

Business and Operational Models for African Biomanufacturing Training Centres



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Abbreviations

| | |
|------------|--|
| AfCDC | Africa Centres for Disease Control and Prevention |
| AU | African Union |
| ATI | African biomanufacturing training initiative |
| PBMC | Peripheral blood mononuclear cells |
| BSL-2 | Biosafety level 2 |
| BTEC | Golden LEAF Biomanufacturing Training and Education Centre |
| CASTL | Canadian Alliance for Skills and Training in the Lifesciences |
| CDMO | Contract Development and Manufacturing Organization |
| cGMP | Current Good Manufacturing Practice |
| CQV | Commissioning, Qualification and Validation |
| CSIR | Council for Scientific and Industrial Research, South Africa |
| CVM | North Carolina State College of Veterinary Medicine |
| DSP | Downstream processing |
| ETC | Extracontinental training centre. Centres used as benchmarks and not located in Africa. |
| FDI | Foreign Direct Investment |
| FF | Fill and Finish |
| FFA | Framework for action |
| FTE | Full time equivalent |
| GIZ | Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH |
| GmbH | Gesellschaft mit beschränkter Haftung |
| ICGEB | International Centre for Genetic Engineering and Biotechnology |
| IPD | Institut Pasteur de Dakar |
| KF | Kina Foundation |
| KWTRP | Kemri-Welcome Trust Research Program |
| LMIC | Low and middle-income country |
| mAbs | Monoclonal antibodies |
| MADIBA | Manufacturing in Africa for Disease Immunization and Building Autonomy |
| mRNA | Messenger RNA |
| MSAT | Manufacturing, Science and Technology |
| NCSU | North Carolina State University |
| NCTM | National Centre for Therapeutics Manufacturing at Texas A&M University |
| NIBRT | National Institute for Bioprocess Research and Training |
| NPEC | National Pharmaceutical Education Centre at the Technological University of Dublin |
| PAVM | The Partnerships for African Vaccine Manufacturing |
| PESTLE | Political, Economic, Social, Technological, Legal and Environmental analysis. |
| QA | Quality Assurance |
| QC | Quality Control |
| RCCCN | Regional Capability and Capacity Centre Network |
| RCE-VIHSCM | The East African Community Regional Centre of Excellence for Vaccines, Immunization and Health Supply Chain Management at the University of Rwanda |
| SAMRC | South Africa Medical Research Council |
| SOP | Standard Operating Procedure |
| STEM | Science, Technology, Engineering and Mathematics |
| TUD | Technological University of Dublin |
| UA | Univercells Academy |
| UCT | University of Cape Town |
| USP | Upstream processing |
| UWC | University of the Western Cape |

Introduction & Background

The African Union (AU) has set an ambitious goal to increase local vaccine production to 60% of the continent's requirements by 2040. The AU's Partnerships for African Vaccine Manufacturing (PAVM), hosted by the Africa Centres for Disease Control and Prevention (Africa CDC), was established in 2021 and estimates between 900-1600 current Full Time Equivalents (FTEs) in manufacturing need upskilling, while an additional 7000-8800 newly qualified FTEs will be required by 2040. Allowing for workforce turnover and other mitigating circumstances 14,000 people will need to be trained to meet the Continent's needs. Training must encompass research and development, process development, upstream processes, downstream processes, formulation, fill and finish operations, and cross-cutting training in analytical testing in a quality control environment. PAVM have been given the mandate to lead the workforce development program to meet those needs.

Challenges

Establishing suitable training centres face challenges including building a facility that can adequately simulate real production processes, the creation of course content and the development of sustainable business models as the overall biomanufacturing ecosystem is established.

At present, several initiatives across Africa, including Institut Pasteur Dakar in Senegal, CSIR in South Africa, the University of the Western Cape also in South Africa, the Kemri Wellcome Trust Research Program in Kenya, the EAC Regional Centre of Excellence for Vaccines, Immunization and Health Supply Chain Management in Rwanda, and the Kina Foundation in Ghana, are exploring options to establish such training centres. These initiatives have secured some funding, although at the time of writing it is not clear what funding is for one-time capital investment and what is committed for continuous support for ongoing training. PAVM proposes to develop Regional Capability and Capacity Centre Networks (RCCCNs) to resolve the three main challenges in talent development: lack of coordination between local talent development initiatives, brain-drain of local talent, and sustainable financing.

Main Aims

BACKUP Health, a global programme of the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH, commissioned by the German Federal Ministry for Economic Cooperation and Development has partnered with the PAVM talent development workstreams to help emerging African biomanufacturing training initiatives (ATIs) assess viable operational and business models. This engagement stems from a realization during the PAVM hosted biomanufacturing workforce development workshop in February 2023 in Pointe Sarène Senegal, that there is significant uncertainty on how to successfully maintain hands-on biomanufacturing training centres on the continent. The primary aim of this report is to identify possible business models to ensure long term viability of ATIs.

¹ *Partnerships for African Vaccine Manufacturing (PAVM) Framework for Action 2022 Version 1*

Objectives

The specific objectives of this report are:

1. Conduct a scoping study of established training centres, identifying successful structural, operational, and business models and lessons learnt to inform the development of possible business models for African initiatives.
2. Provide case studies from a sample of established training centres whose structure or operations might be useful benchmarks for African initiatives.
3. Conduct a baseline assessment of a sample of African biomanufacturing training centre initiatives.
4. Assess potential operational models for two different types of training centres: a small, limited scale centre and a larger, industry scale centre.
5. Consider a scenario with three limited-scale centres located in strategic regions of the continent.
6. Provide advisory services to biomanufacturing training initiatives and other stakeholders based on the study results.
7. Include the main findings and recommendations from a stakeholder workshop hosted by PAVM, Africa CDC and GIZ in Accra, Ghana on October 23rd and 24th, 2023.

Methodology

The methodology to generate this report consisted of the following steps:

1. An analysis of the operational and business model of seven extra-continental training centres, (ETCs) who have engaged with the PAVM initiative. The analysis is based on input from four extensive questionnaires and five semi-structured interviews.
2. An analysis of ATIs using the same questionnaire.
3. Semi-structured interviews with three ATIs, please go to appendix 4 to for the interview questions.
4. Case studies of ETCs are part of this report, each case presented has an operational and business model that may be relevant to ATI's, from multinational structures like ICGEB to discrete centres focused primarily on training like BTEC in North Carolina.
5. The report includes a basic analysis of the key factors that might affect the design and long-term sustainability of ATIs. It estimates capital & operational expenditures and looks at the potential impact of two different scenarios on the long sustainability of an ATI.
6. An intense two-day workshop to verify the findings of the report took place in Accra, Ghana, November 23rd and 24th 2023. A list of participating organizations is in the appendices.

OBJECTIVE 1.

Scoping Study of Established Training Centres

On average the seven participating ETCs have been operating for 10 years. However, the structure of each can vary, for example, five of the seven are not for profit organizations. ICGEB is a large intergovernmental organization, Univercells Academy and Merck's training department are business units within large multinational corporations, BTEC and NCTM are independent institutions within their respective universities and NIBRT is a wholly autonomous organization with a wide network of collaborators and partners.

As legal entities, most are the equivalent of limited liability companies, and their national or state government may hold equity. In terms of their potential engagement with ATIs some of the key attributes or characteristics these centres have developed include.

- *governance and management capacity; for example, financial management, business development, facility design, equipment specifications, sustainable operating models, human resource models, quality assurance both in training and for the operation of the centre.*
- *training capabilities including curriculum development and delivery, digital training and quality assurance of their programs, technology transfer and trainer development programs.*
- *subject matter expertise in biomanufacturing*

Figure 1 summarizes the structures of the different ETCs.

| | Group 1 | Group 2 | Group 3 | Group 4 |
|----------------|-------------------------------|-------------------------------|----------------------|----------------------------|
| | Inter-government Organization | Part of multinational company | Part of a university | Autonomous training center |
| For Profit | | ✓✓ | | |
| Not for Profit | ✓ | | ✓✓✓ | ✓ |

Figure 1. Structure of ETCs.

Organizational structure

Whilst their structures vary, the ETCs are designed to support their primary and secondary missions; provide high quality biomanufacturing training and support direct investment by the pharmaceutical industry into their region. Some ETCs have a board of directors whose remit includes strategy, performance, governance and represent any shareholders or members. They all have strategic and scientific advisory boards. They have a structure to ensure compliance and governance, resource, and revenue oversight. They have clear roles and responsibilities for oversight boards and how they interact with senior management who in turn give direction to the wider management team. The training centres may have between 40 and 100 FTE's including trainers and support staff operating and maintaining the training centre.

It should be noted, in many instances one individual may have several complementary roles in this diagram, which is not a definite list, but indicative of the resources ETCs employ to deliver their programs.



Figure 2. Typical functions and roles most ETCs employ to meet their business objectives.



Figure 3. Typical Leadership structure for ETCs.

Floor-size and equipment

Floor size for the ETCs range from 6,000m² to greater than 7,500m² including administration, classroom, and training laboratories. Typical process development and upstream production suites are 200m², process development and downstream production suites are 250m². Analytical methods development and product testing suites are also approximately 250m². Cell culture labs, if they have one, are about 65m². The facilities are at pilot scale with stainless steel and/or single use equipment. See Appendix 1 for typical floor layouts.

Equipment used by the ETCs includes the following:

- Bench-scale bioreactors.
- Bench-scale filtration and chromatography systems.
- Upstream pilot plant bio-processing suite to 150L operated under 'GMP-simulated' conditions.
- Downstream pilot plant bio-processing suite operated under 'GMP-simulated' conditions.
- Bio-analytical suite supporting the research and training activities operated under 'GMP-simulated' conditions.
- Single use disposable technology including storage, mixers, rockers, 50L and 200L stirred tanks.
- Some have filling suites including freeze dryers and isolator filling lines, suitable for training fill finish operations up to BSL-2.
- Many have research laboratories and analytical equipment including: HPLC, capillary electrophoresis,
- MALDI-TOF, circular dichroism, TOC, LC-MS, UPLC, MALLS, bioburden, microbial, ID, real time PCR and multimode plate readers.

Initial capital investment in the ETCs ranges from €25 million to €30 million for physically larger ones and €4 million for small to medium sized ones. See Appendix 1 for examples of medium and large-scale floor plans from TUD, BTEC and NIBRT. See Appendix 2 for a more detailed list of equipment used by training centres.

Target groups, courses, and throughput

Target groups include recent graduates who require 'bridging' course to prepare them to work in biomanufacturing, employees working for pharmaceutical companies, scientists from research institutions and current academic students whose programs include practical, hands-on training and although fees for academic students are much less than those paid by industry trainees, they are an important part of their business models.

How they identify their target groups depends on their structure and remit, however they all actively engage with external partners from international and government agencies to industry representatives and former students.

The ETCs provide a wide range of courses, offering a combination of industry training and academic programs. The mix of courses depend on their equipment, the capacity of their trainers, government guidance, regional industrial needs, and their relationship with local universities. Their offerings cover the full range of unit operations including cell culture, upstream processes, downstream processes, and fill finish. Most ETCs offer training in utilities, QC analytics and microbiology. In terms of vaccine manufacturing, practical training, that is industry focused, hands-on training, includes filtration, chromatography, formulation, fill finish and QC methods. Links to their offerings are provided in Appendix 3.

Depending on the subject, practical, hands-on, training is normally between 2 to 5 days. However, some in-depth courses can last up to 6 weeks. Class size for hands-on training is typically 10 participants, ranging from 4 to 20 participants. Online programs may be used to support hands-on training or may be offered as stand-alone programs. Their academic programs range from certificates to degrees and masters.

ETCs whose primary focus is training, i.e., groups 3 and 4 in Figure 1, train, on average, 800 individuals from industry, and 700 from academia per year. The maximum number of trainees per centre per year is approximately 1,500 academic students, 1,200 industry trainees, and over 5,000 online participants, equating to over 30,000 training days per annum. These ETCs are either part of a university or have partnerships with universities and even though fees for students on academic programs are much less than those paid by industry trainees, they are an important part of their business models.



Example of operational structure of an ETC

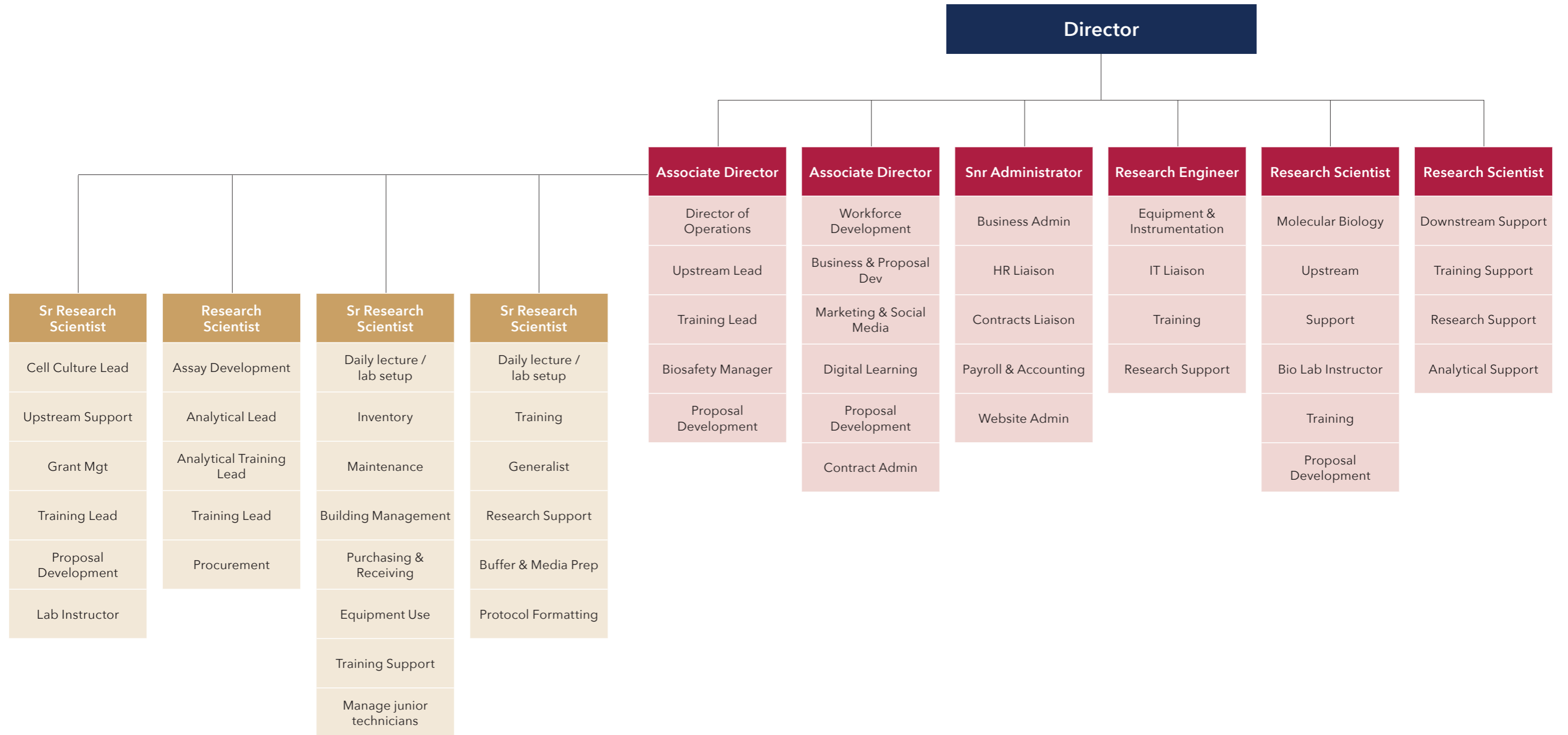


Figure 4. Example of operational structure of an ETC.

Quality control and recognition of training programs

The most valuable recognition of their training courses comes from ETCs reputation and endorsement from trainees and partners. All have quality assurance and quality control procedures around the design, development, and delivery of their courses. Their quality assurance processes are a blend of the systems one would encounter in the learning and development departments of pharmaceutical companies and, when they deliver academic programs, their procedures follow the relevant accreditation requirements. From an industry training perspective, certification of the ETCs courses by an outside organization is not a priority, however courses must be suitable for the industry partner, whether they are building a facility, expanding into a new technology or engaged in continuous professional development programs.

Sourcing of appropriately qualified trainers

Recruitment and retention are challenges for all ETCs, especially as they cannot offer the same salaries and benefits as the pharmaceutical industry itself. From discussions with ETCs, most pay 80% the rate a pharmaceutical company would pay for an equivalent role. Most training staff are full time employees, who are provided with a lot of support and training to ensure they can teach and instruct their trainees effectively. It is expensive and time consuming to recruit, onboard and bring a trainer to the appropriate level and so ETCs invest in diversity, equity and inclusion, career development, family friendly work practices and security of employment as much as they can. Most ETCs have a job classification structure with defined levels, job titles, roles and salary brackets providing a pathway for staff to plan and manage their careers. However, the ETCs do employ short term and contract trainers who have specific skills sets as required.

The ETCs training staff come from industry where they may have been subject matter experts, trainers, or technicians and from universities where they may have been postgraduate researchers or laboratory technicians with experience in similar technologies, some trainers previously worked for equipment vendors.

Each type of training course is different, some require more training support than others, however from the information provided, a new training centre may consider a range of 50 to 140 trainees per trainer per year when planning the resources required, and then quickly identify the correct ratio as the types of programs to be offered are refined.



Analysis of expenditures

Based on feedback from ETCs in groups 3 and 4 of Figure 1, their annual operational expenditure can range from €1.8 million to €9.3 million per year and salaries account for 60% to 70% of operational costs.

These ETCs required €25 million to €30 million to be established and spend up to €1.5 million per year on continuous capital investment. Due to government funding, they can move with technology changes and continue to attract new business. For example, NIBRT have completed a €21 million extension consisting of five research laboratories and training suites in advanced medicinal products including cell and gene therapies.

Mid-size centres invested approximately €4 million initially in CAPEX. These also need ongoing capital investment and NPEC recently updated their manufacturing execution system for €180,000. ETCs who responded to the question estimate they spend between 1% and 10% of revenue on business development. The larger the organization, the less is spent on business development as a percentage of revenue.

Significant costs that vary by ETC will vary at the ATIs, including salaries and associated benefits, rent, consumables inventory and capitalized costs that depreciate over time such as land, buildings, and equipment. Ongoing repairs, maintenance costs can be significant and may be very different across the continent. Overheads, such as management, security, quality systems, IT, business development should also be noted and any business plan for an ATI will need to identify and estimate these costs in detail. Whilst single use bioreactors can be used many times for training, they are expensive. QA systems, training of personnel, especially at start-up, utilities, especially the cost of power and backup power will vary and may be more significant for some ATI's than others.

The graph below is derived from information supplied by ETCs, the amounts vary between each and will vary again when the circumstances of each ATI is considered, however it highlights the major costs, excluding capital investment, that should be considered. Please note, staff at 63% of operational cost, is the average value based on information supplied by ETCs but due to the different services, programs and business models, the other values are informed estimates, and each ATI will need to change those values based on their own business models.

Major costs, excluding capital investment

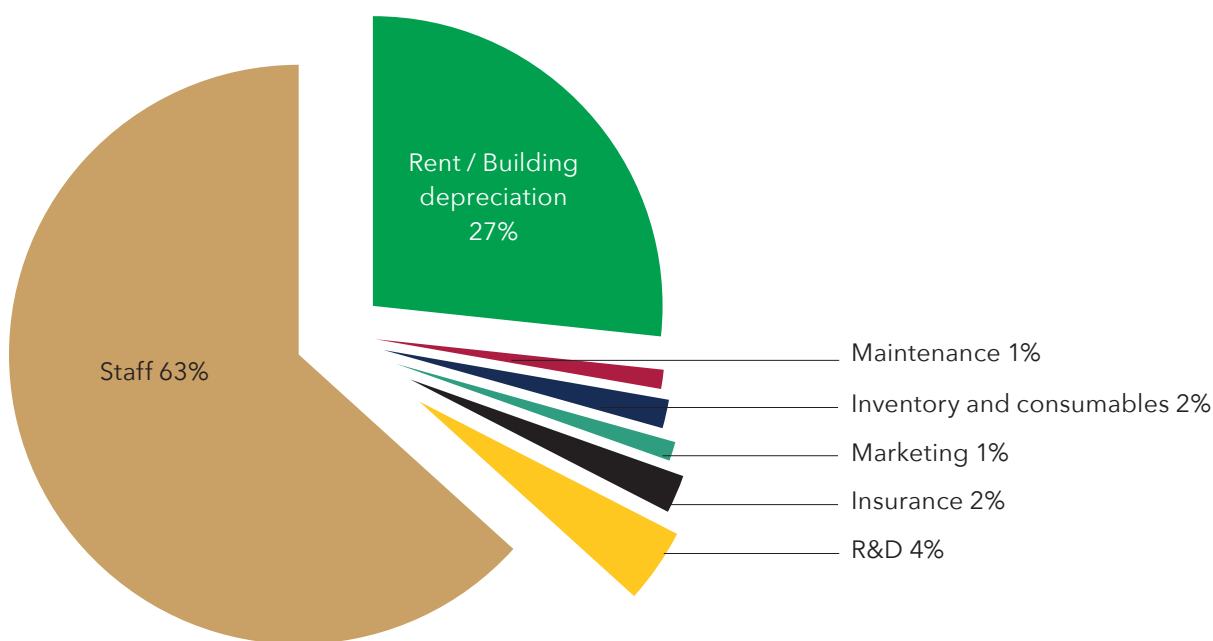


Figure 5. Major operational costs for ETCs, excluding capital investment.

Analysis of income streams

Income for the ETCs ranges from €2.5 million to €10 million per year. None of the ETCs could operate without support, whether it is government support or ongoing investment by their parent organization. For the ETCs in groups 3 and 4 of Figure 1, government support can be up to 100% for capital investment and ranges from 10% of 80% of operational costs. Figure 6 shows a simplified breakdown of income streams. Government funding and revenue from industry at 50% and 30% respectively are the average values from ETCs who provided that information. Funding from R&D and academic programs varies greatly, depending on their portfolio of products, services, and business objectives. For example, one ETC reported income from R&D at 5%, as shown in Figure 6 but another reported 30% of their revenue is from R&D.

Like costs, the amounts of revenue from different sources vary between each ETC and will vary again for each ATI, however the graph does capture the major sources of income, outside of capital investment that should be considered in any business plan. It should be noted, no ETC reported bank loans or private investment as sources of funding. The ETCs serve regional markets that range from 30,000 to 105,000 FTEs working in the pharmaceutical industry. NPEC and NIBRT operate in a market of 60,000 employees, BTEC and NCTM have up to 105,000 FTEs working in pharma within their US state. 85% of the ETCs revenue comes from within their region, which is either a US state or European country.

In conversation with both industry and training centres, pharmaceutical companies budget approximately 2% of their total salary costs towards training and education. There is not a fixed amount per FTE as some of this budget will go on compliance and regulatory training, some employee's might be supported to study a master's, others might get funding to attend a conference. There are many different demands on a company's finite training budget and ETCs must make a compelling case to secure some of those funds.

If we assume the average salary of a pharma employee in the US and Europe is €50,000 then €1,000 per worker per annum is allocated for education and training. For illustration of the economic environment ETCs operate in, assume an ETC operates in a market where 50,000 FTEs work in the pharma industry and it generates annual revenue of €3 million from industry courses, of which €2.55 million is from local manufactures, therefore it must win 5% of the total training budget allocated by all the pharma companies in its region. Assuming an average throughput of 800 trainees per year, this equates to €3,150 per trainee per course. A brief survey of the industry training courses offered by the ETCs shows that this is in line with the fees they charge. This scenario also requires ETCs to secure 70% of their revenue from a combination of government support, academic programs, R&D and providing courses to international or out-of-state trainees. The spreadsheet in the appendices will allow readers to adjust these numbers based on their understanding of the industry in their region.

ETC revenue/funding sources



Figure 6. ETC revenue and funding sources

OBJECTIVE 2.

Case Studies from a sample of ETCs

The previous section summarizes the environments ETCs operate in and the key factors they must manage to ensure ongoing success. The purpose of these examples is to showcase key attributes and resources that may be of value to individual ATIs.

MERCK

Limited scale training centre with capacity development support

Merck Group is an international life science company founded in 1668. Since 2010 Merck has purchased companies that produce life science equipment including Millipore and Sigma Aldrich, these subsidiaries form the foundation of Merck's Life Science Division with approximately €7 billion annual revenue and 22,000 employees. Training is an important section of this business; it can create business opportunities; it helps ensure trainees operate Merck equipment appropriately and Merck's trainers and engineers learn about new methods and technologies their clients may be deploying in addition to Merck equipment. Merck have built eight state-of-the-art training facilities in Europe, North America, and Asia, these are branded as M-Labs. However, this case may be of interest to ATIs who do not have access to the capital investment required to replicate a large or medium sized training centre. Merck have initiated a program to partner with institutions in developing markets, called the Biotech Collaboration Platform. Initially using bench top equipment, it intends to bring hands-on training to regions where none currently takes.

Initially Merck and their partner agree on the scope and specification of a suitable multi-modal platform. Merck supply the equipment; however, their partner must provide a suitable facility and support staff to provide training and maintain the equipment. Merck then deliver, install and together, the partners qualify the devices. Merck train the partners staff on process applications, the devices, and help build capacity by getting teams up to speed on key topics of concern to potential clients from process development to manufacturing challenges.

As multi-modal equipment, it is suitable for training on mRNA, MABs, viral vector and plasmid DNA and covers the full biomanufacturing process from cell culture and clarification to purification and formulation.

The partnership is a long term one that evolves from building capacity initially to further to developing to extending it over time. Initially the ATI will be trained and supported to offer training courses based on their regional priorities, however the medium- and long-term goal is to develop and continuously upgrade the equipment into an R&D platform, expanding capacities according to local process modalities. The centre would adapt its training packages as the regional needs expanded and potentially upscale from training and R&D to GMP where the centre would help drive the capacity development of the regional industry and offer increasingly sophisticated services to meet their clients' evolving requirements.

The initial training courses would be for those new to the industry, courses for intermediate trainees with one or more years' experience would follow and courses for advanced trainees with more than three years' experience would be offered when the training centre has capacity to deliver them. See Appendix 3 for a list of typical training courses an ATI might offer in partnership with Merck.

NIBRT and CASTL

Mid-scale training centres with network support

NIBRT is a world leading research and training facility for the biopharma manufacturing industry based in Dublin, Ireland. NIBRT delivers training to approximately 4,500 trainees per annum and has been a key enabler for the rapid growth of the biopharma industry in Ireland, which has seen over \$13 billion of new capital investment in the last 10 years and directly employs over 60,000 people. Nine out of the 10 largest global biopharma companies have a significant manufacturing presence in Ireland.

The 6,500m² NIBRT facility was opened in 2011 with a further extension of 1,800m² opened in Q3 2023. The NIBRT facility supports a team of approximately 100 staff (including a research team of 45-55 personnel). At the heart of the NIBRT building is the bioprocessing pilot plant, consisting of extensive upstream, downstream, fill-finish, associated analytical facilities and process utilities for both stainless steel and single use bioprocessing. These facilities are all operated in a realistic GMP simulated, manufacturing environment.

Since 2017 NIBRT has developed its Global Partner Program which supports an international alliance of leading training and education organizations to help address the global shortage of a skilled biopharma workforce. The program enables partner organizations to license NIBRT's intellectual property to provide biopharma training and education capability in their region. The program operates on a license model, where NIBRT provides set-up and ongoing support to partners. NIBRT have successfully partnered to establish training centres in Korea, China, Australia, two in Canada, and three in the US and therefore as an existing mechanism, the global partners program could help develop training capability in Africa.

In Q2 2021, CASTL joined the global partners program. CASTL provides training in biopharmaceutical manufacturing for Canada. Based in Prince Edward Island CASTL is a partnership between academia, industry, and government and it was initially created to help address the biopharma workforce shortage in Prince Edward Island and due to its success, has now evolved into a pan-Canadian initiative.

The equipment installed by CASTL is listed in Appendix 2. It cost €2 million and was funded by grants from a federal government agency and the provincial government. In the medium term CASTL are developing a larger training facility on Prince Edward Island and are currently opening satellite training centres, like their current one, in other provinces including Quebec and British Columbia, with support from those provincial governments. CASTL's licensing and support agreement with NIBRT as well as their initial equipment and training courses may be of interest to ATIs. Also of potential interest to ATIs is their plan to support satellite centres across the country in parallel to the growth of the initial centre into a mid-size and then full-scale training centre, this may be a model suitable for ATIs who wish to operate in different countries across Africa and require funding from different governments. As an example of what is possible, in February 2023, CASTL announced a €34 million investment by the Canadian government in a new 'BioAccelerator' to grow biomanufacturing capacity and training in Canada.

ICGEB

Intergovernmental organization

ICGEB is a unique, autonomous, intergovernmental organization with almost 70 member states. Their vision is to be the world's leading intergovernmental organization for research, training and technology transfer in the life sciences and biotechnology. Their mission is to combine scientific research with capacity enhancement, thereby promoting sustainable global development.

ICGEB is a network of affiliated national, subregional, and regional centres with three host countries: the headquarters and biomanufacturing facility is in Trieste, Italy, where the Director-General's Office is located, another component is in New Delhi and another in Cape Town. New Delhi and Cape Town have their own Component Directors who are responsible for delivery of their centres mandate.

ICGEB champions scientific cooperation and advanced education including PhD and postdoctoral fellowships, international scientific meetings, and competitive grants. They facilitate technology transfer and support partnerships that align with their sustainable development agenda. As such training activities are a core feature of their offering and include high level scientific training on biotechnology on a variety of topics and specific trainings on biomanufacturing, production of biosimilars, cGMP and regulatory science. They are included as a case study because their multinational structure and funding model might be a suitable template for an ATI. They are funded by contributions from member states who support the core operational budget necessary for all institutional and research activities. Other specific projects are funded by external partners who provide the amount needed to complete those projects, but the member states ensure the organization has enough resources to fulfil its primary mission.

In total, approximately 70% of their budget comes from assessed contributions* and 30% from external sources which includes grants from funding institutions and collaborations with industry.

Their pricing strategy for training programs is linked to the type of attendees:

- *From LMICs: pricing aims at cost coverage of consumables and part of the involved personnel.*
- *From high income countries: cost coverage of consumables and personnel + 10% overheads.*
- *From for-profit companies: price is subject to negotiation, includes all cost coverage + 10% OVH and may include a mark-up that supports other trainings for LMICs.*

The facility in Trieste offers a range of training programs, from a 2-week, hands-on general biomanufacturing course for up to 10 trainees to specialized training product-specific biosimilar biomanufacturing for 3 to 4 trainees and takes between 4 to 6 weeks. They also offer online training, these are live and interactive sessions that use the internet to overcome geographic restrictions and therefore are usually limited to 10 participants or less, for each session. ICGEB also host around 400 fellows each year who are hosted across their 45 laboratories and work on various life sciences and biotechnology projects.

*The current cost of membership is directly linked to the UN rate, corrected by a multiplier of 0.75, the minimum level of contribution is US\$5,000 and the maximum level of contribution is US\$150,000.

National Centre for Therapeutics Manufacturing (NCTM) and Golden LEAF Biomanufacturing Training and Education Centre (BTEC)

Full-scale Training, Development and Analytical Centres

Both BTEC and NCTM are ideal benchmarks for ATI's who plan to become full-scale training, development, and analytical centres of excellence. Although they both are independent institutions within their respective universities, they can call upon the resources of their universities as required. For example, the College of Veterinary Medicine (CVM) at NCSU have partnered with Institut Pasteur Dakar for several years, following Amartya Sens Capability Approach, ensuring their work together is an equitable partnership. BTEC will call on the resources of NCSU and experience of CVM to ensure any partnership with an ATI follows a similar structure. NCTM, with funding from BARDA, collaborate with Africa CDC providing specialized hands-on programs for African scientists and engineers at their facility in Texas. The courses include an advanced certificate in biopharmaceutical manufacturing, biomanufacturing of vectors for gene therapy and mRNA vaccine manufacturing. The courses are a response to the immediate vaccine manufacturing talent needs on the continent.

Both centres offer education and training opportunities in biomanufacturing to industry employees and university students. Whilst the number of annual trainees is different, one trains on average 300 participants per year and the other, 1,300 including 900 professionals, the structure of their courses are similar, each hands-on course accepts 10 to 12 individuals and lasts between 2 days and 2 weeks. The depth and breadth of their courses have grown over the years based on increasing institutional capability and industry feedback, please see Appendix 2 for a link to their current course offerings. Both centres have well developed human resource policies ensuring trainers and other professionals have career paths which includes ongoing professional development. The quality assurance, course design and delivery, management and administrative structures of both centres are rigorous and would make ideal benchmarks for new ATI's.

The centres state explicitly they are dependent on state or federal funding to remain open. Government funding covers capital investment and supports operational costs. Their respective state governments recognize that the centres bring more value beyond training a work force who earn more than their peers in other industries, their governments recognize the additional benefits of the centres, especially as assets to help attract foreign direct investment. Information from NCTM, BTEC and other ETCs show they receive between 50% and 70% of their annual budgets from their respective governments. Regardless of the amounts, the message from BTEC and NCTM is clear, long term government investment is necessary to build a highly capable biomanufacturing training centre.

Both are now large, highly capable, and extensively equipped training centres ranging from 1,400m² to 4,000m² in training laboratory space, however, it is worth noting the most impactful courses they provide are hands-on technician level training that is focused on basic concepts such as fermentation, cell culture, recovery and purification, fill-finish as well as analytics. 1,000m² of lab space plus a similar allocation of space for classrooms should be sufficient to provide that type of training.

Univercells Academy (UA)

Training, Capacity Development, CDMO support.

UA is included as a case study so ATIs can assess if a partnership with an organization like Unizima, Evotec Biologics or Merck might provide the required support, knowledge sharing, and technology transfer they require.

UA is a division of Univercells, who specialize in the development and production of inexpensive vaccines for poliomyelitis, measles, rubella, polio, rabies, yellow fever, human papilloma virus and hepatitis A. UA are fully aligned with Univercells' mission of 'Biologics for All', and it has worked across the continent of Africa including, Senegal, Algeria, and Mozambique.

As in the Merck case study, training is an important business unit within a larger organization and UA was specifically set up to help build a biomanufacturing workforce in LMICs, sharing the bioprocessing, technological, strategic, business, and logistical expertise of the Univercells Group with its partners. In terms of structure, UA has a centrally headquarters-based product and curriculum development team complemented by field-based trainers who provide hands-on training in biomanufacturing, regulatory affairs and quality assurance, each course is tailored to different skills and experience levels. They use a blended approach combining theoretical modules with hands-on training in multiple languages and in multiple formats based on their participants needs.

Another aspect of their structure that may be of interest to ATIs is their focus on revenue. They have a commercial lead, business development managers, marketing and communications managers and they continuously track the following KPIs:

- *Revenue and revenue growth*
- *Number of sessions of trainings a year*
- *Number of trainees attending each course*
- *Evaluation of the trainings and feedback*
- *Student satisfaction, including relevance of the trainings to their work*
- *% of students recommending the courses to others.*
- *Gross and net profit*

UA are still in a startup phase, and use their CDMO facilities for upstream, downstream and analytics trainings with delivery of their fill-finish courses taking place at other training centres. They plan to invest in a dedicated centre with training labs and classrooms and the design, development, commissioning, and qualification of this facility could be an opportunity for knowledge sharing with ATIs.

OBJECTIVE 3.

Baseline assessment of African biomanufacturing training

ATIs operate in a very different environment to ETCs who either have ongoing government funding or can leverage the resources of their larger organization to support their development and operations. Political, economic, social, technological, legal, regulatory, and environmental factors can change greatly as one would expect from a 30 million km² continent consisting of 54 countries and 1.2 billion people.

Training initiatives of note include programs by the South African Medical Research Council (SAMRC), Kemri-Wellcome Trust Research Program (KWTRP), Kina Foundation (KF), the Centre for Scientific and Industrial Research (CSIR), the University of the Western Cape (UWC) and the EAC Regional Centre of Excellence for Vaccines, Immunization & Health Supply Chain Management (RCE-VIHSCM). These initiatives are either starting in 2024 or are in their first or second year. Each will develop to meet different training biomanufacturing training needs.

Emerging Training Initiatives

Apprenticeships, 'bridging' courses' and post graduate programs.

SAMRC provide a four-month hands-on 'bridging' program to industry for 3rd or 4th year graduates. They train two cohorts of 20 to 25 participants per year.

- *Weeks 1 to 5 covers theory, and the fundamentals of biopharmaceutical manufacturing.*
- *Weeks 6 to 10 are lab based and teaching laboratory rudiments, aseptic techniques, molecular biology, tissue culture, PCR techniques, proteomics, etc.*
- *Weeks 10 to 16 includes upstream and downstream bioprocessing training using facilities at UCT and the SUN bioprocessing groups. The program targets students from disadvantaged backgrounds and provides stipends for the time trainees are on the program.*

KWTRP have an apprenticeship program whereby graduates from across the continent are placed in pharmaceutical factories around the world. The program has set learning objectives and participants return to their home country after the apprenticeship to help build manufacturing and research capabilities. KWTRP hope to support up to 100 apprenticeships during phase 1 of the program. KWTRP also have an outreach program to high schools to encourage students to enter STEM courses in university, ensuring there is a pipeline of graduates ready to work in the pharmaceutical industry.

Like ICGEB in Trieste, Italy, the RCE-VIHSCM is a member multinational organization and member states include Kenya, Tanzania, Uganda, Burundi, and Rwanda. RCE-VIHSCM already offers a Master of Science in Health Supply Chain Management and is developing additional master programs in vaccinology, pharmaceutical analysis, and regulatory affairs. In addition to the master programs, they have trained almost 1,500 health care professionals in short courses. They are also building an extensive collaboration network with academic, industry and research institutions and global organizations.

The Centre for Scientific and Industrial Research (CSIR)

Full-scale Research, Development and Analytical Centre

CSIR is a leading government funded scientific organization that researches, develops, localizes, and diffuses technologies to accelerate socioeconomic prosperity in South Africa. In June 2023 CSIR launched the African Biomanufacturing Workforce Training Program, with the intent to develop a skilled and competent workforce on the continent. It will run over three years and provide a technology development and hands-on training to support and grow biomanufacturing activities on the African continent. The program consists of four courses, biomanufacturing technologies, vaccine production, biopharmaceutical quality management systems and cGMP manufacturing at scale. Each course will take two weeks, CSIR can accept up to 25 applicants and there is funding to cover the travel costs of 10 participants, 5 from South Africa and 5 international applicants.

Like the ETCs, CSIR has an advanced and highly capable support infrastructure. Their training courses ensure participants engage directly with processes such as fermentation, sampling, analysing, and purification. This direct engagement ensures that trainees receive a comprehensive understanding of biomanufacturing processes. The centre's infrastructure is actively used, ensuring that participants get a genuine feel for the equipment and procedures.

CSIR recognizes the importance of trainers being not just knowledgeable but also proficient in knowledge transfer. This dual expertise ensures that trainees receive both depth and clarity in their instruction.

They also welcome collaboration and continuously explore possible partnerships that assist other African countries establish similar training programs, fostering a broader African biomanufacturing ecosystem. Such collaborations are vital for the scalability and sustainability of biomanufacturing training in Africa. They are also essential to avoid duplication and help optimize resource utilization across the continent.

The demand for CSIR's courses is high, one course attracted 153 qualified applications, but only 25 places were available. Such high demand underscores the relevance of CSIR's training program that ensure trainees get hands-on experience, complemented by standard operating procedures and other relevant materials. This blend ensures that trainees are well-equipped to handle real-world biomanufacturing challenges. Also, like the ETCs, CSIR require funding to provide their training programs and they have secured funds to deliver the African Biomanufacturing Workforce Training Program for an initial three years. By the third year, they envision transitioning to a fee-based course structure, ensuring the program's longevity.

Despite its successes, CSIR faces several structural challenges. Travel and accommodation costs for participants remain a significant hurdle. While scholarships are available, they are limited, and participants often grapple with visa challenges, accommodation expenses, and transportation costs. To mitigate these challenges, CSIR has adopted a blended approach, combining online and on-site training. This approach ensures broader accessibility while maintaining the quality of training.

From an African talent development perspective CSIR are limited in the amount of training they can offer because they are primarily a research centre and although training is an important part of what they do, and the courses they offer are a very high standard, utilizing their equipment and expertise, they do not plan to become a training centre similar to the ETCs reviewed previously.

Kina Foundation (KF)

Industry specific bridging course.

Located in Accra, Ghana, the Kina Foundation's mission is to support skills development in the biopharmaceutical industry of Africa, meeting the needs of students and industry professionals through training, workshops, and continuous education.

KF offers a six-month post graduate bridging program, preparing students to work in industry.

- *Month 1: Biochemistry. Genetics. Pharmacology. Physiology.*
- *Month 2: Immunology. Types of vaccines. Principles of vaccination. Research & ethics.*
- *Month 3: GMP, GLP and Biosafety.*
- *Months 4 & 5: Aseptic Manufacturing*
- *Month 6: Cell Culture. Practical hands-on training in aseptic techniques. Media preparation. PBMC isolation methods and ELISpots assays.*

Starting with a cohort of 50 students, KF will train 400 students once all its infrastructure is in place. It currently operates from a rented facility equipped to deliver blended learning programs where students are present in the classroom and expert tutors attend virtually. However, an investment of \$3 million has been earmarked for the construction of a dedicated building including a technical laboratory. This new facility will include upstream to downstream equipment. Although the course is currently taught in English, KF plan to provide the course to French-speaking students. Course content will be translated, and suitably qualified interpreters and assistants will be present as the course is delivered. The teaching model is a hybrid one, combining face-to-face instruction with virtual sessions. This approach allows for the inclusion of international faculty members without the associated travel costs. Students will be on-site, at KFs facility and the faculty may be located internationally.

The biopharma industry's projected demand indicates a need for trained professionals in the sector, for example, Ghana is estimated to need approximately 350 FTEs in the coming years and KFs training program is positioned to cater to this growing demand. This demand is driven by the larger biopharmaceutical industry, including vaccine manufacturing.

From an administrative perspective, KF has displayed a structured approach. The decision to hire a grant manager underscores their commitment to ensuring a continuous flow of funding and growth. This role is crucial in aligning KFs objectives with those of potential funders.

A common theme from ETCs and ATIs is the need for funding, and KFs financial strategy recognizes the risks involved and emphasizes cost-effectiveness. Whilst funding would make the program accessible to many trainees who otherwise could not afford to attend, KF is looking at potential revenue from student fees in the future, these fees would be paid by students or their employers who may pay all or part of the fees. Their proactive stance on funding is evident in their efforts to collaborate with various entities, KF is open to partnerships with academic institutions and potential donors whose objectives align with their mission.

Several structural challenges could impact KFs reach beyond Ghana, these include travel logistics, linguistic barriers, and visa-related issues. However, KFs initiatives, such as linguistic inclusivity and a hybrid teaching model, suggest efforts to mitigate these challenges will be successfully overcome and KF could become a very valuable biomanufacturing training centre across Africa.

The School of Pharmacy at the University of the Western Cape (UWC)

UWC is a research-led university with a focus on access and equity in higher education. They have decades long experience reaching marginalized communities, engaging with them, and successfully supporting students who normally would not participate in tertiary education. This experience will be used by the university when their hands-on biomanufacturing training programs begin, training under and post graduate participants and trainees without formal qualifications but would perform well in a biomanufacturing facility as operators, technicians etc.

Since 2011 The School of Pharmacy (SP) has taught an online master's program in Regulatory Sciences for students across Africa. The program is consistently oversubscribed and to increase accessibility they recently created diploma and certificates courses. In 2023 UWC signed an MOU with the Technological University of Dublin as an initial step in offering a range of courses in pharmaceutical technology by leveraging TUDs experience in delivering programs in biomanufacturing with UWCs understanding of the requirements of participants from Africa. One requirement is to offer hands-on training and therefore SP intend to develop a suite of hybrid courses; online for students who cannot travel to Cape Town and hands-on training for those who can attend.

Currently, SPs infrastructure is a blend of basic equipment and dedicated spaces suitable for expansion and they have earmarked a suitable location for a pilot lab, and they are in discussions with a multinational company to help establish the lab. This partnership should minimize capital outlay and therefore reduce any financial support UWC may need from government or international agencies.

Two of SPs strengths are their online teaching, learning and assessment methodology and their students. SP boasts a unique model where high performing graduates, impacted by their programs, return as tutors, enriching the training experience with their first-hand knowledge of UWCs culture and sharing the challenges and developments they encounter in industry.

Funding remains a challenge. While the university receives subsidies for South African students, it relies on differentiated pricing for non-South African students and SP is exploring grants and partnerships to bolster its financial envelope. A willingness to cooperate with other training centres show a proactive approach to securing funding, especially as they are happy to help build the capacity of other centres across the continent.

UWC's location in Cape Town presents both opportunities and challenges. South Africa has a developing biopharmaceutical sector and both the national and regional governments recognize its importance. While students from Cape Town can benefit from short hands-on training courses, those from the rest of South Africa and the greater continent might require longer courses so travel can be justified. This geographical factor, coupled with potential travel restrictions, visa issues, and language barriers, could affect their reach, however their expertise in teaching and training should mitigate against some of these issues. A model using a mobile training lab that can travel to students is a medium-term goal they would like to explore with potential partners.

In conclusion, UWC, while challenges persist, the university's proactive approach to addressing them underscores its commitment to advancing biomanufacturing training across the continent.

OBJECTIVE 4.

Potential business models

The ETC case studies show some of the business models ATIs might consider, ranging from small scale bench top facilities to medium sized centres like NPEC and CASTL and large-scale centres that may also provide other technical and process development services such as BTEC, NIBRT and NCTM.

The cases also show different organizational structures where ETCs operate as an independent company (NIBRT), are part of a university (BTEC and NCTM), are a business unit within a multinational company (UA and Merck) or, are an intergovernmental organization (ICGEB).

This report examines two possible models for ATIs to consider:

1. a limited scale training centre with enough equipment for core biomanufacturing training, QA/QC analysis and process development, with the potential for modular expansion
2. a large, non-GMP, fully equipped industry-scale centre covering training for upstream and downstream, processes, including fill & finish, QA/QC assays and process development.



PAVM estimates 900 to 1,600 current full-time employees in biomanufacturing need upskilling, while 7,000 to 8,800 newly qualified FTEs will be needed by 2040. They will require training in upstream and downstream processes, fill-finish operations, R&D and process development, analytical testing, and other cross cutting processes. Therefore, between 7,900 and 10,400 FTEs will require training over the next 16 years, that is, between 500 to 650 per annum. That is certainly a viable number of trainees for one ATI, assuming it trains 100% of all potential trainees on the continent. However, for one centre to train all the continents trainees, many issues around language, travel and costs would need to be resolved.

Market growth is assumed to be linear, although a training centre can expect peaks and troughs in demand, especially when a manufacturing plant is being built. The pharmaceutical company will need many FTEs trained before and during commissioning, qualification, and validation (CQV) ensuring the facility is ready for steady state operations. After this phase is complete it will send less trainees to the centre, replacing FTEs who leave and upskilling current workers as part of their career development or in preparation for new products.

Limited scale training centre

CAPEX

The equipment for a limited scale centre should consist of pilot scale bioprocessing equipment that allows trainees to gain practical skills that can be immediately transferred to process scale-up and clean room environments. See Appendix 2.5

The cost of the equipment in this scenario is approximately €1.5 million, including cell culture media prep, cell culture production and clarification, buffer prep, affinity chromatography, viral inactivation and aggregate removal, purification chromatography, polishing chromatography, viral clearance, concentration and diafiltration, filtration and filling. Equipment suppliers might share their equipment with a training centre but there are caveats, for example, the supplier may retain ownership, and the centre may need to pay for maintenance and consumables. NPEC at TUD as a medium scale example, has the following unit operations: 2-litre fermentation, 10-litre fermentation, 20-litre fermentation with media tank and harvest tank, coarse filtration, fine filtration, pre-mix, final-mix, pasteurization, CIP, instrumentation header experiments and bottle filling.

For this report, the following is assumed: *

| | |
|--|-----------------------|
| Equipment: | €1.5 million |
| Commissioning, qualification, and any validation that may be required, | €200,000 |
| Contingency | 15% |
| Transport costs | 10% |
| Total | €2.125 million |

To allow for initial expansion, assume the ATI will build a 600 m² facility.

| | |
|--|-----------------|
| Building cost per m2 Including black utilities = €1,150 x 600: | €690,000 |
| Contingency | |
| Transport costs | 10% |
| Total | €862,000 |

Total Cost for new facility and equipment

€2.9 million

As a comparison NPECs equipment cost €4 million in 2002. The price differential is due to many reasons, including advances in technology, and NPEC installed fixed stainless-steel equipment with a fully functioning clean in place / steam in place process which may not be necessary of a limited scale ATI. They also have some industrial scale equipment, for example 10-litre and 20-litre fermenters with media tanks and harvest tanks.

**These assumptions are based can be changed in the spreadsheet in the appendices. For example, building costs will vary between countries, some centres may already have a building, others may decide to rent facilities, however from discussions with ETCs and ATIs the amounts presented are indicative of expected costs.*

OPEX

Staff requirements for a limited scale module will be approximately 20 FTEs and include:

- 4 senior managers overseeing operations, finance, strategy, and business development liaising with key stakeholders.
- 4 mid-level managers overseeing training schedule, maintenance, QA, and accounts etc.
- 7 trainers, including senior trainers and administration.
- 1 lab technician
- 2 maintenance and facilities personnel
- 2 security officers

Salaries

| | | |
|------------------------|---------------|----------|
| 1 x Head of Department | = 1 x €63,000 | €63,000 |
| 4 x Manager level | = 4 x €55,000 | €220,000 |
| 4 x Supervisor level | = 4 x €24,000 | €96,000 |
| 9 x Technician level | = 9 x €20,000 | €180,000 |
| 2 x Worker level | = 2 x €3,000 | €6,000 |

Total Cost of salaries per annum €565,000

Using ETCs as a benchmark; salaries are 63% of OPEX, therefore annual OPEX = €869,000.

In discussions with ATIs and subject matter experts working in Africa, some consumables and utilities may cost more, especially as a percentage of overall costs. Therefore, for initial budgeting purposes assume salaries will be between 55% and 65% of total operation costs, each ATI can then refine actual costs based on local conditions.

Although the ATI might operate as a not-for-profit organization, it should still ensure a positive cash flow and maintain the ability to invest and deal with unexpected issues, therefore a minimum of 15% net asset gain should be the target of any training centre, setting an income target from all sources between €1.0 million to €1.2 million.

Funding

Again, using the ETCs as a benchmark

| | | |
|---------------------------------|--------------------|----------|
| Revenue from industry | = 30% of income or | €300,000 |
| Revenue from academic programs | = 15% | €150,000 |
| Revenue from R&D | = 5% | €50,000 |
| Government and external funding | = 50% | €500,000 |

Note: it is assumed capital expenses are funded as non-repayable loans or grants from government agencies and funders. Whilst government agencies might hold equity in an ATI, loans and private equity are not considered for this report. If the experience of ETCs is relevant to the African context, ATI's will be profitable as a stand-alone business, therefore calculations of NPV, IRR, WACC and Payback are not required.

Training courses

Based on the equipment, training could include short-term hands-on courses, with or without theoretical training.

| | | |
|-------------------------------------|----------------|--------------------|
| Bioprocessing Entry | 1.0-day course | 1.0 day practical |
| Biomanufacturing | 5.0-day course | 4.0 days practical |
| Downstream Processing | 2.0-day course | 2.0 days practical |
| Upstream Processing | 3.0-day course | 2.0 days practical |
| Intro to Normal flow filtration | 1.0-day course | 1.0 day practical |
| Intro to tangential flow filtration | 1.0-day course | 1.0 day practical |
| Basic Chromatography | 1.0-day course | 1.0 day practical |
| Normal flow filtration equipment | 2.0-day course | 2.0 days practical |
| Tangential flow filtration | 2.0-day course | 2.0 days practical |
| Sterility Testing | 1.0-day course | 1.0 day practical |
| Environmental | 1.0-day course | 1.0 day practical |
| Single Use Technologies | 2.0-day course | 2.0 days practical |
| Fill Finish | 2.0-day course | 2.0 days practical |

See Appendix 3, which shows how these offerings may expand.

Throughput & industry fees

The spreadsheet in Appendix 4 will allow the user to adjust all the variables so for the purpose of illustration it is assume a limited scale training centre will instruct 200 industry trainees per year, for an average of 2 days per course. A thorough market analysis is outside the scope of this report, each ATI will need to conduct a full assessment of their market to determine if this scenario is optimistic or underestimates demand.

The cost per two-day course for industry clients should be €1500, with an annual income of €300,000. This fee is roughly half the cost of similar courses in the EU and USA. Scheduling 200 trainees per year should not be an issue, especially if class sizes range from 5 to 10 trainees per course as this equates to one or two training days per week.

The model also includes revenue of €150,000 from academic partnerships and programs. The fees a centre can charge for academic programs will be less than industry fees, however scheduling 600 training days at €250 per day is possible, and the centre can take larger class sizes from universities and increase the percentage of each course taught in classrooms or online.

The model allows some revenue from R&D. There are many advantages to engaging in R&D; it builds close relationships with industry and academic partners, especially if there is a long-term plan to become a CDMO, and it will support career development and staff retention. One challenge will be managing time and resources, if R&D earns 5% of income, it should not cost much more than 5% of OPEX. Centres will need a pricing strategy for R&D, especially if it becomes a larger part of their business.

Full scale training centre

The equipment for a full-scale centre will be extensive, go to Appendix 2 for an indicative list of upstream, cell culture equipment and downstream, purification equipment. Media and buffer preparation equipment and filling equipment are also listed. This range would allow a centre to offer a suite of training courses that replicate almost all the processes needed to manufacture vaccines.

The cost of the equipment is approximately €35 million, however as Appendix 2 shows, the cost varies greatly, and a centre will need to specify the right equipment for the unit processes and modalities it wishes to cover. Again, equipment suppliers might share their equipment with a training centre, but the same caveats remain as outlined previously.

CAPEX

With reference to Appendix 2, for the purpose of this exercise, assume the following:

| | |
|-----------------------------------|--------------------|
| Equipment: | €22 million |
| Installation, CQV where required. | €2.9 million |
| Contingency | 15% |
| Transport costs | 10% |
| Total | €31 million |

To allow for some expansion, assume the ATI will build a 2500m² facility.

| | |
|--|---------------------|
| Building per m ² including black utilities = €1,150 x 2,500m ² = | €2.9 million |
| Contingency | 15% |
| Transport costs | 10% |
| Total | €3.6 million |

Total Cost for new facility and equipment **€35 million**

OPEX

Separate to any R&D function, ETCs employ approximately 50 FTEs at a ballpark cost of €3 million, with individual salaries ranging from €35,000 to €180,000. Whilst there are differences between the structure of US and European ETCs approximately 30% of FTE's earn more than their organizations average salary, with the remainder earning less.

Like a limited-scale centre, some consumables and utilities may cost more in Africa than in Europe or the US and salaries may range between 55% and 65% of total operational costs and each centre will need to refine actual costs based on their business model.

| | |
|--|--------------|
| Total Cost of salaries per annum = 50 x €28,000* | €1.4 million |
| Using ETCs as a benchmark, salaries = 63% of OPEX = | €2.2 million |
| Contingency and Net Asset Gain of 15% equals target revenue of | €2.5 million |

**Based on the structure of ETCs in Groups 3 and 4 of Figure 1 and their ratio of higher and lower salaries etc.*

Funding

| | | |
|---------------------------------|--------------------|---------------|
| Revenue from industry | = 30% of income or | €750,000 |
| Revenue from academic programs | = 15% | €375,000 |
| Revenue from R&D | = 5% | €125,000 |
| Government and external funding | = 50% | €1.25 million |

Note: it is assumed capital expenses are funded as non-repayable loans or grants from government agencies and funders.

As already stated for the limited scale centre, whilst government agencies might hold equity, loans and private equity are not considered for this report.

Training courses

Based on the extended list of equipment a full-scale centre will have, training courses will include all the courses listed for a limited scale centre plus a large percentage of the options provided by ETCs like NIBRT, BTEC and NCTM. See Appendix 3 for the range of courses a full-scale training centre can offer. An ATI will need to work with external partners such as PAVM and vaccine manufacturers to ensure they build the infrastructure and capacity to offer training courses required in the short and long term.

Throughput & industry fees

Appendix 4 will allow the user to adjust the variables.

Assuming the large-scale centre trains all the FTE's who require training; between 500 to 650 participants per year, and the cost allocations are like ETCs, to reach €750,000 in revenue from industry, the centre should charge €1500 per 2-day course.

If they train more than 500 participants they can invest in future growth, reduce their academic programs which typically pay less per participant than industry courses, or reduce the need for funding from external bodies.



OBJECTIVE 5.

Possible scenarios

The authors were asked to consider two possible scenarios based on the report findings. There are many possible combinations of full, medium, and limited scale centres located in different regions that may develop over time. Two different scenarios were examined: the first considered two additional limited scale centres and the second considered two full scale centres plus two limited scale centres. The second scenario was deemed to be unviable at present and is not included.



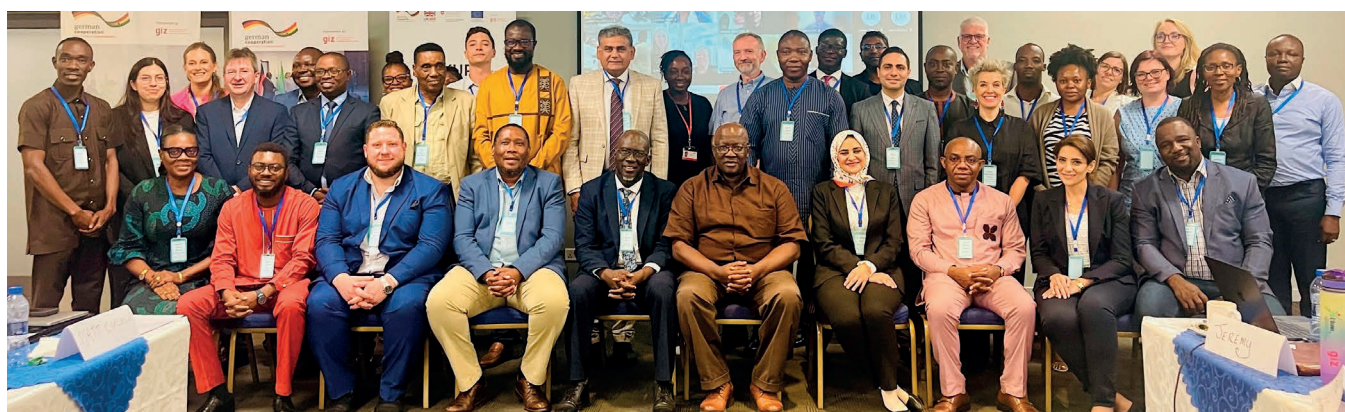
If 500 to 650 FTEs require training per year, two additional limited scale centres should be sustainable, all things being equal. This assumes their business models secure the necessary revenue, for example, 25% to 35% of revenue from industry, 10% to 20% from academia, 0% to 10% from R&D and the remainder from government and external funding. Each centre should be free to evolve to meet regional needs and requirements but collaborate and share resources as much as possible, including online content, train the trainer programs, shared license fees etc.

Language issues have not been touched upon in this report and although English, French, Portuguese, and Arabic will be understood by many trainees, trainees at operator and technician level might only speak their native languages or wish to engage in general discussions in their native language and three centres in different regions would be in a better position to accommodate linguistic diversity.

Conclusion and recommendations

This report does not capture all the biomanufacturing training that is taking place in Africa. Of the ATIs who engaged with the authors, only CSIR has the equipment and capacity to rival an ETC at this moment in time. CSIR's primary focus is research and development and so their training numbers are constrained. Kina Foundation has a foundational curriculum and a plan to develop their own center and use a development lab for hands-on training in the medium term. All going well, between 200 and 400 recent graduates could be trained annually at KF. UWC delivers online post graduate programs in regulatory sciences, will launch online courses in pharmaceutical technology in 2024 and intends to build a small-scale pilot lab for hands-on training in 2024. RCE-VIHSCM delivers a related masters' program and is developing more, they also offer shorter training courses. KWTRPs apprenticeship program will see up to 100 postgraduates gain valuable experience working in factories from six to twelve months and their outreach program should help ensure a future pipeline of trainees as more are attracted to STEM courses.

Therefore, as far as can be ascertained, there is no equivalent training center to an ETC on the continent of Africa. This is a strategic weakness that will inhibit the growth and development of the African biomanufacturing industry, however it is also an opportunity because some ETCs offer courses on older technology while they adapt to new technologies and modalities. ATIs have an advantage as they can focus on the current needs of the African biomanufacturing industry who will exploit the latest advances in science and engineering. With the proper support and ambition, the first sentence in this paragraph will hopefully be rewritten in the near future, stating, 'there is no equivalent training center to the African biomanufacturing training centers in the US or Europe.'



Based on the results of the initial research and the two-day workshop in Accra Ghana, we recommend the following:

Priority Recommendations

1. Promote collaboration between training centers across Africa: Establish a forum for ATIs as part of the PAVM Talent Development Workstream. Topics may include opportunities and challenges, sharing resources such as curricula and developing standardized and efficient training practices for a greater impact.
2. Publish guidelines identifying key factors to establish and maintain a successful training center.
3. Conduct a benchmarking and operational readiness project to ensure ATIs have the capacity to deliver essential biomanufacturing training courses as quickly as possible.
4. Create an interactive dashboard to track progress towards PAVMs 2040 goals starting with training and expanding to the other programs within the PAVM Framework for Action.
5. Engage with the Technology Transfer and IP workstream to develop a technology transfer training program.

6. Prioritize practical training: Integrate lab sessions, industry visits, and where possible, internships for hands-on experience.
7. Foster deeper ties with the biomanufacturing industry and equipment suppliers to align training with industry needs.
8. Build strategic partnerships with ETCs: Collaborate for technology transfer and knowledge exchange, train the trainer programs, and resource sharing.

Sustainability and Funding

9. Optimal scenario: Start with three limited-scale training centers at strategic locations, considering various factors like market size, technology, and training budgets.
10. Advocacy: Collaborate with PAVM to advocate for long-term government funding. Long term funding for ATIs is essential, however governments can also enable the success of ATIs through changes to policies, taxes and income support for the ATIs and pharmaceutical industry in general.
11. Engage with stakeholders for diversified funding: Secure multiple funding sources for long-term sustainability.
12. Sustainability: Explore income opportunities beyond traditional funding, like integrating with universities or research centers, offering process development services, consultancy services and potentially producing clinical trial batches under cGMP.

Operational and Business Planning

13. Develop detailed business plans for ATIs: Provide a roadmap for ATI evolution, outlining goals, markets, and revenue sources.
14. Develop 5 to 10-year strategic plans: Focus on growth, sustainability, and adapting to industry changes.

Coordination and Collaboration

15. Industry needs: Engage with the industry through PAVM to determine current and future training needs.
16. Coordination: Facilitate engagement between industry, ATIs, and ETCs for training courses conducted outside of Africa.
17. International cooperation: Consider a regional structure like the ICGEB model if securing funding from one government is challenging.
18. Organize annual curriculum review meetings: Engage stakeholders to ensure centers offer relevant and effective training programs.
19. Implement robust feedback systems: Gather insights from trainees, government, regulatory and industry stakeholders for continuous improvement.
20. Gap analysis: Collaborate with PAVM and industry stakeholders to identify and bridge curriculum gaps.

Accessibility and Inclusivity

21. Offer training materials in multiple languages: Enhance accessibility and inclusivity for a broader audience.
22. Trainees needs: Offer courses to individuals without degrees but with transferable skills from related industries.

Appendices

Appendix 1. Examples of floor plans

Large Scale Facility Floor Plans

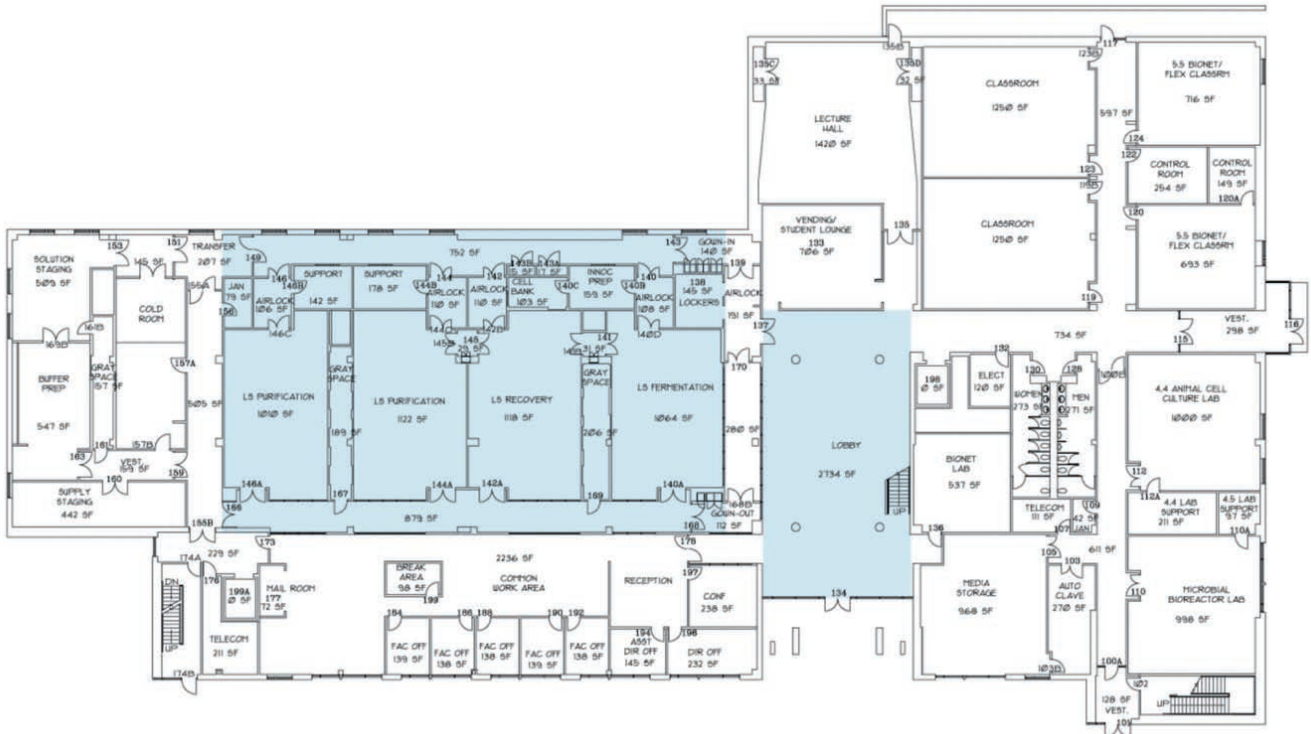


Figure 7. BTEC ground floor

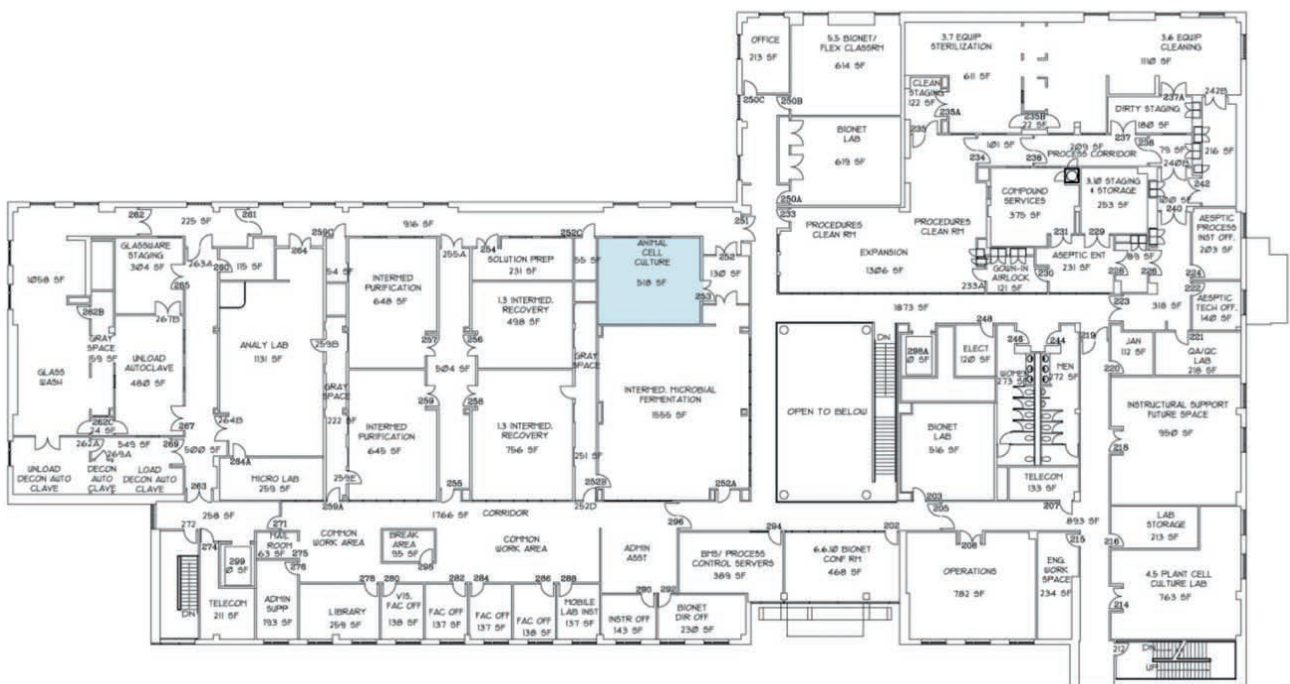


Figure 8. BTEC first floor

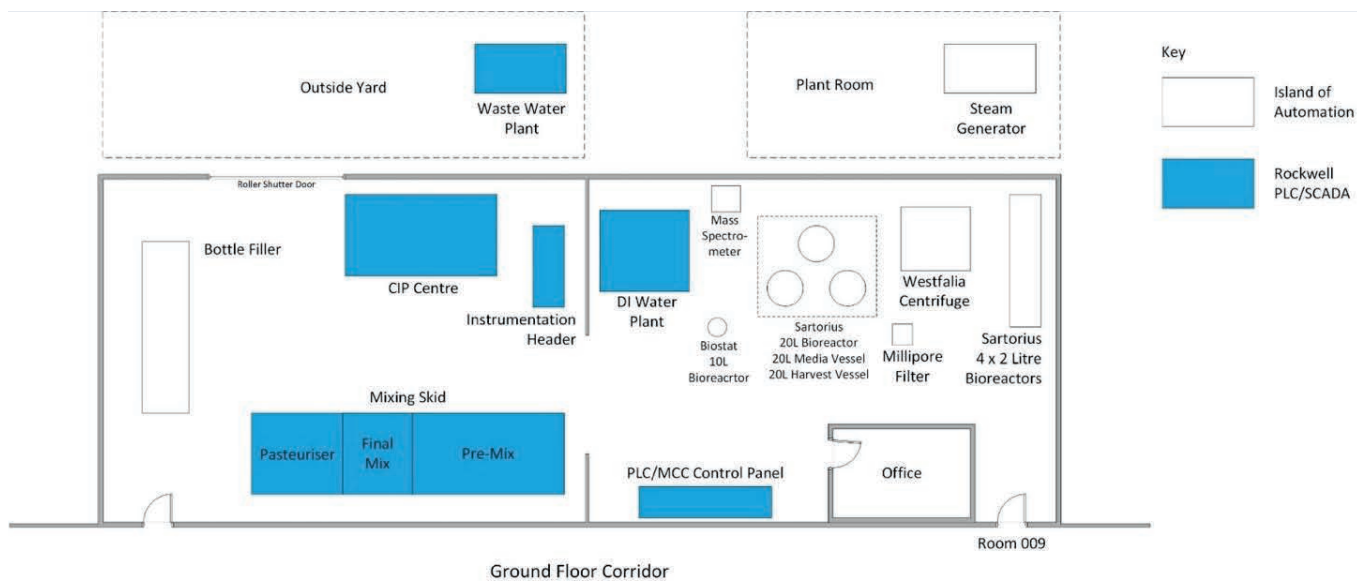


Figure 9. NPEC Plan

The Pilot Plant was built in 2002 and is a non-qualified, non-GMP environment. The Plant is used to simulate pharmaceutical and bio-pharmaceutical operations and is used as a laboratory environment for student experiments as part of the various pharmaceutical production and pharmaceutical science courses at undergraduate and post graduate level.

The pilot plant consists of the following:

- 4 x 2-litre Sartorius fermentation
- 10-litre fermentation
- 20-litre fermentation with media tank & harvest tank
- Course filtration
- Fine filtration
- Pre-Mix
- Final-Mix
- Pasteurization
- CIP (Clean in Place)
- Instrumentation Header
- Wastewater
- Deionized Water Plant
- Bottle Filling

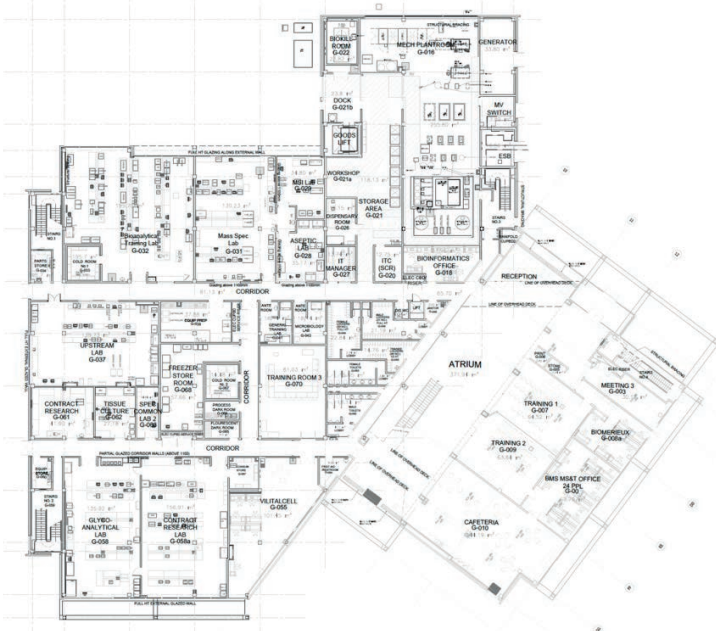


Figure 10. NIBRT ground floor

The overall facility at NIBRT is 6,500m² divided over two floors.

The facility breaks down into four main functional areas name the research labs, training labs, administration space and facilities/utilities.

The overall training space is approximately 2000m² which is purposely been divided into functional areas including upstream pilot plant, downstream pilot plant, fill finish training suite, quality control training labs add three classrooms.

Functional areas divided and separated as this enables different training programs to be run in parallel and to maximize the utilization of the facility.

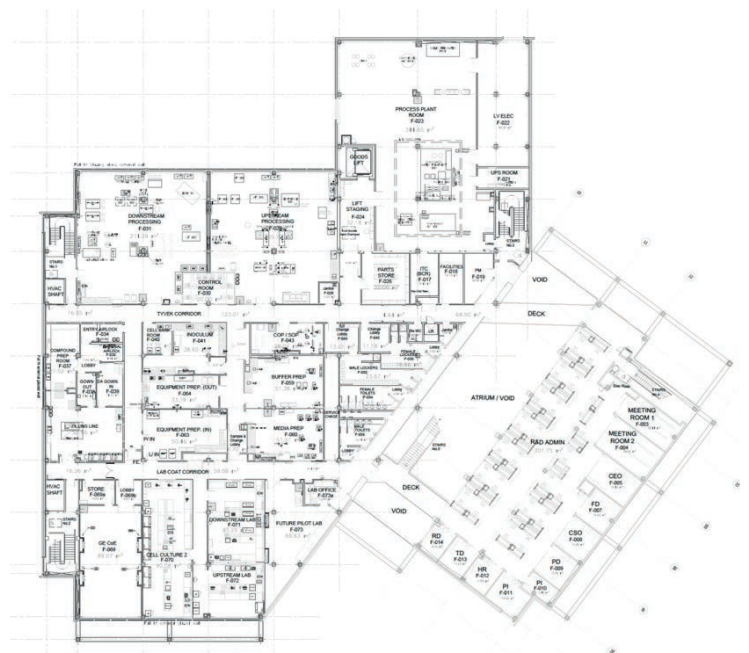
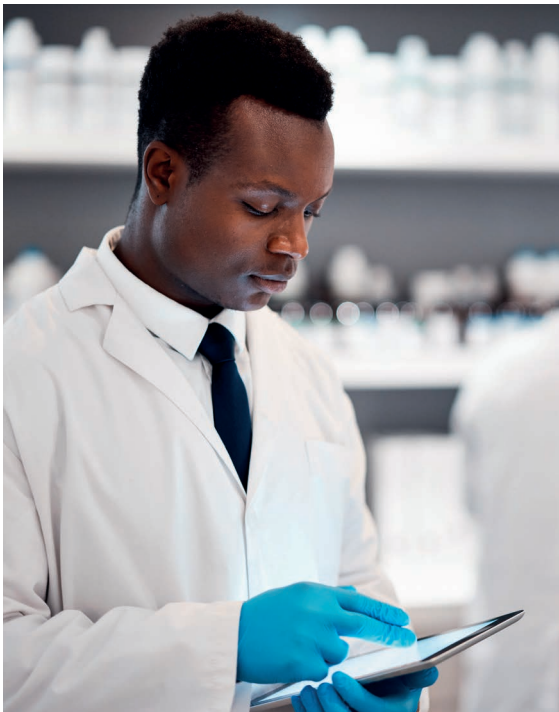


Figure 11. NIBRT first floor

Appendix 2. Pilot scale equipment and costs

Process equipment that is typically contained in a pilot scale biopharma manufacturing upstream or cell culture suite.

| Equipment | Capacity | Estimated Range (€) (ROM) | |
|--|----------|---------------------------|-------------------|
| Bioreactors/Fermenters stainless steel | 150L | €20,000 | €100,000 |
| SU Bioreactor skid | 30L | €10,000 | €50,000 |
| Disposable stirred tank bioreactor | 200L | €5,000 | €30,000 |
| Media Preparation Systems | | €10,000 | €100,000 |
| Bench-top disk-stack Centrifuge system | | €5,000 | €20,000 |
| Disk-stack centrifuge | | €10,000 | €100,000 |
| Incubators | | €500 | €10,000 |
| Cell Harvesting Systems | | €10,000 | €100,000 |
| Perfusion Systems | | €10,000 | €200,000 |
| Analytical Instruments | | €10,000 | €1,000,000 |
| Bench-top microfiltration system | | €1,000 | €10,000 |
| Disposable Depth Filter | | €50 | €500 |
| Stainless Steel depth filter housing | | €500 | €5,000 |
| Total | | €92,050 | €1,725,500 |

List of all the typical process equipment that is contained in a pilot scale biopharma manufacturing downstream or purification suite.

| Equipment. | Capacity | Estimated Range (€) (ROM) | |
|---|----------|---------------------------|-------------------|
| Centrifuges | | €1,000 | €100,000 |
| Filtration Systems | | €1,000 | €200,000 |
| Ready to Process Chromatography Columns | | €500 | €10,000 |
| Membrane Chromatography | | €500 | €5,000 |
| Ultrafiltration/Diafiltration | | €10,000 | €100,000 |
| Tangential Flow Filtration Systems | | €10,000 | €100,000 |
| Evaporators | | €1,000 | €100,000 |
| Freeze-Thaw Systems | | €10,000 | €100,000 |
| Viral Inactivation Systems | | €10,000 | €100,000 |
| pH Adjustment Systems | | €1,000 | €20,000 |
| Mixing Systems | | €100 | €100,000 |
| Buffer Preparation | | €10,000 | €50,000 |
| Storage Tanks | 150L | €500 | €5,000 |
| Analytical Instruments | | €5,000 | €500,000 |
| Disposable Depth Filtration | | €50 | €500 |
| Total | | €60,650 | €1,490,500 |

List of process equipment that is required for media and buffer preparation to support a biopharma vaccine or mAb manufacturing at process pilot scale.

| Equipment | Capacity | Estimated Range (€) (ROM) | |
|--|----------|---------------------------|-------------------|
| Weighing and Dispensing Systems | | €1,000 | €1,000,000 |
| Mixing Tanks. | | €500 | €50,000 |
| Filtration Systems | | €1,000 | €200,000 |
| Ultrafiltration/Diafiltration System (UF/DF) | | €10,000 | €1,000,000 |
| Purified Water Systems | | €1,000 | €1,000,000 |
| Autoclaves/Sterilizers | | €1,000 | €100,000 |
| pH and Conductivity Meters | | €50 | €5,000 |
| Heat Exchangers | | €10,000 | €1,000,000 |
| Homogenizers | | €500 | €500,000 |
| Storage Tanks and Vessels | 50L | €1,000 | €20,000 |
| Storage Tanks and Vessels | 200L | €2,000 | €50,000 |
| Transfer and Distribution Systems | | €1,000 | €1,000,000 |
| Clean-in-Place Systems (CIP) | | €5,000 | €1,000,000 |
| Total | | €34,050 | €6,925,000 |

List of the major equipment required for a pilot scale sterile filling suite and associated support services such as equipment preparation, formulation, filtration, inspection, and bulk packaging.

| Equipment | Capacity | Estimated Range (€) (ROM) | |
|--|----------|---------------------------|--------------------|
| Laminar Airflow Hood Small | | €8,000 | €15,000 |
| Isolator/Glovebox | | €5,000 | €1,000,000 |
| Vial Filling Machine | 50vpm | €10,000 | €1,000,000 |
| Formulation Equipment | 50L | €5,000 | €1,000,000 |
| Filtration Equipment | | €5,000 | €1,000,000 |
| Capping and Sealing Machines | 50vpm | €5,000 | €500,000 |
| Inspection Machines | 50vpm | €10,000 | €1,000,000 |
| Sterilization Equipment | | €1,000 | €1,000,000 |
| Lyophilizer/Freeze Dryer | | €5,000 | €1,000,000 |
| Bulk Packaging Equipment | | €10,000 | €100,000 |
| Clean-in-Place Systems | | €5,000 | €1,000,000 |
| Sterilization-in-place Systems | | €5,000 | €1,000,000 |
| Media and Buffer Preparation Systems | | €5,000 | €1,000,000 |
| Environmental Monitoring Systems | | €5,000 | €1,000,000 |
| Total | | €84,000 | €11,615,000 |
| Estimated range for major equipment in a pilot scale training facility | | €270,750 | €21,756,000 |

List of equipment installed by the CASTL facility.

| Biopharma Training Room | Training Prep Room | Cell Culture Training Lab |
|--|--|---|
| -20, -80 Freezer Chemical Fume Hood Centrifuge 58140 R Bioreactor 200L Bioreactor RM 50 Hollow Fiber Filer Holder - Single Filter Mass Spec Forced Air Incubator 6.3 CF 120V. TFF Skid Filter Integrity Test Sterile Tube Fuser - dry Chromatography Skid | Sterilizer Glassware washer CO2 incubator Vertical Laminar Flow Hood VCM 600 6FT Gowning training and observation area Other Classroom x 10-15 students Meeting room Offices, kitchen, toilets | Tissue Culture Incubator Inverted microscopes Centrifuge mini pH conductivity meter Horizontal Laminar Flow Hood HCM-600 6FT Water bath 20L |



Appendix 3. Examples of training courses provided by ETCs.

Courses provided as part of Merck's Biotech Collaboration Platform

Foundational (no or limited experience in industry)

- *Biopharma Entry Course (1 day)*
- *Upstream I (1 day)*
- *Upstream II (1 day)*
- *Intro to Normal flow filtration (1 day)*
- *Intro to tangential flow filtration (1 day)*
- *Intro to Single Use Technologies (1 day)*
- *Basic Chromatography (1 day)*
- *Operate Normal flow filtration Process Equipment (2 days)*
- *Operate tangential flow filtration Process Equipment (2 days)*
- *Perform Sterility Testing (1 day)*
- *Environmental Monitoring School (1 day)*

Intermediate (1+ years' experience)

- *Fundamentals of Clarification Processing (1 day)*
- *Optimize and scale up of Normal Flow Filtration Process (2 days)*
- *Optimize and scale up of Tangential Flow Filtration Processes (2 days)*
- *Operate Single-Use Technologies (2 days)*
- *Operator Certification for Pilot and Process Chromatography Column Packing (2 days)*
- *Virus Filtration Process Development and Validation: Best Practices (1.5 day)*
- *Operator Certification of Automatic Filter Integrity Testing (2 days)*

Advanced (3+ years' experience)

- *Understanding Upstream Cell Culture Processes: Theory, Hands-on Operations, & Case Studies (2 days)*
- *Advanced topics in optimization, design, and operation of tangential flow filtration (TFF) processes (up to 4 days)*
- *Optimization, Implementation, and Scale Up of Single Pass TFF (SPTFF)*
- *Considering QbD & DoE in Chromatography and Column Packing (1 day)*
- *Understanding regulation of aseptic processing and filtration applications (1 day)*
- *Good design practice for filter sterilization (1 day)*

M-Labs: <https://my.matterport.com/show/?m=7ZpPoWxHu8N>

Some of the courses and programs provided by ETCs.

| | |
|----------|---|
| NIBRT: | https://www.nibr.ie/training-and-education/training-courses/ |
| BTEC: | https://www.btec.ncsu.edu/academic/courses/index.php |
| NCTM: | https://nctm.tamu.edu/training/ |
| ICGEB: | https://www.icgeb.org/activities/meeting-and-courses/ |
| UNIZIMA: | https://unizima.com/workforce-development/ |
| NPEC: | https://www.tudublin.ie/research/innovation-and-enterprise/technology-gateways-and-centres/micra/industry/consultancy-and-training/ |

Appendix 4. Questionnaire and interview questions

Questionnaire sent to both ETCs and ATIs

1. What are the goal and mission statements of your training center?
2. Please describe the organizational structure of your center, including the roles and responsibilities of key stakeholders such as the board of directors, management team, staff, and trainers.
3. What is the legal status of your training center (e.g., non-profit, for-profit, government-funded, etc.)?
4. What are your general plans or strategy for your training center's future?
5. Who are the target groups for your training programs (e.g., recent graduates, mid-career professionals, existing employees in the biomanufacturing industry)?
6. How did you identify these target groups?
7. What is your throughput of trainees, i.e., how many trainees can you accommodate per session or per year?
8. What are the primary sources of funding for your center? Please specify the proportion of revenue comes from tuition fees, government grants, private investments, industry partnerships and grants, and other sources.
9. Do you have different pricing strategies for different regions or cohorts of trainees?
10. Approximately what percentage of your revenue is spent on business development, sales, and marketing?
11. Approximately, what is your projected revenue for the next 5 years?
12. Approximately, what is your Gross Margin?
13. Briefly, what are your financial sustainability plans if your main funding streams should end?
14. What additional financial risks have you identified and what measures have you put in place to mitigate them?
15. What is your typical annualized capital expenditure (CAPEX)?
16. What has been your biggest CAPEX over the last 5 years?
17. What is your annual operational expenditure (OPEX)?
18. What are the biggest components of your OPEX?
19. Have you applied for and/or received short-term or long-term funding for your CAPEX or OPEX? If so, please share who the sources were, as per the NDA, this will not be shared if we are requested not to do so. It will form a general guide for other centers who may need similar funding.
20. What are the key performance indicators (KPIs) you use to measure the success of your biomanufacturing training center?
21. As new African training initiatives decide on the technology to support, please list your key infrastructure and technology (including already committed future investments) that directly support your training programs.
22. Please share the approximate floor size (total area) you have for your different types of training (classrooms, laboratories, unit processes etc.)
23. Briefly, how do you intend to maintain and upgrade your facilities and equipment over time to meet changing needs within the biomanufacturing industry?

24. Please provide a list or a link your current training programs
25. Are there any new training programs planned for the next two years?
26. How do you ensure your training programs meet the needs of your target groups and comply with industry standards?
27. How do you ensure the technology used at your training center meets the needs of your client pharmaceutical companies?
28. How do you source trainers and ensure they are qualified to teach the courses you offer?
29. What strategies do you have in place to ensure the continuous professional development of your trainers?
30. How does your center demonstrate that it meets industry needs and standards?
31. What are your key quality control and quality assurance procedures for your training programs?
32. How do you plan to maintain and improve the quality of your training programs over time?
33. What systems do you have in place for receiving and addressing feedback from students and industry partners?
34. How does your training center currently collaborate with industry, academic, and financial partners?
35. Do you have local or international partners to help deliver specified trainings?
36. What are the main structural factors affecting your reach beyond your home country (travel, language, visas, etc.)?
37. What key advice would you give to a new biomanufacturing training center looking to establish itself?
38. From your experience, if a new African Training Initiative began training with a limited set of courses using small scale equipment for core biomanufacturing training and process development, what training courses and equipment should they prioritize?
39. Can you estimate the area they would need for such a center? If possible, please estimate the approximate area for offices, classrooms, labs, unit operations they should consider?
40. Can you estimate the budget, for example as \$/square meter, for such a center?
41. Again, from your experience, what future modules would you suggest they consider developing, for example, QA/QC, fill finish, etc.
42. Also, from your experience, if a new African training initiative wishes to become a full scale non-GMP, fully equipped industry-scale training center for upstream and downstream development and manufacturing processes including fill-finish, QA/QC etc., can you identify the major capital and operational expenditures they should include?
43. Can you estimate the budget, for example as \$/square meter, for a full-scale center?
44. Would your center like to explore a possible long-term partnership with a new African Training Initiative?
45. What input or support would you like from established training centers?
46. Would your center like to explore a possible long-term partnership with an established training center?

Interview Questions

1. What is your vision for establishing biomanufacturing training centres for Africa?
2. What is your strategy to ensure sustainability and growth?
3. What training and courses do you give or plan to give?
 - a. what are their modalities (mRNA, mAbs, viral vectors etc.)?
 - b. what unit processes do you cover? USP, DSP, Fill Finish, QC Analytics etc.?
 - c. what is the scope of your courses, from manufacturing to QC to validation etc.?
 - d. what is the means of delivery: hands-on, online, or blended?
 - e. what equipment and facilities do you currently have?
 - f. what additional equipment would like to acquire?
 - g. do you have the required trainers and course content?
4. What is your current and future staffing plan?
5. What type of help/support/partnership would be most beneficial to you?
6. How can AfCDC, PAVM and others help? Perhaps influencing government policies, sourcing funding, interacting with industry?
7. Would you like support to get your operations to a 'steady state', for example with administration, HR, finance, governance, grant writing, specifying equipment, negotiating with vendors etc.
8. Do you need current or future financial support for CAPEX and OPEX?
9. What support and type of collaborations would you like with other centres?
10. Can you share with us some of the already identified or anticipated challenges you are dealing with? And can you share some of your solutions to those challenges?



Appendix 5. List of Participating Organizations at the 2-day Workshop

Organizations who participated in the workshop include:

- African Union.
- Africa CDC Partnerships for African Vaccine Manufacturing (PAVM).
- African Research Universities Alliance (ARUA).
- Armauer Hansen Research Institute (AHRI), Ethiopia.
- Biogenerics, Egypt.
- Biomanufacturing Training and Education Centre (BTEC) at North Carolina State University, USA.
- Bloom Public Health, Nigeria.
- Cheikh Anta DIOP University, Senegal.
- Council for Scientific and Industrial Research (CSIR), South Africa.
- Department of Health and Human Services, USA.
- Department of Science and Innovation, South Africa.
- Egyptian Authority for Unified Procurement (UPA) Egypt.
- Faculty of Capacity Development, Ireland.
- Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH
- Innovative Vaccine Initiative (IVI), Korea.
- Innopharma Labs, Ireland.
- International Centre for Genetic Engineering and Biotechnology (ICGEB).
- Kemri Wellcome Trust Research Project, Kenya.
- Kina Foundation, Ghana.
- Merck, South Africa.
- National Centre for Therapeutics Manufacturing at Texas A&M University, USA.
- National Institute for Bioprocess Research and Training (NIBRT) Ireland.
- South African Medical Research Council.
- Technological University of Dublin, Ireland.
- The Biovac Institute, South Africa.
- The EAC Regional Centre of Excellence for Vaccines, Immunisation and Health Supply Chain Management (RCE-VIHSCM), Rwanda.
- Thermo Fisher Scientific, South Africa.
- United States Pharmacopeia.
- University of the Western Cape, South Africa.
- Unizima, Belgium.
- UVU Bio, South Africa.

Appendix 5. Spreadsheet

The spreadsheet is provided as a separate document.



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