support of clinical stakeholders in the quality use of pharmaceutical products. It is a discipline which combines high level technical skills with the ability for effective communication with clinical personnel and management of statutory responsibilities relating to safety monitoring and reporting.

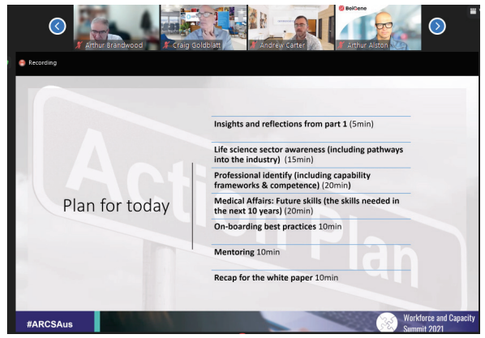
The participants in this workforce stream reported similar skills shortage challenges as reported in other streams. This has driven a far more flexible approach to recruitment. An example shared during the summit was the changing practice of medical qualifications being required for medical directors, with these roles now being filled by individuals with a wider range of technical and scientific backgrounds (but this also speaks to the changing role of a medical director and medical affairs in general). This presents a challenge to competency frameworks as the landscape evolves. Some of that evolution is driven by a need to be flexible in the face of skill shortages.

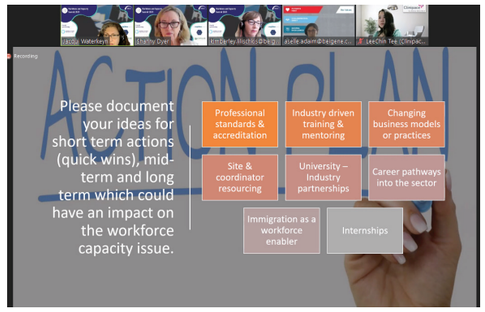
Remote working is introducing competition from overseas. There were anecdotal reports of US organisations hiring remote working medical affairs staff in Australia at salaries considerably higher than the local standards here.

The following statistics must be treated with caution owing to the small sample size of organisations reporting on medical affairs.

- 50% of organisations anticipated growing medical affairs headcount in the next 12 months
- 25% expressed concern about the ability to recruit from the domestic workforce and reported that this had become harder since the advent of COVID–19
- There was no reported use of visa holders
- All organisations operated competency frameworks for Medical Affairs
- 75% operated trainee or internship programs
- 75% reported digitalisation as having a major impact with all organisations supporting remote working and 75% considering offshore hiring in medical affairs
- Remote working is introducing competition from overseas. There were anecdotal reports of US organisations hiring remote working medical affairs staff in Australia at salaries considerably higher than the local standards.

The importance of supporting the complete career journey of those entering the profession was seen as central to recruitment and retention and an area for industry wide improvement. The first 9 months in a role were seen as being critical, with companies needing to invest in induction, support, and training for new hires. Such support is particularly challenging for remote workers which is also on the increase as companies decentralise workforces post COVID–19.





mRNA MANUFACTURING

There has been exhaustive national debate about how manufacturing may be supported and how to improve translational research to realise a greater share of the value of Australian research to expand local industry. The COVID–19 pandemic has also put into sharp focus the weakness or absence of sovereign capacity in the production of some essential medical products, especially vaccines.

It was not the purpose of the summit to recapitulate that debate. However, the nature of Australia's therapeutics manufacturing sector is evolving and that has a central impact on the requirements for its workforce. Therefore, the mRNA Manufacturing workforce stream devoted some effort to what were seen as the priorities in industry development and what effects that had on skills requirements.

An immediate priority is to increase pilot scale capacity for vaccine manufacture. This would be an enabler of greater clinical trial activity at Phase I/II. This retains IP in Australia for longer,

There was a consensus that the immediate priority is to increase pilot scale capacity for vaccine manufacture. This would be an enabler of greater early phase clinical trial activity. This retains Investigational Product (IP) in Australia for longer, growing value here. It is also an enabler of development of larger scale manufacture.

The appropriate scale of Australian vaccine manufacture is determined by the domestic and export market opportunities.

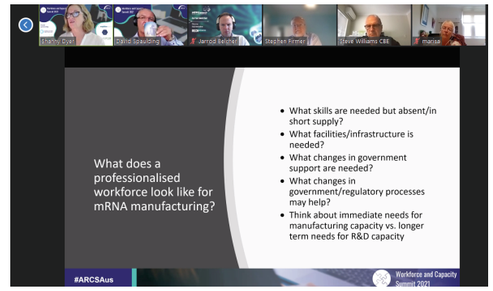
- Assuming ongoing requirements for approximately annual booster doses against COVID–19 or other emerging viruses implies a scale of the order of 30–50 million doses of vaccine.
- Most developed nations are proceeding to establish sufficient sovereign capacity if it does not already exist, which limits export opportunities to traditional developed markets in Europe and North America.
- There was general consensus that there are opportunities to develop capacity to serve developing nations in SE Asia and the Pacific Islands, which are unlikely to be able to achieve self–sufficiency. This implies a potential for manufacturing on the scale of 500 million doses, supported by humanitarian and WHO procurement programs.
- There are other near neighbours (particularly Singapore and Thailand) with technical capacity and opportunities to engage and cooperate with these countries should be explored.
- There are obvious humanitarian and diplomatic opportunities in developing such capacities.

Responding to COVID–19 exposed some specific deficiencies in mRNA vaccine manufacturing capabilities and Australian pharmaceutical manufacturing capacity more generally.

- There are few suitable facilities for mRNA vaccine fill–and–finish operations and none at the scale envisaged for export manufacture.
- Access to Active Pharmaceutical Ingredients (APIs), the active ingredients in drug preparations, was of key concern. Most APIs are sourced internationally, and some are available from limited or even single suppliers (e.g., certain antibiotics). This was seen as a critical strategic risk.
- Large scale fill–and–finish capabilities needs either substantial government assistance or a multinational to support (and cannot be addressed by a pilot facility).
- Access to both APIs and to fill–and–finish facilities are prerequisites for a sustainable sovereign industrial capacity.

The skills and processes involved in mRNA vaccine manufacturing were seen as largely conventional, utilising standard biopharmaceutical processes and equipment. Most of the expertise is in the equipment and the handling of ethanol (flammability).

For the next 5 years, most mRNA manufacturing is expected to be at the clinical scale, and vaccines aside, most of the treatments are going to be small scale going forward. There is very active state government support underpinning these activities. Critical mass is needed to make further progress. This can be achieved if we can properly integrate the industry and university sectors.



Establishment of large–scale manufacturing requires targeted active government support and intervention. The particularly successful model used in Ireland was discussed. While the Irish life science manufacturing model was initially established by significant corporate tax breaks, it is now self-sustaining. This has been achieved by the university sector and industry working together to develop comprehensive training integrated with university research and industrial technology development, making Irish engineers and scientists such as a valuable global commodity.

Another example was the approach taken by Singapore, where the central government funded large numbers of training positions in therapeutics manufacturing. This provided confidence for large scale inbound investment and led to the establishment of the extensive therapeutics manufacturing precinct at Tuas, now home to production facilities for many global MedTech and pharma organisations.

Concerns were raised about the hazards of government attempting to pick winners and the dangers of big, bold initiatives that involve single companies or entities that may cannibalise the industry. There was consensus that the changes needed should be broad based and be incremental in scale in order to develop long term sustainability.

Considering the international historical experience, the current capabilities of Australia's existing pharmaceutical manufacturing sector, and the potential for a staged approach with initial pilot scale development, the following were identified as key issues in establishing the required sovereign capacity in mRNA vaccines and expansion of the sector more generally.

- Some specific technical skills in mRNA technologies and in laboratory–scale activities e.g. chromatography and nanoparticle processing, are in very short supply and the industry will need to be able to recruit internationally to strengthen capacity in these areas.
- Developing these capacities will require quality systems training, initially Good Laboratory Practice (GLP) for pilot– scale operations and subsequently pharmaceutical Good Manufacturing Practice (GMP) for commercial–scale operations. There are some training offers already available, but there has been limited take up to date. This may be because some of the facilities are based at universities, and more needs to be done to build GLP skill sets in these institutions.
- The need for better integration of universities and industry was a clear consensus. This brings advantages including more substantial technology transfer and more vigorous cultural exchange, encouraging scientists and engineers to move more easily from academia to industry and vice versa.
- Larger scale manufacturers will require extensive training in pharmaceutical processes under GMP. It was noted that other nations had been supported by direct government support for the industry–wide training activities required, and which will be necessary for sustainable capacity in Australia.

GROWING CAPACITY

Although each of the workforce streams brought their own unique perspectives on the workforce and capacity challenges facing the MTP industry, there were several clear themes emerging.

- **Competency frameworks**

  There is an urgent need for nationally agreed and independently defined professional competency frameworks. These were seen as the key enabler. Nationally accepted competency frameworks would focus training providers on industry needs. They would support more consistent recruitment practices, provide a clear professional development target for those seeking to enter the profession, and support definition of clearer career paths within the industry.

  There was a consensus that ARCS Australia, as the pre–eminent national professional body in the MTP industry, should proceed to develop and maintain such frameworks.

- **Training**

  There is a need for greater provision of industry training, of appropriate scale, tailored to address specific industry needs. Training will not be consistent or adopted unless set within the national competency frameworks – which are therefore a key enabler of nationally standardised training provision. This will ensure that the training is seen to add value both for individual participants and the industry as a whole and drive its uptake.

- **mRNA manufacturing capacity**

  The establishment of mRNA manufacturing should begin with pilot–scale vaccine and other pharmaceuticals manufacturing with the capacity to support an enlarged clinical trial activity. This will allow rapid development of the necessary skill sets and bring immediate benefits from longer retention of IP in Australia, capturing a greater share of the value of innovation. Such pilot–scale capacity will provide a sound foundation for larger commercial–scale capacity. The expansion of capacity to full commercial scale will require substantial additional investment, likely in cooperative arrangements between government and global manufacturers . Such expansion will need to be enabled by ensuring adequate investment in training.

- **Industry – university cooperation**

  Continuing to improve the integration of university and industry R&D will allow more effective translation of invention and much more mobility of skilled workers between the two. Initiatives that provide conduits between industry and academia were seen as the best use of the government's effort, with targeted support and investment that keeps the sector engaged and developing in partnership.

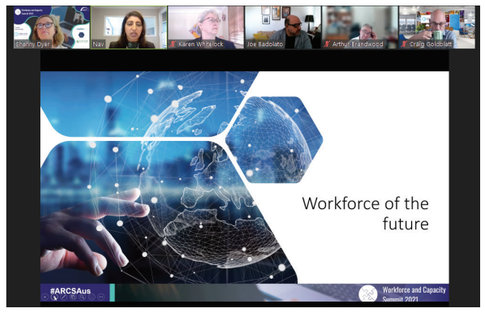
- **Growing the workforce**

  Skill shortages can only be solved by increasing the pool of skilled workers and by increasing the competency of incumbents. This requires a combination of approaches:

  - Industry outreach to increase the awareness of the MTP industry amongst those studying in the science, engineering, and clinical fields to encourage entry to the industry. This outreach should also include cooperative efforts in the provision of tertiary training.
  - Effective and efficient visa and residency pathways for overseas skilled workers in order to fill current gaps in availability and to acquire critical skills for industry development. These pathways should be continually monitored and adjusted to optimise for the needs of industry.
  - Industry awareness of the pathways available needs to be improved to ensure improved utilisation.
  - Provision of government incentives for provision of training services and of incentives for organisations (especially smaller companies) to invest in training.
  - The COVID–19 pandemic, combined with the possibilities created by digitalisation of the workplace, has resulted in widespread and enthusiastic adoption of flexible working arrangements to the benefit of the workforce and businesses alike. It is clear some of these changes will be long lasting and consideration of work force requirements and capacity need to be set in the context of these new paradigms. Properly implemented, flexible working brings increased productivity, better work life balance and much greater geographical flexibility (including internationally) for recruitment. There are also challenges – in maintaining cohesive workplace culture and ensuring adequate communication amongst remote workers.

- **Opportunities from the pandemic**

  Industry and governments should together take advantage of the opportunities created by COVID–19. There is much greater public awareness of the industry, of the importance of international supply chains, and of having sovereign capacity to manufacture essential medicines. There is a new understanding of the importance of regulations and the role of the TGA. This change in the public mood presents an environment conducive to the necessary industry reforms and government investment with broad public support.



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