Celebrating sector collaboration on COVID-19 vaccines

The work of BioIndustry Association (BIA) member companies in supporting COVID-19 vaccine manufacturing efforts is an incredible case study in the work our sector can achieve through close collaboration between different parts of the life sciences ecosystem. The work of the BIA COVID-19 Vaccine Manufacturing Taskforce was explored in further detail at the BIA's bioProcessUK conference 1-2 December 2020. The Taskforce has been supporting manufacturing and scale up efforts for both the Oxford University Jenner Institute's ChAdOx vaccine and Imperial's RNA Vaccine.

As the third largest biotech and life sciences cluster in the world, the UK has a proud historical track-record of science and medical discovery. The UK life sciences and biotech sector has almost 6000 companies operating within it and supports 482,000 jobs, two-thirds of which are outside London and the South East, giving the sector a strong foundation of diverse innovative companies with highly-skilled workforces and industrial capability already working on ground-breaking treatments and products. As the COVID-19 virus spread, it was clear that networking the incredible expertise and resources of the BIA membership would be a key strategic priority for us as a trade association.

The BIA's manufacturing community has been at the heart of efforts to understand the challenges of the manufacturing and scale up of a successful COVID-19 vaccine. Industry and academics from all corners of the UK have contributed their expertise and resources, to find solutions to this monumental challenge by supporting both the Oxford University Jenner Institute's ChAdOX and Imperial's RNA vaccine. The ChAdOx vaccine (now AZD1222) was co-invented by the University of Oxford and its spin-out company, Vaccitech.

As these projects moved from advice to multi-million-pound contracts, there was a natural stepping-off point for the BIA from the point-of-delivery co-ordination. That moment arrived in July, where we handed over the delivery baton to the UK Government's Vaccines Taskforce.

The experts and capacity organised via our initial Taskforce continue to deliver their vaccines work directly to the Government. The BIA has retained a strategic advisory function ready to help but is not responsible for overseeing the programme management of what has become a series of key UK State deliverables.

Please read on for more details on the work of the BIA COVID-19 Vaccine Manufacturing Taskforce.

How did it start?

The BIA in mid-February, building on its work from the Ebola crisis, conducted an audit of its manufacturing community to assess supply chains and to understand if we had the manufacturing capability here in the UK, to support the scale up of a successful COVID-19 vaccine.

After considerable interest from a number of member companies, the BIA convened the BIA COVID-19 Vaccine Manufacturing Taskforce to support efforts to assess UK supply chains and scale up any successful COVID-19 vaccines by Oxford University and Imperial College London.

The taskforce supported the Jenner Institute's adenovirus vaccine candidate at the University of Oxford, led by Dr Sandy Douglas, with Professor Sarah Gilbert and the Clinical BioManufacturing Facility. There was a successful bid to UK Research and Innovation (UKRI) in partnership with BIA members Pall Biotech, Fujifilm Diosynth Biotechnologies, Cobra Biologics, Cell and Gene Therapy

Catapult, the Vaccines Manufacturing Innovation Centre (VMIC) and Oxford Biomedica to develop rapid scale up of such a vaccine. Along with CPI, members of this group also supported the work of Imperial College London, led by Professor Robin Shattock, on their mRNA vaccine.

The group was chaired by Ian McCubbin OBE, Chairman of RoslinCT, and assigned experts to relevant workstreams and appointed leads to report back on a weekly basis. These workstreams were broken into Adenovirus vaccine, mRNA vaccine manufacture and formulation, antibody, fill finish, supply chain, progress on the Vaccine Manufacturing Innovation Centre (VMIC) and communications.

Netty England, bioprocessing consultant at the BIA, explains: "The number and variety of companies coming forward from the manufacturing audit meant we were able to approach the Jenner Institute and Imperial with a real solid offer of help.

"We had a group which spanned all areas of drug manufacturing combined with the scientists and researchers working on the drug discovery. By putting these groups together, we could assess and estimate in real time what manufacturing capability would be needed to support progress of the vaccine to pre-clinical and human clinical trials, and if successful, what would be required to get this out to patients."

Working collaboratively at speed

The development of a vaccine takes seven years on average from discovery to being accessed by patients. The global demand for a COVID-19 vaccine remains at an unprecedented level. The Taskforce worked at rapid pace to assess and mobilise existing UK manufacturing capacity for COVID-19 vaccines. The group also explored where capacity would have to be added.

Kit Erlebach, Strategic and Transformational Venture Manager FUJIFILM Diosynth Biotechnologies explains, "Through the BIA's COVID-19 Vaccine Manufacturing Taskforce, we were able to coordinate with other companies and wider supply chain in the public interest. Our Chairman, Steve Bagshaw led these conversations which centred on "what can we do to supply the UK with what they need to get a vaccine?"

"What this meant is that when the list of items came from Oxford or Imperial, or anywhere else, we worked out what we needed and were able to communicate it with all suppliers. This gave us one route into those organisations to say, this is what the vaccines are asking for – each supplier can then separately answer what they can do to help. Another benefit was everyone getting the information at the same time, so all of us were able to prioritise separately our individual supply chains."

Steve Bates, Chief Executive of the BioIndustry Association says: "Workstream leads were meeting on a weekly basis to share updates and latest thinking which was invaluable in those early days as lockdowns began. Members were able to go to these meetings and say 'we have found X but we need Y to make this happen', with the capability in the group other companies were able to raise their virtual hands and say 'yes, we can help with that'.

"We have undersold somewhat, that when you look at the makeup of this group, how many of the companies are commercial competitors. Perhaps the most important and long-lasting impact of this work, is the level of collaboration between the different parts of the sector."

This thought is echoed by Dave Tudor, Managing Director – MMIC, Biologics and Quality at CPI: "The Taskforce has shown what can be achieved through collaboration rather than competition, and we believe that the relationships forged between companies, research centres and academia will continue to advance bioprocessing in the UK.

"The creation of a triple helix partnership between Academia, Industry and Government (including innovation infrastructures) has enabled quick understanding, fast decision making and action response. The creation and cementing of these collaborative relationships for new and novel modalities will help to grow and secure innovation in the UK and globally."

Peter Coleman Chief Executive of Cobra Biologics agrees: "At Cobra, we have seen unprecedented collaboration between companies and that extra communication channel into industry was incredibly useful too."

Dr Stephen Ward, Chief Manufacturing Officer at the Cell and Gene Therapy Catapult, adds: "The Taskforce's rapid, collective response has seen academia and industry pooling their shared knowledge and capability to expedite the process from clinical trials to manufacturing, doing so with the unified goal of doing what is best for the country and the global population. In bringing industry and academia together, the Taskforce is speeding up the process that will quickly deliver a vaccine to patients."

Working with government

As governments around the world reacted to the pandemic, the BIA ensured that the work of the group was aligning to the UK Government's response to COVID-19. Steve Bates of the BIA explains: "Our Taskforce was able to provide information directly to Sir Patrick Vallance and with the appointment of Kate Bingham in May, we were able to strengthen and deepen those links in the Government's Vaccine Taskforce.

"Within government, to be able to draw on this expert advice to understand the challenges of scaling up and manufacturing vaccines at pace has been critical in securing vaccine supply and aiding planning efforts on deployment of COVID-19 vaccines here in the UK.

"The Taskforce was also able to help develop business cases for funding. We were able to tell government 'this is what we're going to need to scale up Oxford or Imperial' and the success of getting £14m invested early by the Government in April for developing COVID-19 vaccines, helped lay the manufacturing foundations before AstraZeneca took over."

Dave Tudor explains how Taskforce members were brought into government efforts: "CPI was invited to be part of the UK Government's Vaccine Manufacturing Taskforce in March and played a key role in identifying UK options for development, manufacture and supply of RNA vaccines."

Kit Erlebach remarks: "Through Ian McCubbin and Steve Bates, the information we were providing was going directly into the Government's Vaccine Taskforce to help them with vaccine planning efforts - it was a real asset for the UK bioindustry, having a trade association with those sector wide and government links."

A deal was struck in April between Oxford University and AstraZeneca, which added valuable industrial heft in the efforts to support research, manufacturing and distribution of the ChAdOx vaccine. BIA member companies at this very moment continue to support the production of the AstraZeneca and Oxford University adenovirus vaccine.

Ian McCubbin reflects on the success of the taskforce: "There is no doubt that the BIA Taskforce created the momentum to form the UK based supply chains for the Oxford University & AstraZeneca vaccine and the Imperial RNA vaccine, which accelerated the development and scale up of the AstraZeneca vaccine in particular."

Projects the BIA Vaccine Manufacturing Taskforce supported:

- Helped plans to bring forward the opening of the Vaccine Manufacturing Innovation Centre (VMIC)from 2022 to 2021
- Creating a legacy GMP capability at the CPI National Biologics Manufacturing Centre in Darlington
- £100 million was awarded by the Government to fund a Cell and Gene Therapy
 Manufacturing Innovation Centre in Braintree, which is due to become fully operational in
 December 2021
- The Government also awarded £4.7m for new training facilities and an online platform to boost vaccine as well as cell and gene therapy skills, through the Cell and Gene Therapy Catapult
- Secured initial government grant funding for manufacturing and scale up of Oxford and Imperial vaccines
- Members engaged with the MHRA to ensure the regulator understood areas of flexibility

Dave Tudor reflects on these successes: "Government investment in the triumvirate of CPI, CGTC and VMIC has been a critical achievement which will provide a wide ranging and comprehensive capability for the UK. The legacy that this work will leave will not only be critical for the pandemic response but will provide also provide a lasting capability for long term growth of the economy."

Kit Erlebach adds his thoughts on how the MHRA have operated during this period: "Where we have seen another gain is with the MHRA. The MHRA's position has been incredibly clear that they won't be cutting any corners, but they have created flexibility for industry to explain how we're manufacturing vaccines faster and how we plan to overlap."

Stephen Ward explains how the funding the Cell and Gene Therapy Catapult has received, is being used to develop the next generation of workers in bioprocessing: "The Advanced Therapies Apprenticeship Community, which we deliver in close collaboration with industry, has also been playing their part. ATAC's first graduate, Emilia Reyes Pabon, has worked as a Level 3 Operations Technician apprentice at the University of Oxford's Clinical BioManufacturing Facility. Through upskilling and training new blood coming into the workforce, ATAC has been nurturing talent that has shown a measurable impact in developing the ChAdOx vaccine, including helping to define standard operating procedures in this new field of research. Well done Emilia – what a way to start your career!"

The online training platform, part of the £4.7m of funding by the Government and led by the Cell and Gene Therapy Catapult will be launched at <u>bioProcessUK</u>, while the national training centre networks are currently being developed.

What does this mean for the future of UK bioprocessing and manufacturing?

While immediate attentions rightly focus on tackling COVID-19, what future opportunities exists for the UK's bioprocessing and manufacturing community moving forward?

Peter Coleman: "Bioprocessing and medicine manufacturing have a much better profile than before the pandemic. There is now a greater understanding of the vital role the likes of Cobra play in life science product development and shows the opportunities for the UK to be a leading global manufacturer if we have the right fiscal landscape. Through the work the BIA has done, they have really enhanced the profile of the wider UK Advanced Therapy Medicinal Products manufacturing sector.

Dave Tudor: The UK bioprocessing industry has always been collaborative, demonstrated through the success and achievements of sector initiatives such as BRIC and BioProNET. This Taskforce has demonstrated this further, bringing in more players and working against challenging timelines.

"If we consider RNA manufacture specifically, the work of the Taskforce will leave a legacy that positions the UK as a global leader in the development and manufacture of this breakthrough platform technology. Advanced drug encapsulation systems are critical to the success of advanced therapy treatments and the UK has the opportunity to take the lead in some key areas of this science advancement, e.g. Lipid Nano Particle development and scale-up, through key nanoformulation and drug delivery expertise at CPI and other UK partners."

Stephen Ward: "In showing the importance of robust supply chains on a national and international level, I believe we will see a nationally adopted roadmap and framework that will quickly upscale future Advanced Therapeutic Medicinal Products. By coordinating a national infrastructure across private and public sectors, we could see new treatments delivered to patients with unique and complex conditions.

"I also believe that the work of the Taskforce will develop a greater awareness in the importance of life sciences in manufacturing and supply in maintaining the health of the nation and driving economic growth. The subsequent effect would be a continued investment in UK skills to meet the needs of a growing workforce."

Ian McCubbin: I really hope it will give the UK confidence and lay deeper foundations for economic prosperity by creating more manufacturing capability, and jobs"

Steve Bates concludes: "My favourite phrase to describe this period is 'sometimes nothing happens for decades, but sometimes decades happen in a weekend.' What I mean by that is some of the things we thought would take years to achieve have, through this pandemic accelerated at an unprecedented pace.

"The work of this group and others has revealed to policy-makers the need for having a growing and thriving manufacturing capability here in the UK. As global economies emerge from COVID-19 we will be making the case that investment in this area will be fundamental in delivering economic growth, highly skilled and well paid jobs and most crucially, enhancing our world leading capability here in the UK to tackle future pandemics."

ENDS

The BIA engages its manufacturing community through the work of its Manufacturing Advisory Committee and by supporting the work of the Medicine Manufacturing Industry Partnership, with industry colleagues. For further information, please contact Jack Fellows, Communications and Media Manager at the BioIndustry Association.