Discover Medicine

Review

Building vaccine and biotherapeutics manufacturing capacity in Africa: a practical approach

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Abstract
The outbreak of COVID-19 pandemic exposed the fragility of global health systems especially in the developing world. Global disparities in the readiness to respond to pandemics were laid bare. These were manifested as lack of access to essential vaccines and therapeutics as well as challenges with cold chain including storage and transportation. As a result, various initiatives to build vaccines and therapeutics manufacturing capacity in Africa pivoted around Africa Centers for Disease Control and Prevention (CDC) as a coordinating agency. Appropriate characterization of the continental landscape is critical to developing a response strategy for building drug and medical product manufacturing capacity. Equally, strategies from South-East Asia will inform the development of an African continental strategy. This paper advocates for the need to follow an ecosystems' approach to building drug manufacturing capacity. In practical terms, this translates in simultaneous investment in research and manufacturing infrastructure, establishing a biotech incubation supportive system, nurturing contract research organisations (CROs), contract development and manufacturing organisations (CDMOs), and contract manufacturing organisations (CMOs) and promoting a robust collaboration culture in the ecosystem. Partnerships with a technology partner and technology transfer partner, followed by a technology platform are essential steps in setting up a CDMO as a stepping stone to vaccine and biologics manufacturing in Low-and-Middle-Income-Countries. The role of the public sector in seeding healthcare product manufacturing capacity through PPPs or direct SOE mode is critical.

Keywords Ecosystems approach · PPP · SOE · CDMO · Clinical research · Vaccine ecosystem · Collaboration · Technology platform

1 Introduction

Coronavirus disease 2019 (COVID-19) has exposed the weaknesses in the public health systems across Africa. It has laid bare the lack of pandemic preparedness and emergency response to infectious disease outbreaks. What is critical during pandemics and disease outbreaks is access to essential vaccines, therapeutics and surveillance and diagnostic

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infrastructure to enable speedy response. In the aftermath of COVID-19 pandemic, what became clear is that the global public health infrastructure is fragmented with challenges ranging from poor healthcare infrastructure, shortage of adequately trained healthcare personnel, lack of access to essential medicines, medical consumables and diagnostic devices, supply chain challenges, cold chain issues and high cost of medicines in low-and-middle-income countries (LMICs).

Compounding the challenges of pandemics, Africa's disease burden includes infectious diseases including malaria, yellow fever, dengue fever, tuberculosis (TB), human immunodeficiency virus (HIV) infection, and cholera amongst others. However, lifestyle/non-communicable diseases constitute a large portion of the disease burden especially diabetes, cancer heart disease and respiratory diseases [1]. Adding to this complexity, climate change has compounded the infectious disease burden through exposing weak sanitation infrastructure leading to cholera outbreaks in countries such as Zambia and Malawi [2–4].

This complexity of healthcare challenges in Africa requires complex solution strategies. Responding to pandemics such as cholera, high-burden infectious diseases (eg. TB and HIV) and rising non-communicable diseases requires an ecosystems approach that comprises of public institutions, non-governmental organizations (NGOs) and the private sector. This review explores strategies for building medical products manufacturing capacity in Africa. It covers the alignment of Africa Centers for Disease Control and Prevention (CDC)'s goals with regional initiatives, learning from South-East Asia, and the adoption of an ecosystem approach. Key areas include developing manufacturing infrastructure, regulatory frameworks, and financing models. The roles of contract development and manufacturing organisations (CDMOs), academia, and industry in vaccine manufacturing are examined, alongside the importance of hands-on training and human capacity development. It also addresses leveraging product development partnerships and enhancing market access.

2 The Africa CDC strategic goals alignment

The African Union has set a goal for local production of 60% of vaccines administered in Africa by 2040. The background to this noble cause is because Africa lags behind the rest of the world in manufacturing vaccines and biotherapeutics that are administered to its citizens. The continent, therefore, relies on imports for safeguarding the health of its population. This presents challenges owing to a combination of factors including prohibitive cost of medicines, supply chain challenges and counterfeit medicines whose individual and combined effect prevent access to safe and efficacious medicines. Added to this dilemma is vaccine and therapeutics export bans during pandemics as nationalism takes precedence to human welfare and justice. Lack of skills and expertise in vaccine development and manufacturing, high cost of equipment and facilities, financing constraints and absence of robust medical insurance or universal health care ecosystem are the factors constraining drug manufacturing capacity in Africa. However, the advent of COVID-19 has accelerated the need to build drug manufacturing capacity across the continent as part of pandemic preparedness. It has also invigorated efforts to revamp and strengthen public health systems across the continent including surveillance systems and diagnostic laboratory infrastructure. Various initiatives are afoot to address this undesirable situation on the continent, with training being in focus. The Partnerships for African Vaccine Manufacturing (PAVM) under Africa CDC has crafted a Framework for Action (FFA) targeting 6 areas: Market Design and Demand Intelligence (pooled procurement system), Access to Finance (Deal preparation and financing facility), Technology Transfer and intellectual property (IP), Regulatory Strengthening, research and development (R&D) and Talent Development (regional capacity and capability network), and Infrastructure Development as action points to achieve its goal of localizing production of 60% of administered vaccines on the continent [5, 6]. The current work explores practical steps to integrating the action points to build manufacturing capacity. In this regard, the experience of South-East Asia could be enlightening.

3 Insights from the South-East Asian trajectory

3.1 South Korea

The pharmaceutical industry in Korea developed from finished products (packaging) and drug substances (fill & finish) in the 1960 s, development of processes (1980 s), early phase drug development (1990 s) to developing innovative drugs in the 2010 s [7]. Development of innovative drugs was a product of strengthened clinical trial capacity which

drove value in R&D and ultimately manufacturing [8]. In this case, strengthening the capacity to conduct clinical trials increased the number of quantitative and qualitative clinical trials conducted in the country by big pharma [8]. The correlation between improved clinical trial capacity and R&D seems obvious in this case. Improved quality assurance through Manufacturing Practice (GMP) guidelines significantly improves the quality of pharmaceutical/medical products. Good Laboratory Practice (GLP), Good Clinical Practice (GCP), and GMP drive value in R&D, clinical trials and manufacturing. It is clear from the Korean example that R&D thrives in an environment with strong clinical trial capacity. Developing research capacity was critical to transitioning to developing innovative products.

3.2 Singapore

Singapore followed a different strategy focused on driving investment in pharmaceutical industry through a series of attractive strategies. Creating robust IP rights, strengthening the regulatory environment and investment in training a skilled workforce in the biopharma sector all contributed to creating an investment-friendly environment. The likes of GSK, Merck, Novartis, Pfizer have a footprint in Singapore and have set up worldclass research and development centres that tackle global health challenges including cancer, neurodegenerative disorders and tropical diseases [9]. Research and innovation underpin the Singapore strategy for building capacity.

The strategies followed by Korea and Singapore pivot around research and development to build capacity across the entire value chain. While both countries followed different paths to establishing full bio/pharmaceutical manufacturing capacity, building strong research and development (R&D) stands central to their success.

3.3 Indonesia

Indonesia provides an insightful model for building capacity in the production of vaccines and therapeutics. Capacity was built on the template of state-owned enterprises (SOEs) benefiting from state financial and other support. Technology transfer thrived on the back of existing manufacturing capacity (which the vaccines SOE provided), domestic market and government policy which recommended the use of a target vaccine [10, 11]. This underscores the critical role of the state in seeding capacity through a sunk cost approach to establishing a manufacturing facility through leveraging technology transfer. This case illustrates the importance of government policy in ensuring domestic market access for local manufacturers. However, it must be pointed out that Indonesia has a large market compared to small population nations in sub-Saharan Africa. For these countries, a regional manufacturing facility approach may be more prudent and a strategic prioritization in the context of global capacity for pandemics [12].

3.4 Thailand

A different approach was taken by Thailand which leveraged existing infrastructure such as pilot plants, research institutes, vaccine reference standards central storage facilities and others to build capacity [13]. Focusing on vaccine platform technologies, capacity was built through targeted investment in research and development through grants and other support. Harnessing Public–Private Partnerships (PPPs), the strategy leveraged expertise from the private sector with targeted state financial and other support to move research from the laboratory bench to the market [14]. Investment in research and development was done in parallel with strengthening the regulatory capacity. This approach can only work where some capacity exists, such as pilot and research facilities and industrial research. The strategy to focus on vaccine platform technologies for both R&D and manufacturing is useful for Africa in its efforts to build capacity. However, notably, efforts to build capacity should be driven by the public sector through targeted long-term investment in R&D infrastructure and leveraging PPPs.

3.5 India

The role of the state in promoting capacity in vaccines and therapeutics development and manufacturing is best illustrated by the Indian model. Its pharmaceutical industry was built on the backbone of state entities including Pasteur Institute of India and Haffkine Institute for Training, Research and Testing, Central Drugs Research Institute and others

[15]. The Indian model was based on creating a plethora of public sector institutes across the pharmaceutical landscape that includes manufacturing of vaccines, pharmaceuticals, active pharmaceutical ingredients (APIs). The focus was on building skills in the pharmaceutical sector as a goal, rather than success of these SOEs. The public sector support drove private investment in the pharmaceutical sector [15]. Additionally, targeted support for research in priority vaccines and biotechnology programmes at universities was provided by the Department of Biotechnology. Though this approach is similar to that of Indonesia, the Indian approach had a broader focus. The lesson from the Indian experience is that investments to build vaccine and therapeutics development and manufacturing capacity should be long-term with less emphasis on short term success. Investment in a plethora of SOEs aligned with the vaccine and biologics manufacturing ecosystem is, therefore, recommended.

4 An ecosystems approach for Africa

The health product manufacturing industry is multi-faceted comprising end-to-end manufacturing, drug substance or active pharmaceutical ingredient manufacturing, excipients manufacturing, contract development and manufacturing, contract research, medical/pharmaceutical consumable supply, medical device development and a robust cold chain landscape. Additionally, a robust regulatory environment is indispensable to ensuring quality and efficacious products. The experience of Ireland and Singapore has demonstrated that a skilled workforce has potential to drive investment in the biopharmaceutical sector [16]. However, given the ecosystem nature of drug manufacturing, Africa requires a hybrid strategy integrating elements from the experience of, particularly, Indonesia, Thailand and India. South Korea started with premixes to augment skills training while simultaneously building a robust regulatory environment [8]. The aforementioned approach was accompanied by simultaneous investment in infrastructure for research and development to drive organic growth. An essential addition is focused mandatory training programmes for doctoral and postdoctoral students to nurture an entrepreneurial mindset while promoting translational research skills. Graduates from such a programme would be entrepreneurial researchers, innovators in industry and venture entrepreneurs, helping them bring their research to impact via commercialization [17]. Examples of this approach is the Graduate Certificate in Entrepreneurship (Canada) and the research-based innovation training (Norway) to nurture entrepreneurial thinking and promote transformational invention to innovation.

As illustrated by the South-East Asia examples, especially Indonesia and India, state support in the form of SOEs covering R&D and manufacturing is critical to building local manufacturing capacity. Bolstering R&D should happen in parallel with skills training to retain talent on the continent through gainful employment and innovative entrepreneurship. Entrepreneurship will drive commercialization of research discoveries to expand the absorptive capacity of the industry. Public sector investment in vaccines and biologics projects should take on a long-term approach with emphasis on building skills rather than financial success of the entities.

5 Building the manufacturing landscape

5.1 The role of incubator platforms in translational research

In parallel with investing in skills development is the need to nurture and expand the biotechnology industry through support for research institutions. A nascent industry offers fertile ground for venture capital in the initial stages to seed health biotech innovation. Though high-risk, it is a big canvas of innovation that can birth a broad pipeline of drug candidates. Investing in impactful and translational research and subsequent support to commercialize output is critical to turning ideas, technologies and products into viable businesses. Incubator platforms that offer access to laboratory facilities, research equipment, and equipment for product development help to reduce the financial burden on spin-off biotech start-ups. Additionally, incubators can provide an ecosystem of mentorship, advisory expertise on business development, scientific and technical challenges, regulatory compliance, IP protection, fund raising, market strategy and networking opportunities [18].

Biotech incubators and accelerators are critical to early-stage drug development [19, 20]. These platforms offer a bridge between translational research and commercialization of impactful discoveries. To position research institutions as drivers of biotech innovation, incubators and accelerators translate research into healthcare products. These platforms are, therefore, critical pillars in transitioning from bench to market place. They drive innovation through providing a developmental platform on which R&D hinges. UVUBio is an open access biotechnology laboratory platform serving as a launch pad for innovative companies [21]. This biotech incubator launching pad offers a series of short skills training courses in bioprocessing to bridge the hands-on skills gap in industry. UVUBio offers project-based upstream and downstream experiential training including formulation of final product. This platform is unique in Africa and has established a footprint in Rwanda to augment the fledging ecosystem in that east African country. Such focused facilities offering project-based experiential learning opportunities are essential to bridging the skills-gap while promoting translational research and shaping the bench to market journey of research discoveries.

Lack of gainful employment and inadequate research infrastructure and opportunities are the main drivers of talent loss on the continent through emigration to the industrialized parts of the world [22, 23]. A supportive environment that provides a clear path to commercializing research discovery will be an attractive option for researchers. To this end, incubator facilities are best established as PPP between government, universities and the private sector as necessary components in the medical product manufacturing ecosystem.

5.2 Drug substance/API, CMO, CDMO and CRO

Spin-offs or start-ups are by their very nature one-product companies with no manufacturing infrastructure and constrained financial ability to invest in capital intensive equipment such as fill and finish or other manufacturing and/or analytical equipment. Start-ups may also not have specialist expertise on board in areas such as analytical services, formulation development or clinical trials capacity. The contract manufacturing model fills this gap by offering end-to-end product manufacturing, drug substance/API manufacturing or fill and finish services for various dosage forms.

This gap is an opportunity for CDMOs (formulation, analytics, process development & scale-up, manufacturing), CMOs (manufacturing or fill and finish) or CROs (clinical trials & regulatory support) to help start-ups navigate the tricky journey to obtaining marketing authorization for their products. While CMOs and CDMOs often have no product ownership, their expertise and specialist infrastructure such as formulation, process development and manufacturing of injectable dosage forms or fill and finish operations, respectively, are an essential part of the manufacturing capacity ecosystem (Fig. 1). These entities have emerged driven by the need for specialist expertise and manufacturing infrastructure to get new products to the market as well as well as the speed at which new biopharmaceutical therapies are developed [24–26]. This includes enacting policies that drive foreign direct investment in attracting multinationals such as Sartorius, Cytiva or Fischer Scientific to establish CMO manufacturing and/or setting up research facilities or production of subsidiary materials such as single use bags for the vaccine industry [27].

5.3 Evolution of contract research and contract manufacturing in Asia Pacific

The CDMO market has taken center-stage as an important component in bringing innovative medical products to the market. The growth in the CDMO/CMO/CRO market is driven by demand for new therapies, research and development and increased number of clinical trials being conducted [28, 29]. This suggests that investment in research capacity can drive the need for pre-clinical development, clinical development, manufacturing and regulatory support, nurturing the evolution of the CDMO/CMO/CRO ecosystem. This is approach can inform Africa's strategy to build the CDMO ecosystem.

5.4 Excipient manufacturing

Excipient manufacturers supply compounds used in formulation of medicines such as stabilizers, lubricants, taste masking substances used in tablet coating as well as disintegrants and dispersants. Excipients are critical to manufacturing and can constrain manufacturing capacity if there are supply limitations or banning especially during pandemic outbreaks. The strategy to build capacity should mandatorily include seeding excipient manufacturing through PPP or as a public sector initiative.

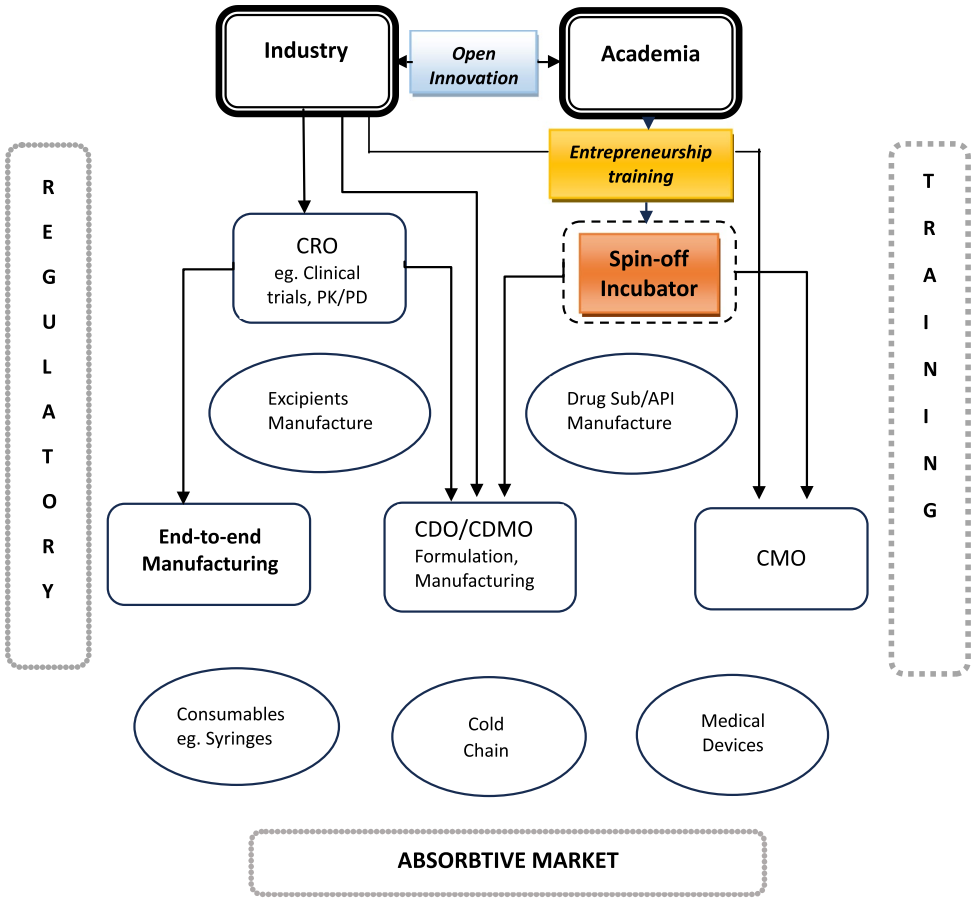


Fig. 1 Mapping the elements of the medical product manufacturing ecosystem

6 Academia, industry and R&D for vaccine manufacturing

A insightful model for driving capacity building in research, development and manufacturing of vaccines and therapeutics is provided by the Council for Scientific and Industrial Development (CSIR) in South Africa. A statutory body, CSIR has well-equipped bench- and pilot scale research laboratories to conduct proof of concept as well as scale-up of biomanufacturing [30]. Working closely with universities and industry, CSIR conducts contract research on behalf of industry by enlisting graduate students for the projects. Registered students at universities take industrial research projects at CSIR and become part of the research ecosystem that brings products to the market. This ecosystem enables skills transfer while providing a sustainable model for CSIR. However, CSIR also provides hands-on training and skills development in biologics (vaccines and biotherapeutics) manufacturing as part of the SAVax programme to build local vaccine manufacturing capacity [31]. The role of CSIR is therefore dualistic in nature encompassing research and development as well as hands-on skills training.

In the United Kingdom, the Medicines Manufacturing Skills training Centre (RESILIENCE) brings together universities and employers to drive capacity in Advanced Therapy Medicinal Products (ATMP) in particular [32]. Its R&D and training facility links with industry for consultancy process scale-up services in addition to providing Continuing Professional Development (CPD) courses to industry [33]. Championing the smart partnership between academia, industry and research institutions, the FlexBio facility is hosted by Harriet-Watt University with industry being its clients. UCL-Oxford VaxHub follows a similar model [34]. It is a consortium of universities and industry partners structured around a well-equipped hands-on training and research facility.

At national, regional, continental, and global level, the WHO biomanufacturing workforce training hub (GTH-B) provides training in biomanufacturing to augment skills development efforts for LMICs [35].

Commercializing research discoveries requires supportive infrastructure including intellectual property protection office (IP Office), incubation fund and facilities to refine the discoveries and the existence of CDMOs to navigate the

intricacies of process development, regulatory challenges and clinical trials. This requires targeted public support for universities to enable translational research. Funding from donors like GAVI would be critical in this regard. However, incubation facilities lend themselves well to a PPP agreement, where the private sector takes an active role in moving discoveries from bench to market to enhance their product portfolio.

7 Hands-on training and research facility

The lack of critical skills and expertise in defined areas of vaccine development and manufacturing has been identified as one of the most important ingredients constraining capacity in LMICs [36, 37]. The aforementioned examples illustrate that centralizing all training under one hands-on training and research facility should underpin efforts to build vaccine and biotherapeutics research, development and manufacturing capacity.

Besides enabling smooth coordination of activities and logistics, a centralized hands-on facility will serve as a hub for cross-pollination on research while ensuring skills transfer. Figure 2 illustrates how such a facility would function within the broader ecosystem. This model promotes translational research capacity at universities through offering a route to commercialization of research discoveries. Proof of concept studies, formulation development as well as scale-up and process development are essential steps in the bench to market journey of spin-out companies. Implicitly, this partnership promotes skills development in both research, process development, formulation, scale-up and other activities related to vaccine and biologics manufacturing. Industry brings in research relevance, which in turn enables the research facility to work on industry projects and thereby enabling trainees to get real-life learning exposure. Collaboration with industry ensures a steady flow of funding for the facility bolstering its sustainability. Very often, industry funds the various pieces of equipment such as bioreactors and other processing equipment as well as analytical instruments enabling the facility to have competitive capacity to conduct research, offer services and produce better equipped students. As such, the hands-on research and training facility offers a platform for academia-industry collaboration on an open innovation platform (Fig. 1), driving translation research.

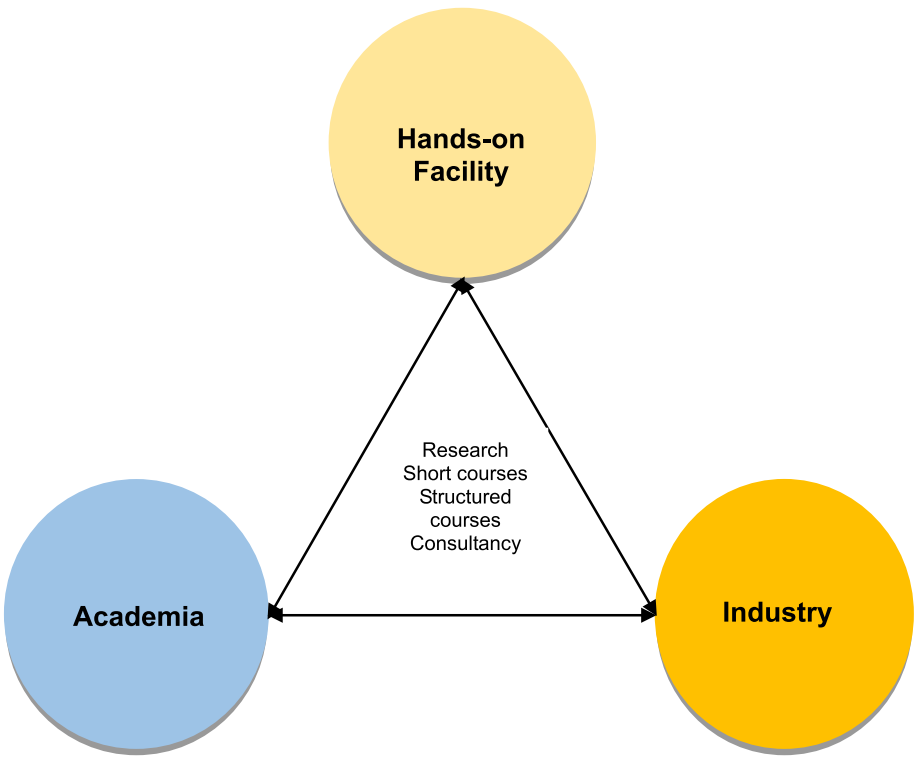


Fig. 2 A proposed model for a hands-on research and training facility

8 Human capital retention strategies

Developing a skilled workforce is critical for establishing and sustaining medical products manufacturing capacity [38]. Investment in education and training programmes tailored to the pharmaceutical and biotechnology sectors is essential. Collaboration between industry, academia, and government can help create specialized curricula that address the specific needs of the manufacturing industry. Training programmes should cover areas such as pharmaceutical sciences, engineering, quality control, and regulatory affairs to ensure a well-rounded skills set among professionals.

Retaining skilled professionals within Africa presents a significant challenge, often due to more attractive opportunities abroad. To address this issue, African countries need to create conductive environments that offer competitive salaries, career development opportunities, and job satisfaction. Implementing policies that encourage local talent to stay, such as providing research grants, professional development programmes, and incentives for trainees, can help mitigate brain drain and support the continent's manufacturing growth.

Regional and continental collaboration is crucial for maximizing Africa's human capital potential. Initiatives like the Pan-African University and the African Union's Agenda 2063 emphasize the importance of education and skill development [39, 40]. By fostering regional networks of professionals, sharing best practices, and facilitating mobility across borders, Africa can build a resilient and skilled workforce capable of driving the continent's manufacturing agenda. Collaborative efforts can enhance knowledge exchange and create a unified approach to human capital development in the medical products sector.

9 Leveraging the power of product development partnership

Product Development Partnerships (PDPs) are a critical resource to build drug development capacity in Africa. PDPs develop a pipeline of products and often leverage the global health research ecosystem to bring products to the market. Ease of administration and affordability drive their research and development primarily because their target market is LMICs. This model has worked as evidenced by the eradication of meningitis in Africa through MenAfriVac® [41]. PDPs have an impressive record bringing drugs, vaccines, diagnostics and other health technologies to the market since 2010 [41]. Given the impactful R&D output of PDPs, leveraging this model would be prudent for Africa. However, for Africa to meaningfully take advantage of the strengths of PDPs, targeted and deliberate investment in state-owned manufacturing facilities and R&D institutes or through PPP agreements is imperative. While R&D drives innovation, which is a critical link to leverage the PDP ecosystem, it is incumbent on governments to establish vaccine, biologics or medical device manufacturing facilities to leverage the technology transfer options offered by PDPs for building production capacity. Developing drugs or therapeutics requires the presence of CDMOs for formulation development and for developing the manufacturing process. Intricately tied to this is manufacturing the clinical batch material (engineering run). In addition to the need for having clinical trial capacity, a robust regulatory environment is indispensable. The aforementioned highlight the importance of an ecosystem approach to build medical products manufacturing capacity. Following the PPP model of Thailand, the public sector in Africa could actively leverage this mode to establish CDMOs as development hubs for both scale-up and commercial manufacturing through technology transfer.

Some public health organizations have teamed up with World Health Organization (WHO) to avail their technologies to drug, vaccines or medical device manufacturers to LMICs. Such agreements are legally facilitated by Medicine Patent Pool (MPP) which also enabled technology transfer of the mRNA technology to 15 LMICs through the WHO mRNA Technology Transfer Hub at Afrigen Biologics based in Cape Town, South Africa [42]. Recently WHO and MPP signed an agreement with a global in vitro diagnostics company to sublicense the manufacture of rapid diagnostic testing technology [43]. The existence of rapid diagnostic test (RDT) manufacturers in the manufacturing ecosystem is critical to leveraging such a sub-license agreement. Manufacturers can take advantage of supported drug manufacturing through technology transfer support provided by NGOs. For example, drug manufacturing entities can advantage of calls for proposals to establish monoclonal antibody production capacity in LMICs [44]. However, this presupposes that a drug manufacturing company already exists to take advantage of such an opportunity. This can be achieved through SOEs and/or CDMO/CMO under a PPP agreement.

Examples of various PDPs include Hilleman Laboratories, IVI and PATH and cover areas including manufacturing laboratories, vaccine R&D, clinical trials and manufacturing training and product development and access [41, 45,

46]. Recently, a partnership between Hilleman Laboratories and Bharat Biotech brought a much-needed oral cholera vaccine (Hilchol®) to the market. Developed by Hilleman Laboratories, the oral vaccine will be produced by Bharat Biotech through technology transfer from the PDP, bolstering global capacity of this vaccine [47].

Greater collaboration has been shown to speed up the development of vaccines and getting them to the market [48]. This can take the form of data sharing between research institutions, vaccine developers and governments to enable speedy delivery of essential vaccines to the market [49, 50]. Leveraging capacities of different partners through collaborations is, therefore, an essential part of developing and nurturing a vaccine and biologics manufacturing ecosystem in Africa.

In a nutshell, an integrated approach comprising nurturing talent through training, establishing incubator facilities to support start-ups and venture companies and providing incentives for big pharma to set up CMO manufacturing and research facilities is critical to building vaccine manufacturing capacity on the continent [51].

10 Establishing the building blocks

The hands-on bioprocessing training and research facility plays a crucial role embedding critical skills in the workforce in various aspects of vaccine development and manufacturing. These skills include early upstream development such as media formulation and development to the entire bioprocess of drug substance (antigen) and drug product manufacturing and analytics, Quality Assurance/Quality Control, GMP, GLP, GCP, warehousing and logistics.

Taking vaccine manufacturing as an illustrative example, the availability of critical bioprocessing skills is a driver of investment in the biopharmaceutical sector. At the far end of the triad is the need to identify and establish strategic technology partnerships (Fig. 3). The essential complementary components required for seeding manufacturing of vaccines are:

1. Identifying vaccine candidates and their antigens for local production.
2. Establish the production platform. Prioritize innovative vaccine platform technologies eg. Viral vector and mRNA-based technology

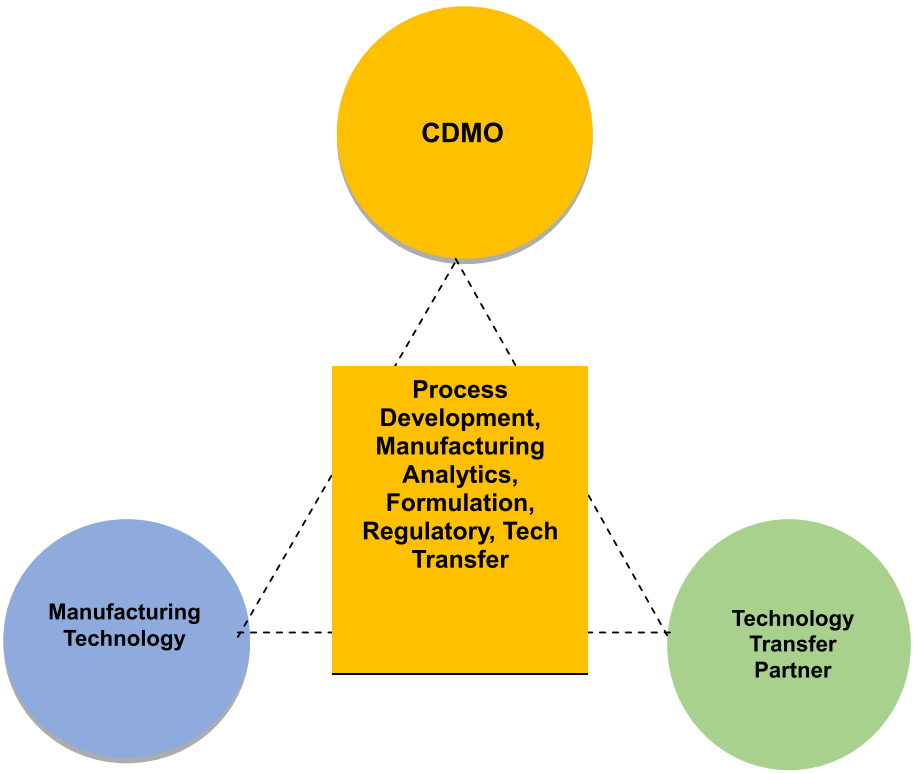


Fig. 3 A schematic illustration of the strategy to establish a CDMO. A CDMO can be set up on a PPP platform. Public sector support is critical to its building expanded capacity

3. Establishing a partnership with a manufacturing technology partner that involves technical support and is aligned with the production platform of choice
4. Establishing technology transfer agreements
5. Establishing a CDMO as a vehicle to seed commercial manufacturing

10.1 The technology platform options

Viral vectors have been used to deliver antigens to elicit a protective immune response in prophylactic immunization. Various viral vector vaccines have been developed for a range of infectious diseases including HIV, severe acute respiratory syndrome coronavirus 2 (SARS-Cov-2), Rabies, Influenza, Human papillomavirus (HPV) and Malaria [52]. The Oxford/AstraZeneca vaccine also called Vaxrezvria or CoviShield is based on the Adeno-Associated viral vector platform.

While the above viral vectors vaccines have been based on Adeno Viral Vectors (AAV), viral vectors are finding increased use in gene therapy especially in ex-vivo genetic engineering for chimeric antigen receptor T (CART) cell therapy applications. However, the single biggest challenge is manufacturing large amounts of plasmid and Lentivirus (Vector) to meet gene therapy demands [53]. The ability to significantly scale the production of viral vectors will unlock the full potential of gene therapy, lower cost and enable access to these lifesaving therapeutics. This presents an opportunity to build capacity in the manufacture of plasmids and viral vectors for both viral vectored vaccines and gene therapy market. As a platform technology, viral vectors have applications in vaccines, gene therapy (e.g., CART cell therapy), and the delivery of therapeutic antibodies (monoclonal antibodies). Monoclonal antibodies have found application in treating influenza and many other infectious diseases [54]. There is a demand and unmet need for monoclonal antibody production in LMICs to provide access to these essential medicines. The viral vector technology, therefore, offers an important platform to build capabilities across multiple products for LIMCs.

The mRNA technology has transformed vaccine development with respect to speed to market and vaccine effectiveness. COVID-19 vaccines (SpikeVax and Comirnaty) were developed in an unprecedented short period with both vaccines producing effectiveness of 94.1% and 95% respectively [55–57]. However, importantly, mRNA platform technology has found application across a broad spectrum of disease targets including cancer and many other infectious diseases [58–60]. The transformative nature of mRNA vaccine technology makes it a suitable platform for LMICs looking to establish broad technical manufacturing capacity.

However, established vaccine technologies like whole organism (live attenuated or killed), conjugate, toxoid or subunit vaccines offer an attractive option as they find application in both human and animal diseases. Building capacity in these enables a One Health approach to tackling broader public health issues including zoonotic outbreaks, antimicrobial resistance (AMR) and drug residues in food among others. To seed vaccine manufacturing in Africa, efforts should be on platform technologies which enable building capacity across multiple healthcare products such as the viral vector platform, on which the production of vaccines, gene therapy products and monoclonal antibodies are based.

10.2 Technology transfer underpins manufacturing capacity

Technology transfer is a critical skill in building manufacturing capacity especially for LMICs. In the light of emerging pandemics and the need for pandemic preparedness, technology transfer is a route to enhancing access to essential vaccines and therapeutics through building local manufacturing capacity in LMICs [36]. The case of the WHO mRNA Technology Transfer Hub hosted by Afrigen Biologics and Vaccines demonstrates the value of technology transfer to build vaccine manufacturing capacity [61]. Following on the training in bench-scale manufacturing of *AfriVac2121* (COVID-19 vaccine), a technology transfer was carried out, transferring the manufacturing process, analytical methods and assays, raw material specifications, equipment specifications and the facility design and specifications to participating companies (spokes). This was followed by technology transfer of the validated commercial process as well as the dossier (product). Fifteen companies from Argentina, Brazil, Bangladesh, Vietnam, Indonesia, India, Serbia, Tunisia, Egypt, Senegal as well as South Africa received the technology transfer facilitated by Medicines Patent Pool [42].

This move enabled participating vaccine manufacturers and state research institutes to gain capacity in mRNA vaccine manufacturing for disease targets of importance in their respective geographical locations. The platform nature of mRNA technology enables various vaccines to be produced by changing the target sequence of the infectious organism of interest. Skills in technology transfer facilitate building capacity in vaccine manufacture on technology partnerships template. Establishing CDMOs would position LMICs to build local vaccine and biologics manufacturing capacity through technology transfer partnerships [61]. With local biomanufacturing capacity established, technology transfer transitions

to accelerating bringing needed biotherapeutics to the market. As such, technology transfer becomes critical in the journey from research discovery to commercialization, driving translational research in the process.

11 The CDMO model

11.1 Driving biologics manufacturing capacity through CDMO

Establishing a CDMO offers the opportunity to seed manufacturing capacity through structuring critical partnerships in technology transfer and manufacturing technology. Figure 3 provides a schematic illustration of the strategy as expounded above. The CDMO will have on board expertise in cell lines, bacterial and viral-based production systems, host organisms, bioprocess development, GMP-compliant manufacturing, analytical testing, vaccine and biologics regulation as well as technology transfer. This is complemented by specialized equipment, a facility with fit-for-purpose manufacturing spaces and expertise (human capital). The CDMO offers an easy integration of development and manufacturing under one roof, enabling smooth transition during in-bound technology transfer from R&D to manufacturing. The GMP-compliant facility can manufacture clinical batches for phase I–III trials in addition to contract manufacturing. This facility will contribute to added capacity in pandemic preparedness during outbreaks. It will also add to the global capacity when added capacity is required to produce billions of doses during pandemic outbreaks such as COVID-19. Regional capacities where extensively relied upon to rapidly ramp up production during COVID-19. The Serum Institute (India) produced Oxford-AstraZeneca vaccine (Covishield/Vaxzevria) under contract from AstraZeneca while Aspen Pharmaceuticals (South Africa) manufactured Johnson & Johnson vaccine (Ad26.Vov2.S). The capacity in equipment, facility, expertise and manufacturing enables these companies to win the contract manufacturing ensuring access to essential vaccines for the local populations. The COVID-19 pandemic and its global nature has jolted large vaccine manufacturers to constantly look for technology transfer opportunities that are sustainable and have a strong business case [62]. This development presents an opportunity for LMICs to take leverage to build capacity. Following the example of India, Indonesia and Thailand, public sectors in Africa could establish CDMOs as SOEs or through a PPP focusing on platform technologies for biologics manufacturing as long-term investment projects. The aim would be building skills and expertise in the long-term in order to seed a private biotechnology start-up ecosystem.

11.2 The CDMO business model

On the basis of the technology transfer and technology partner, a newly created CDMO can opt for a platform technology for development and manufacturing of viral vectors vaccines provided the national regulatory authority has attained Maturity Level 3 (ML3), which enables application for WHO prequalification. However, in the absence of ML3, the strategy could be to produce viral vector raw material, plasmids and clinical batches for clinical trial applications in a GMP-compliant facility as a stepping stone to full vaccine manufacturing. The interim manufacturing strategy will help build capacity in skills, expertise and equipment to broaden the scope of services the CDMO will offer.

The lack of critical skills and expertise in defined areas of vaccine development and manufacturing has been identified as one of the most important constraint on capacity in LMICs [36, 37]. A Viral vector design and manufacturing operation will provide an opportunity for local scientists to gain critical skills and expertise in the application of molecular biology to the design of plasmid expression systems, host selection and cell line development. Process development and subsequent pilot scale manufacturing of viral vectors follow on the creation of an efficient and stable expression vector, providing opportunities for local scientists and bioprocess engineers to gain and enhance their skills in scale-up and process science in a GMP-compliant environment. Analytics is the corner stone of any vaccine and therapeutics biomanufacturing operation as it underpins quality assurance and quality control. However, competencies and expertise in bioanalytics and bioassays can be best acquired in routine operation settings resembling a commercial operation. As such, a running viral vector manufacturing operation offers the best opportunity to build expertise in bioassays and analytical techniques. The ability to create master cell banks (MCB), working cell banks (WCB) and virus seeds is an important part of any commercial vaccine and therapeutics bioprocess operation. Cell banks are the heart of a company's existence as its IP, the loss of which would spell disaster for the entity. As such, skills in creating, maintaining and using cell banks and virus seeds are of the foundation of commercial vaccines and biologics biomanufacturing. The skills training in vaccine development and manufacturing will come full circle in clinical batch manufacturing in a GMO-compliant facility.

Using one platform technology that is well characterized in terms of safety, a CDMO can produce vaccines, monoclonal antibodies and gene therapy products such as CART cell therapeutics. Additionally, this strategy enhances pandemic preparedness as a required vaccine can be accelerated to the market during an outbreak when the platform is well characterized.

12 Regulatory frameworks and compliance in Africa manufacturing

Developing robust regulatory frameworks across Africa is essential for ensuring the safety, quality, and efficacy of medical products and fostering a sustainable manufacturing sector [63]. Several African countries have made significant progress in advancing their regulatory systems to achieve Level 3 maturity. Tanzania, for example, has enhanced its regulatory environment through the Tanzania Medicine and Medical Devices Authority (TMDA), which focuses on implementing GMP and conducting rigorous post-market surveillance [64]. South Africa and Egypt have established comprehensive regulatory frameworks with strong governance structures and compliance systems that align closely with international standards [65, 66]. Similarly, Ghana's Food and Drug Authority (FDA) has improved its regulatory processes by emphasizing safety and quality control [67], while Nigeria has made strides in combating substandard products through the National Agency for FDA control (NAFDAC) [68]. Zimbabwe has recently progressed to level 3 maturity by strengthening the Medicines Control Authority of Zimbabwe (MCAZ) with improved inspection practices and regulatory reforms [69].

While reaching level 3 regulatory maturity is a significant achievement, advancing to level 4 presents new challenges for these countries. Achieving the highest level of regulatory maturity requires not only compliance but also the capacity to foster innovation and improve efficiency [70]. South Africa and Egypt are closer to this stage due to their advanced infrastructure and stronger regulatory governance. Other countries, such as Ghana, Nigeria, and Zimbabwe, need to focus on building technical capacity, better resource allocation, and enhancing regional harmonization efforts. Aligning with international standards is crucial for effectively managing new regulatory challenges and improving market access [71]. Initiatives like the East African Community Medicines Regulatory Harmonization (EAC-MRH) programme have been crucial in these advancements, especially for countries like Tanzania that benefit from shared resources and expertise [72].

Achieving higher level of regulatory maturity in Africa is vital for the pharmaceutical industry and public health. Advanced regulatory systems provide a solid foundation for providing high-quality medical products, fostering public trust, and ensuring safety. They also attract investment by reducing compliance risks and encouraging local production and international partnership. Moreover, harmonized regulatory frameworks facilitate smoother cross-border trade, improving access to essential medicines and supporting economic integration across the continent [73]. As more African countries strive for level 4 maturity, they set the stage for competitive and sustainable pharmaceutical sector that meets both regional and global standards.

13 Conclusion

The strategy for building vaccine and biotherapeutics manufacturing capacity in Africa requires an ecosystems approach that includes building research capacity and nurturing entrepreneurship, incubation infrastructure, CROs, CMOs and CDMOs as part of the trajectory to move from bench to market. However, the point of coalescence for the aforementioned is a hands-on research and training facility providing skills training across the needs of the entire ecosystem and supporting both industry and academic research. It is equally important to leverage strategic collaboration with PDPs and big pharma for technology transfer and technology partnerships for defined expertise in building vaccine and biotherapeutics manufacturing capacity. However, to leverage technology transfer through PDPs, governments should drive the establishment of manufacturing facilities and research institutes as SOEs or leveraging PPP agreements to provide the template upon which to build capacity through technology transfer. Talent retention strategies are critical to stemming the tide of brain drain. In this regard, it is critical to both nurture an entrepreneurial mindset in researchers and provide the supportive infrastructure for commercializing of research discoveries. This work recommends a structured approach for LMICs to build vaccine manufacturing capacity with the public sector involvement taking center-stage. The need for focus on platform technologies in vaccine manufacturing in particular is emphasized.

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