

COMMENTARY

Pioneering technological innovation and sustainability in vaccine manufacturing to ensure pandemic preparedness and global access

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The COVID-19 pandemic demonstrated the potential of accelerated vaccine development and manufacturing but also exposed systemic weaknesses in global preparedness and equitable access. Today, with the world still at risk of new pandemics exacerbated by climate change, there is an urgent need to reimagine vaccine manufacturing through the dual lenses of technological innovation and environmental sustainability. In this article, we explore key enablers for minimizing waste and embedding circular economy thinking into vaccine research and production. We discuss VaxHub Sustainable as an example of how to integrate multidisciplinary expertise to support vaccine technology innovation and minimize the environmental footprint of vaccine manufacturing. By aligning pandemic preparedness with sustainable bioprocess design, this work aims to ensure resilient vaccine manufacturing for the future.

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Vaccines are one of the most important tools we have in promoting global health and wellbeing. A recent report estimates that in the last 50 years over 150 million lives (six lives every minute), of which 101 million have been infants, have been saved by the WHO Expanded Programme on Immunization, launched in 1974 [1]. During the COVID-19 pandemic, vaccines are estimated to have saved over 20 million lives worldwide [2]. While vaccine

development has historically taken decades, the recent development, manufacturing and deployment worldwide of COVID vaccines within 18 months demonstrated that this can be achieved more quickly—but at a large financial cost. The Independent Panel, co-chaired by the RH Helen Clark and HE Ellen Johnson Sirleaf, that reviewed the global COVID-19 response found weak links at every point of the chain of preparedness and response, and concluded

that major losses could be prevented by sustained domestic investment in public health [3]. The WHO have highlighted a list of pathogens that should be monitored for their epidemic potential [4] and we remain at risk of new pandemics, e.g., H5N1 and mpox. Meanwhile, a recent report highlighted that the world is still in many ways unprepared [3].

In the case of seasonal influenza vaccine, manufacturing capacity has remained relatively constant over the last 5 years, at around 1.53 billion doses [5]. Despite the need for global access, the Global Vaccine Market Report [6] found that just ten manufacturers were supplying 75% of total vaccines doses (excluding COVID-19), with the rest being manufactured by more than 80 stakeholders. The vast majority of vaccines required by the African and Eastern Mediterranean regions continue to come from outside these areas. This has led to increasing calls for initiatives to establish and support more regional development and manufacturing. Such initiatives include the establishment of the Regionalized Vaccine Manufacturing Collaborative formed by the World Economic Forum, the regional manufacturing strategy by GAVI and the mRNA Technology Transfer Programme sponsored by the WHO.

COVID vaccines relied heavily on new technologies in which the UK had a leading role, especially the development of the adenoviral vector systems used by the Oxford-AstraZeneca collaboration. Moving forward, however, will require significant research on a broader range of technologies. To enable the UK and the world to be better prepared for the next pandemic and improve and support local manufacturing, initiatives could focus on:

- ▶ De-risking manufacture of new vaccines by strategically innovating for a selected range of the most promising platform technologies (established and novel/disruptive);

- ▶ Developing manufacturing options that improve the product quality and so immunogenicity;
- ▶ Streamlining manufacturing process development with novel responsive solutions and advanced digitalization strategies;
- ▶ Enhancing stability and needle-free administration routes.

In addition, given the increased risks posed by climate change and wider sustainability challenges, initiatives to improve both the economic and environmental sustainability of vaccine manufacturing and supply will be essential. The vision of initiatives like EPSRC-funded Manufacturing Research Hub for a Sustainable Future (VaxHub Sustainable) is to embed sustainability in research objectives as well as in operations, all designed to minimize environmental impact and carbon emissions, while maximizing use of resources and decreasing waste. VaxHub Sustainable brings together a multidisciplinary team of leading researchers with decades of cumulative experience in all aspects of vaccine design and manufacturing research, as well as industry scientists and policymakers, to propose radical change in vaccine development and manufacturing technologies.

THE UK POLICY LANDSCAPE

The adoption at scale of sustainability-focused innovations in the vaccine manufacturing sector requires a joined-up policy approach across multiple areas including infrastructure, cross-sectoral knowledge sharing, regulation and standards, which address existing barriers whilst creating incentives that accelerate such innovations. The **UK Industrial Strategy**, as well as the **upcoming Circular Economy Strategy for England**, present

clear opportunities for the UK government to set out its long-term vision and the policy mechanisms to drive investment in technologies that enable sustainability and resource circularity. At an international level, other countries have committed to ambitious goals for harnessing the potential of such technologies, with the European Commission launching a Biotech and Biomanufacturing Hub as part of its strategy to boost biotechnology and biomanufacturing in the EU [7].

A key element of advancing sustainability in vaccine manufacturing, and in the life sciences sector more broadly, is the facilitation of close collaborations between academia, industry and policymakers [8], which is a key pillar of the work of **VaxHub Sustainable**. Collaboration is also important across the supply chain, including with other sectors such as clean energy and digital technologies. Government action can help to create a robust innovation ecosystem by fostering knowledge sharing and cross-sectoral collaborations on net-zero and wider sustainability challenges [9,10]. An illustrative example is the **Sustainable Medicines Manufacturing Innovation Programme**, led by Innovate UK, which focuses on enhancing the UK's pharmaceutical manufacturing innovation ecosystem and promoting sustainable practices.

The pharmaceutical industry is highly regulated due to the importance of ensuring the safety and efficacy of its products, including vaccines. At the same time, regulatory standards can act as a barrier when it comes to increasing the sustainability of vaccines [9]. For example, it is challenging to change manufacturing processes to meet sustainability goals once they have been approved as meeting GMP standards [11]. If regulation is to support the adoption of sustainability-focused changes across the pharmaceutical industry, a more proactively enabling approach is required; more specifically, the assessment of new products by the regulator could include sustainability

as a criterion, alongside quality, efficacy, and safety [12]. This would also require having an agreed framework that clearly articulates which sustainability-related factors should be measured and what data should be collected and reported. Any such framework would also be dependent on having a common language for bioprocess development, similar to the minimum information standards developed for biosciences [9]. The recently created **Regulation Innovation Office** focuses on engineering biology as a key emerging technology and could be well-placed to incentivize innovations geared towards sustainability in vaccine manufacturing through targeted regulatory reform.

Common standards and metrics have an equally essential role in supporting innovation in sustainable vaccine manufacturing. There is currently a lack of unified methods, data systems, and metrics for measuring and communicating the environmental impact of medicine manufacturing, which has led to fragmentation and different stakeholders using different sustainability targets [9,13]. The UK Government could provide leadership and enable the adoption of sustainability measurements and standards by building on existing initiatives like the **BSI Environmental Impact of Pharmaceutical Standards Hub**, which is aiming to build consensus on a method for assessing the environmental impact of medicines.

ENVIRONMENTAL IMPACT TOOLBOX & WASTE REDUCTION

Although the pharmaceutical industry is a significant contributor to greenhouse gas emissions (GHG) [14], this has not been researched to the same extent as in the case of other industries [15]. When compared to other industries, there is also a notable lack of low-carbon pharmaceutical products [9,16]. One of the challenges is that claims of sustainability for bioprocesses need to be substantiated with evidence.

Life Cycle Assessment (LCA) tools are currently being implemented at all stages of the manufacturing supply chain, and there are pressures on suppliers to provide data on sustainability impacts. The ISO standard specifies four steps to conduct any LCA: goal and scope definition, life cycle inventory, life cycle impact assessment, and interpretation. The system boundary is defined upfront and determines what is counted when evaluating footprint. Drawing this boundary in a fair manner to be able to compare new manufacturing systems side-by-side requires knowledge of the wider production workflow to prevent discounting of impacts that lie outside of the factory gate [17]. For instance, cell-free synthesis still relies on production of enzymes, which requires associated fermentation-based resource. Converting inventory data to impact assessments relies on LCA databases that have relatively few of the key ingredients used in vaccine manufacturing: media components, buffers and also materials used for single-use equipment. This makes translating inventory data into process impacts rather cumbersome, and relies on calculating this from scratch, or making substitutions that can be a source of inaccuracy. Conjoint efforts to contribute to databases such as EcoInvent will increase the ability of the field to produce consistent LCA information. Biological manufacturing has a number of aspects that are distinct from chemical synthesis; notably, process variability and the generation of biogenic carbon. Within the sector we need thought leadership to harmonize how these factors are considered. After the impact assessment, while carbon is a primary focus of—due to net zero pressures—it is vital that this is not the sole criteria that is used for decision making. Solutions that drive down carbon can have unintended consequences; for example, driving up land use change or other emissions or reducing the lifespan of

the components. Therefore, sustainability must be considered in a truly holistic manner. For emerging production systems, the ability to perform *ex ante* LCA enables developers to leverage the design freedom to embed sustainability at an early stage, where the greatest gains can be made while navigating considerable uncertainty [18]. Decision-making in sustainability is surprisingly complex, and to facilitate good choices requires a fluency in LCA amongst members of the industry, and clearer mechanisms to communicate the trade-offs between options.

One innovative approach could be to consider vaccine manufacturing as part of industrial ecology, which involves systematically considering the relationships between society, the economy, and the natural environment. Within this framework, the circular economy has been an umbrella concept [19] to describe techniques for prolonging resource utilization by understanding the mass and energy flows of a system. By considering opportunities for reuse, recycling, and remanufacturing the industry can minimize waste. Yet the biopharma industry, including the vaccine manufacturing space, has not been a visible participant due to tight regulations, concerns about release of genetically modified organisms or lack of compatible solutions.

The view that the ‘polluter pays’ is a key principle behind EU environmental policy. Biotechnology at scale, especially bioprocesses that rely on substantial purification strategies, inevitably generate substantial aqueous waste streams. Recycling through membranes is a potential option, but this has implications on brine generation and energy consumption that must be balanced [20]. Alternatively, industrial symbiosis is one approach where value can be derived from spent materials by cascading waste streams through activities that share requirements for specific inputs. There are few examples of this at scale, but Kalundborg Symbiosis in Zealand,

Denmark has several biotech participants [21] who receive steam, share treated surface water, produce biogas from spent biomass after enzyme manufacturing, and supply surplus heat to district heating schemes. The demonstrable success of Kalundborg illustrates the importance of the carbon-water nexus. Activating networks such as this involve entities outside the company framework and creating trusted partnerships. As aforementioned, an engaged network, comprising stakeholders from the sector (academia, industry, policy makers, and other organizations worldwide), is vital to ensure technological innovation while minimizing environmental impact.

Design of integrated solutions for resource management also enables companies to achieve insetting, as opposed to offsetting, of emissions, where the facility itself is an important place to begin. Viewing the manufacturing site itself as having the capacity to remediate, or participate in ecological cycles, is an opportunity for innovative design and the creation of green infrastructure [22]. Understanding which loops can potentially create a relationship between inner and outer parts of the building offers the potential for creative thinking about potential allied industries that could operate in symbiosis to a manufacturing site. This will require a mapping of available waste streams, and the development of compatible technologies that are able to work in synergy with the scale of operation.

NEXT STEPS

The recent pandemic and the frequency and extent of epidemic episodes worldwide has put pressures on governments for sustained investment in vaccine manufacturing, especially focusing on new vaccine technologies that have proven the most successful in an emergency scenario. Given

the multi-disciplinarity and complexity of some of the challenges in the sector (i.e., vaccine immunogenicity, process and analytical development, thermostability) the additional question of quantifying and minimizing environmental impact needs a coordinated approach, as well as appropriate methodologies and standards. While the current framework for LCA methodology (ISO standard) provides a general template, producing life cycle assessments that are comparable is challenging. Similarly, the current LCA databases are not comprehensive in regard to the types of inputs relevant to biotechnological manufacturing, for example media formulation, or single-use consumables. On the other hand, while quantitative assessments are crucial for hotspot analysis and decision-making, it would be interesting to plan for facilities to be embedded within a circular economy and aim to address key aspects around the use of waste and novel facility design, in particular if regulatory constraints make any substantial bioprocess changes prohibitive. Future plans might include considerations of the impact of single-use equipment, use of which is increasingly widespread within the biopharmaceutical manufacturing industry, as well as solutions towards process intensification.

Knowledge transfer from VaxHub Sustainable points towards a more integrated process design methodology based on exchanges between biological and engineering approaches, supported by continual technological innovation. In the short term, this can be enabled by increasing literacy in the field of sustainability. Ultimately, this aligns with a triple bottom line to minimize resource consumption, which has clear economic incentives. As future facilities for pandemic preparedness are constructed globally, there is a window of opportunity to embed inherently sustainable design at all stages, becoming an exemplar for other bioprocesses.

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