Submission

2016 National Research Infrastructure Roadmap Capability Issues Paper

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Introduction to Patheon.

Patheon Biologics Brisbane facility was opened in 2013 and has been operational since that date. As part of the greater Patheon group, we offer comprehensive contract development and reliable cGMP manufacturing. With a 100% success rate, we help our clients gain a competitive advantage for both traditional biopharmaceuticals and biosimilars. We provide integrated end-to-end, fully integrated services for both drug substances and partner with our global sites for drug products. We pride ourselves at putting the client at the centre of everything that we do to ensure the medicines of the future are delivered on time and on budget. Patheon take pride in delivering a simplified supply chain that accelerates development and keeps our clients ahead of their competition in the rapidly changing world of biologics.

We maintain flexible capabilities across all bioprocessing stages and our expertise spans multiple mammalian cell lines, including CHO, myeloma, hybridoma and PER.C6 ®. We are continuously investing in our facilities to ensure our clients have immediate access to leading-edge technologies, innovative solutions and unique financing opportunities.

Our staff bring more than 20 years of manufacturing experience to the site, including working with more than 240 biologic programs in the past. We are experienced and know how to transform your discovery into a drug substance via sustainable processes designed to scale from preclinical development to commercial manufacture. We offer a range of process types including batch, fed-batch, perfusion and chromatography processes leveraging either single-use and / or stainless steel systems.

Brisbane has a strong track record since opening in 2013, offering both clinical manufacturing, analytical services, process validation, technical transfer, commercialization strategies and flexible biomanufacturing solutions for our clients.

The majority of our Brisbane clients are emerging and midsize companies. We also work with the world's 20 largest pharmaceutical companies globally. Companies

put their trust in Patheon for our proven expertise in bringing drug candidates from preclinical development through production. Patheon clients have earned twice as many NDA approvals as those of any other CDMO (Source: PharmSource ® Trend Report, March, 2016) and the ability to launch products anywhere in the world.

Over the coming years, Brisbane will be expanding further to accommodate multiple phase III clinical products approaching commercialization. Clients worldwide prefer Patheon for commercial manufacturing as they recognize their product will be in the capable hands of an experienced project manager and cross-functional team at world-class facilities in Europe, North America and Australia. Patheon offer full regulatory support, including preparation of CMC documentation.

Patheon have been the recipients of at least 1 award per annum since opening, including the 2014 ISPE Manufacturing Facility of the year award for Process Innovation, the Frost and Sullivan CMO of the year award in 2015 and also the Patheon CEO award in 2016 for Talent Development.

Since its inception, Patheon has worked closely with NCRIS partners such as the

National Biologics Facility (NBF) located at AIBN ('The Australian Institute for Bioengineering and Nanotechnology' at UQ (the University of Queensland), St. Lucia QLD. Many of our talented staff have originated from this group and have been developed into key leadership positions in the global Patheon network. In addition, the NBF has provided the first "feeds" into Patheon helping with both the early stage development of cell lines, but also providing materials and advice to both public and private groups to facilitate the translation of great research into a commercially viable option for emerging Australian biotech companies. This key partnership has facilitated further cohesion of Biotechnology and Industry through continued staff engagement, sharing best practice and support of intern students.

Question 1: Are there other capability areas that should be considered?

Commercialisation strategies. Continued support of new start ups to learn how to commercialise great research and support to learn how to gain venture capital funding in this space would add value and prevent large companies overseas buying up Australian investments and therefore, taking the profit overseas.

Question 2: Are these governance characteristics appropriate and are there other factors that should be considered for optimal governance for national research infrastructure.

The governance key characteristics outlined in Section 3.2 advocating strong governance of capabilities with appreciation of the requirements of the private sector with a strong ethos of academic: industrial collaboration are critical for the success of the Biologics network in Australia.

Question 3: Should national research infrastructure investment assist with access to international facilities?

From Patheons' experience, the NBF provided strong international linkages to global research groups which an international company such as Patheon would expect to leverage.

Question 4: What are the conditions or scenarios where access to international facilities should be prioritised over developing national facilities?

Where the benefit to the National facilities long term would benefit from a strategic short term investment in the International space (ie staff expertise development lacking in Australia)

Question 5: Should research workforce skills be considered a research infrastructure issue?

Very much so, and Patheon have relied heavily in the last few years from the skillset developed by staff working at NBF enabling Patheon to become profitable in such a short period of time (within 1 year of start up). In return, Patheon commit to local universities and facilities to offer internships and academic support.

Question 6: How can national research infrastructure assist in training and skills development?

Staff exchanges and further staff development across both sites will continue to foster both the ethos of industrial engagement from academia but also foster a greater transition of ideas and collaboration from which the NBF can benefit.

Question 7: What responsibility should research institutions have in supporting the development of infrastructure ready researchers and technical specialists?

Research Institutions should acknowledge the role they play in developing a "knowledge economy" and continue to foster the development of infrastructure which lends itself to industrial partnerships.

Question 8: What principles should be applied for access to national research infrastructure, and are there situations when these should not apply?

No comments

Question 9: What should the criteria and funding arrangements for defunding or decommissioning look like?

No comments

Question 10: What financing models should the Government consider to support investment in national research infrastructure?

Similar programs like the ARC grants for Academia and industry where funding is only provided where an industrial link/support is in place would help here. For eg, Patheon as part of an ARC grant with the AIBN in 2017 onwards will fund 5 PhD students and 1 postdoctoral researcher working alongside GE Australia and CSL Melbourne.

Question 11: When should capabilities be expected to address standard and accreditation requirements?

Appropriate KPIs for true 'translational" projects should include SMART objectives with time limitations and regular review.

Question 12: Are there international or global models that represent best practice for national research infrastructure that could be considered?

We see the NCRIS scheme as a worlds "best practice" scheme. NBF has fit well into the Australian Biotechnology Space and has been critical for small emerging Biotech to gain the necessary support, product development and access to bioprocessing equipment which emerging Biotech lack capital funding to access themselves.

Other key global facilities would include the Irish NIBRT which offers industrial training on bioprocessing equipment and training programmes for industry. It was heavily funded by the Irish government attracting key world experts and is now considered a centre of excellence in Europe.

Question 13: In considering whole of life investment including decommissioning or defunding for national research infrastructure are there examples domestic or international that should be examined?

No Comments

Question 14: Are there alternative financing options, including international models that the Government could consider to support investment in national research infrastructure?

No comments

Health and Medical Sciences

Question 15: Are the identified emerging directions and research infrastructure capabilities for Health and Medical Sciences right? Are there any missing or additional needed?

Patheon was delighted to read that NCRIS consider the importance of biologics to the current global market as a key emerging capability need.

Question 16: Are there any international research infrastructure collaborations or emerging projects that Australia should engage in over the next ten years and beyond?

Given the growing importance and activities in the Biologics field, Patheon supports the need to enhance the research infrastructure capabilities in this area. Key considerations such as those listed facilitate stronger ties between facilities such as the NBF and Patheon.

Question 17: Is there anything else that needs to be included or considered in the 2016 Roadmap for the Health and Medical Sciences capability area?

A consideration of a matching small “semi-automated” vial fill capability in Australia for emerging biotech companies who would like to undertake pre-clinical trials in Australia would benefit small capital starved clients trying to commercialise their product and gain exposure to the clinical market. Commercial vialling lines are very expensive and out of the range of most small companies.

Environment and Natural Resource Management

No Comments

Question 18: Are the identified emerging directions and research infrastructure capabilities for Environment and Natural Resource Management right? Are there any missing or additional needed?

Question 19: Are there any international research infrastructure collaborations or emerging projects that Australia should engage in over the next ten years and beyond?

Question 20: Is there anything else that needs to be included or considered in the 2016 Roadmap for the Environment and Natural Resource Management capability area?

Advanced Physics, Chemistry, Mathematics and Materials

No comments

Question 21: Are the identified emerging directions and research infrastructure capabilities for Advanced Physics, Chemistry, Mathematics and Materials right? Are there any missing or additional needed?

Question 22: Are there any international research infrastructure collaborations or emerging projects that Australia should engage in over the next ten years and beyond?

Question 23: Is there anything else that needs to be included or considered in the 2016 Roadmap for the Advanced Physics, Chemistry, Mathematics and Materials capability area?

Understanding Cultures and Communities

No Comments

Question 24: Are the identified emerging directions and research infrastructure capabilities for Understanding Cultures and Communities right? Are there any missing or additional needed?

Question 25: Are there any international research infrastructure collaborations or emerging projects that Australia should engage in over the next ten years and beyond?

Question 26: Is there anything else that needs to be included or considered in the 2016 Roadmap for the Understanding Cultures and Communities capability area?

National Security

Question 27: Are the identified emerging directions and research infrastructure capabilities for National Security right? Are there any missing or additional needed?

No comments

Question 28: Are there any international research infrastructure collaborations or emerging projects that Australia should engage in over the next ten years and beyond?

No comments

Question 29: Is there anything else that needs to be included or considered in the 2016 Roadmap for the National Security capability area?

Strengthening the capability of centres such as NBF working with key vaccine development groups may facilitate rapid response to future pandemics by enabling the rapid bioprocess development needed to respond to such a crisis

Underpinning Research Infrastructure

No comments

Question 30: Are the identified emerging directions and research infrastructure capabilities for Underpinning Research Infrastructure right? Are there any missing or additional needed?

Question 31: Are there any international research infrastructure collaborations or emerging projects that Australia should engage in over the next ten years and beyond?

Question 32: Is there anything else that needs to be included or considered in the 2016 Roadmap for the Underpinning Research Infrastructure capability area?

Data for Research and Discoverability

No comments

Question 33 Are the identified emerging directions and research infrastructure capabilities for Data for Research and Discoverability right? Are there any missing or additional needed?

Question 34: Are there any international research infrastructure collaborations or emerging projects that Australia should engage in over the next ten years and beyond?

Question 35: Is there anything else that needs to be included or considered in the 2016 Roadmap for the Data for Research and Discoverability capability area?

Other comments

If you believe that there are issues not addressed in this Issues Paper or the associated questions, please provide your comments under this heading noting the overall 20 page limit of submissions.