



Queensland Biomedical and Life Sciences 10-Year Roadmap

Discussion paper for consultation | June 2016

Image acknowledgements: Cook Medical, Patheon Biologics and Translational Research Institute.

The Department of State Development

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Contents

Executive summary	2
Purpose.....	3
Scope.....	4
Data	5
Vision.....	5
Industry overview	6
Global market.....	6
Australia.....	8
Queensland	9
Comparative advantages and opportunities	11
Strong skills base.....	11
Supporting infrastructure	12
Agile, innovative and entrepreneurial advanced manufacturers	14
Government policies and programs	16
Queensland	16
National	17
Challenges	20
The translation imperative	20
Building an entrepreneurial culture.....	21
Access to capital investment	23
Collaboration	25
Promoting the sector.....	27
Measuring success.....	28
Addressing future opportunities.....	29
Have your say	30
Questions	30
Glossary	32
References	32

Executive summary

As part of the A\$405 million Accelerating Advance Queensland initiative, the Queensland Government is creating an environment to foster emerging and priority sectors with global growth potential. The biomedical and life sciences sector is one of the priority sectors that will play an important role in diversifying Queensland's economy and ensuring Queensland workers have access to the new jobs of the future.

The biomedical and life sciences sector in Queensland is underpinned by excellence in science and operates within a global value chain. Investment of previous Queensland governments has been extremely successful in building world-leading research institutes and science capacity and capability in areas including tropical and infectious disease, vaccine development and delivery, and telemedicine.

As a result, Queensland has built up internationally comparative advantages supported by world class infrastructure in advanced imaging, genetic/genomic services, biofabrication, preclinical and early phase clinical trials, pilot scale biopharmaceutical manufacturing and manufacturing of niche pharmaceutical products, medical devices and diagnostics. These advantages make Queensland

well placed to respond to global demands for products and services for personalised and preventive medicine. The state's geographic proximity and shared time zone with Asia, as well as a shared tropical climate, also provides Queensland with the opportunity to capitalise on these emerging global markets.

Whilst the biomedical and life sciences sector in Queensland is still relatively small, it is home to a handful of large, multinational biomedical and life sciences manufacturing businesses. The sector is supported by a small, but growing, community of startup companies, underpinned by a robust research sector. Startups are vital to future job creation and prosperity. It is therefore critical that as a state we build a vibrant, local startup community to secure our comparative advantage in this sector. At the core of this is tolerating and managing a higher risk appetite, whilst making sound business decisions.

Through investment in Advance Queensland programs, the Queensland Government is demonstrating its commitment to the sector by supporting high growth, innovation-based businesses and building an entrepreneurial culture.

Queensland has existing and emerging clusters of industry at

different stages of maturity, research institutes including universities, and state-of-the-art hospitals. While Queensland is fortunate to be home to these health and knowledge precincts, planning for the future growth of these precincts requires a whole-of-state focus to ensure collaboration is fostered across the biomedical and life sciences supply chain, targeting areas in which Queensland has a comparative advantage. Successfully capturing domestic and international market opportunities will require continued collective action by research institutes, industry and government to make targeted and strategic decisions with a long-term view to ensure success.

This discussion paper has been developed to inform the preparation of a Biomedical and Life Sciences 10-Year Roadmap and Action Plan (the roadmap) for Queensland. Questions are posed in the paper to stimulate discussion. Your feedback will ensure the roadmap effectively guides future decision-making for a productive, innovative and sustainable biomedical and life sciences sector in Queensland.



Purpose

As part of the Advance Queensland Supporting Priority Industries Program, the Department of State Development (DSD) is developing a Biomedical and Life Sciences 10-Year Roadmap and Action Plan (the roadmap) for Queensland. The whole-of-government roadmap will be developed in conjunction with industry, investment and research partners.

Major investments in the biomedical segment of the life sciences industry in Queensland, made by previous governments, have resulted in a mature research capability and a small but growing community of startup companies. Queensland also has a handful of large, multinational biomedical and life sciences manufacturing businesses. Established and emerging health and knowledge precincts provide

opportunities to further grow the sector through existing and new enterprises.

The purpose of this discussion paper is to stimulate broad engagement with stakeholders and obtain feedback to inform the development of the roadmap.

The paper provides a broad overview of the industry—globally, nationally and locally. The opportunities and challenges set out in the paper have been developed through preliminary consultation with industry peak bodies and businesses.

DSD is seeking input from stakeholders about the opportunities and challenges facing existing and emerging enterprises. Questions are posed in the paper to assist your feedback.

The Queensland Government will work with stakeholders to develop a vision and objectives for the future of the state's biomedical industry, supported by an action plan.

The development of the roadmap is an opportunity to build on Queensland's comparative advantages in areas such as advanced imaging, genetic/genomic services, biofabrication, preclinical and early phase clinical trials, pilot scale biopharmaceutical manufacturing, and manufacturing of niche pharmaceutical products, medical devices and diagnostics, to boost economic growth and create the high value knowledge jobs of the future.

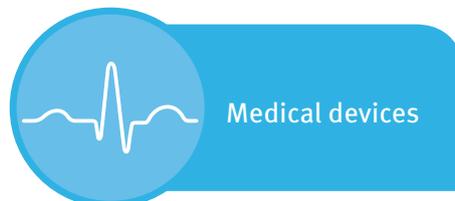
Scope

The life sciences sector in Queensland includes activities in human and animal health and disease (biomedical sciences). The life sciences sector also encompasses applications in agricultural, environmental and industrial biotechnology.

The roadmap will focus on the application of the biomedical life sciences to leverage existing Queensland industry strengths, and capitalise on the Queensland and Australian governments' investment in research, development and innovation. The roadmap will target the following industries:

- medical devices and diagnostics
- pharmaceuticals
 - traditional and bio-pharmaceuticals¹
 - vaccines/drug discovery
- complementary medicines
- supporting digital technologies.

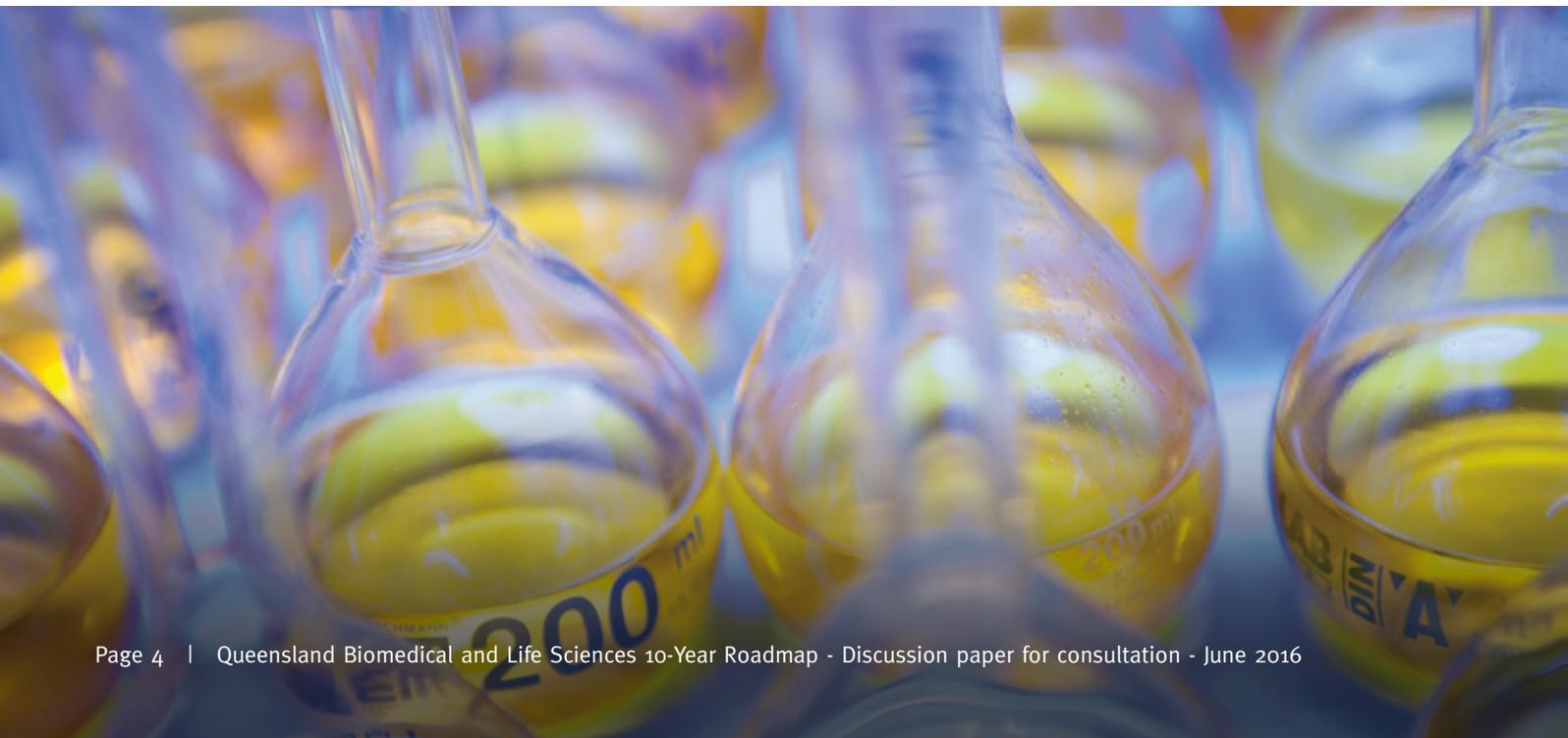
Targeted industries



It also aligns the Queensland Government's approach with the Australian Government Industry Growth Centres Initiative. This national initiative identifies the potential of the medical technology and pharmaceutical sector as one of its six areas of focus aimed at

driving industry growth in areas of national competitive strength.

This ensures Queensland is well placed to leverage the National Innovation and Science Agenda (NISA) to drive smart ideas that create business growth, local jobs and global success.



Data

Economic analysis of the biomedical and life sciences sector is complex. For the purposes of this discussion paper, information has been derived from multiple data sources. Industry-specific data was obtained through the Queensland Life Sciences Industry Report 2012 prepared by Venture Pro for the Department of Science, Information Technology and Innovation (DSITI). This report is used to provide the headline figures for the economic contribution of the industry in Queensland as it is based on a comprehensive survey of 139 industry members of Life Sciences Queensland.

The survey data has been supplemented with more up-to-date ABS data, using Australian and New Zealand Standard Industrial Classification (ANZSIC) four digit industry codes, and also IBIS World four digit industry profiles to provide a deeper understanding of the latest developments in the sector as

well as a regional breakdown and economic outlook. However, these do not align with the scope of this project as closely as the survey data, as the sector is not readily defined by ANZSIC codes, which provide a narrower scope. The relevant ANZSIC industry codes include:

- Human pharmaceutical and medicinal product manufacturing (1841)
- Veterinary pharmaceutical and medicinal product manufacturing (1842)
- Medical and surgical equipment manufacturing (2412)

These activities provide a proxy for the 'manufacturing subset' of the biomedical industry which is a key focus of the Queensland Government's initiatives to drive the growth of the biomedical and life sciences sector in Queensland. It should be noted that this excludes the 'services component', such as research services, clinical trials and

business support/IT. Though captured by separate ANZSIC industry codes these activities cannot be separately identified with regards to biomedical activities.

Question 1:

A more up-to-date profile of the Queensland biomedical and life sciences sector is needed. What do you consider is a reliable method for data capture to accurately profile this industry in Queensland?

Question 2:

Does the vision statement reflect a challenging but achievable vision for the industry in Queensland? If not, what is a realistic ambition given the nature of the industry?

Vision

By 2026, Queensland will be home to an integrated and globally competitive biomedical and life sciences sector, recognised for its strong skills base, supporting infrastructure, advanced manufacturing capabilities, and world leading research and development, delivering sustained economic growth to create the knowledge-based jobs of the future.

Industry overview

The biomedical industry is science-driven and highly regulated.

Advances in biology and technology are driving personalised and preventive medicine.

The convergence of biology and technology will drive the future of healthcare.

Rising cost of healthcare is placing public health budgets under pressure. Publicly funded healthcare providers are seeking to place greater responsibility on consumers to manage their own health.

Consumer expectations and demand for access to the latest healthcare services are increasing.

Ease of travel and the rise of infectious disease is generating worldwide demand for improved diagnostics and anti-infective treatments.

Availability of investment funding and intellectual property (IP) protection are critical to future growth of the industry.

Question 3:

Barriers to accessing emerging global markets include access to finance and skills and industry regulation. Do you agree? What other barriers do you see for the biomedical industry in Queensland? At a state level, what can be done to assist companies to participate in the global marketplace?



Biopharmaceutical manufacturing facility, Patheon Biologics, at Princess Alexandra Hospital, Brisbane



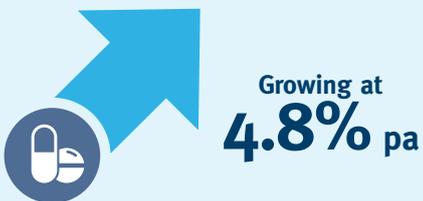
Global market²

The biomedical industry is forecast to undergo steady growth over the next four to five years:

Medical devices and diagnostics



Pharmaceutical industry



This growth is due to:

- cutting costs
- developing strategies for more efficient R&D methods
- completing mergers and acquisitions

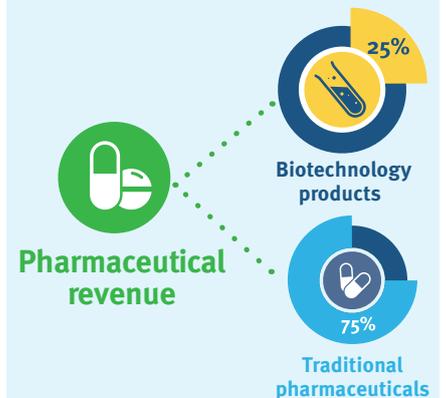
Global sales of medical devices and diagnostics



In vitro diagnostics



Pharmaceutical industry



Emerging markets



The biomedical industry has an increased focus on emerging markets which offers new opportunities for Queensland.



Australia³

Medical devices and diagnostics industry



A\$11.8 billion
revenue
2012-2013



A\$3.4 billion

Medical devices & diagnostics industry manufacturing
2015-2016

Pharmaceutical manufacturing industry

A\$7.5 billion
in revenue
2015-2016



2.5% pa



2016-2021

Revenue increase
Medical & surgical equipment

New inventions
2706

2001 — 2012

13th
globally



Pharmaceutical manufacturing

Pharmaceutical manufacturing
0.8% pa to 2021

Biotechnology industry revenue



Growing at
4.4% pa

A\$8.7 billion
by 2021

Biotechnology
innovation potential
global ranking



5th

Australia ranks fifth in the world for biotechnology innovation potential behind the United States, Singapore, Denmark and New Zealand.

The index considers factors such as productivity, IP protection, intensity, workforce/education, policy and stability.



Queensland⁴

Therapeutic
medicines
and devices
2011-12


A\$2.7
BILLION
TOTAL INCOME


EMPLOYEES

6086 Full time
employees



A\$2.85b TOTAL
EXPENDITURE

Biomedical
manufacturing
2014-15



A\$275
MILLION
EXPORTS



389 businesses
in Queensland

Queensland accounts for **18%** of
biomedical manufacturing
businesses in Australia

Biomedical manufacturing activities are highly geographically specialised in the south east corner of the state including Brisbane City and Ipswich, with emerging health and knowledge precincts on the Sunshine Coast and Gold Coast.

In Australia, companies Cook Medical, Cochlear and ResMed are responsible for around 20% of the total inventions in the medical devices field:⁵

- o Cochlear has a significant presence in Queensland, producing external components of the cochlear implant systems at their Brisbane manufacturing facility.

The company’s main headquarters is in New South Wales.

- o Brisbane is the Asia Pacific headquarters for Cook Inc., the largest privately owned medical device company in the world. Cook Medical employs almost 500 staff at its manufacturing facility in Queensland.

Queensland has a substantial complementary medicines manufacturing industry, with companies including Integria Healthcare, Health World Limited and Sanofi Aventis Consumer Healthcare.

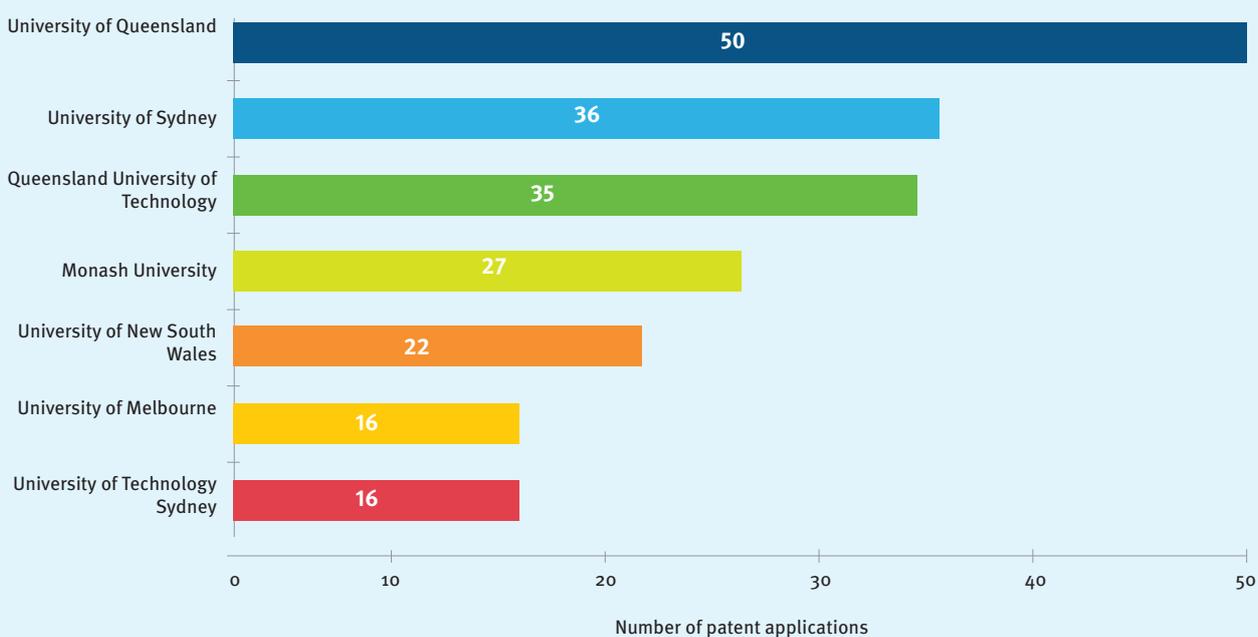
Queensland is in the top two Australian states and territories for

scientific impact in drug discovery, biochemistry, applied microbiology and biotechnology, molecular biology, genetics, animal science and zoology, and cellular molecular neuroscience.⁶

QIMR Berghofer Medical Research Institute (QIMR Berghofer) is currently ranked 7th in the world for patent citation rate.⁷

Queensland universities, University of Queensland (UQ) and Queensland University of Technology (QUT), are two of the top three Patent Cooperation Treaty (PCT) filing⁸ universities in Australia (Figure 1).

Figure 1 – Top patent-filing universities in medical devices technology⁹



Comparative advantages and opportunities

The biomedical and life sciences industry operates within a global value chain. Success for Queensland may involve becoming a world leader in specific stages of the value chain by building on its comparative advantages, including:

- strong skills base (including, research, world recognised clinicians and state-of-the-art health and medical research facilities)
- supporting infrastructure
 - advanced imaging
 - genetic/genomic services
 - biofabrication
 - preclinical and early phase clinical trials capability and capacity
 - pilot scale biopharmaceutical manufacturing (GMP)
- agile, innovative and entrepreneurial advanced manufacturers of niche pharmaceutical products, medical devices and diagnostics, for example, Cellular Immunotherapy Manufacturing (GMP).

Question 4:

Is the profile of Queensland's comparative advantages accurate? Are there any other known or emerging comparative advantages?

Question 5:

Which of Queensland's comparative advantages have the greatest potential for the state to grow a sustainable biomedical industry?

Strong skills base

Queensland has state-of-the-art health and medical research facilities and hospitals and has attracted world-class medical researchers and clinicians.

An assessment of health and biomedical research in Queensland, undertaken by the Office of the Queensland Chief Scientist and Queensland Health in 2014, identified the following research strengths:

- disease areas:
 - tropical and infectious diseases
 - kidney disease
 - neurodegenerative and behavioural disorders
 - cancer, with particular expertise in skin and prostate
 - cardiovascular and respiratory diseases.
- vaccine development and delivery, including:
 - development of the world-first cervical cancer vaccine Gardasil
 - research towards development of a needle-free vaccine delivery solution, with strong industry support
 - early phase clinical trials of a new approach to a malaria vaccine.
- telemedicine
- basic research:
 - molecular and cellular biology
 - drug design and discovery
 - immunology and pharmacology.

In addition to these findings, Queensland has strengths in the

following areas that support the development of new biomedical products:

- electronics
- ICT and data management
- biomedical engineering
- material sciences.

The environment in Queensland is ripe for the exploitation of research excellence embedded in our research institutes, universities and hospitals through:

- the push to translate academic research into investable outcomes, driven by commercialisation entities or the entrepreneurial activity of researchers or clinicians
- the opportunity for industry/end users to connect into the state's research base, to commercialise products, processes or services
- industry leveraging research expertise as needed to support the development of commercial products.

This is supported by the findings of the recent Regional Queensland 2015: Startup Ecosystem Report.¹⁰ The report confirmed that the involvement of local universities in the innovation/startup eco-system is very important.

Question 6:

Does the expertise identified in this paper accurately reflect the state's strengths? Are there other strengths that can be developed or ways existing strengths can be further exploited?

Case study - The Medical Engineering Research Facility

The QUT Institute of Health and Biomedical Innovation's Medical Engineering Research Facility (MERF), opened in 2008, is the first facility to support the full cycle of research, validation, commercialisation and training activities necessary to ensure widespread adoption of new medical devices and techniques throughout Queensland and globally. MERF was established through investments by previous Queensland governments to meet Australia's emerging needs in orthopaedic and artificial organ research; and provides a comprehensive suite of research and training facilities at the one location at The Prince Charles Hospital.

MERF has three main research facilities - anatomical and surgical skills laboratory, biological research facility and research laboratories. These are supported by operating theatres, cell culture laboratories, materials testing laboratories and mechanical and electrical workshops.

www.qut.edu.au

Supporting infrastructure

Queensland has strong supporting infrastructure in the areas of:

- advanced imaging
- genetic/genomic services
- biofabrication
- preclinical and early phase clinical trials capability and capacity
- pilot scale biopharmaceutical manufacturing (GMP).

Queensland has a network of service providers supporting the translation of biomedical and life sciences research outcomes into higher value, investable products, with capabilities in regulatory affairs, financial services (including R&D tax services), recruitment, and intellectual property and other legal services.

Advanced imaging

Supported by Advance Queensland, the Siemens Innovation and Translation Centre has been established at the Translational Research Institute (TRI) as a partnership between QUT, UQ, Queensland Health, Mater Research and global medical devices developer and manufacturer, Siemens Healthcare. The partnership will aid the development of new medical imaging technologies and protocols leading to major efficiencies in healthcare delivery.

Queensland has significant existing capability including:

- Herston Imaging Research Facility
- Centre for Advanced Imaging and the Queensland Brain Institute (both at UQ)
- Australian Cancer Research Foundation Centre for

Comprehensive Biomedical Imaging at QIMR Berghofer

- Magnetica Limited which develops highly customised magnetic resonance imaging solutions for the healthcare industry. Magnetica's leading product is based on technology developed in partnership with UQ.

Case study - Australia's leading advanced imaging facility

Brisbane hosts the nation's most advanced medical imaging research facilities that will drive innovative medical outcomes almost beyond our imagination. The Herston Imaging Research Facility (HIRF), supported by the collaborative research alliance between UQ, the Royal Brisbane and Women's Hospital, QUT and QIMR Berghofer, with healthcare company Siemens as industry partner, has the potential to revolutionise treatment of major diseases not just in Queensland, but globally.

HIRF, located on the Herston Campus, breaks new ground for imaging specialists with scanners that offer hybrid imaging techniques such as magnetic resonance imaging (MRI) and positron emission tomography (PET) scanning in a single machine. The scanners are different from those being used now for diagnostic imaging of patients as they combine anatomical, molecular and functional processes to help researchers improve understanding of disease and to quickly determine whether treatments are effective.

HIRF brings together the most advanced imaging technology to combat human disease. HIRF will drive the next generation of image-guided therapy for individual patients, building capacity and adding to the growth in demand for new approaches in personalised medicine.

www.uq.edu.au

Phase I Clinical Trial: Researchers test a new drug or treatment in a small group of people (e.g. 20-80) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.

Phase II Clinical Trial: The drug or treatment is given to a larger group of people (several hundred) to see if it is effective and to further evaluate its safety.

Phase III Clinical Trial: The drug or treatment is given to large groups of people (from several hundred to several thousand) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments and collect information that will allow the drug or treatment to be used safely.

Phase IV Clinical Trial: Studies are done after the drug or treatment has been marketed to gather information on the drug's effect in various populations and any side effects associated with long-term use.

Genetic/genomic services

Queensland is already leading the way in many areas of genetics and genomics. Genomics will play an important role in the future of healthcare, in particular personalised healthcare treatments and measuring the risk of developing diseases. This capability received a major boost under the Advance Queensland initiative, with a \$25 million investment in a consortium of multidisciplinary researchers and clinicians. This alliance consists of UQ, QIMR Berghofer, the CSIRO, QUT and Queensland Health. It creates a clinically driven and patient focused program to help translate genomics research into practice in the healthcare industry.

Other significant investment in this area includes:

- o support for the Brisbane node of the Australian Genomics Research Facility (at UQ) through the National Collaborative Research Infrastructure Strategy (NCRIS)
- o UQ participation and Australian Government support of the International Cancer Genome Consortium
- o support for the Queensland Facility for Advanced Bioinformatics.

Biofabrication

Queensland is home to world leading capabilities and facilities in

biofabrication, exploiting 3D printing to advance clinical outcomes.

QUT and Griffith University are undertaking leading applied research in the use of 3D printing for the development of new biomaterials, implantables and delivery solutions that are addressing current and emergent medical needs. The Australian National Fabrication Facility (ANFF), established under NCRIS, provides a research base through access to state-of-the-art fabrication capabilities, including biofabrication, via a network of eight nodes in Australia.¹¹ ANFF has an established node in Queensland (ANFF-Q) across two universities (UQ and Griffith University).

Preclinical and early phase clinical trials – capability and capacity

The biomedical and life sciences sector in Queensland has steadily built up a portfolio of companies with expertise in conducting and managing preclinical and early phase clinical trials (I and II), supporting the development and commercialisation of new therapeutic products.

Q-Pharm Pty Ltd, co-located within QIMR Berghofer and adjacent to one of Queensland's leading quaternary and tertiary referral teaching hospitals (The Royal Brisbane and Women's Hospital), specialises in

the conduct of Phase I and Phase II clinical trials and vaccine studies for national and international sponsor organisations.

Queensland is also home to a number of other contract research organisations supporting clinical trials in the pharmaceutical and biotechnology sector, including companies such as TetraQ, which provides preclinical and clinical testing services.

Queensland's strengths in early phase studies are complemented by excellent support for later stage trials in the state's public hospitals.

Pilot scale biopharmaceutical manufacturing (GMP)

Queensland is home to the only two companies in Australia with dedicated Good Manufacturing Practices (GMP)¹² biopharmaceutical manufacturing capabilities. Compliance with GMP ensures that medicinal products are of a high quality¹³ and ensures the safety of subjects undergoing early phase, investigational clinical trials.

Patheon Biologics, co-located with the TRI adjacent to the Princess Alexandra Hospital, undertakes GMP manufacturing of biopharmaceuticals using mammalian cell lines. Complementary services are provided by PharmaSynth Pty Ltd which

conducts GMP manufacturing of biopharmaceuticals using bacterial cell lines at their Darra facility.

Between 2009 and 2013, Phase I activity in Australia grew by more than 80%,¹⁴ presenting a significant opportunity for Queensland companies servicing this space. The Australian Government, in partnership with industry and other stakeholders, is undertaking

regulatory reforms to secure the future of the clinical trials sector in Australia.

Agile, innovative and entrepreneurial advanced manufacturers

Spin-offs and startups

By providing smaller biomedical and life sciences companies with access to world-class expertise, networks and scientific facilities, Queensland's infrastructure is supporting the creation of spin-off businesses and providing an opportunity for startup businesses to grow scale and access new markets. These successful startup companies encourage future investment and commercialisation opportunities.

Innovative manufacturing technologies

Queensland is also home to some of Australia's most innovative manufacturers of medical technologies. Cook Medical manufactures devices developed in Australia and successfully exports its products across the globe. Cochlear is manufacturing electronic componentry for its ground-breaking cochlear implants here in Queensland.

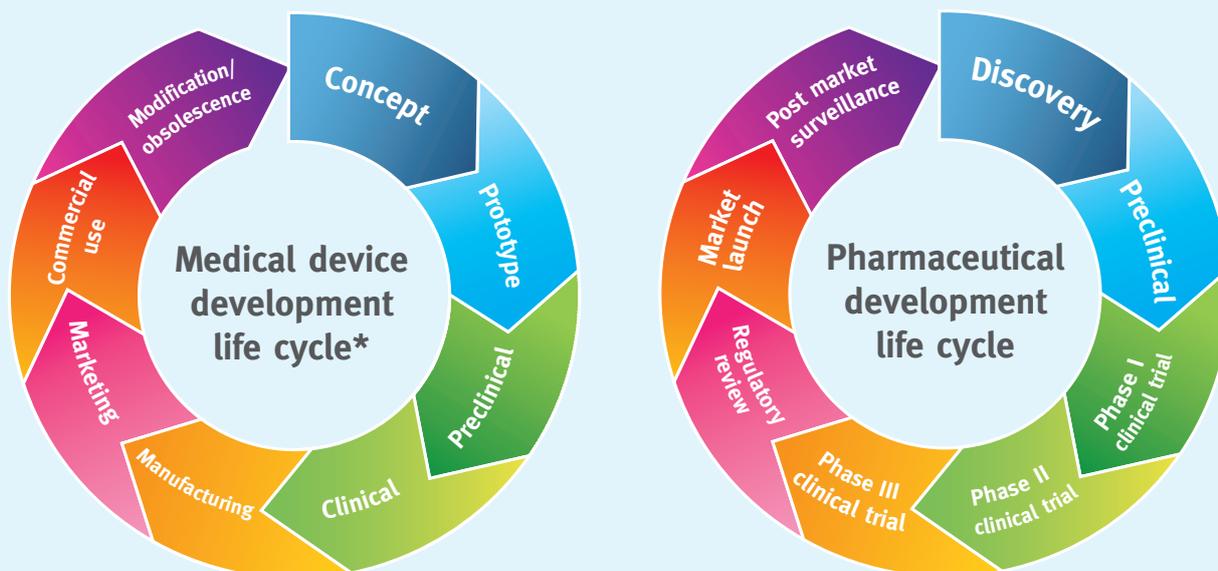
Question 7:

Does the existing infrastructure meet the needs of industry? If not, what additional infrastructure is required to support the growth of the biomedical industry?

Question 8:

What lessons can be learnt from the past experiences of startups in the sector in Queensland?

Figure 2: Biomedical and life sciences product cycle



*Regulation of medical devices is complex, risk based and dependent upon the class of device. The regulatory process can affect a significant portion of the product development life cycle.

Case study—Vaccine delivery technology startup success

The novel vaccine delivery technology originating from Professor Mark Kendall at the Australian Institute of Bioengineering & Nanotechnology at UQ is being commercialised by Vaxxas Pty Ltd. The venture capital funded technology startup company has attracted A\$40 million capital investment and will commence human trials this year. Vaxxas' research and development based in Brisbane's Translational Research Institute at the Princess Alexandra Hospital precinct has scaled the Nanopatch from use in small models to prototypes for human use.

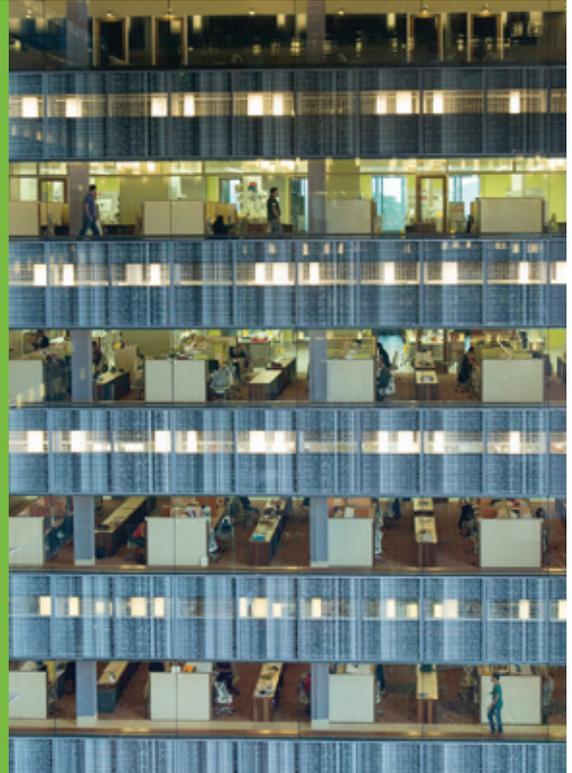
Case study—Immuno and cellular therapies startup success

Queensland biopharmaceutical company Dendright Pty Ltd is a start-up company established in 2005 by UniQuest, UQ's commercialisation company, assisted by funding from the Australian and Queensland Governments. Dendright was established to commercialise the discovery made by researchers at UQ's Diamantina Institute focusing on re-educating the body's immune response.

In 2012, Dendright entered into a R&D collaboration with Janssen Biotech Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson, to develop and commercialise a vaccine-style therapeutic approach to treat rheumatoid arthritis.

In 2015, results from the Phase I clinical trial demonstrated that the new treatment is safe and effective in suppressing the immune response. If the delivery of this technology proves successful in patients with rheumatoid arthritis, it could also be applied to other autoimmune diseases such as Type 1 diabetes.

Translational Research Institute building, Brisbane »



Case study—Queensland's manufacturing capabilities

Cochlear is a world leading manufacturer of hearing devices, developing and bringing to market a range of implantable hearing solutions. Cochlear has been manufacturing Cochlear implants in a facility located in Newstead since it acquired the privately owned, Brisbane-based manufacturing company Crystalaid Manufacture Pty Ltd in 2007.

In 2013, Cochlear invested A\$3 million to expand and diversify the activities undertaken at the Newstead facility to include a new clean room to support microchip processing operations, demonstrating Cochlear's commitment to advanced manufacturing in Queensland.

Cochlear employs approximately 200 people at the Newstead facility and produces more than 400 types of products annually.¹

¹ www.cochlear.com

Government policies and programs

Queensland

The Queensland Government's strategic investments in biomedical and life sciences' capabilities over the last decade have left an enduring legacy, making a significant impact on Queensland's competitiveness in terms of its global reputation for science excellence and its research capability.⁴⁵

Queensland is well placed to leverage the challenges and opportunities inherent in developing a sustainable, productive and innovative biomedical and life sciences sector in the state.

The outcome of this discussion paper will be the roadmap and action plan, which will take a whole-of-government approach to supporting,

developing and growing the biomedical and life sciences sector in Queensland.

In May 2016, Queensland Health released *My health, Queensland's future: Advancing health 2026*. *Advancing health 2026* establishes a common purpose and a framework for the health system in Queensland, including a focus on pursuing a

Advance Queensland programs

In 2015–16, the \$180 million Advance Queensland initiative kick-started our innovation journey by helping to maintain our research strengths, encourage entrepreneurship and startups, and connect researchers with industry. A range of program and partnerships are already working to build capability, foster collaboration, attract investment, stimulate jobs growth and encourage an entrepreneurial culture.

The 2016–17 Accelerate Advance Queensland budget initiatives are focused on accelerating our innovation effort and sustaining the momentum built over the past 12 months. New programs will unlock the potential of businesses to innovate, harness existing strengths, grow our regions, and support future generations.

Advance Queensland programs include:

- Advance Queensland Research Fellowships support post-PhD researchers with matched funding over three years to undertake research with industry that addresses Queensland's Science and Research Priorities
- Advance Queensland Innovation Partnerships position Queensland as a global innovation hub with grants to Queensland research organisations to collaborate on research projects with industry.
- Advance Queensland Ignite Ideas Fund accelerate the commercialisation of Queensland ideas into innovative products and services to secure investment, grow business, and launch into global markets.
- Advance Queensland Industry Accelerators encourage the development of innovative products and services in Queensland to increase the productivity of our key industries and encourage investment by local and global players in Queensland technology.

For details on how the Queensland Government is investing in the jobs of the future visit advance.qld.gov.au.

Case study—Advance Queensland Research Fellowship

An Advance Queensland Round 1 Research Fellowship has been granted for a project to develop new technology for detecting and diagnosing skin cancers. The recipient of the Research Fellowship has been funded to partner with UQ and Brisbane-based Micreo Ltd. The current prototype is too large for use in clinics; and this project aims to consolidate the electronics, improve imaging performance to discriminate tumours from healthy skin tissue, and produce a new system that is portable and available for use within clinics.

strong innovation and research culture. In line with this focus, in late 2016 Queensland Health will develop a new Health Innovation, Investment and Research strategy.

The forthcoming Advanced Manufacturing 10-Year Roadmap and Action Plan, another initiative of the Department of State Development, will help ensure that Queensland capitalises on opportunities in niche areas of knowledge-intensive manufacturing, including medical equipment and pharmaceuticals.

Advance Queensland, the government's flagship agenda, is creating an environment to foster priority sectors with global growth potential. The 2016–17 Accelerate Advance Queensland package includes Industry Accelerators to increase the productivity of key industries and encourage investment into Queensland, and the Industry Attraction Fund to further diversify economic activity by value adding to existing industries and harnessing growth in emerging industries.

These and other Advance Queensland programs are supporting Queenslanders in the bid to make products, processes and services investment-ready and build our global reputation as a state where ideas are translated into real outcomes.

National

Australia and Queensland support and understand the value of innovation, entrepreneurship and collaboration as drivers of economic growth. Australia's regulatory environment, including the R&D Tax Incentive, the Clinical Trial Notification (CTN) Scheme and IP

protection regime, is recognised by the biomedical and life sciences sector as a significant comparative advantage for Australia in commercialising new discoveries.

R&D Tax Incentive

The R&D Tax Incentive, designed to boost competitiveness and improve productivity by encouraging industry to engage in R&D, is critical to the growth of the biomedical and life sciences sector. The incentive reduces the cost and risk of undertaking R&D and helps companies to create new or improved products, processes or services by reducing their tax burden.

Companies conducting eligible R&D activities may qualify for a refundable tax offset of up to 45%.

A review of the R&D Tax Incentive concluded in April 2016 and is currently being considered by the government.

Clinical Trial Notification Scheme

Australia has an efficient, cost-effective regulatory pathway for clinical trials, with a review cycle that takes only four to eight weeks.¹⁶

For clinical trials involving products not entered on the Australian Register of Therapeutic Goods, there are two schemes under which clinical trials can be conducted—the Clinical Trial Exemption (CTX) Scheme and the CTN Scheme, with the vast majority of trials approved through the CTN Scheme.¹⁷

The CTN Scheme provides Australian-run clinical trials early entry into first-in-human studies and rapid start up times for all phases of clinical trials in general. Under the CTN Scheme, the Therapeutic Goods Administration

(TGA) is not required to review any data relating to the trial. Instead the responsibility falls to the local approving ethics committee, resulting in faster approval times than in other jurisdictions.

In contrast, the CTX Scheme is an approval process. Under the CTX Scheme an application for approval to conduct a clinical trial is made directly to the TGA. The clinical trial cannot commence until written approval is provided by the TGA.

Australian run pre-clinical and clinical trials are underpinned by excellence. Quality design and conduct of clinical trials ensures a high level of data integrity, providing clients with the comfort that the data produced is robust, valid and secure.

Intellectual property protection

The biomedical industry is heavily dependent on IP protection, and a competitive IP system is essential to the future success of the industry.¹⁸ Australia is a signatory to a number of international agreements that protect IP, and Australia's IP regime ranks fifth globally in the Global IP Index, based on effectiveness and administrative performance.¹⁹

The protection of IP in Australia is subject to regular review, and the improvement of IP practices has been promoted by the Australian Government.²⁰ Under the Australian Government National Innovation and Science Agenda (NISA), changes to the IP system will be made to ensure that IP rights will be treated the same as other depreciating assets for taxation purposes. This will allow companies to recover a greater percentage of their costs associated with IP protection.

National Innovation and Science Agenda

The broader reform under NISA will enhance the ability for enterprises in the biomedical and life sciences sector to better compete internationally, with the introduction of:

- tax breaks to ensure early-stage innovative companies have access to investment capital²¹
- expanded funding arrangements in relation to venture capital investment to improve access to capital²²
- depreciation deductions for assets such as patents and copyright over their economic rather than statutory life—making them a more attractive investment proposition²³
- reforms to insolvency laws to align more closely with the US approach by, for example, reducing the bankruptcy period and mitigating directors' personal liability for insolvent trading, hence encouraging entrepreneurs²⁴

- amendments to visa restrictions to attract and retain entrepreneurs to Australia.²⁵

Australian Innovation and Manufacturing (AIM) patent box

The Queensland biomedical industry is leading national industry support for a 'patent box' style tax incentive, known as the Australian Innovation and Manufacturing (AIM) Incentive. This incentive would offer a reduced tax rate on qualifying profit from IP, and is similar to schemes offered in 10 other countries including the UK, France, Switzerland and China.

The patent box process is intended to extend the benefits derived from R&D tax incentives to the manufacturing industry by encouraging companies to locate high value jobs and activity associated with the development, manufacture and exploitation of patents within the home country. It would encourage IP commercialisation and associated manufacturing and other spill-over benefits to stay in Australia.

Question 9:

How important is the R&D Tax Incentive in attracting and retaining companies in Australia? How would industry be affected by a change to the R&D Tax Incentive?

Question 10:

How would the AIM patent-box incentive benefit industry?

Question 11:

Are there any regulatory changes needed at a national, state or local level to enable industry growth?

Case study—Exporting Queensland medical technology innovation to the world

Cook Medical Australia, founded in 1979 and located in Brisbane's Eight Mile Plains, is the Asia Pacific headquarters for Cook Inc., the largest privately owned medical device company in the world.

Cook Medical Australia is a leader in the R&D of endovascular stents and IVF technologies and is the only manufacturing site in the world that produces custom made stent grafts for the treatment of abdominal aortic aneurysms.¹ In 2014, Cook Medical Australia manufactured more than 10,000 stent grafts for the treatment of aortic aneurysms, more than 3000 custom-made medical devices and 750,000 needles to assist in the treatment of reproductive health.¹¹

Cook Medical Australia successfully demonstrates the strength of Queensland's local manufacturing capabilities in the biomedical and life sciences sector. Furthermore, it is a great example of the successful collaboration and co-location between R&D and manufacturing.

¹ Chamber of Commerce and Industry Development, Industry Futures Report – Manufacturing.

¹¹ <http://aamc.org.au/portfolio-items/cook-medical-australia/>



Challenges

In 2013–14 the main impediments to business performance identified by Australian industry in response to an ABS survey varied between industry segments. The medical and surgical equipment manufacturing segment identified lower profit margins to remain competitive (33%) and lack of customer demand for goods or services (29%) as their most significant impediments. The lack of customer demand was an impediment identified particularly by smaller businesses and it would appear to illustrate the highly competitive nature of the industry rather than a lack of demand for the goods and services produced by the industry. However, lack of access to additional funds (30%) and the cost of inputs (31%) were most significant to the manufacturers of human pharmaceutical and medicinal products.

During preliminary consultation, Queensland peak bodies and industry identified only two of these impediments as key concerns—the lack of access to funds and the availability of skilled persons. The challenges raised by industry peak bodies and businesses are set out below.

Question 12:

In your experience, are the barriers set out in Figure 4 the main impediments to business performance? What initiatives have been effective in assisting your business overcome barriers and why have they been successful?

The translation imperative

Traditionally, Queensland’s biomedical and life sciences sector has demonstrated an outstanding record of research excellence. However, translating and commercialising research remains a significant challenge. This is due to high barriers to entry in the biomedical and life sciences sector, including:

- o high and rising costs of R&D due to the degree of specialisation in the industry, declining R&D productivity and the need to

sustain R&D levels to remain competitive

- o high costs and long timeframes associated with bringing a product to market
- o an increasing regulatory burden (this is a highly regulated industry)
- o the fast rate of technological change and the need to stay at the forefront of technological innovation
- o access to highly skilled and qualified staff.²⁶

Australia, as a whole, performs poorly against measures of the

Figure 4 – Barriers to biomedical business activities or performance, 2013–2014 (a),(b)²⁷



■ Medical and Surgical Equipment Manufacturing

■ Veterinary Pharmaceutical and Medicinal Product Manufacturing(e)

■ Human Pharmaceutical and Medicinal Product Manufacturing

(a) Proportions are of all businesses in each output category

(b) Businesses could identify more than one barrier and were not asked to rank barriers in order of significance.

(c) Includes businesses that reported lack of skilled persons within the business and/or within the labour market.

(d) Examples of environmental factors include drought, insect plague and compliance with water restrictions.

(e) Some data not available for publication

translation of research into tangible commercial outcomes. The Global Innovation Index, Innovation Efficiency Ratio,²⁸ compares innovation inputs (including research, infrastructure, and education) with innovation outputs (knowledge creation, impact and diffusion). In 2015, Australia ranked 72nd out of 143 countries. Australia also ranks very poorly in measures of collaboration between industry and the publicly funded research sector in comparison to other OECD countries.²⁹

Better translation of biomedical research into tangible commercial outcomes for Queenslanders would:

- facilitate the growth of new businesses and job opportunities
- help drive exit opportunities (mergers, acquisitions, licensing of technologies) further down the value chain and hence towards higher economic returns
- foster a commercially savvy research base in the state
- grow exports.

The challenge facing Queensland to improve the translation of research into commercial products, processes or services is intrinsically linked to the challenges of building an entrepreneurial culture, access to capital investment and collaboration, addressed below.

Building an entrepreneurial culture

The biomedical and life sciences sector requires a highly skilled and educated workforce. In addition to the required technical skills, growth in the biomedical and life sciences sector requires a workforce with a broad range of skills in:

- entrepreneurialism, management and leadership
- regulatory affairs
- clinical strategy
- project management
- international markets.

These are of key importance to the success of a business, as companies need the skills to effectively promote

their capabilities to investors in order to attract funding.

Initial consultation with the biomedical and life sciences sector in Queensland has identified building entrepreneurial skills and a supporting environment to exercise these skills as critical. These findings are consistent with the Australian Government’s review of venture capital (VC) and entrepreneurial skills.³⁰ Overseas VC firms in particular, noted that entrepreneurial skills were a problem area for Australian startups and that entrepreneurs needed to better understand target markets and milestones before pitching internationally. The review found that fostering a supportive entrepreneurial and VC ecosystem was the most effective way of retaining and attracting skilled entrepreneurs and supporting skills development in this area.

Case study—Translating research into commercial outcomes for Queensland

Peplin, a Brisbane-based biotechnology company, was established in 1998 to advance research being undertaken by Dr James Aylward at the QIMR Berghofer into the anti-cancer properties of natural products.

Peplin entered into Phase I clinical trials in the USA to commercialise ingenol mebutate for solar keratoses and basal cell carcinoma, followed by Phase II clinical trials in Australia in 2005 and Phase III clinical trials in 2008 and 2009.

LEO Pharma, an independent research-based pharmaceutical company in Denmark, acquired Peplin in 2009 for US\$287.5 million.

In 2012 LEO Pharma launched the product Picato, a gel to treat actinic keratosis based on the ingenol mebutate substance, in 13 countries worldwide. The ingenol mebutate substance is manufactured on the Gold Coast in Queensland.

Advance Queensland is creating an environment to support entrepreneurial skills and businesses. Queensland universities are also working to embed entrepreneurial skills in students and researchers, through programs such as the outbluebox Innovation Challenge.

Of the top five startup companies (across all sectors) in Australia in 2015,³¹ three were based on biomedical technologies that originated in Queensland – Spinifex Pty Ltd (#2), Admedus Ltd (#3)

and Vaxxas Pty Ltd (#5). Though these companies are no longer headquartered in Queensland, some R&D is still conducted in the state.

Queensland needs to better leverage the wealth of knowledge in established biomedical companies, including their broad understanding of the market and opportunities, to provide realistic guidance to inventors and future entrepreneurs about the economic value proposition of ideas.

Entrepreneurialism is a balance between making good business decisions, while tolerating a level of risk. The broad regulatory reforms under NISA for startups will encourage entrepreneurialism and acknowledge the need to manage risk. For example, the proposed reforms to insolvency laws to address the risks associated with being an early stage investor or a director of a startup in Australia, will support entrepreneurs and investors to take a calculated risk.

Case study—Fostering a culture of innovation, entrepreneurship and collaboration

The Johnson & Johnson Innovation 2015 Industry Excellence Awards recognised Brisbane-based healthcare company Ellume as the Emerging Company of the Year for its development of simple, highly sensitive and reliable diagnostics for infectious diseases and by linking the results of those tools to optimal therapy.¹

Ellume successfully demonstrates the value of fostering a culture of innovation, entrepreneurship and collaboration within the biomedical and life sciences sector to drive economic growth in Queensland.

Founded in 2010 and located in East Brisbane, Ellume has developed simple and safe sampling methods to enable the detection of pathogens in blood, swabs and respiratory secretions. Ellume's first product is the Respirio Flu Test (RFT). The RFT is the world's first at-home, non-invasive, ultra-sensitive test for detecting and differentiating influenza A and B (seasonal and pandemic) in 20 minutes. The RFT detects all strains of influenza A, removing the need for seasonal modifications seen in vaccines and is designed for use by the consumer directly.

Ellume has negotiated the regulatory approach with the US Food and Drug Administration, and is confident in the approval of the test in the US, subject to satisfactory safety and efficacy data. The RFT is currently undergoing clinical evaluation studies and Ellume is preparing for clinical validation studies in Australia in mid-2016 and in the US in December 2016.

Ellume is actively progressing the development of subsequent products which have significant unmet or under-met needs in the global community, including Respiratory Syncytial Virus (RSV), HIV, malaria and chlamydia. In March 2016, Ellume received A\$50,000 under Advance Queensland's Knowledge Transfer Partnerships program to work on the development of the product for diagnosing RSV.

¹ <http://www.ausbiotech.org/updates/details.asp?id=1309>



Question 13:

What are your experiences in accessing skilled workers? Where are the skills gaps? What can be done by industry and by government to improve access to skilled labour?

Access to capital investment

Access to capital remains a perennial problem for the biomedical and life sciences sector in Australia and a key barrier to growth. High risk capital is critical for smaller enterprises at early stages of business expansion. These enterprises are exposed to significant development risks, strict regulatory requirements and long lead times.

Many millions of dollars will be spent taking a nascent technology or a novel chemical, compound or molecule to the market. The direct cost of taking a single drug from discovery through to market is US\$428 million or approximately US\$2.6 billion when account is taken of those potential products that fail.³²

US companies generally have more access to high levels of VC than businesses in other jurisdictions.³³

The VC market is competitive. Investors define risk appetite based on the investment criteria for a fund. The risk appetite of current investors favours the investment of funds in late stage clinical trials or medical technologies with a clear short term value inflection point. In its Pharma Half-Year Review 2015, the

industry journal EP Vantage confirms a funding trend with VC investment favouring later-stage companies.

This leaves a gap in available VC funds with capital and risk appetites for investing in startup and early phase drug development opportunities, particularly from preclinical trials through to end of Phase II.

The proposed tax incentive for early stage investors and new arrangements for Venture Capital Limited Partnerships are initiatives set up by the Australian Government to address some of these concerns.

The Medical Research Commercialisation Fund (MRCF) brings together a formal collaboration of more than 50 of Australia's leading medical research institutes and research hospitals—including nine institutes in Queensland.³⁴ The recently-raised A\$200 million MRCF3 fund is supported by leading Australian industry superannuation funds including AustralianSuper, StatewideSuper, HESTA and HostPlus, and has been established to support the development and commercialisation of early-stage biomedical and life sciences companies. The Queensland Government provides a grant to support the activities of the collaboration in the state and Brandon Capital has recently appointed a Brisbane-based investment manager to lead activities in Queensland.³⁵

The Australian Government's A\$250 million Biomedical Translation Fund

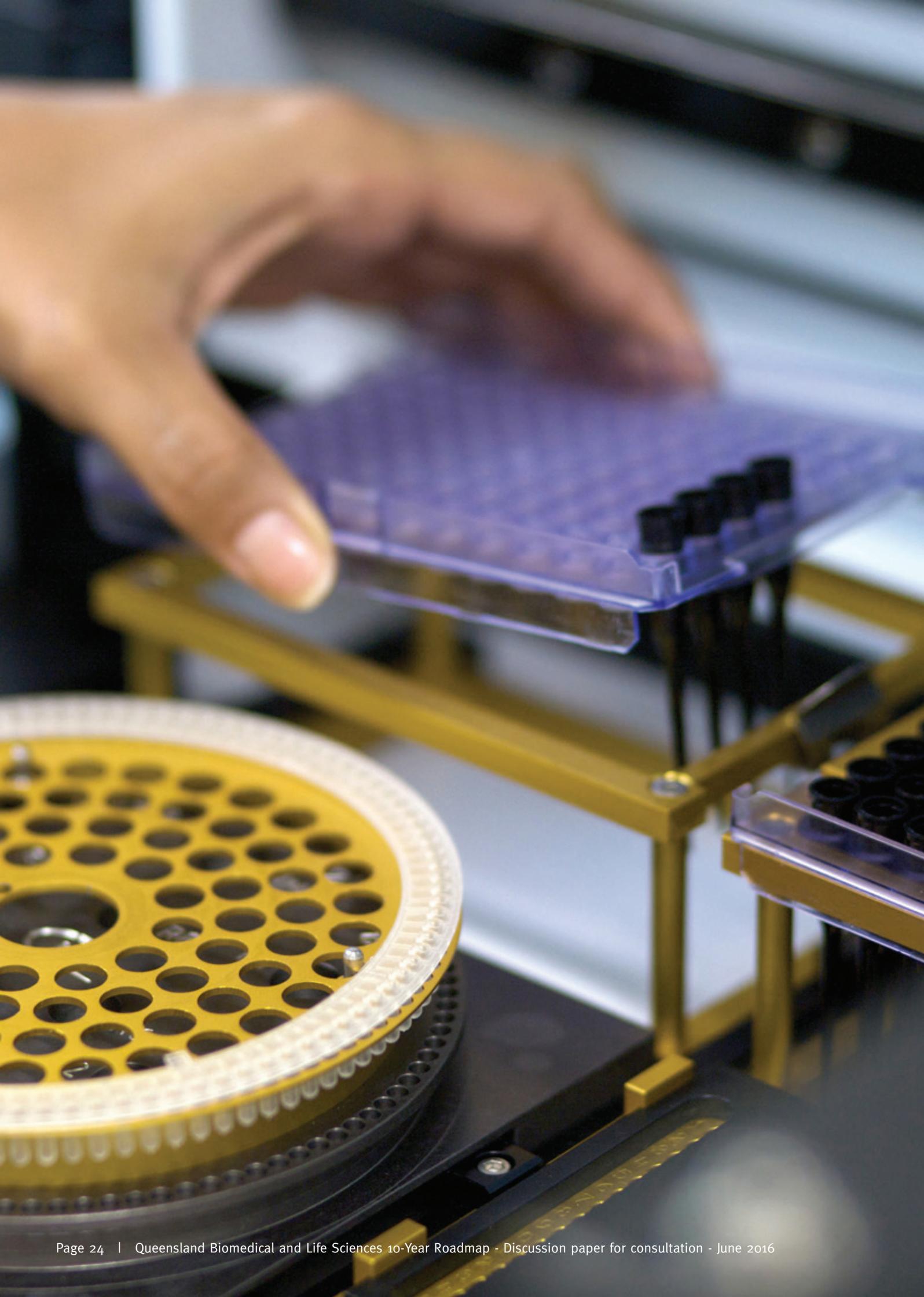
(BTF) was set up in 2016. The BTF is a co-investment fund which is anticipated to leverage an additional A\$250 million in funds from private investors and is expected to provide a boost for biomedical and life sciences businesses seeking capital investment.

Nationally, other potential sources of capital investment for biomedical and life sciences companies include the:

- A\$200 million CSIRO Innovation Fund for co-investment in new spin-offs and existing startups
- A\$8 million Incubator Support Programme, commencing 2016-17, aimed at growing the next generation of innovative and high performing Australian businesses, which will coordinate and promote support for entrepreneurs and startups through the Australian Innovation Network.

Nationally, the Australian Government's R&D Tax Incentive is a key draw card for attracting investment to Australia, providing non-dilutive capital. It not only supports local companies undertaking R&D, but has also played a key role in investment attraction encouraging international firms to engage Australian service providers to undertake R&D in Australia.

The local biomedical and life sciences sector is partnering with major national industry peak bodies, such as AusBiotech and the Medical Technology Association of Australia (MTAA), to lobby the Australian Government in relation to policies and initiatives critical to increasing



the capital necessary for the sector. For example the R&D Tax Incentive and the proposed AIM patent-box style incentive.

At a state level, Advance Queensland is providing important funding to assist companies leverage private investment through the Business Development Fund and Ignite Ideas program.

There remains strong global and national competition for investment so Queensland will have to work hard to attract capital.

Question 14:

What are your experiences in accessing capital? How could access to capital be improved? What are the lessons learnt?

Collaboration

Building critical mass

Critical mass will be essential if Queensland is to compete globally in the biomedical industry. A constant challenge to building this scale is the global nature of the industry where it is common for invention, manufacture and delivery of products and services to be spread between a number of organisations and jurisdictions worldwide. Additionally, we are also challenged to address the low levels of collaboration between businesses and research organisations in Australia when compared with international standards.³⁶

Strong levels of collaboration domestically and internationally within the value chain will help generate sufficient critical mass to enable Queensland to capture the opportunities. It will also ensure Queensland is well connected within the global value chain enabling Queensland to respond to emerging prospects. Connections between industry, clinicians and researchers at an early stage of the development life cycle, increase the chance of capitalising on openings as they arise.

Multi-national companies are increasingly exploring outsourcing, partnerships and contract research/manufacturing options to deliver value to their organisation.

There can be a number of advantages to taking this approach. In the pharmaceuticals industry, even a small reduction in the timing of drug development can result in significant cost savings. Using contract research or manufacturing organisations reduces development times and may provide cost advantages, particularly where the services are located in countries such as India or China which are comparatively low-cost. However, while traditionally big pharmaceutical and medical technology companies have outsourced low value, high volume work, companies are now looking to outsource activities higher up the value chain.³⁷



The Queensland Government is working to build critical mass through the development of health and knowledge precincts and strategic alliances to take advantage of this high value outsourcing.

To ensure the ongoing global relevance of the sector in the state, the Queensland Government is supporting Queensland's biomedical research organisations to partner with business in the translation of research excellence into healthcare products, processes and services. Advance Queensland is supporting the following global innovation partnerships:

- o **UQ Emory Drug Discovery Initiative (QEDDI):** to facilitate the discovery and development of new drugs. The initiative draws on the drug discovery and commercialisation expertise of Uniquist (the commercialisation company of UQ), Emory University's Institute for Drug Discovery and Drug Innovation Ventures@Emory (DRIVE)
- o **Johnson & Johnson Innovation Partnering Office at QUT:** providing Queensland researchers and companies with access to the research, investment and commercialisation expertise of multinational healthcare company Johnson & Johnson.

Over the years, the Queensland Government has also established government level strategic alliances that support development of the sector. Queensland currently has formal arrangements with China, North America and New Zealand. These arrangements facilitate access to people and skills, infrastructure and markets.

Question 15:

How do you see a culture of collaboration between research and industry being fostered within Queensland?

Question 16:

How can Queensland build the scale of the biomedical and life sciences sector?

Clusters/precincts

A Health and Knowledge Industry Profile for South-East Queensland is currently being prepared to identify the comparative advantages and competitive strengths of each health and knowledge precinct in South East Queensland.

Existing and emerging precincts in South East Queensland include:

- o Princess Alexandra Health Precinct
- o Health City Springfield Central
- o Herston Health Precinct
- o Oceanside Health Hub and Sunshine Coast Health Campus
- o Gold Coast Health and Knowledge Precinct
- o Brisbane Technology Park
- o Health and Food Sciences Precinct at Coopers Plains.

These health and knowledge precincts comprise clusters of industry and research institutes, (including universities and state-of-the-art hospitals) with the capacity to drive innovation through

collaboration, knowledge exchange and the sharing of infrastructure. Each precinct is at a different stage of maturity.

While Queensland is fortunate to be home to these health and knowledge precincts, the local competition between precincts may be acting as a barrier to inter-disciplinary collaboration and the transfer and sharing of knowledge within the biomedical and life sciences supply chain. Research demonstrates that a greater, faster transfer of knowledge between research institutes and industry leads to increased innovation.³⁸ Planning for the future growth of these precincts requires a whole-of-state focus to ensure collaboration is fostered across the biomedical and life sciences supply chain targeting areas in which Queensland has a comparative advantage.

A key opportunity for Queensland exists to foster a stronger culture of collaboration between research institutes and industry across the state to ensure the biomedical and life sciences sector continues to thrive in the state. Queensland is well positioned to harness this opportunity to attract business, investment and partnership opportunities to the health and knowledge precincts.

Future challenges for ensuring the success of Queensland's health and knowledge precincts may include:

- o land tenure
- o planning control
- o access costs
- o ownership models
- o connectivity within and between precincts.

Question 17:

What are the attributes of a successful health and knowledge precinct?

Question 18:

What are the factors that would attract industry to locate in Queensland's health and knowledge precincts? (For example, value of land, access to infrastructure etc.)

Promoting the sector

As the biomedical and life sciences sector in Queensland continues to mature and grow, its focus needs to move to promoting the sector within Queensland, Australia and internationally.

The Queensland Government has a long standing commitment to the annual BIO International Convention held in the USA. For the last 17 years the government has led a delegation and did so again in San Francisco in June 2016.

The Queensland Government has also provided substantial support to local industry body, Life Sciences Queensland Limited (LSQ). LSQ actively promotes the capabilities and investable opportunities of its members to strategic partners and investors.

LSQ is responsible for delivering and coordinating business support

Case study—Co-location facilitating collaboration

Queensland's capabilities in fostering collaboration within the biomedical and life sciences supply chain have now been realised at the Princess Alexandra Health Precinct. The Translational Research Institute (TRI), opened in 2013, is the largest medical research institute in the southern hemisphere and is an Australian-first, translating medical innovations into products to improve healthcare. The TRI combines the research strengths of the Princess Alexandra Hospital, UQ, QUT, the Mater Research Institute and the Queensland Government.

The TRI research labs, specialist facilities, Clinical Research Facility and Innovation and Translation Centre are co-located with Patheon Biologics, the first pilot scale mammalian biopharmaceutical manufacturing facility in Australia. The Innovation and Translation Centre, established with funding from the Queensland Government's Advance Queensland initiative, operates in collaboration with Siemens Healthcare.

The co-location of these facilities adjacent to the Princess Alexandra Hospital enables diagnostics, therapies and treatments to be discovered, developed and clinically tested within the same health and knowledge precinct.

Translational research projects at the TRI are progressed through the following internationally accepted translational pathway model:

- T1 – innovation published and patented
- T2 – clinical study
- T3 – clinical trial
- T4 – clinical practice
- T5 – international adoption and assessment.

There are a number of translational research projects underway at the TRI which are at different stages of this model. The Gardasil HPV Cervical Cancer Vaccine has achieved the T5 milestone. A vaccine for Herpes Simplex Virus has achieved the T4 milestone, and is currently undergoing Phase II human trials for vaccine efficacy.



« TRI's Prof Ian Frazer AC, Australian of the Year 2006 and co-inventor of the cervical cancer vaccine, administering a Gardasil injection.

to promote and raise awareness of Queensland's biomedical and life sciences capabilities.

A future challenge for raising the reputation of the biomedical and life sciences sector in Queensland is leveraging LSQ's marketing success to deliver business and employment opportunities for the sector in Queensland.

To build on LSQ's role, the Queensland Government, in partnership with the private sector, may play an increased role in marketing, promoting and raising awareness of Queensland's capabilities and expertise in the biomedical and life sciences sector internationally, nationally and locally.

Question 19:

How can the state government continue to assist industry in promoting the sector?

Measuring success

A successful biomedical and life sciences sector in Queensland will have a dynamic ecosystem which delivers economic development outcomes for all Queenslanders as well as improving the health and wellbeing for millions globally. With significant global competition, determining what success looks like and how this will be measured during the implementation of the roadmap is critical.

Global leadership in areas of comparative advantage requires tracking and evaluating the effectiveness of existing pathways to commercialisation, understanding the factors that drive success and where reforms are needed.

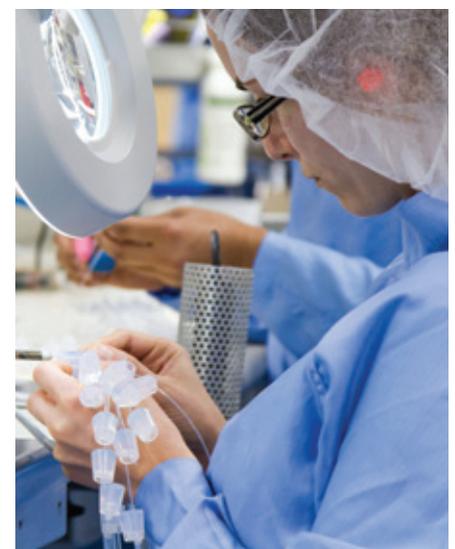
This should include ensuring Queensland develops and optimises pathways for adoption, diffusion and evaluation of locally developed medical devices and diagnostics into its local health system.

Included in the mix of evaluating success will be measuring:

- the growth in the number of local enterprises in this sector in Queensland and the growth in size of existing and new local enterprises
- the number of jobs in the sector and supporting sectors
- contribution to GDP
- growth in new commercial products
- capital invested in sector
- merger, acquisition and other company maturation outcomes.³⁹

Question 20:

What measures do you consider appropriate to evaluate the success of the biomedical and life sciences sector?



Addressing future opportunities

The biomedical industry in Queensland is still relatively small. Queensland is home to a handful of large, multinational biomedical manufacturing businesses supported by a small but growing community of startup companies and a robust research sector.

To build scale and add value in a global value chain will require collaboration between government, industry and research institutes. Based on preliminary consultation with industry, options to build scale and add value could include:

- enhancing service innovation—biomedical and life sciences businesses can add real economic value, maintain and improve competitiveness and profitability, defend existing market share and grow new markets through the introduction of innovative service concepts to support their existing business activity. This could occur through two key mechanisms:
 - adding value to a business’ product—developing services that support delivery or use of the company’s product, differentiate the product in market and build in competitive advantage
 - cost efficiency—introducing innovative, cost efficient solutions to the financial, technological, and transport and logistical challenges facing businesses
- focusing on higher value, specialised, technology rich manufacture (often lower volume) of therapeutic medicines, medical devices and diagnostics
- building on segments of the biomedical and life sciences sector where Queensland has an existing comparative advantage (e.g. infectious diseases)
- building entrepreneurial and business skills in researchers and inventors
- aligning incubators and startup precincts with a large, successful and innovative manufacturing business that can mentor the general business, regulatory, commercialisation, marketing and finance skills of researchers, inventors and product developers
- growing capacity and capability in health economics and exploiting existing capabilities to assist businesses and researchers in prioritising their investment in biomedical research and its translation into commercial outcomes
- offering businesses the opportunity to receive effective, coordinated and educated assistance from government via a single point of entry. For example, assistance could be handled through a case manager with knowledge of the industry’s regulatory barriers who is available to provide clients with personalised advice (a business model that has worked well in trade and investment agencies within government). For Queensland companies intending to expand or seeking funding from overseas, support is available from Trade and Investment Queensland and AusTrade, which

can provide advice on exporting and international markets and business introductions.

Question 21:

What other support would be of assistance to biomedical enterprises establishing and growing in Queensland?

Question 22:

What is the one thing the Queensland Government could do to achieve the greatest positive impact for the biomedical industry?



Have your say

The Queensland Government wants to hear from all stakeholders. You are invited to provide a submission on all or any of the questions listed below. The questions are not intended to be exhaustive and you are encouraged to raise any other issues. Submissions can be made through the following methods:

- by email to biomedical@dsd.qld.gov.au
- by post to Biomedical and Life Sciences Project Manager, Industry Development, Department of State Development, PO Box 15009, City East Qld 4002
- online at www.statedevelopment.qld.gov.au/biomedical

Please send your comments and submissions by 5.00 pm on 5 August 2016.

For more information telephone (07) 3452 7310 or visit the website at www.statedevelopment.qld.gov.au/biomedical

Questions

Data (p. 5)

Question 1: A more up-to-date profile of the Queensland biomedical and life sciences sector is needed. What do you consider is a reliable method for data capture to accurately profile this industry in Queensland?

Vision (p. 5)

Question 2: Does the vision statement reflect a challenging but achievable vision for the industry in Queensland? If not, what is a realistic ambition given the nature of the industry?

Industry overview (p. 6 - 10)

Question 3: Barriers to accessing emerging global markets include access to finance and skills and industry regulation. Do you agree? What other barriers do you see for the biomedical industry in Queensland? At a state level, what can be done to assist companies to participate in the global marketplace?

Comparative advantages and opportunities (p. 11 - 15)

Question 4: Is the profile of Queensland's comparative advantages accurate? Are there any other known or emerging comparative advantages?

Question 5: Which of Queensland's comparative advantages have the greatest potential for the state to grow a sustainable biomedical industry?

Question 6: Does the expertise identified in this paper accurately reflect the state's strengths? Are there other strengths that can be developed or ways existing strengths can be further exploited?

Question 7: Does the existing infrastructure meet the needs of industry? If not, what additional infrastructure is required to support the growth of the biomedical industry?

Question 8: What lessons can be learnt from the past experiences of startups in the sector in Queensland?

Government policies and programs (p. 16 - 18)

Question 9: How important is the R&D Tax Incentive in attracting and retaining companies in Australia? How would industry be affected by a change to the R&D Tax Incentive?

Question 10: How would the AIM patent-box incentive benefit industry?

Question 11: Are there any regulatory changes needed at a national, state or local level to enable industry growth?

Challenges (p. 20 - 28)

Question 12: In your experience, are the barriers set out in figure 4 the main impediments to business performance? What initiatives have been effective in assisting your business overcome barriers and why have they been successful?

Question 13: What are your experiences in accessing skilled workers? Where are the skills gaps? What can be done by industry and by government to improve access to skilled labour?

Question 14: What are your experiences in accessing capital? How could access to capital be improved? What are the lessons learnt?

Question 15: How do you see a culture of collaboration between research and industry being fostered within Queensland?

Question 16: How can Queensland build the scale of the biomedical and life sciences sector?

Question 17: What are the attributes of a successful health and knowledge precinct?

Question 18: What are the factors that would attract industry to locate in Queensland's health and knowledge precincts? (For example, value of land, access to infrastructure etc.)

Question 19: How can the state government continue to assist industry in promoting the sector?

Question 20: What measures do you consider appropriate to evaluate the success of the biomedical and life sciences sector?

Addressing future opportunities (p. 29)

Question 21: What other support would be of assistance to biomedical enterprises establishing and growing in Queensland?

Question 22: What is the one thing the Queensland Government could do to achieve the greatest positive impact for the biomedical industry?

Any other comments?

Glossary

ABS	Australian Bureau of Statistics	MTAA	Medical Technology Association of Australia
AIM	Australian Innovation and Manufacturing	NCRIS	National Collaborative Research Infrastructure Strategy
ANFF	Australian National Fabrication Facility	NISA	National Innovation and Science Agenda
ANZSIC	Australian and New Zealand Standard Industrial Classification	PCT	patent cooperation treaty
BTF	Biomedical Translation Fund	QIMR Berghofer	QIMR Berghofer Medical Research Institute
CSIRO	Commonwealth Scientific and Industrial Research Organisation	QUT	Queensland University of Technology
CTN	Clinical Trial Notification Scheme	R&D	research and development
CTX	Clinical Trial Exemption Scheme	RFT	Respirio Flu Test
DSD	Department of State Development	RSV	Respiratory Syncytial Virus
DSITI	Department of Science, Information Technology and Innovation	TGA	Therapeutic Goods Administration
FTE	full-time equivalent	TMD	therapeutic medicines and devices
GMP	Good Manufacturing Practices	TRI	Translational Research Institute
IP	intellectual property	UQ	University of Queensland
LSQ	Life Sciences Queensland	VC	venture capital
MRCF	Medical Research Commercialisation Fund		

References

- 1 Biopharmaceuticals are those created by biological processes from living organisms as opposed to those that are chemically synthesised.
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- 3 Data sourced from: MTA, Medical Technology in Australia: Key facts and figures 2014; IBISWorld Industry Reports C2412, C1841 and X0001; Australian Department of Industry 2014, Australian Medical Devices – A patent analytics report; and 2016 Scientific American Worldview overall scores.
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