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VACCINE INSIGHTS

SPOTLIGHT ON:
Vaccine manufacturing 2022... & 2032

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VACCINE INSIGHTS Volume 1, Issue 6

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VACCINEINSIGHTS

VACCINE MANUFACTURING 2022... & 2032

SPOTLIGHT

COMMENTARY

Breaking the cycle: building vaccine manufacturing capacity in Africa

Patrick Tippoo

The COVID-19 pandemic had brought inequities in access to vaccines into sharp relief and highlighted the importance of manufacturing vaccines within low and middle-income countries. The road ahead has many challenges but with optimism and perseverance, I believe we can build a more sustainable vaccine ecosystem in Africa.

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On November 8, 2002, Charlotte Barker, Editor, *Vaccine Insights*, spoke to Patrick Tippoo about building vaccine manufacturing capacity in Africa. This article has been written based on that interview.

Post-COVID, everyone agrees that vaccine manufacturing capacity on the African continent must be increased. The question no longer is if but how. The value of local production is twofold: first, to ensure timely access to vaccines in Africa when required, especially when there is a global shortage; and second, to contribute to the global supply chain of these critical products. Vaccines should be produced in Africa not only for Africa but as part of the greater vaccine ecosystem to which African manufacturers can contribute once they are operating at scale.

The Africa Centers for Disease Control and Prevention (Africa CDC) and African Union Commission have proposed an ambitious

target of manufacturing 60% of vaccines used in Africa within the continent by 2040. The question now is how best to make flexible, diversified, and scalable local vaccine manufacturing in Africa a reality.

HARNESSING MOMENTUM

Politically, the level of attention on vaccine manufacturing capacity in Africa in the past 3 years has been unprecedented. Impressive progress was achieved in a short space of time. A meeting in April 2021 gave rise to the Partnership for African Vaccine Manufacturing (PAVM), bringing together political, technical, financial, regulatory, and other stakeholders. In December 2021, PAVM published its Framework for Action, outlining current needs, challenges, and proposed interventions [1].

However, some stakeholder groups have a limited attention span – not necessarily because they are uninterested, but because there are many competing issues. So we must make the most of this moment of focused attention from stakeholder groups within and outside the continent on the criticality of building manufacturing capacity. We have to ensure that enough momentum is created now to carry us into the future, even when the immediate attention garnered by the pandemic dies down.

BREAKING THE CYCLE

Building vaccine manufacturing capacity in Africa needs to be considered as a coin with two sides: a) establishing and b) sustaining. As difficult and challenging as it is to establish these capacities (requiring infrastructure, skilled workforce, access to technology and know-how, enabling regulatory capability, etc.) it is the easy part. The real challenge is the issue of sustainability. How do we keep these operations going in the face of the embedded technical complexities, long timelines, and huge capital expenditure requirements?

Funding is a major challenge, with many African vaccine companies reliant on funding organizations and development finance institutions. However, these institutions will only invest in sustainable projects, with a positive return on investment. In turn, a positive return of investment is inextricably linked to market demand and market share for product manufactured in Africa. And herein lies the issue, which, at first glance, might not be obvious, as we have a huge and growing market for vaccines in Africa.

The market structure in Africa is complex. There are very few countries on the continent that self-procure vaccines – the majority depend on Gavi subsidies and supply through UNICEF. This creates a 'chicken and egg' situation in which manufacturers cannot break into the market without achieving the economies of scale that allow competitive pricing, but funding institutions will not finance companies to scale without some form of guaranteed share in the global/African market. African vaccine manufacturers need to be supported in escaping this negative loop to achieve economies of scale that will allow them to become competitive in the global market.

Breaking that loop through interventions that secure access to markets (in Africa) for African vaccine manufacturers will also encourage technology transfer partnerships. The incentive would be market access.

Encouragingly, in response to a call from the African Union to offer concrete support for vaccine supply security on the continent, Gavi has initiated work on a new business model to support the establishment of a long-term, sustainable full value chain African vaccine industry. Depending on the outcome of this development, it could be a significant step toward breaking the cycle.

THE ROLE OF GOVERNMENTS

In parallel, political buy-in and long-term commitment are needed from African governments to support local manufacturing

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efforts by building regulatory capacity, proactively engaging with local producers in their regions to remove obstacles, and giving assurances that self-procuring countries will purchase locally manufactured products.

Of course, a government is not a homogenous entity, and sometimes there is a lack of alignment between different arms of government. A more coordinated approach within governments should be embedded structurally and legally into the policy frameworks of African countries to ensure long-term policy coherence in support of local manufacturing.

Another key role of governments is in regulation. Vaccines are one of the most highly regulated products in the world, and rightly so. Without regulatory capacity within a country, vaccines cannot enter the market. Delays in clinical trial approval, dossier review, and facility audits present a challenge to the sustainability of manufacturing organizations and operations. Companies operating within tight margins simply cannot afford to wait years for regulatory approval.

One way to increase regulatory capacity is by coordinating and harmonizing between countries so that if regulators in one country lack the capacity to review a new vaccine, they can lean on colleagues in other countries.

Regulatory capacity is critical – but equally important is regulatory efficiency. To shorten regulatory timelines, the process must be expedited without cutting corners or impacting patient safety. The speed of processing applications is largely dependent on experience, system efficiency, and resource availability. This will also be key when African vaccine manufacturers seek to achieve WHO pre-qualification, currently essential to access the Gavi market. Progress is being made on increasing both regulatory capacity and efficiency through initiatives such as the African Vaccine Regulatory Forum and the recently endorsed African Medicines Agency

Lastly, as far as the role of African governments is concerned, countries that do not self-procure vaccines must ensure that they request locally produced vaccines from Gavi wherever possible.

AFRICAN VACCINE MANUFACTURING INITIATIVE: THE VOICE OF THE INDUSTRY

African vaccine manufacturing initiative (AVMI) is the voice of the vaccine industry in Africa, established in 2010 with the mission of advocating for the building of vaccine manufacturing capacity on the continent. Over the last year or two, AVMI has been intimately involved with the PAVM, and has been charged with leading a project within the Framework for Action of the PAVM: Bold Program 4, focusing on technology transfer and IP. AVMI has developed an implementation plan detailing specific activities to ensure that the high-level targets and objectives set out in the Framework for Action can be achieved. AVMI has also been involved in supporting and contributing to other FFA Bold Programs (infrastructure, market shaping, research and development, and workforce development).

We see ourselves playing a crucial role, joining forces with the bigger group of stakeholders to keep the flag flying and the momentum going for advancing sustainable vaccine manufacturing capacity in Africa over the long term. We believe that continuity is critical in this space.

A BRIGHT FUTURE

Developments and progress seen since the pandemic are encouraging. Building on the base prior to 2020 provided by Biovac, IPD, IPT, Vacsera, and Innovative Biotech, other companies and organizations have also made announcements, are rolling out plans, or have entered the vaccine manufacturing space (Afrigen, Aspen, Institut Pasteur Morocco, Biovaccines, DEK, Atlantic Life Sciences, BioVAx, to name a few). Will this be the trajectory-changing opportunity that we've

all been waiting for? I am optimistic that it is, but we need to remain vigilant, diligent, and tenacious. We must work together and individually to ensure our collective success. It is not enough for one company to prosper and grow – we need multiple players on the continent to succeed. The market in Africa is huge and I believe that vaccine manufacturers can serve our countries and our continent in a way that ensures a sustainable future and ultimately allows us to compete globally and provide security of vaccine supply in Africa when needed most.

This is not a mission to become totally independent and completely internally self-reliant. Rather, we recognize the role and contribution that this capacity in Africa can make towards a diversified set of manufacturing capabilities around the world through partnerships and interdependence.

We cannot become globally competitive overnight. There will be a window of time where special dispensations will be needed to allow this fledgling industry to grow and get to a point of holding its own on the global stage. Yes, it is a difficult undertaking – if it was easy it would have been done already – but that is no excuse not to do it. I am persuaded that there is unprecedented recognition across a broad group of stakeholders, both from within and outside the continent that building a sustainable vaccine industry in Africa is clearly necessary. The cost of not doing it outweighs the cost of doing it by far, not only in terms of money and economics but also in terms of national and regional health impact.

We therefore have no option but to do it.

BIOGRAPHY

PATRICK TIPPOO is Head of Science and Innovation at Biovac. He is a founding member and the Executive Director of the African Vaccine Manufacturing Initiative (AVMI), advocating for the establishment of vaccine development and manufacturing capacity in Africa. He has championed AVMI's engagement with the Africa CDC-led Partnership for African Vaccine Manufacture (PAVM) in the development of the Framework For Action, a ground-breaking continental initiative to ensure that Africa has the necessary capacity to produce routine and pandemic vaccines. He served as Vice President of the Developing Country Vaccine Manufacturers Network (DCVMN) and is the chair of the board of the recently formed Emerging BioPharmaceuticals Manufacturing Network (EBPMN).

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1. PAVM Secretariat. Partnerships for African Vaccine Manufacturing (PAVM) Framework for Action. *Africa CDC* (March 3 2022)

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INTERVIEW

Vaccine manufacturing: the future is global

Charlotte Barker, Editor, BioInsights, speaks to **Matthew Downham,** Director, Manufacturing & Supply Chain Networks, CEPI

MATTHEW DOWNHAM is the Director, Manufacturing & Supply Chain Networks for Coalition for Epidemic Preparedness Innovations (CEPI). After a PhD in biochemical engineering at Birmingham University, UK, and a post-doctoral research fellowship in biomolecular sciences at Liverpool John Moores University, he joined the biopharmaceutical industry in 1997 and worked in vaccine R&D for companies including Novartis Vaccines & Diagnostics and AstraZeneca. He joined CEPI as the Sustainable Manufacturing Lead in 2021.

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CEPI's Matthew Downham discusses improving production efficiency with new platforms and tools, and how CEPI and its collaborators are working towards more geo-diversified vaccine manufacturing.

Q What was your route to working with vaccines?

MD: I have always worked within the biopharma sector – primarily with vaccines but also antibodies.

After gaining a PhD in biochemical engineering, completing a post-doc and lecturing for a few years, in 1997 I transitioned to biopharma. I entered the pharmaceutical industry, where I was to stay for almost 25 years, working for a number of small biotechs and major pharmaceutical companies. I was interested in vaccines from the start – one of my first key roles was within the pre-clinical manufacturing of novel, peptide-based conjugate vaccines.

I left AstraZeneca, where I had been working on live attenuated flu vaccines, at the end of 2020 to join the non-government organization CEPI, in a role that involves close collaboration with the vaccine industry.

Q What are you currently working on with CEPI?

MD: My group and I are working on the establishment of a preferred partner facility network. CEPI is developing a range of vaccines for pathogens such as MERS, Rift Valley fever, chikungunya, and Lassa, which typically do not have existing vaccines. These vaccines will need to be manufactured for GMP, clinical trials, and commercial use.

We are working with low and middle-income countries (LMICs) to start manufacturing vaccines closer to where disease outbreaks are occurring. That's what we are working towards, and that involves collaborating not only with industry, but with a whole load of other players, including the WHO, GAVI, UNICEF, and the Gates Foundation.

Q What are the main bottlenecks in vaccine manufacturing right now?

MD: One of the key challenges is creating geo-diversified vaccine manufacturing to ensure equitable access. This requires not only the building of facilities but also the infrastructure behind them, including a skilled workforce, within these regions. As the COVID pandemic has highlighted, another challenge is the supply of critical consumables, such as vials.

During the COVID-19 pandemic, billions of additional vaccine doses were required around the world. How can we sustain these huge fluctuations in demand? Ensuring there is a global free flow of trade to supply the materials needed is critical. Overall, there is a range of challenges and bottlenecks, but the key driver is to geo-diversify vaccine manufacturing and ensure that supply is facilitated, particularly for regional or local outbreaks.

There is a ripple effect along the supply chain, whereby if a single piece of tubing or filter is unavailable, it can disrupt the entire process. It's like a line of dominoes – if one is out of place, the whole thing stops working.

Q What are the unique challenges of manufacturing RNA vaccines compared with other vaccines?

MD: mRNA has proven itself for COVID but that does not automatically mean that it can be used for every pathogen. Leveraging the latest information learned from

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Covid mRNA vaccines and applying it to other diseases is the next step CEPI is working on with multiple manufacturers. Another element to be considered is the requirement for mRNA to be stored at temperatures of less than -70°C, which makes it difficult to distribute and supply these vaccines in remote or challenging geographies. Freezer farms at this temperature are expensive to power and manage, which makes it challenging for low-income areas. There is a need to develop a more stable format for mRNA vaccines and CEPI has a call for proposals to mitigate the temperature requirements. There is a lot of promise and excitement in LMICs about making mRNA vaccines in the future.

"The generic element of the single-use modular facility gives the flexibility to expand vaccine manufacturing, particularly in challenging regions."

Q What are the key innovations and trends that will give the vaccine biomanufacturing facility of tomorrow the flexibility it will need?

MD: single-use consumables and modular facilities are key because they allow easier tech transfer between facilities, countries, and companies, using the same modular units at both sites. That facilitates the manufacturing quality control and quality assurance processes. It also aids monitoring; for example, a facility in Africa could have a platform technology monitored, controlled, and supported from Germany, or anywhere across the globe. The generic element of the single-use modular facility gives the flexibility to expand vaccine manufacturing, particularly in challenging regions.

Q What will be needed in terms of scale-up and continuous manufacturing?

MD: This is something that CEPI has pioneered: our 100-day mission is an aspiration to be able to manufacture a new vaccine within 100 days, which leverages lessons learned from the COVID pandemic. It is unprecedented, given vaccine manufacturing typically takes five or even ten years from concept to vaccine. We aim to leverage the lessons learned from COVID in terms of scale-up and innovative manufacturing, which also lends itself to the maintenance of equipment, technologies, and human skillsets. However, innovation is needed to achieve this goal – a CEPI survey has highlighted that traditional manufacturing equipment is still prevalent in low-income countries, and there is a need to bring more modern equipment to these manufacturing sites.

Q How do you see the interaction of single-use consumables and continuous manufacture?

MD: You can have a series of single-use bioreactor bags, working in a continuous operation, almost like a fermenter. Continuous manufacture is possible with batch components. Batch manufacturing can keep rolling in a continuous setting, continually being produced and supplied. This involves organization from quality control and quality assurance and availability of single-use components, which are key elements in continuous manufacturing.

Last year, there was a shortage of a particular plastic clip that secures tubing to bioreactor bags. They are just small clips, but they are bespoke and specific for that manufacturing process and when they weren't available, the integrity of the bag could not be maintained and it stopped the manufacturing process. This is a good example of the criticality of ensuring synchronization across the board.

Q How can we increase productivity and yield?

MD: Increasing yields and improving efficiency relate to cost-effectiveness. For example, if vaccine manufacturing is established in one country, but vaccines are cheaper in another, organizations and governments will ultimately choose the cheapest option, even if it is further away. Therefore, it must be ensured that production is efficient, cost-effective, and sustainable for the facility moving forward.

Q How is CEPI working towards those goals?

MD: As I already mentioned, we're working with preferred partner facilities, particularly in LMICs, to support them to implement innovations, scale-up, train staff, and more.

We have also been working closely with the World Trade Organization to facilitate the free flow of goods. How can we get critical consumables and materials not only to the countries where they are required but also to individual manufacturing facilities within the country? This requires coordination along the supply chain, including factors such as border controls and export licensing.

CEPI has been working on an element called the COVAX marketplace, which we established with COVAX partners. This facilitates the trade and exchange of consumables and materials to support COVID vaccine manufacture. We have found that this is particularly beneficial to meet the demand when supply needs to be increased. Now, we are working with the US State Department to have a clearing house that facilitates the availability of critical consumables and raw materials for all vaccine and biopharma products, not just COVID, and allow us to meet future surge demand.

Q How important is collaboration in terms of improving vaccine production for the future?

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MD: It was an incredible achievement to supply COVID vaccines within a 360-day window, and that took a phenomenal amount of collaboration with other organizations. The COVID pandemic has highlighted how complex the process of vaccine supply is, and collaboration between organizations from different sectors is important to ensure demand is met.

"...vaccine manufacturing facilities will have smaller and more modular components and will be geo-diversified such as they are linked and synchronized, which would enable manufacturing and supply to be more carefully managed and accessible."

Q What do you think are the key success factors to bring novel technologies and innovative tools into LMIC settings?

MD: The key factor is the successful operationalization aspect of novel technologies and innovative tools. At the moment, CEPI is working with The Institute Pasteur de Dakar on a multi-dose bag that fits on the arm of the administrator. One bag holds approximately 200–250 doses, improving the rate of multiple-dose administration. This is particularly beneficial in settings where high numbers of individuals congregate for mass vaccinations.

Q How will a vaccine manufacturing plant in 5–10 years differ from today?

MD: I think vaccine manufacturing facilities will have smaller and more modular components and will be geo-diversified such as they are linked and synchronized, which would enable manufacturing and supply to be more carefully managed and accessible.

AFFILIATION

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VACCINEINSIGHTS

VACCINE MANUFACTURING 2022... & 2032

SPOTLIGHT

Sourcing quality raw & starting materials at a reasonable cost during the pandemic

Caryn Fenner
Executive Director of the mRNA Hub,
Afrigen Biologics Ltd

"Enabling LMICs to better face and respond to future pandemics will require changes to how and where raw and starting materials are sourced."

VIEWPOINT

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The COVID-19 pandemic has intensified existing disparities in access to raw and starting materials in low- and middle-income regions. Initiatives from CEPI, GAVI, WHO, and others aim to mitigate the impact, but in the long term, local production of materials is essential for a sustainable vaccine manufacturing ecosystem.

Sourcing raw and starting materials is a complex topic, covering everything from securing supply to ensuring appropriate grade and cost. As Executive Director of the WHO-funded mRNA Vaccine Hub at Afrigen Biologics Ltd in South Africa, I have seen first-hand how the COVID-19 pandemic affected all of these aspects. I will focus on mRNA vaccine production, but I believe the challenges are applicable to other vaccine platforms and even to the manufacturing of other medicines and diagnostics.

Challenges already existed in sourcing raw and starting materials for vaccines in Africa pre-pandemic. For example, few suppliers will hold stock within the customer's country, which imposes long lead times simply due to logistics. However, during the pandemic, the existing challenges were intensified, affecting not only vaccine production for COVID-19 but also for existing non-COVID vaccination programs. At the height of the pandemic, suppliers struggled with securing air freight, with shipments only possible when ordering large quantities in advance. However, buying in bulk could lead to space constraints, products that would reach the expiry date long before they could be utilized, and cash flow challenges (common in smaller biotech's and/or start-ups).

Suppliers of reagents and enzymes for mRNA vaccine manufacturing were mainly producing research-grade materials when the pandemic started. When it became clear that mRNA vaccines would be key in the fight against COVID-19, suppliers not only had to rapidly ramp up capacity but also ensure pre-GMP and GMP grade materials could be provided. This resulted in a lag. Suppliers who had strategic foresight and deep pockets were able to increase their capacity by either ramping up production and/or adding manufacturing sites, but global shortages remained.

Beyond raw and starting materials for the vaccine itself, vaccine manufacturers were faced with excessive lead times for consumables and single-use items due to the massive increase in demand. Not enough microchips were available to meet the demand for equipment and instruments. The borosilicate glass needed for billions of vaccine vials could also not be supplied in time, due to the high demand for silica sand, used in everything from solar panels to concrete.

To address these challenges, and the many other challenges caused or exacerbated by COVID-19, many helpful initiatives mushroomed. These included the Access to COVID-19 Tools-Accelerator (Act-A) – a global collaboration to accelerate the development and production of, and equitable access to, COVID-19 tests, treatments, and vaccines. The Accelerator was launched in April 2020, during the first wave of COVID-19, and was conceived as the world's end-to-end solution to end the COVID-19 pandemic. The partnership comprises three pillars: Diagnostics, Therapeutics, and Vaccines. The latter is known as COVAX and is led by the Coalition for Epidemic Preparedness Innovations (CEPI), GAVI, and WHO.

Subsequently, CEPI and COVAX partners launched an innovative 'marketplace' to accelerate the global production of COVID-19 vaccine doses by matching suppliers of critical inputs with vaccine manufacturers who urgently needed them to produce vaccines for fair and equitable distribution through COVAX. Initially, the focus was on the distribution of vaccines, and primary packaging. Later, this was extended to other single-use materials and consumables, raw materials, reagents, and excipients. However, in hindsight, these initiatives may not have been enough in circumstances where demand far outstripped supply.

Afrigen joined the CEPI marketplace network to mitigate the lengthy lead times it was experiencing with certain raw materials and single-use items. Here, manufacturers looking to off-load current stock (for example, materials purchased as part of a redundancy plan that would not be ready to utilize within the given expiry date) could be connected with manufacturers urgently seeking

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those particular items. However, we experienced some challenges in using the marketplace network. The process could be lengthy, and pricing was often an issue. Often the manufacturer we connected with was ready with the list of materials they had to offer, but pricing was unavailable. We were often asked to make an offer. As a new manufacturer in the field, what is a reasonable offer? Matching the manufacturer's cost, including shipping, and covering additional shipping costs to our location made this option unattractive. In these cases, the scheme might give us quicker access, but not lower costs. It was also common to find that the items on offer would be potentially useful in the future but did not meet our current urgent needs.

Fortunately, Afrigen was able to rely on the loyalty of its existing suppliers and forge strong collaborations with new suppliers. We found that Afrigen's role as the 'hub' of the WHO mRNA technology transfer program [with commercial recipients in 15 low- and middle-income countries (LMICS forming the 'spokes'] provided stronger negotiating power when dealing with suppliers – they expressed a desire to be the preferred partner of the initiative and were more open to finding ways to contract lead times and offer better pricing.

Enabling LMICs to better face and respond to future pandemics will require changes to how and where raw and starting materials are sourced. Local and regional manufacturing of raw and starting materials is needed to truly ensure the security of supply. This is reliant on building the vaccine manufacturing ecosystem. This will not happen overnight, and until then we need to continue to lobby to secure the supply chain for LMICs; this is slowly changing but the Global North is still at the front of the queue.

Some suppliers have initiated Global Health Equity programs or business divisions that provide holistic solutions targeted specifically to customers in LMICs. Here public-private partnerships (e.g., Supplier + WHO + UNICEF + Clinton Health Access Initiative (CHAI) + Africa CDC) provided aid for target countries in their pandemic response. Additionally, raw materials and equipment stock were specifically allocated and ring-fenced for LMICs.

I believe COVID-19 has proven that strengthening supplies of raw and starting materials is essential in achieving the wider goal of localized vaccine manufacturing. Without it, we cannot have a sustainable vaccine manufacturing ecosystem.

BIOGRAPHY

CARYN FENNER is Executive Director of the Global mRNA Technology Transfer and Training Hub at Afrigen. The Hub is a WHO-led public/ private partnership consortium to advance mRNA vaccine development and manufacturing for Africa and other LMICs. Caryn joined Afrigen Biologics in 2016 as Senior Scientist and Laboratory Manager of the Adjuvant Formulation Centre. Before joining Afrigen Biologics, she held a research position at the Centre for Bioprocess Engineering Research (CeBER) at the University of Cape Town (UCT), focusing on new product and process development using microbial and enzyme technology. Caryn has extensive technical experience in biomanufacturing of recombinant proteins and therapeutics and is a member of the UCT seed fund investment committee and an advisor to the SA government's Department of Science and Innovation on Health Innovation-related programs. She has also recently served as an external evaluator on the SAHPRA COVID-19 expert committee. Caryn Fenner is an alumnus of Rhodes University, and the UCT, obtaining a BSc honors in Biotechnology and a PhD in Bioprocess Engineering, respectively.

AFFILIATION

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FASTFACTS

Collaboration to develop modular facility proof-of-concept for multi-modal bioprocessing activities

Jerome Dalin, Senior Consultant– EMEA Traditional Modalities, Bioprocessing Strategy Operationalization, Merck
and **Thomas Hauser**, Business Development Manager, EMEA, G-CON

In the context of a more globalized world and as shown in pandemic situations such as COVID-19, pharmaceutical manufacturing must adapt to fluctuations in demand, newly approved treatments, or new multimodal activities and platforms. Modular drug manufacturing facilities can help to provide that flexibility. In this poster, two industry-leading solutions providers propose a proof-of-concept to build a standardized and competitive solution for multimodal biologic manufacturing in 12 months.

WHY EXPLORE MODULAR, MULTIMODAL BIOPROCESSING?

Customer expectations were at the heart of the drive to design a facility of the future to produce multiple types of vaccines and biologics. Key customer barriers were identified as a lack of availability of skilled personnel, regulatory hurdles, and a limited supply chain.

Customer needs for this facility included the requirement for a multi-modal, modular site with equipment that integrates single-use technology. The need for flexibility while remaining competitive was a key incentive behind the facility of the future, as was the need for a custom or pre-designed facility, with or without process equipment. Additional challenges to consider included mental barriers, cross-contamination, cost, localization, and scheduling.

PROOF OF CONCEPT

Two industry leaders, G-CON and Merck KGaA Darmstadt Germany, have developed a proof-of-concept proposal for a 12-month project to build a turnkey solution integrating process equipment into a modular facility for multimodal biologic manufacturing in a single plant. Examples of different modality production suites are illustrated in Figures 1 and 2.

This predesigned and prefabricated modular facility is designed for specific processes/templates with standard equipment for bulk manufacturing. The facility will include physical process segregation for multi-modal activities, such as vaccines, monoclonal antibodies, mRNA, or any biologics. It will feature fast expansion scalability, allow mobility, and be adaptable to process changes.

A timeline for the building of a two-modality site under normal market conditions is presented in Figure 3.

ROADMAP FOR FUTURE

A potential roadmap for the future could include greater emphasis on sustainability, such as building a facility with a neutral carbon footprint and continuous processing using the BioContinuum™ Platform. The cloning of sites could reduce regulatory burden and the training of new staff. Furthermore, automation (Bio4C™ suite) plus the addition of robots and cobots could be used to support biologic manufacturing, for example in sampling or process monitoring.

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Figure 1. Proof-of-concept for modality suite A — a Chinese Hamster Ovary (CHO) cell-based platform production unit.

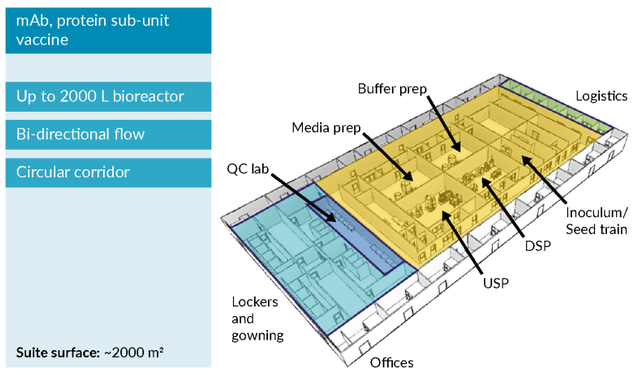


Figure 2. Proof-of-concept for modality suite B — a viral production unit.

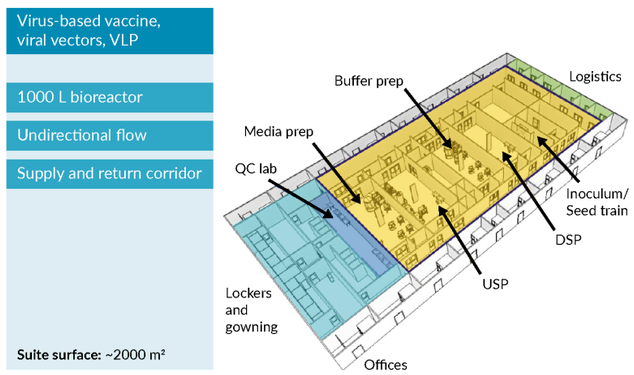
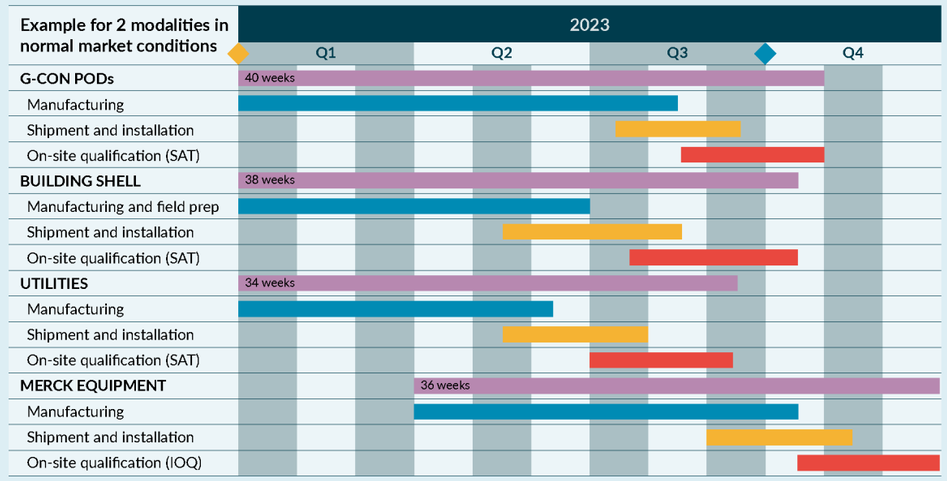


Figure 3. Proof-of-concept 12-month timeline for project plan.



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