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The Quad should Commit to a Bio-hub in India

Shambhavi Naik, Dirk van der Kley, Saurabh Todi, Daniel Pavlich

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This document proposes that the Quad countries collaborate with each other to establish a Quad Biomanufacturing Hub in India to capitalise on the economic potential of the biomanufacturing industry and address potential vulnerabilities. Each Quad country brings together a unique set of capabilities that can be capitalised on to promote innovation and strengthen supply chain resilience.

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I. Introduction

Modern biotechnology will completely transform the global industrial system as the world substitutes chemical products with biological alternatives. A McKinsey report from 2020 argues that as much as 60 per cent of the physical inputs to the global economy could, in principle, be produced using modern biotechnology—about one-third of these inputs are biological materials (wood or animals bred for food) and the remaining two-thirds are nonbiological (plastics or fuels) that can potentially be produced or substituted using biology[1].

The potential to transform the field of biomanufacturing is also illustrated in a recent report released by the White House. The US expects "In 20 years, [to] demonstrate and deploy cost-effective and sustainable routes to convert bio-based feedstocks into recyclable-by-design polymers that can displace more than 90% of today's plastics and other commercial polymers at scale"[2]. If achieved, this would transform the global petrochemical industry and help solve our global plastic waste problem. Similar modern biotechnology efforts are underway for milk, meat, pharmaceuticals, oils and numerous other industries. Individually, these industries are worth many billions or trillions of dollars. Combined, they make biotechnology one of the most economically lucrative emerging technologies.

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Authors

Shambhavi Naik and Saurabh Todi,
The Takshashila Institution

Dirk van der Kley and Daniel Pavlich,
Australian National University

However, beyond the obvious economic value, there is significant strategic and social value in modern biotechnologies. The products produced by modern biotechnology are or will be essential for the production of food, energy, and the management of health. Those that control the IP and supply chains will potentially control key determinants of society's technological progress. There are also numerous potential military applications for biotechnology that range from food security to new, lightweight polymers, to understanding the potential of highly effective biological weapons (which are banned under international law).

Given the immense economic and strategic importance of these technologies, it is vital that countries do not place themselves in a vulnerable position. The growth in biotechnology - from the creation of novel products to their manufacture and sale - will require collaboration between countries. The Quad has sought to address this potential vulnerability by establishing a Critical and Emerging Technology Working Group that will monitor trends in critical and emerging technologies, such as synthetic biology, genome sequencing, and biomanufacturing, and also identify opportunities for cooperation within Quad.

As such, we recommend that Quad countries establish a biomanufacturing hub in India to capitalise on the economic potential of the biomanufacturing industry and address potential vulnerabilities. Each Quad country brings

together a unique set of capabilities that can be capitalised on to promote innovation and strengthen supply chain resilience.

II. The Need for a Quad Biomanufacturing Hub

The Quad nations (Australia, India, Japan, United States) are among the largest democratic economies in the Indo-Pacific. There is already a broad agreement among Quad countries on the need to address such supply chain vulnerabilities. The four countries have complementary strengths that can be combined to create a coherent Quad biotech program. These include the significant funding capability of the United States; advanced biotechnology innovation ecosystem and intellectual property (IP) of Australia, Japan, and the United States; India leads in the magnitude of skilled manpower; and availability of land and other material resources across all Quad countries.

The proposed biotechnology hub will address two key areas of potential vulnerability. First, it will seek to develop and protect the underlying IP that feeds into new products which involve the editing of microbes' DNA so they can produce the desired output. Second, the hub will support the scale-up process to support the "biologization" of existing industries. We envisage a Quad biomanufacturing hub as a platform to coordinate and collaborate

within the biotechnology sector between the Quad countries. The hub will focus on the following three areas:

1. Strengthening the physical infrastructure for biomanufacturing
2. Strengthening workforce capabilities for biomanufacturing
3. Increasing visibility of available opportunities for funding or collaboration

III. India as the Quad Biomanufacturing Hub

India is a natural choice for hosting such a hub. It is the nation best positioned to compete with China to prevent supply chain bottlenecks and strategic vulnerabilities in the production of key societal goods. It has the benefit of an extensive, established infrastructure and expertise in pharmaceutical manufacturing, including the low-cost production of biological vaccine inputs, as well as many biotechnology start-ups. This skill set and workforce can help India become an international biomanufacturing power.

According to the data compiled by The Australian Strategic Policy Institute, India is one of the leading countries in the field of biomanufacturing after the United States and China in both quality of research output (Figure 1) and in

the share among top publications (Figure 2). This advantage can be further cultivated through the combined efforts of Quad countries.

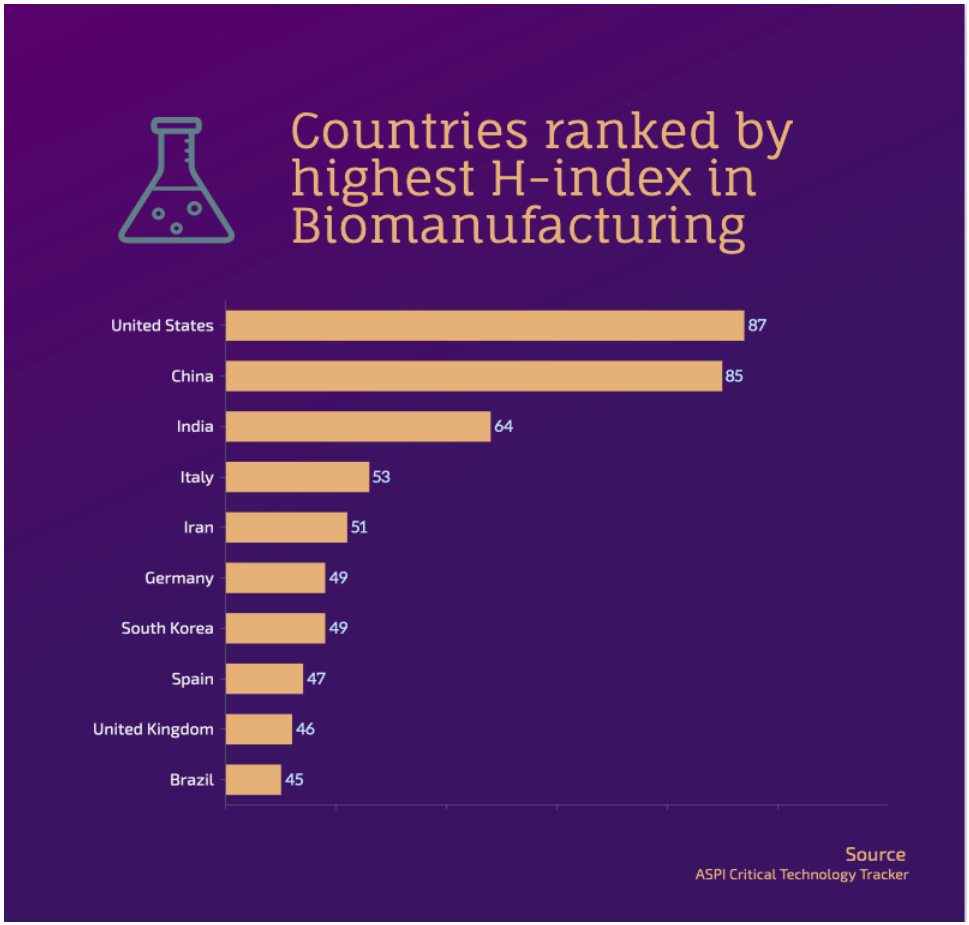

Figure 1 – Countries ranked by highest H-index in Biomanufacturing (Source: ASPI)[3]

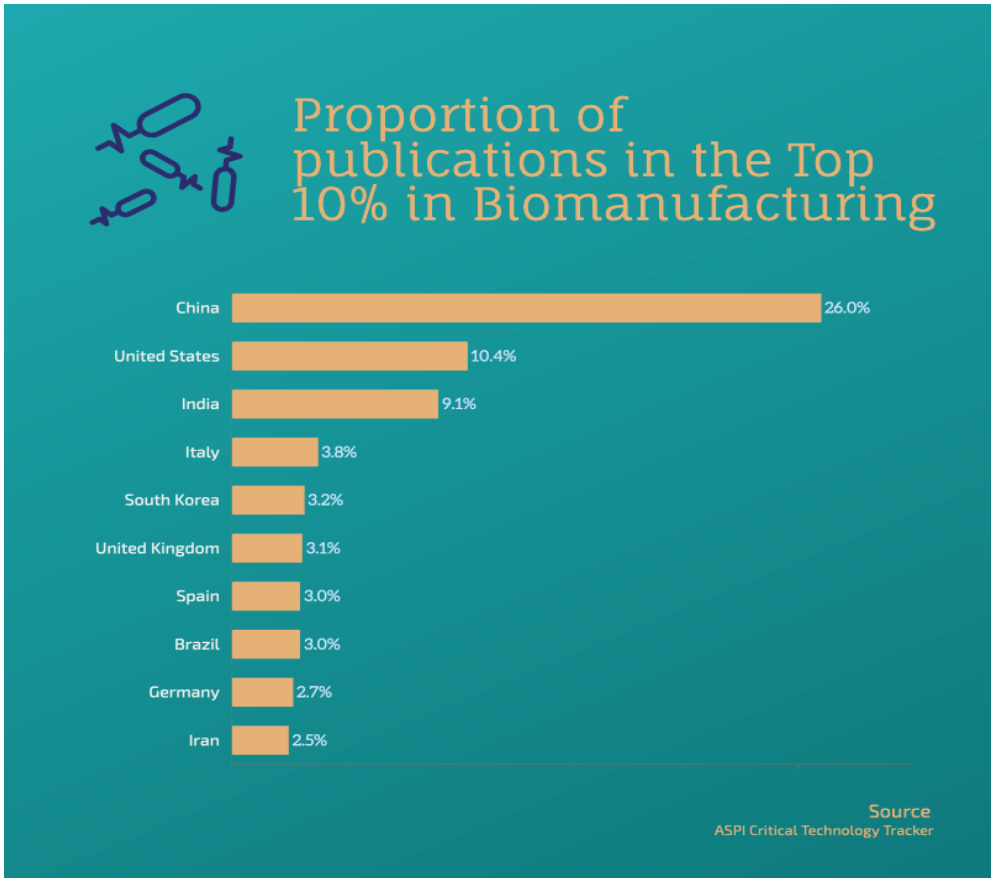

Figure 2 – Proportion of publications in the Top 10% in Biomanufacturing (Source: ASPI)[4]

India has the greatest potential to produce biomanufacturing products at a competitive price point, especially in the low-cost manufacturing of

enzymes, reagents and other research materials and equipment. As per industry analysis, cost of life sciences manufacturing in India is approximately 33% lower when compared with that of the US[5]. However, there are several constraining factors that need to be addressed to fully utilise India's biomanufacturing potential. India needs a massive capability uplift (as would any country in order to be a world-leading biomanufacturer). A major component of such an effort would be to promote primary research and development in the biomanufacturing field.

The leading academic research on biomanufacturing is happening in China. High-quality research does not always translate into real-world products, yet it demonstrates a strong research base on which it can build biological manufacturing capability. Quad countries must encourage further primary research in this sector, as well as a concurrent focus on industrial capacity. Without both the capability and capacity to produce at scale, the biomanufacturing revolution will pass the Quad by.

India also boasts multiple joint bilateral biotech collaborations with Quad countries, such as the Australia-India Council grants program (which includes numerous biotechnology projects each year), the Australia-India Strategic Research Fund (which includes biotechnology projects every year), the Japan-India dialogue (which includes agricultural projects), and a whole suite of disease surveillance projects between the US and India. Biotechnology has also been identified as an area for potential collaboration

under the newly announced U.S.-India initiative on Critical and Emerging Technology (iCET). This is the only tip of the pre-existing iceberg, which can be leveraged into multilateral initiatives involving all Quad partners.

IV. Structure and Functions of the Quad Biomanufacturing Hub in India

India already has various biotechnology hubs, especially in the southern region of the country. Thus, this proposal does not require establishing a hub from scratch but rather advocates for utilising the Quad to augment India's pre-existing efforts. We suggest three main areas in which the hub could work:

Strengthening the physical infrastructure for biomanufacturing

The Indian government has already committed to establishing India as a global biomanufacturing hub over the next few years. The India Bioeconomy Report published in 2022 by India's Biotechnology Industry Research Assistance Council (BIRAC) assesses the potential for a 10 million litres fermentation capacity to be set up in India in the next 3-5 years, a 10X increase from the current capacity of 1 million litres[6].

At this stage, Europe is the leader in bio-fermentation capacity globally.[7] But given the rapid changes in the industry, most of the future biomanufacturing capacity is yet to be built. Relatively little funding has gone into process optimisation to produce at scale when compared with the genetic engineering of novel microbes.[8] This is due to the uncertainty of future demand in the private sector, which will cause a significant shortage of biomanufacturing capacity if continued.

China is putting huge resources towards capturing the biomanufacturing market as it did with small molecule active pharmaceutical inputs (APIs), despite Europe's current lead in bio-fermentation capacity. Adrian van den Hoven, Director General of Medicines for Europe, states, "China and India are getting close to reaching the standards required for exporting biopharmaceuticals – and when this happens there is likely to be a lot of consolidation in the biopharma market."[9] The same will eventually be true in other biomanufacturing sectors, even in a potentially less globalised world.

In the section dedicated to the bioeconomy in China's 14th five-year plan (as well as a later 2022 standalone document on the bioeconomy from the National Development and Reform Commission), biomanufacturing at scale was a central theme across multiple applications such as plastics, oils, and industrial food production. The report states that there is a need to "solve the funding needs of companies for R&D and manufacturing[10]." Many countries express similar sentiments; however, China has successfully dominated

manufacturing on many emerging technologies. There is good reason to believe they will be successful in this endeavour.

India's efforts to compete with China will take time, and support. First, India does not create or possess IP for many patented products and will require licenses for production. Second, significant investment will be required to build new biomanufacturing facilities so that commercial scale-up is possible. Third, the cost of biomanufacturing will remain high until a large-scale threshold is crossed. Until then, Indian products will likely remain more expensive than their Chinese counterparts, necessitating the sourcing of like-minded partners for India to work with in the initial stages of developing a domestic biomanufacturing ecosystem.

These partners should be able to share with India the requisite technological expertise, and funding in order to support the shared interest in reducing dependency on China.

The proposed hub can play a critical role in this regard. It would facilitate discussions around tech transfer to help expand India's biomanufacturing sector. It would serve as a platform to connect savvy investors who would potentially be willing to invest in biomanufacturing facilities. Finally, Quad governments could jointly establish a biomanufacturing fund, administered through the hub.

Strengthening workforce capabilities for biomanufacturing

All countries that seek to build a biomanufacturing sector will need a workforce capability uplift, and India is no exception. While India has plenty of people trained in life sciences, they are often unable to access cutting-edge technology or training, creating difficulties in innovation. Examples of this could include high-throughput genetic screening technologies, flow cytometry, or novel types of CRISPR genetic manipulation.

Permanent training facilities could be established in universities around the Quad hub to aid this function. If necessary, experts from other Quad countries could perform the training, made easier through the recent policy changes in India, which allow the establishment of foreign universities, can encourage scholar exchange programs for this purpose. Bengaluru already has large biology and healthcare workforce, so the city is a natural choice for the hub.

Training should also occur on the commercialisation of R&D. This is a common challenge for non-US countries in the Quad as universities struggle to match their US counterparts in commercialising their R&D.[11] Currently, this "training" is often done informally through university outreach programs like Kyoto University's On-site laboratory program. This program includes partnerships with the University of California San Diego, the University of California Los Angeles, and the Gladstone Institutes, all of

which help showcase Kyoto University's research to potential US commercial partners.[12] Creating a formal training program to incorporate into the hub in order to teach the necessary skills regarding the commercialisation of research is crucial. On top of this, all the various programs that currently exist for collaboration between the other Quad countries and India can put their offices within the hub to build the rich network of connections that are so vital to creative innovative ecosystems.

Lowering barriers to research and commercial collaboration

Relative to their capabilities, Quad countries do not collaborate much on biotechnology. The easiest metric to measure the scope and depth of such collaboration is joint academic paper publications. Although academic papers do not represent all possible collaboration, they are still a useful guide to observe trends. Australia publishes more than double the papers with China than the other three Quad members combined on biochemistry, molecular biology, and genetics. Other members follow a similar trend (Figure 3).

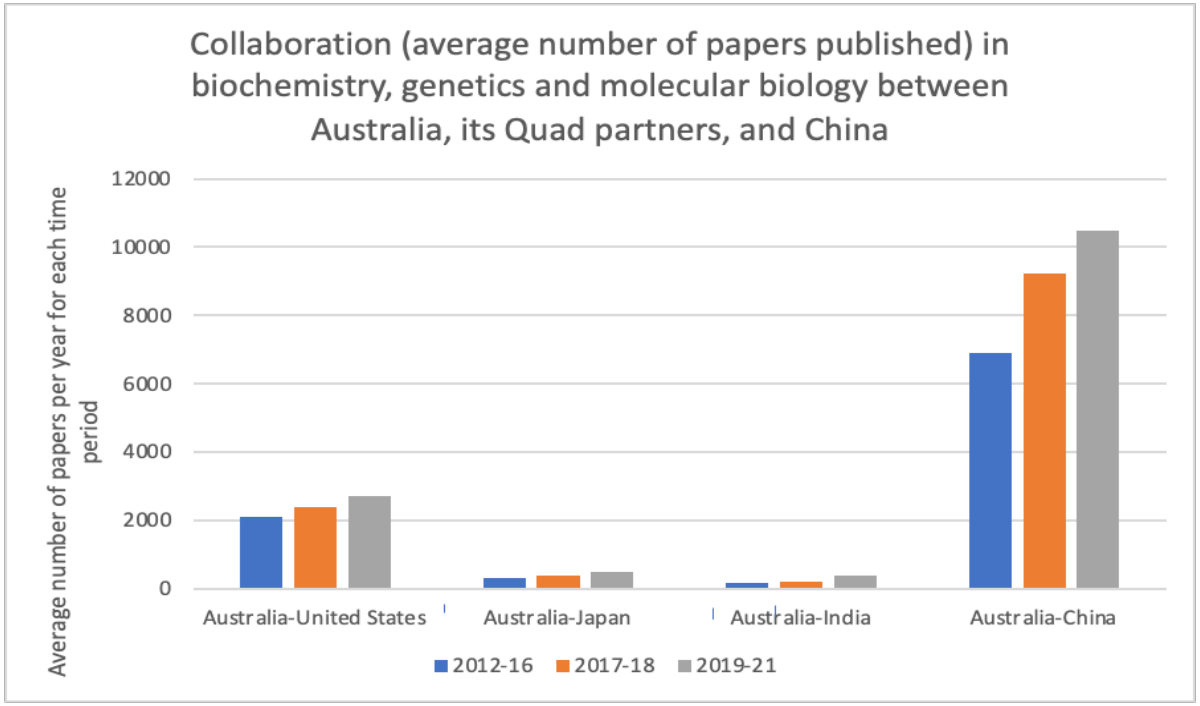

Figure 3 –Joint publishing between authors in Australia, Quad countries, and China (Source: Scival)

In the field of synthetic biology (Figure 4), which is a revolutionary emerging technology where genetic information of organisms can be edited to produce output that can be sold as products, China has the largest share in the top 10% most cited research papers according to data collated by the Australian Strategic Policy Institute.

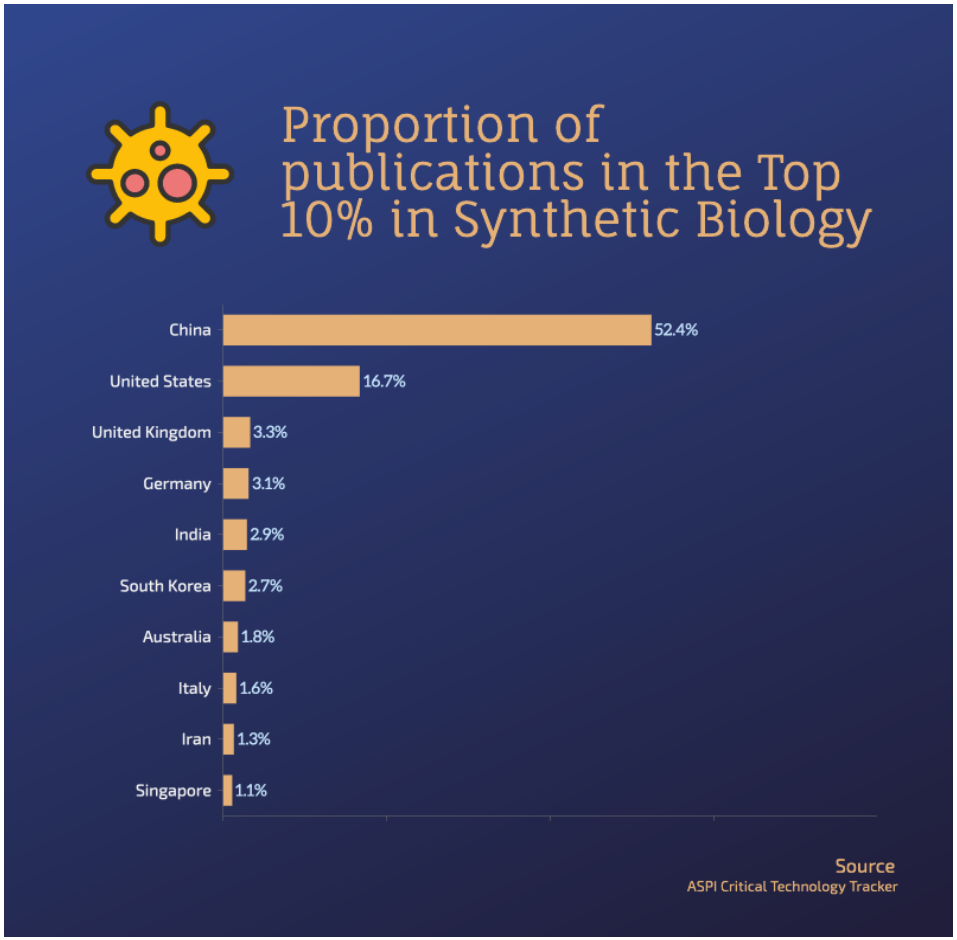

Figure 4 – Proportion of publications in Top 10% in Synthetic Biology (Source: ASPI)[13]

Both these pieces of information indicate an urgent need to increase academic research collaboration among Quad countries.

The proposed hub will help facilitate cross-Quad collaboration in this regard. It will initially exist as a place where the administration of all the current bilateral government efforts can be housed together inside the hub. This opens opportunities for more interaction between government representatives.

We also recommend the establishment of a research collaboration office within the hub. One major barrier to research collaboration between India and other Quad partners is that for Indian academics, it takes, on average, 70 days to get an interview for a visa application at US missions in India, and longer yet to get the visa[14]. This hampers the ability of Indian scientists to attend conferences in the US which is vital to develop the networks for collaboration.

One option is to simply speed the visa process up, which the US government is in the process of doing.[15] A more innovative approach is to offer a suite of rapidly approved visas through the research collaboration office which are flexible, quick and can allow many opportunities, such as six-month lab secondments at short notice.

Furthermore, both the biomanufacturing hub itself and the research collaboration office must help harmonise the language, regulations and data-sharing regarding biomanufacturing. This is important as these areas serve as a large barrier to the international collaboration needed to secure biomanufacturing supply chains for Quad nations. In order for this to occur,

the hub must utilise a shared language surrounding biomanufacturing, as well as create a standard of best practice for data sharing. The hub must also strive to produce a set of regulations that allow access to the commercialisation of products in each Quad nation, yielding maximum return on investment. While difficult, this harmonisation will not only boost collaboration efforts within the Quad but will also provide a scaffold for international collaboration within biomanufacturing. This allows a "Quad +" attitude to eventuate, further harnessing the capabilities of nations outside the Quad.

V. Conclusion

The biomanufacturing hub in India can capitalize on the economic potential of the biomanufacturing industry and address existing and potential vulnerabilities in the global system. Due to its established infrastructure and expertise in pharmaceutical manufacturing, as well as its potential for low-cost manufacturing, India can become a leading country in biomanufacturing to allow the Quad to compete in this key area. The hub can play a key role in this.

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