A collaboration between
AusBiotech and MTPConnect

AusBiotech
AUSTRALIA'S BIOTECHNOLOGY ORGANISATION

MTPConnect
Australia's Life Sciences
Innovation Accelerator

National Biotech and Medtech Development and Commercialisation Summit 2024

Discussion Paper

2024

About AusBiotech

AusBiotech is Australia's leading national and global advocate for life sciences. With a more than 3,000 strong industry led member network, we leverage our unique national convening power to support our members' growth – by building an Australian life sciences ecosystem that leads in development and commercialisation, to create high-quality, innovative life sciences companies.

Our national network of biotech and medtech experts means we are able to support our members at all stages of their lifecycle through advocacy, connection and knowledge sharing. We partner broadly to enable our members' success and promote Australian life science innovation in national and international marketplaces.

As a not-for-profit organisation dedicated to the growth and prosperity of a thriving Australian life science sector, our strategic focus brings an expert lens to translation, development and commercialisation – the precursors to productivity and factors crucial to enabling life sciences as a future part of Australia's modernised economy.

About MTPConnect

MTPConnect is Australia's Life Sciences Innovation Accelerator – an independent, not-for-profit organisation established by the Australian Government to champion the continuing growth of Australia's vibrant medical products sector.

MTPConnect forges stronger connections between research and industry to help maximise opportunities for Australians to not only make scientific and technological breakthroughs, but to see them developed through the proof-of-concept stage and successfully translated and commercialised.

We achieve these outcomes with a focus on improving collaboration and commercialisation, funding cutting-edge innovations, improving management and workforce skills, optimising the regulatory and policy environment and improving access to global supply chains and strategic international markets.

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Joint Foreword from the CEOs of AusBiotech and MTPConnect

As Australia's two leading national organisations focused on the growth of Australian biotechnology and medical technology companies – and the life sciences sector more broadly – AusBiotech and MTPConnect are delighted to deliver Australia's first *National Biotech and Medtech Development and Commercialisation Summit*.

The life sciences sector already makes an invaluable contribution to the Australian economy, from growth in high paying and highly skilled jobs to manufacturing exports. The sector is also foundational to the health and wellbeing of Australians. This is why the Australian Government deems the sector a critical technology field and priority area for future prosperity.

Globally, combined pressures of pandemics, stressed supply chains, chronic disease, aging populations, climate change, health inequities, and geopolitical tensions – along with the rapid pace of innovation – have propelled our industry to the forefront of societal discourse.

The convergence of these national and global factors demands intentional thinking and unified solutions. This context also presents unparalleled opportunity for advancement of our industry and its impact on the health, wellbeing and productivity of our nation.

The focus of the National Biotech and Medtech Development and Commercialisation Summit 2024 is unashamedly on how Australia can supercharge the "Development" in its health and medical Research & Development (R&D) strategies. While we are recognised as a global leader in research, ranking in the top 10 on the Global Innovation Index, we slip down to 30th for outputs from that research.

Gaps in biomedical and medical technology product development limit our ability to achieve commercialisation success. Strategies to address these gaps and bring more life-saving medical products from research labs all the way through to market and patients are critical. The ability of our sector to fully realise the 'D' in R&D is the key to this.

Now is the time to provide a forum for deep conversation about how we can further build on our health and medical research strengths and grow and retain a thriving translation and commercialisation-orientated biotech and medtech sector.

We have a unique opportunity in the run up to the next Federal election. The Summit is the first time that so many senior leaders within our industry have come together to tackle these critical issues. We intend to harness the insights and collective experience of industry to arrive at solutions that are both sector-led and -owned and those that require Government support, creating a clear roadmap and a crystalised voice to Government.

The Summit is a bringing together of the many conversations we are already having as a sector, and it will, no doubt, be the start of many conversations to come. We have developed this paper to focus those discussions and set the scene for the Summit. This paper canvasses the policy context, industry challenges and barriers to driving our "Development and Commercialisation" capability and outcomes across the sector – and fully leverage Australian-generated innovations and discoveries. Beyond the Summit itself, we invite and welcome all input and voices and encourage robust discussion and the testing of assumptions.

We wish to acknowledge the contribution of members of AusBiotech's Policy Taskforce in shaping the focus of the Summit and this discussion paper.

We look forward to hearing from you – Australia's industry experts, innovators and policy makers – as we explore the exciting opportunities and challenges for Australia in supercharging the 'D' in R&D.

Rebekah Cassidy
CEO AusBiotech

Stuart Dignam
CEO MTPConnect

Setting the Scene

To inform discussion and ensure we start with a shared understanding of the context in which our sector currently operates, the below outlines the industry setting from two perspectives: our place in the broad global and national context; and a more focused view on who we are as an industry.

Global Context

Globally, the biotechnology industry is attracting unprecedented attention. The combined pressures of pandemics, chronic disease, aging populations, climate change, health inequities and geopolitical tensions – along with the rapid pace of innovation – has brought health innovation to the fore. Health security, medical sovereign capability, investment competition, system agility and skilled employment have now become matters of critical national importance. Biotechnology is also increasingly joining defence as a focus for security,[1] and being called upon to deliver solutions in these areas.

Governments are not only looking to the biotechnology industry to respond to these challenges but are also looking to the sector as the key to global competitiveness, national prosperity and productivity.

Responding to the national importance and opportunities of the sector, many Governments across the globe have developed whole of government strategies including France, the Republic of Korea, United Kingdom and India.

Global Pressures

- **Regional conflicts/geopolitical tensions**
- **Climate change – supply disruption from natural disasters and health impacts of climate change**
- **Supply chain vulnerabilities**
- **Pandemic**
- **Chronic disease**
- **Communicable disease**
- **Health inequities**

....have global inplications on

Health security, medical sovereign capability, investment competition, system agility, skilled employment, supply chains, global collaborations and alliances

Snapshot:

The biotechnology industry is increasingly critical globally, as governments recognise its role in addressing health, security, and economic challenges and driving national prosperity through strategic, cross-sector innovation.

National Context

Equally, Australia's future economy, prosperity and competitive edge rely on a thriving biotechnology sector. The discoveries, technologies and advancements we make across the diverse life sciences ecosystem have the potential to transform lives, improve health outcomes, generate jobs and grow the economy.

As an industry, we have long understood the value of supercharging the 'D' in R&D. Australia is one of the most productive biomedical research nations in the world. Yet, when it comes to commercialisation, the Australian investment ecosystem invests only four cents in biomedical companies for every dollar invested in the US.[2]

This is an already stark gap to close, and the current global context serves to heighten the urgency.

The Australian Government, as well as States and Territories, recognise the necessity and opportunity of the sector. Biotechnologies are identified as one of the seven critical technology fields on the Australian Government's *List of Critical Technologies in the National Interest*. Earlier this year, the Australian Government announced 'Medical Science' as one of the seven priority areas for future prosperity through the *National Reconstruction Fund*. The review of *Australia's National Health and Medical Research Strategy* and the *Future Made in Australia Act* have also cemented the importance and value of speed to market for Australian generated ideas and innovations. In doing so, the Government has recognised the need to leverage our sector to generate economic and social benefits.

Further, biotechnology is increasingly becoming an important element of our role in international security and diplomacy. Most recently, biotechnology and health security in the Indo-Pacific region were on the agenda at the 2024 Quad Leaders' Summit hosted by the United States. While the recognition of our sector is not new, its critical role has been distinctively elevated. In the future, delivering on biotechnology will form part of Australia's contribution to the global world order and it is critical that this is both recognised and delivered upon.

As a sector, we need to be unashamedly ambitious about harnessing this opportunity to promote sector innovation, growth and development.

The statistics and policy settings show that, while the momentum is there, the climb is steep:

- It can typically take 7–15 years and up to $2.5 billion to bring one biomedical product from early research to market, with little or no revenue.[3]
- Australia ranks 26 out of 34 OECD countries when it comes to commercialising innovations.[4]

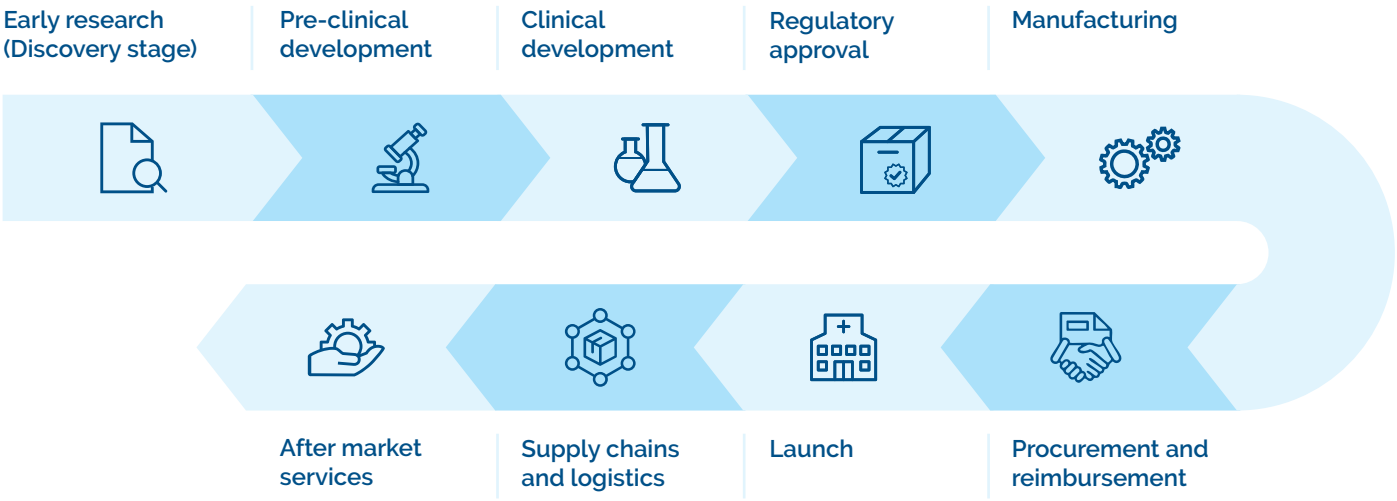
At the same time, Australia has world-class expertise and capability. These include comparative advantage in education, a skilled workforce, early-stage clinical trials strength, stable government institutions, trusted regulatory system and access to advanced infrastructure and digital capabilities.

National Context (continued)

However, to move beyond these widely recognised but stubbornly unresolved statistics, we need to address the challenges and barriers. Supply chains for medicines are vulnerable, sovereign capabilities remain limited and access to capital and people with the right skills is needed to grow and mature our companies.

The role of Government in health is immense and cannot be ignored. It is the educator, the early-stage research funder, the regulator, the procurer, the administrator, the employer of much of the primary healthcare and research workforce, and the funder of universal healthcare as outlined below. Therefore, moving the sector forward will require a unified voice, deep collaboration and a whole pipeline approach, noting that many solutions will sit outside Government policy remit and will need to be both sector-led and -owned.

The policy landscape across the biotech and medtech value chain



Key enablers: education, skills and capability; workforce; Intellectual Property; funding, investment and capital; collaborations and partnerships (national and international); legal and regulatory frameworks; infrastructure; sovereign capability and manufacturing; business environment; data and digital technology; Health Technology Assessment; procurement; supply chain; logistics; trade relations and diplomacy; export; patients and consumers.

Relevant Government Portfolios and Institutions

Commonwealth

- Health and Aged Care
- Industry and Science & Resources
- Education
- Foreign Affairs & Trade
- Social Services
- Climate Change, Energy, the Environment and Water
- Agriculture, Fisheries and Forestry
- Defence
- Home Affairs
- Treasury
- Finance
- Attorney General's
- Cth Agencies
- Cth Institutes
- Universities

State

- State Governments portfolios
- Hospitals and Health Services
- Research institutes

Snapshot:

To secure Australia's economic future and global role, a unified, ambitious approach is essential to overcome commercialisation challenges and fully leverage the biotechnology sector's potential for health, security, and economic growth.

Australia's Life Sciences Capability

The biotechnology sector is one of Australia's greatest value-add industries and has a strong base with clear depth despite a challenging two years following the global COVID-19 pandemic. Opportunities exist to leverage this foundation and support the sector's ongoing growth, especially for commercialisation and growth within existing businesses.

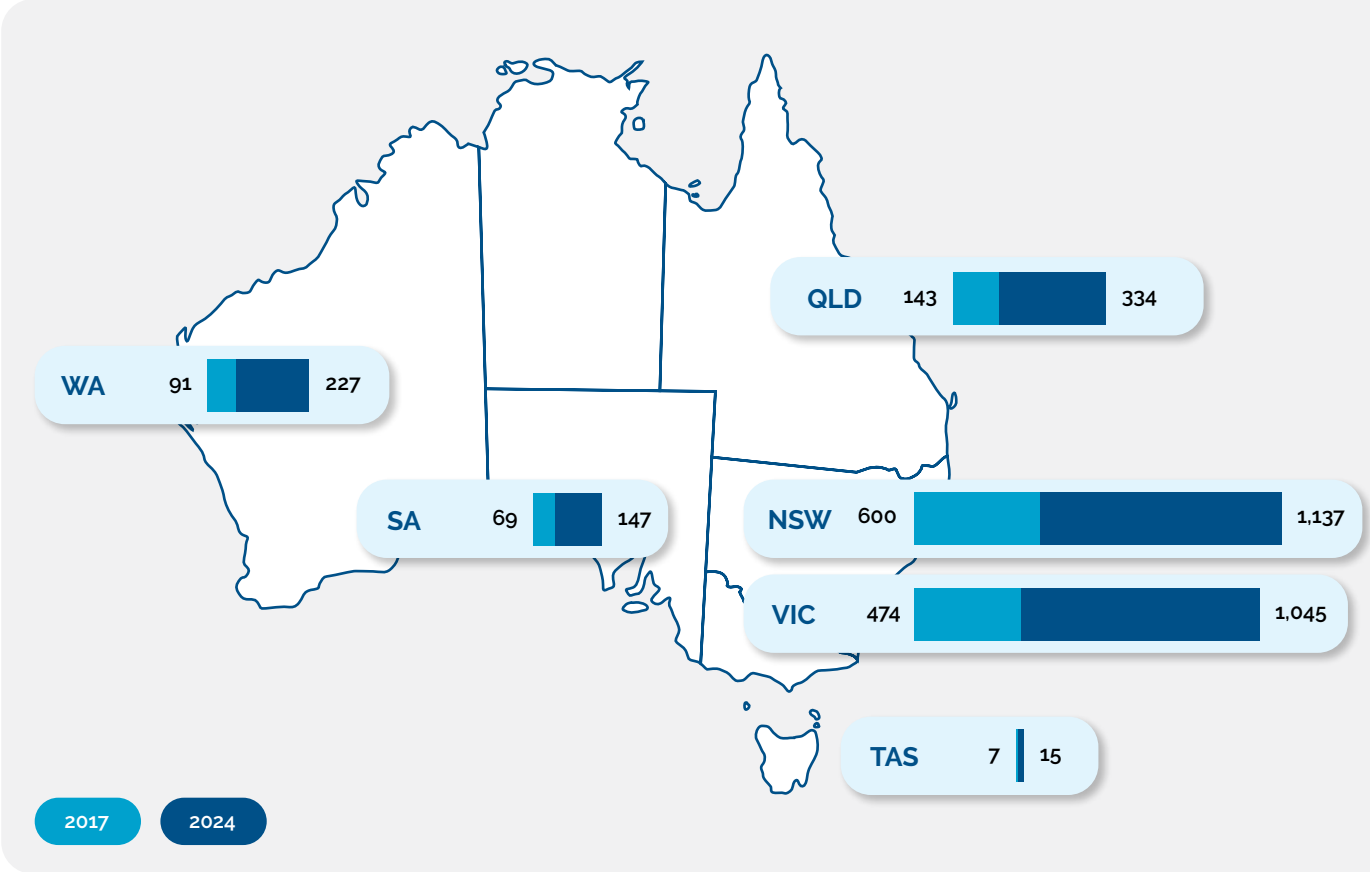
The capability of the Australian life sciences sector can be mapped in three ways:

1. **Aggregate size and productivity** of the sector, which may be measured in terms of numbers of companies, gross value-added and growth rate;
2. **Sector completeness**, meaning that each element of the sector is sufficiently strong to support an ecosystem capable of thriving in both domestic and international markets; and
3. **Partnership capability**, where the sector is appropriately developed to interlink with international partners. This capability includes both comparative advantage and the capacity to work cooperatively at a global level.

By Aggregate Size and Productivity: Scale and Maturity of the Sector

There are 2,905 life science organisations across the life sciences ecosystem, with 1,592 biotech and medtech companies (Figure 1).[5]

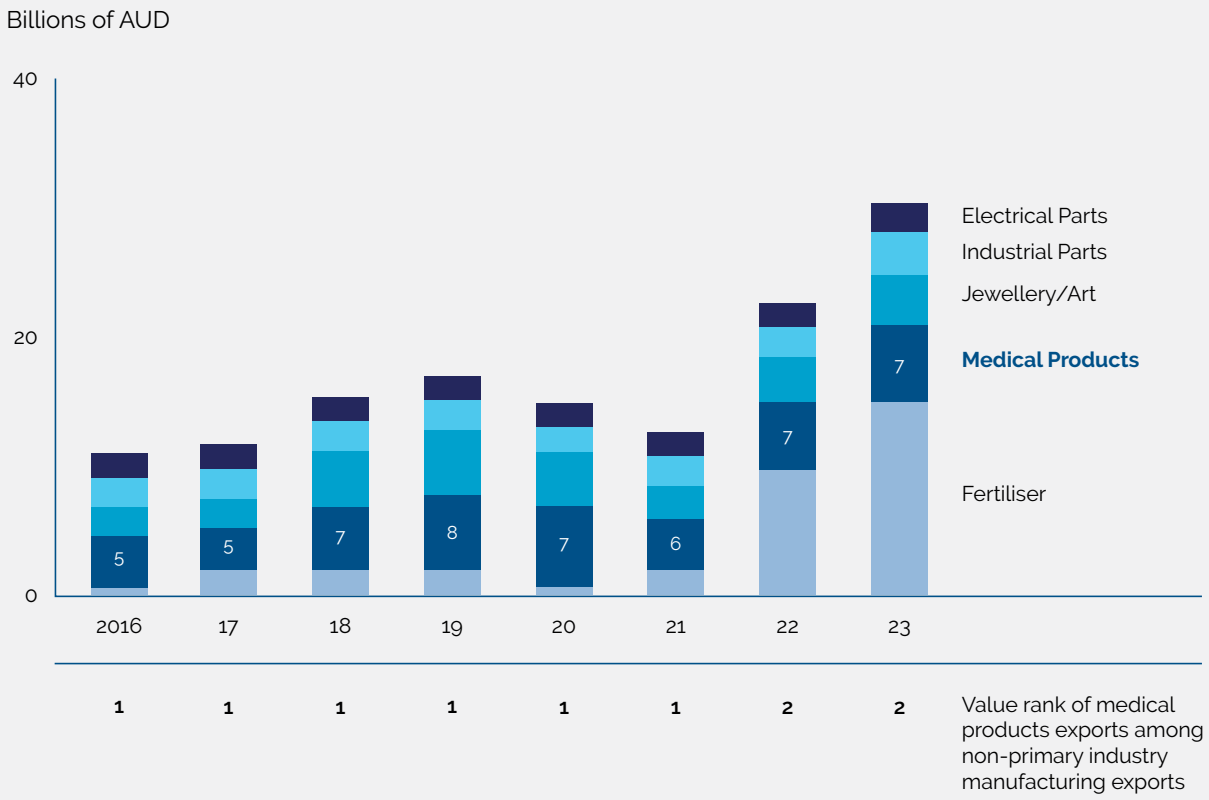
Figure 1: Number of Biotechnology Companies



Australia's Life Sciences Capability

While the numbers of companies and gross value-add continues to grow (6.3 per cent, 2016 – 2023), Australian exports of medical products have remained resilient through the period of pandemic shock. It was the second most valuable non-primary value-add export (after fertiliser) in 2023, but cumulatively since 2016, it is the greatest value-add export in Australia (Figure 2).

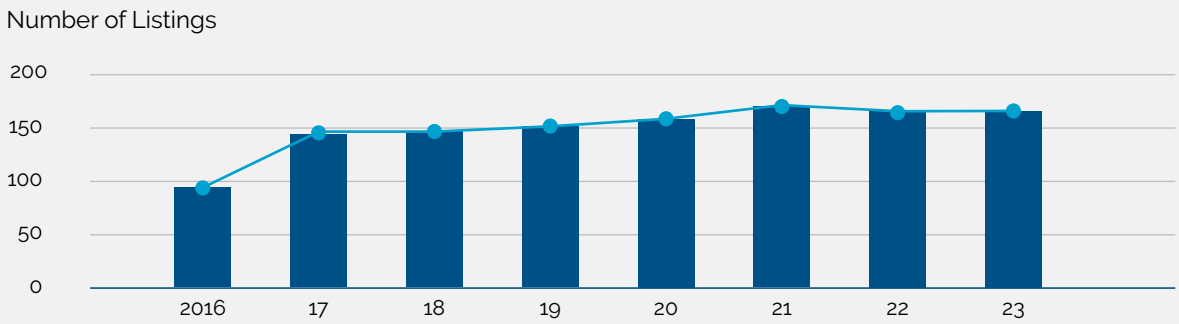
Figure 2. Australian Exports for Key Value-Add Industries* (CY2016–23)



**Key value add industries are the top 5 industries by exports which produce some form of manufactured good, excluding basic refining operation and primary industry Source: ABS; L.E.K. analysis*

At the same time, the number of ASX-listed medical product companies has remained unchanged since 2021 (Figure 3). Medical listings rose by 4.2 per cent per year from 2017 to 2021, supported by low interest rates and favourable valuations.

Figure 3. ASX Companies Within the Medical Products Sector (CY2016–23)



Source: ASX; S&P global; University of Queensland; Brandon Capital Partners; Australian Investment Council; Refinitiv; PwC; Pitchbook; L.E.K. Research and analysis

Snapshot:

Despite resilient exports in Australia's life sciences sector, challenging conditions have stalled public listings, underscoring the need for robust strategies to drive continued industry growth.

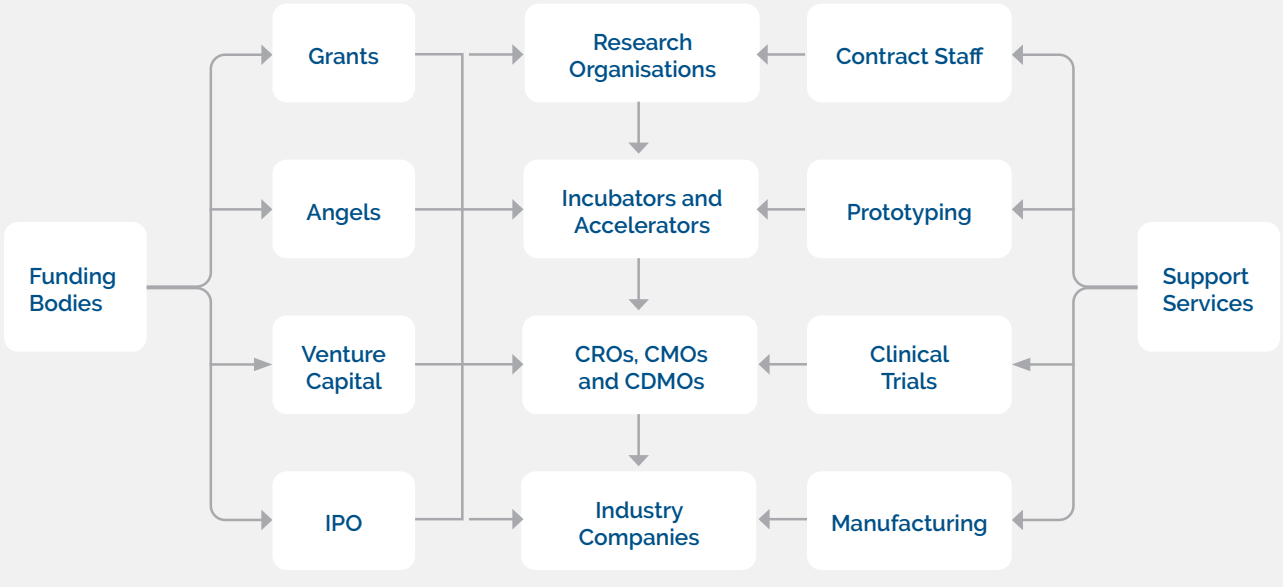
By Employment

There are close to 350,000 biotech jobs spread across Australia.[5]

Given that the most recent data from the Australian Bureau of Statistics show there are 20.8 million jobs across Australia,[6] this means the life sciences sector employs about 1.7 per cent of the working population or around 1 in every 60 Australian workers.

These employees are engaged not only in direct R&D but also in all the various support functions detailed below (Figure 4).

Figure 4: Australia's Life Sciences Ecosystem



Australia's Life Sciences Capability

Excluding those companies providing support functions, there is a stark difference in employment between large, mature companies and start-ups – with the largest 12 companies responsible for one-third of total employment, and half of the sector employing fewer than 4 per cent or 1 in 25 employees.[7] While this indicates growing maturity as well as enthusiasm for renewal and new discovery across the sector, gaps clearly remain.

Snapshot:

The biotechnology sector's workforce, while growing and diverse, reveals a clear divide between large, established companies and smaller startups, highlighting both sector maturity and the need to bridge employment gaps to support sustainable growth.

By Sector Completeness: Depth and Sustainability

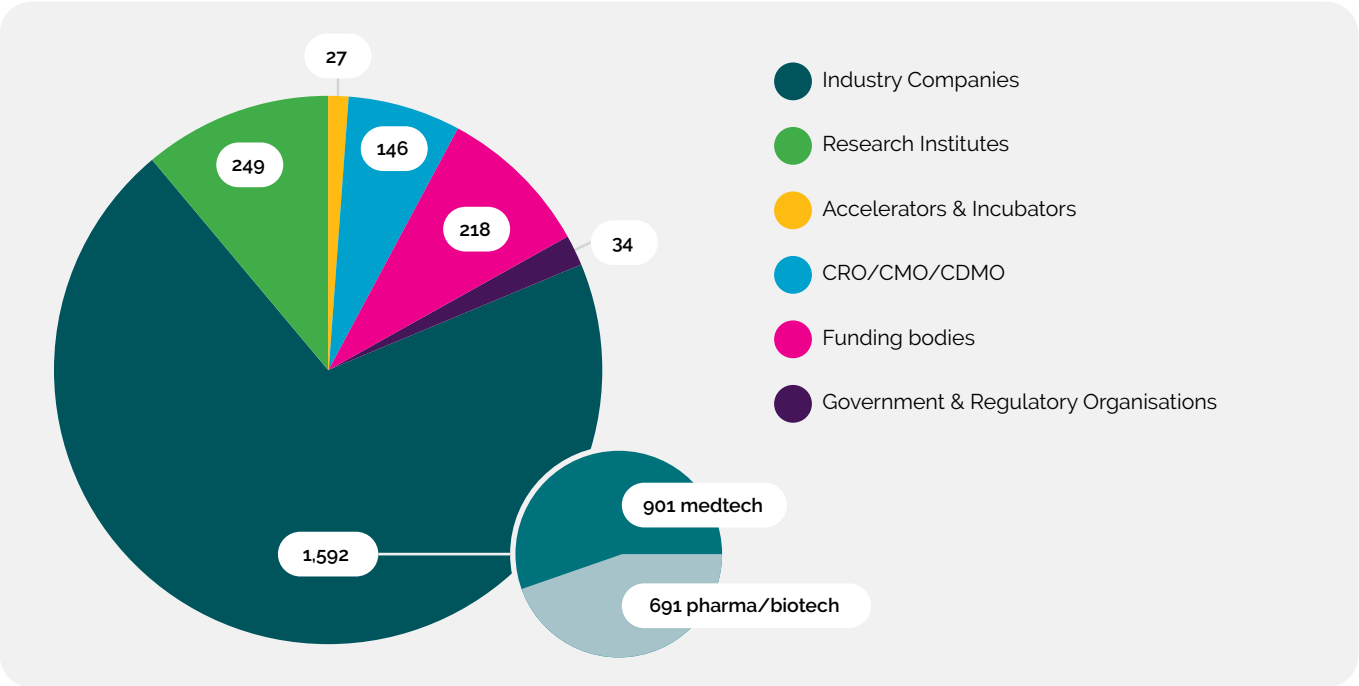
For Australia's life sciences sector to act as an interdependent ecosystem, each element of the ecosystem (Figure 4) needs to have sufficient capacity in the form of two main elements:

1. The environments in which a product or technology evolves from an initial concept to a marketable product; and,
2. The support services needed to enable an idea to thrive and progress through the regulatory process and other systems that any successful product must pass through.

As is commonly recognised, not every medical innovation progresses through its full life cycle within Australia. While it is a source of frustration that many promising early-stage ideas are exported to the US or Europe, this is often due to raw differences of scale and may actually positively contribute to Australia's capability to partner with others. It is not in itself evidence of limited completeness or capacity of the Australian biotech sector.

The most recent data shows a strong base, clear depth and a maturing biotech sector (Figure 5).

Figure 5. What Makes Up Australia's Life Science Ecosystem?



The spread of companies and other sector elements points to the strengths and depth of Australia's life sciences ecosystem, with an appropriate ratio between the different elements.

It also demonstrates that Australia's life sciences sector possesses the necessary range of support and other services and capabilities for a product to realise its complete life cycle within Australia, even though it may ultimately migrate in part or whole to larger markets, particularly for manufacturing and/or to access capital.

Snapshot:

Australia's life sciences sector is capable of supporting innovations through their life cycle, while strategic international partnerships enable further growth and access to larger markets.

Partnership Capability: Flexibility, Futureproofing and Security

Australia has significant comparative advantage in biotechnology, not the least of which is a number of leading international universities.[8] Our high levels of education[9] and maturing sector has the capacity to attract and support a skilled workforce.

The importance of our highly skilled and experienced workforce contributes to our attractiveness as a location for clinical trials with a recent KPMG report noting that:

"The country's exceptional clinical trial researchers, a diverse patient pool, skilled workforce, English-speaking population, availability of secure and advanced infrastructure, a seasonal difference to northern hemisphere markets, a trusted regulatory system, and advanced digital capabilities also make Australia an ideal location for high-quality clinical trials".[10]

This is supported by a strong rule of law – particularly in relation to Australia's robust intellectual property regime – as well as Australia's comparative political stability. Further, as noted above, Australia has a complete and well-integrated market for all the elements needed to support a successful and maturing biotechnology sector.

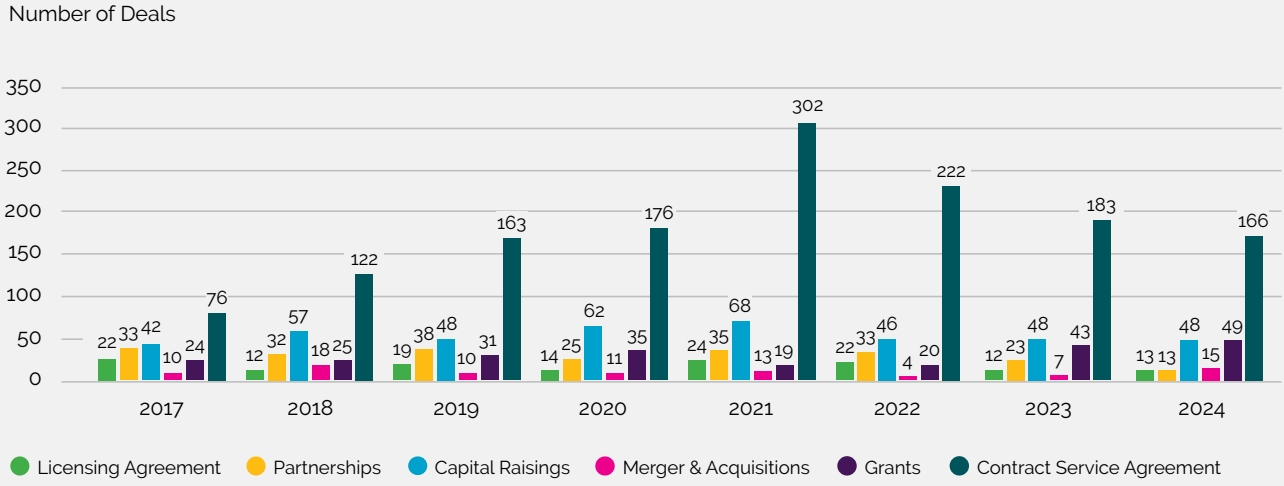
This is important not only for the retention of domestic capital and attraction of international capital, but because development of biotechnology is increasingly undertaken on a multi-jurisdictional, cooperative basis. With biotechnology increasingly joining defence as a focus for security,[1] the capacity to effectively partner on the world stage will be critical in realising the opportunities of the current global context, as well as the risks.

The importance of global partnerships and access is difficult to overstate, particularly in relation to the US market. In comparison to the AUD$226 billion market size (USD$149 billion)[11] noted above, there are at least 10 multinational pharmaceutical companies whose individual market capitalisations exceed this amount. Six of these – including the largest at USD$839 billion – are headquartered in the US.[12]

Partnership is critical to the Australian biotechnology sector with around AUD$67 billion worth of deals done domestically and internationally between 2017 and 2024. However, as demonstrated in Figure 6, in the pharmaceutical part of the sector deals over this period are dominated by contract service agreements with true partnerships in a small minority. The medtech part of the sector looks strongly similar.

Australia's Life Sciences Capability (continued)

Figure 6: Number of Deals by Type, Pharma/Biotech, 2017-2024[5]



Developing increasing numbers of true partnerships is likely to require the following:

- A more intensive understanding of Australia's comparative advantage, either in terms of technology and expertise or simple geographic security. This requires deliberate and detailed analysis;
- Leadership at the bilateral and multilateral levels; and
- Collaboration with the biotech and medtech sector to identify which international partners to work with to best leverage comparative advantage and multilateral priorities.

Snapshot:

Australia's life sciences sector, supported by a skilled workforce, strong regulatory environment, and strategic partnerships, must deepen collaborative efforts to leverage its comparative advantages and secure its role in the global market.

Discussion Topics

As an industry, we have long understood the impact of and need to supercharge the 'D' in R&D. But we know we are not there yet – and there are still significant questions and complexities that require clear and deliberate solutions to get us there. Solutions are required from within the sector itself, and also from Governments.

The following discussion topics have been developed after hearing about the challenges and opportunities from the many voices across our diverse sector – from start-ups, small- and medium-sized enterprises (SMEs), multinational companies, investors, manufacturers, peak bodies, research institutes and policy makers. AusBiotech's Policy Taskforce, made up of a cross-section of industry leaders, also significantly contributed to the shaping of these questions.

If you are attending the Summit, we ask that you consider these questions in advance and come ready to share your expertise as we collectively wrestle with these topics, challenge our assumptions and drive forward solutions.

If you are contributing to this discussion via our survey, we invite your input by 22 November 2024

Topic 1: Protecting and Advancing Australia's Future Health

Biotech and medtech are core to Australia's future. Leveraging and expanding our current capability will ensure that we can grasp the opportunities offered by our exposure to global markets, trends and challenges, while simultaneously minimising the risk posed by them. Our competitive advantage and the capabilities we have and need will stand us in excellent stead to ensure we play our role in advancing Australia's health security and sovereign capability, enhancing national productivity and strengthening global alliances

97%

of all diagnostic raw materials and components being imported.[13]

over 90%

of prescription medicines are imported.[13]

How can our medical innovators advance Australia's future health security and enhance our national productivity?

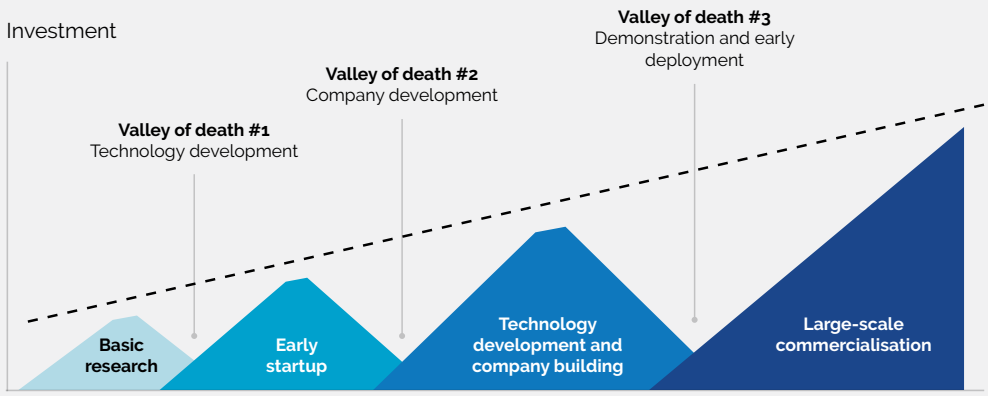
1. What medical development and manufacturing capability does our nation have now?
2. What do we need for the future?
    a. How can our medical innovators help to better protect our communities against medical shortages and supply-chain disruptions?
    b. What development and manufacturing capabilities do we need to ensure Australia remains an advanced and competitive biotech and medtech nation?
3. What could our future competitive advantage be?
    a. Are there any niche opportunities that should be prioritised for future protection and advancement of health, productivity, national sovereignty and trade?
4. How does the sector seize global opportunities and understand geopolitical challenges?

Discussion Topics

Topic 2: Moving Beyond Early-Stage Development and Commercialisation

Australia is a world leader in research and in developing intellectual property in drug development and medical devices. While data show a strong base, clear depth and a maturing biotech sector, Australian companies are still predominantly pre-revenue SMEs in the early stages of translating medical research into commercial products. Overall, 87 per cent of medtech, biotech and pharmaceutical companies are SMEs.[5] Challenges moving from basic research to large-scale commercialisation are shown in Figure 7.

Figure 7. Challenges Moving from Basic Research to Large-Scale Commercialisation [14]



Market shaping is intended to help smooth these valleys to accelerate innovation and employment

Source: Adapted from Financing the Clean Industrial Revolution by Bill Gates.

Note: The valley of death refers to the gap in funding that exists when companies want to transform a proven concept into a viable and affordable product.

This is also reflected in the clinical trials landscape, where early phase (Phase 1 and 2) trials have driven growth in clinical trials in Australia since 2016, with late phase clinical trials continuing to decline in an increasingly competitive global market. Between 2016 and 2022, the number of Phase 1 and 2 trials grew by 54 per cent, whereas the number of phase 3 and 4 trials decreased by 2 per cent.[15]

We are missing out on opportunities to develop early-stage companies into sustainable and globally significant businesses in a range of areas. Realising and optimising these opportunities is critical to deliver growth, as is attracting and leveraging the existence of large organisations and multinationals in Australia.

How can Australia continue to mature by growing more companies beyond early stage into globally significant sustainable businesses, including at-scale commercialisation and manufacturing, as well as ensuring that we continue to attract and retain the larger companies needed to support a thriving and productive ecosystem?

1. What is required to attract and retain at-scale manufacturing of Australian innovations?
2. What is the role that large Australian anchors and multinationals can play in growing and enabling Australia's biotech and medtech ecosystem?
3. What attracts investment (beyond the early stage) in a competitive global market?
4. How can Australia attract more late-phase (phase 3 and 4) clinical trials?

Topic 3: Growing the Capital Pool and Optimising Its Use

Biotech and medtech companies rely on a combination of grants, angel investment, venture capital and public listing to commercialise medical innovations. Access to capital is the number one barrier to commercialisation in Australia.[16] The number of ASX-listed medical product companies has remained unchanged since 2021[17] moving companies away from Australian listings. Venture capital is concentrated among a few firms, and growth and accessibility is not keeping pace with global markets.

Government funding has always been critical for the sector because of the high risk and long-term investment required. Australia has an extensive network of Government grants, incentives and funds available to biotech and medtech companies, including at the State and Territory levels. However, questions remain about the effectiveness of these programs in generating investor confidence; whether efficiencies could be made, particularly in light of potential duplication and state competition; and whether they are providing support where it is needed most. In addition, stringent eligibility criteria can often exclude parts of the sector and override the intent of programs.

As a sector, we need to consider not only expanding the capital pool from both Government and non-Government sources, but also optimising the deployment of existing capital to ensure it is directed toward areas that generate the greatest impact.

How can we best access Australia's private and public capital pool to strategically grow our nation's medical development, commercialisation and manufacturing capability?

1. What is the role of Government in investing or enabling investment in biotech and medtech organisations in Australia?
2. How do we ensure that intent for sector growth is supported by opportunities to build national capacity and capability?
3. What should the role of Federal and State Governments be in creating greater confidence in the sector within the investment community?

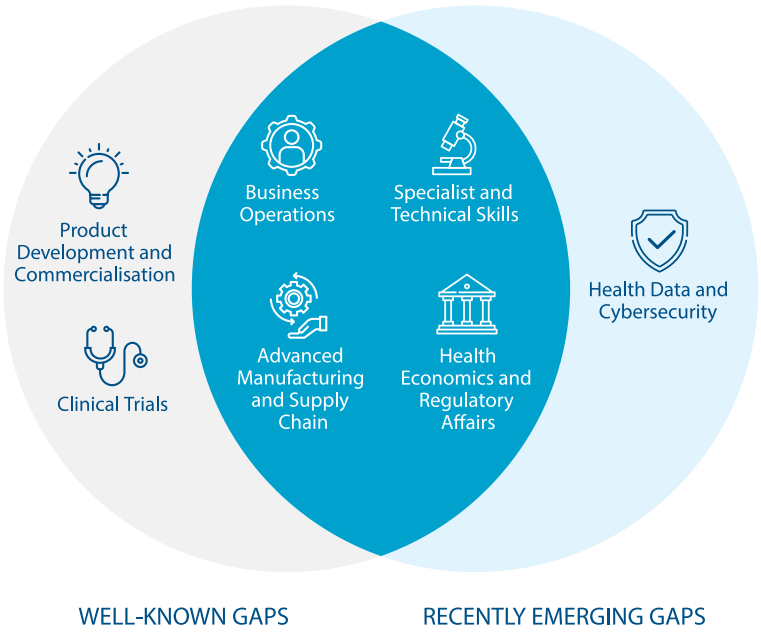
Discussion Topics

Topic 4: Building a "Development" Focused Workforce

The sector's growth and sustainability depend on a skilled workforce, yet challenges in attracting, developing, and retaining talent—especially in research translation, clinical applications, and commercialisation—persist. Despite over 350,000 jobs,[5] SMEs and large companies struggle to secure skilled staff. MTPConnect's recently completed *Researcher Exchange and Development within Industry (REDI)* Initiative examined areas of workforce shortage and skills gaps (Figure 8), new training programs, mentoring and industry placements and fellowships. While such programs help, closing remaining gaps and expanding successful initiatives is essential for the sector's continued success.

Figure 8. Skills gap[11]

The 81 skills gaps were categorised into seven themes, which can be further characterised into well-known and recently emerging skill gaps as per the diagram.



How can we shift our strategies to grow, support and retain a workforce that can support a mature biotech and medtech ecosystem?

1. What initiatives are already in place that have helped support our biotech and medtech workforce to mature?
   a. By Government?
   b. By industry?
2. Are these initiatives effective and what are the real gaps that we are seeing today?
3. What is needed to ensure that we have the workforce required for changes in technologies, therapies and products over the next 10–20 years?

Next Steps:

We look forward to discussing these questions at the Summit. Following the Summit, we will develop a comprehensive white paper that turns our insights into actionable outcomes and recommendations.

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A collaboration between
AusBiotech and MTPConnect

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