The skills agenda for vaccine manufacturing

On 30 May 2022, the Future Vaccine Manufacturing Research Hub (the 'Vax-Hub) held an online sandpit workshop to discuss the skills agenda for vaccine manufacturing. The workshop brought together the Vax-Hub team with a range of national and international stakeholders involved in vaccine development, manufacturing, delivery, and policy.

Context

The current COVID-19 pandemic has proven that global vaccine manufacturing capacity is insufficient to meet demand, particularly in times of crisis. Throughout the pandemic, those living in low and middle-income countries (LMICs) have borne the brunt of COVID-19 vaccine dose shortages; countries with the highest incomes have been vaccinated 10 times faster than those with the lowest,[1] and those vaccines which were available were largely imported from high-income countries and through the COVAX scheme.[2] As a result, stakeholders around the world are working to increase global vaccine manufacturing capacity, particularly in LMICs, (with notable activity on the African continent),[3] for better global health security and equity.

Enhanced manufacturing capacity in LMICs will likely rely largely on technology transfer, where the knowledge and ability required to carry out a manufacturing process is shared from an originator to a secondary user. In order to support successful technology transfer, a supply of locally-based skilled workers is required to execute the complex processes to manufacture a vaccine, particularly in bioprocessing, regulation, and quality assurance. In the African continent alone, it is estimated that 10,500 new employees must be trained in vaccine development and manufacturing to meet ambitions for the African vaccine

Key points

1. In order to achieve the ambitions to increase global vaccine manufacturing capacity and conduct successful technology transfer, especially in LMICs, concerted efforts are required to train a new workforce of highly skilled bioprocessing specialists.
2. There are skills shortages in a range of different vaccine manufacturing activities covering the entire value-chain for vaccine manufacturing ranging from vaccine discovery to logistics, production and quality control.
3. Organisations such as the Vax-Hub could play a valuable role in providing additional training capacity, especially in new and innovative processes, but coordination with existing networks and manufacturers to identify gaps where training opportunities are lacking is vital.

The Vax-Hub

The Vax-Hub is a five-year research programme (2018-2023) funded by the UK's Department of Health and Social Care's Official Development Assistance programme, the UK Vaccine Network. The Vax-Hub's mission is to secure supply of essential vaccines to LMICs.

At the time of writing, the team are planning a succession "Vax-Hub 2" in order to continue the important work undertaken by our team throughout the first Hub. Process development studies using single-use technologies as well as next-generation sequencing methods have enabled rapid process development of the ChAdOx-1 viral vector vaccine, more than 2.8 billion doses of which have now been delivered worldwide.

"We are very excited to be a translational spoke within the Vaccine Manufacturing Hub and to collaborate with the team on developing new technologies to improve the expression of our Dengue vaccine, shorten development times and benefit from economic models to achieve low costs."

- PT Biofarma Indonesia

manufacturing industry to develop, produce, and supply over 60 per cent of the total vaccine doses required on the continent by 2040.[4]

The workshop

The aim of this workshop was to identify the key gaps in vaccine manufacturing skills development opportunities in LMICs to build the necessary workforce for local production of vaccines and identify how a future research programme "Vax-Hub 2" could build on existing training resources and activities to contribute to local manufacturing efforts. To prepare participants for the ensuing discussions, presentations were provided by:

- The Vax-Hub, who informed participants of training activities undertaken in the first Hub, which included funding nearly 50 places for LMIC manufacturing staff to attend CPD courses in vaccinology and bioprocessing run by the Vax-Hub lead organisations, the University of Oxford, and University College London. Other activities included the development of an online training course 'Towards improved tools and technologies for vaccine manufacturing', which is expected to be freely available to LMIC biotech professionals and academics by the end of 2022;
- The Coalition for Epidemic Preparedness (CEPI), who shared insights gathered on existing workforce training initiatives as part of a mapping exercise conducted by the COVAX Manufacturing Taskforce;[5] and
- The World Health Organisation (WHO), who shared learnings from various training programmes undertaken by the organisation and provided insights into gaps in provision that they uncovered as part of establishing their mRNA technology transfer Hubs.[6]

This report summarises the discussions from the two questions put to our participants, (namely: what are the biggest skills shortages, and what activities should the Vax-Hub prioritise), and highlights possible training activities for the Hub to take forward in a future research programme.

What are the biggest skills shortages in the vaccine manufacturing industry?

In addition to a general shortage of graduates entering the vaccine and bioprocessing sectors, a range of different vaccine manufacturing activities were highlighted by participants where there were particularly pressing skills shortages. These activities covered the entire value-chain for vaccine manufacturing ranging from vaccine discovery to logistics, production and quality control. Some specific examples included;

- Moving a vaccine from the research and development (R&D) phase into production. This included implementing the requirements set out in Good Manufacturing Practices (GMP), a set of guidelines used by regulatory agencies to ensure that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use.

- Building on the previous point, participants felt that a gap existed in the implementation of quality by design (QbD) principles and quality management systems to assess and deliver products to a high standard.
- When expanding manufacturing from a single site to multiple locations, or through technology transfer, participants highlighted knowledge and skills gaps in demonstrating comparability between processes and products produced at those sites. Within the same site, challenges were highlighted around showing comparability between batches of product.
- Skills for regulatory strengthening, which has been identified as a key pillar of the Partnerships for African Vaccine Manufacturing initiative.[3] It was felt shortage of individuals competent in regulatory sciences would result in local vaccine manufacturing efforts being hampered through a lack of local regulatory frameworks and creating an innovative and enabling environment for vaccine manufacturing.

Which training initiatives should the Vax-Hub prioritise?

There was consensus that training needs vary widely according to the location of a manufacturer and their level of current vaccine manufacturing knowledge. As such, consultation with vaccine manufacturers and relevant stakeholder networks, e.g. the Developing Countries Vaccine Manufacturing Network (DCVMN), is key. Participants were broadly supportive of the Hub's current and future training plans and shared additional ideas on how these could be enhanced:

- At the UK level, participants felt that the Vax-Hub should prioritise activities that would encourage a pipeline of talented individuals to enter the sector, with the focus ranging from schools-based outreach to doctoral training. Linking with complementary sectors such as the cell and gene therapy sector was recommended and in particular the Advanced Therapies Skills Training Network (ATSTN).[7] A stronger UK workforce would help build the number and availability of 'sending partners' for the technology transfer activities necessary to enhance capacity for local production.
- Participants agreed that the Vax-Hub plans to launch an open-access online training course would provide value to its network of manufacturing partners and could form part of the continuous professional development opportunities offered and encouraged by those companies. The online format would allow flexible uptake by the widest number of staff in a manufacturing organisation. Certification for completing the different modules provided was strongly encouraged, with eCornell offering a potential model to adopt.[8] It was highlighted that the training material should be offered in the local language to provide the most utility. Whilst most aspects of the training course could be offered online, participants emphasised that a hybrid model with some hands-on experience is essential. This blended approach would enable the 'receiving partners' for technology transfer to take up the knowledge and embed new processes more successfully.

Participant list by organisation

The workshop brought together 15 participants from the following organisations:

- Cell and Gene Therapy Catapult (CGTC)
- Coalition for Epidemic Preparedness Innovations (CEPI)
- Foreign Commonwealth and Development Office (FCDO)
- Gavi
- Medicines Patent Pool
- PATH
- PT Biofarma
- Vabiotech
- Vax-Hub
- World Health Organization (WHO)

Technology transfer is the act of sharing the knowledge and ability required to carry out a manufacturing process from an originator to a secondary user. Challenges can include local capabilities and the strength of supply chains.

References

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2. COVAX Access to COVID-19 Tools (ACT) Accelerator. www.who.int/initiatives/act-accelerator/covax
3. "Africa is bringing vaccine manufacturing home", Nature, 602, 184 (2022). www.nature.com/articles/d41586-022-00335-9
4. Partnerships for African Vaccine Manufacturing (PAVM) Framework for Action, 2022. africacdc.org/download/partnerships-for-african-vaccine-manufacturing-pavm-framework-for-action/
5. CEPI COVAX Vaccine Manufacturing Taskforce. cepi.net/news_cepi/covax-manufacturing-task-force/
6. WHO mRNA vaccine technology transfer hub. www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub).
7. Advanced Therapies Skills Training Network. www.atskillstrainingnetwork.org.uk/
8. eCornell. ecornell.cornell.edu/

- Further to the point above, support for hands-on GMP training and those initiatives which could help manufacturers improve their quality management processes would be welcomed.

Conclusion and next steps

In order to achieve the ambitions to increase global vaccine manufacturing capacity and conduct successful technology transfer, especially in LMICs, concerted efforts are required to train a new workforce of highly skilled bioprocessing specialists. This covers a very broad range of roles and activities from bringing new graduates into the sector to the continuous professional development of those already in the vaccine manufacturing sector, or related ones such as the cell and gene therapy sector. Organisations such as the Vax-Hub could play a very valuable role in providing additional provision, especially in new and innovative processes, but coordination with existing networks and manufacturers to identify gaps where training opportunities are lacking is vital. The Vax-Hub will use the ideas generated in this workshop to inform the activities in their research proposal for a Vax-Hub 2 to continue and build on activities from the first research cycle. This proposal is being developed in Spring/Summer 2022.

Our research

This workshop and report was produced in partnership with UCL STEaPP's Policy Impact Unit (PIU) as part of the work carried out by the Future Vaccine Manufacturing Research (Vax-Hub). The Vax-Hub is jointly led by UCL and the University of Oxford and funded by the Department of Health and Social Care's UK Vaccine Network, and managed by the EPSRC.

To find out more, please visit: https://www.ucl.ac.uk/biochemical-engineering/research/research-and-training-centres/vax-hub

Vax-Hub team: contributors

The Vax-Hub is co-directed by Professor Dame Sarah Gilbert (sarah.gilbert@ndm.ox.ac.uk), Pandemic Sciences Institute at the University of Oxford, and Professor Martina Micheletti (m.micheletti@ucl.ac.uk), Department of Biochemical Engineering, UCL. Dr Penny Carmichael (p.carmichael@ucl.ac.uk), is a policy advisor to the Vax-Hub and is based in the PIU.