Building capacity for drug development process in Africa—A workable model

Chinedum Peace Babalola1,2, Olayinka Adejoke Kotila1,2, Babatunde B. Samuel1,2, Oladapo Adetunji1,3, Grace Olusola Gbotosho1,4, Jones O. Moody1,5, Adewale Muyiwa Adeyemi2, Olufemi Adegbola1, Gbekel’Oluwa Akin yele1, Oludele A. Itiola1,3, Joseph Fortunak6

1 Centre for Drug Discovery, Development and Production, Faculty of Pharmacy, University of Ibadan, Ibadan, Nigeria
2 Department of Pharmaceutical Chemistry, Faculty of Pharmacy, University of Ibadan, Ibadan, Nigeria
3 Department of Pharmaceutical and Industrial Technology, Faculty of Pharmacy, University of Ibadan, Ibadan, Nigeria
4 Department of Pharmacology and Toxicology, Faculty of Pharmacy, University of Ibadan, Ibadan, Nigeria
5 Department of Pharmacognosy, Faculty of Pharmacy, University of Ibadan, Ibadan, Nigeria
6 Department of Chemistry, Howard University, Washington DC, United States

Keywords
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Centre of excellence
Drug discovery
Quality medicine

Correspondence
Chinedum Peace Babalola
Department of Pharmaceutical Chemistry
Faculty of Pharmacy
University of Ibadan
Ibadan
Nigeria
peacebab@gmail.com

Abstract

Background: Africa’s reliance on drug importation translates to disproportionate transfer of foreign exchange and incessant drug shortages, among other vices. Africans, therefore, need to build capacity in drug discovery, development and production. This article showcases a workable model with an innovative approach of teaching together personnel drawn from Nigeria’s academia, pharmaceutical industry and medicine regulation agency. Method: Didactic training via postgraduate programmes was designed with hands-on experience in drug synthesis and production. Training and research objectives formed the core of activities. Result: The Centre for Drug Discovery, Development and Production (CDDDP), Faculty of Pharmacy, University of Ibadan, was established through grant funding from the MacArthur Foundation. The Centre runs two postgraduate degree programmes, has graduated over forty students, organised four workshops, two international conferences, and translated scientific findings to over eleven finished products. In 2014, the African Medicines Regulatory Harmonisation Programme designated CDDDP a Regional Centre of Regulatory Excellence and since 2019, it has partnered with the United States Pharmacopeia to promote the quality of medicines in low- and middle-income countries (LMIC). Conclusion: Capacity building in drug development processes in an LMIC has been developed with resultful outcomes and is proposed as a workable template for other LMICs.

Introduction

Access to essential medicines in Nigeria and Sub-Saharan Africa is presently limited by importation. About 90% of available medicines in Sub-Saharan Africa are imported mainly from Asia, with a few from Europe and the United States of America. Local production is needed to prevent stock-outs of essential medicines (Quick et al., 2005; Pheage, 2017; Shukar et al., 2021). Inadequate pharmaceutical innovation and sufficiently qualified pharmaceutical scientists within Africa are severely hampering the continent’s ability to discover and develop medicines that meet local needs. Existing facilities and academic programmes have not been able to address this problem because there is a shortage of trained personnel required to discover and produce medicines in Sub-Saharan Africa. Similarly, academic institutions are not positioned to fill the gap.

Access to safe and efficacious medicines is not optimal for most people in Sub-Saharan Africa. Consequently, countries spend substantial amounts of foreign currency to import medicines (Berger et al., 2010; Adebisi et al., 2022). A shortage of qualified professionals has deterred the growth and development of a private pharmaceutical sector capable of providing high-quality, safe, and effective essential medicines in these regions (Ogilvie et al.,...
Furthermore, Africa suffers from a lack of pre-qualified facilities for drug production and, hence the need for training of personnel for such facilities. The market survey carried out by a team of pharmaceutical experts confirmed the need for specialised training in drug development (Berger et al., 2010; Odeku et al., 2019; Signé, 2021). A needs assessment conducted among members of the Pharmaceutical Manufacturing Group of Manufacturers Association of Nigeria (PMG-MAN) showed that over 90% of the study population have a keen interest in registering for a graduate programme designed to specialise in drug discovery, development, and production if such exists in their immediate environment. This assessment was done by the authors of this article.

Presently, four pharmaceutical manufacturers out of the over 180 in Nigeria or the Economic Community of West African States (ECOWAS) sub-region have facilities pre-qualified by the World Health Organisation (WHO) for production and quality assurance of essential medicines, although a few others are working hard to be pre-qualified (WHO, 2014; Anyakora et al., 2017). In 2011, the WHO reported a 28.5% average failure rate in the quality of antimalarials in sub-Saharan African countries, with Nigeria having the highest incidence rate of 63.9% (World Health Organisation, 2011). These challenges inspired a team of researchers from the Faculty of Pharmacy, allied departments in the University of Ibadan and international collaborators to apply for a MacArthur Foundation grant for higher education to create a Centre of Excellence for Drug Discovery, Development and Production. Higher education is crucial for developing a skilled health workforce and increasing health research capacity. Therefore, it should receive a higher priority in national and regional educational and developmental agendas (Agyepong et al., 2017). University systems and the premier university in Nigeria offer an excellent platform for knowledge transfer, capacity building, human capacity development, and marriage of town and gown in evidence-based research, discovery and implementation of systems and structures that facilitate societal developments. This paper therefore describes the conceptualisation and development of a Centre of Drug Discovery, Development and Production (CDDDP) as an adoptable model or template for drug development processes in LMICs.

Table la: List of principal investigators and co-investigators of CDDDP

<table>
<thead>
<tr>
<th>Name</th>
<th>Designation</th>
<th>Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professor Chinedum Peace Babalola</td>
<td>Principal investigator</td>
<td>Faculty of Pharmacy, University of Ibadan</td>
</tr>
<tr>
<td>Professor O.A. Itiola</td>
<td>Co-principal investigator</td>
<td>Faculty of Pharmacy, University of Ibadan</td>
</tr>
<tr>
<td>Professor J.O. Moody</td>
<td>Investigator</td>
<td>Faculty of Pharmacy, University of Ibadan</td>
</tr>
<tr>
<td>Professor Grace O. Gbotosho</td>
<td>Investigator</td>
<td>Faculty of Pharmacy, University of Ibadan</td>
</tr>
<tr>
<td>Dr. M. A. Odeniyi</td>
<td>Investigator</td>
<td>Faculty of Pharmacy, University of Ibadan</td>
</tr>
<tr>
<td>Dr. B.B. Samuel</td>
<td>Investigator</td>
<td>Faculty of Pharmacy, University of Ibadan</td>
</tr>
<tr>
<td>Dr. O.A. Adetunji</td>
<td>Investigator</td>
<td>Faculty of Pharmacy, University of Ibadan</td>
</tr>
<tr>
<td>Mrs. Olajinka Kotila</td>
<td>Investigator</td>
<td>Faculty of Pharmacy, University of Ibadan</td>
</tr>
<tr>
<td>Professor Steve Byrn</td>
<td>Co-investigator</td>
<td>University of Purdue, Illinois, USA</td>
</tr>
<tr>
<td>Professor Joseph Fortunak</td>
<td>Co-investigator</td>
<td>Howard University, Washington, USA</td>
</tr>
<tr>
<td>Pharmacist Kunie Okelola</td>
<td>Co-investigator</td>
<td>Secretary Pharmaceutical Manufacturing Group of Manufacturers Association of Nigeria (PMG-MAN), Lagos, Nigeria</td>
</tr>
<tr>
<td>Professor K. Gammaniel</td>
<td>Co-investigator</td>
<td>Director, National Institute for Pharmaceutical Research &amp; Development, Abuja, Nigeria</td>
</tr>
<tr>
<td>Professor Bolane Adeniyi</td>
<td>Co-investigator</td>
<td>Faculty of Pharmacy, University of Ibadan</td>
</tr>
<tr>
<td>Professor S.O. Idowu</td>
<td>Co-investigator</td>
<td>Faculty of Pharmacy, University of Ibadan</td>
</tr>
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</table>

Methods

In collaboration with international and local partners (Tables la-b), the principal investigator met to conceptualise and design a centre that will be focused on capacity building for Africa to make its own drugs in Africa by African scientists. This team’s expertise included over thirty years of industrial experience from drug discovery to successful product launch, drug formulation experts, top-notch knowledge in the field of herbal resources for medicines, bioavailability/bioequivalence expertise, chemists with experience in drug synthetic techniques, to mention a few.
The common goal was to increase the critical mass of pharmaceutical experts from the processes of drug discovery up to production. Specific objectives of the Centre were: 1) to develop curricula and run professional postgraduate diploma and Masters programmes in drug development, industrial and regulatory pharmacy as well as short courses in good pharmaceutical practices (GxP) that will be for target groups; 2) strengthen existing facilities for research and development (R&D) in drug discovery, development, and production; 3) develop pharmaceutical products from the Centre’s research findings; and 4) establish a current good manufacturing practices (cGMP) facility pre-qualifiable by WHO for quality assurance of medicines circulating in the sub-region.

The novelty of the project was to provide a platform for seamless interactions between the academia, pharmaceutical industry (Pharma), and drug regulatory agency on drug discovery and development processes (See Figure 1). Funding for the project was to be sought through application to funding calls. Each specific objective had planned activities mapped out in line with the objective and are summarised in Table II.
Table II: CDDDP objectives and strategic mapping of the projected milestones

<table>
<thead>
<tr>
<th>Objective</th>
<th>CDDDP strategic activities</th>
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<tbody>
<tr>
<td>To develop curricula and run professional Postgraduate Diploma (PGD) and Masters programmes</td>
<td>Curricula development retreat. Presentation of curricula before Faculty of Pharmacy Postgraduate Committee. Presentation of curricula before Postgraduate School board for approval. Advertisement of the Postgraduate programme to target groups. Admission of students for the Postgraduate programmes. Train admitted students using the approved curricula.</td>
</tr>
<tr>
<td>Staff capacity development and training</td>
<td>CDDDP staff exchange programme with collaborators/partner institutions. Systematic increase in the pool of local faculty trained in drug discovery, development, and production processes.</td>
</tr>
<tr>
<td>Workshops and training courses for target groups</td>
<td>Carry out needs assessments in target groups. Conduct hands-on training workshops in areas of observed deficiencies. Hold international conferences involving stakeholders in pharmaceutical strengthening systems.</td>
</tr>
<tr>
<td>To develop pharmaceutical products from Centre’s research findings</td>
<td>Development of: (i) antifungal cream, (ii) quinine suppositories, (iii) synthesis of Artemisinin</td>
</tr>
<tr>
<td>To establish a cGMP facility pre-qualifiable by WHO for quality assurance of medicines</td>
<td>Establishment of a state-of-the-art laboratory for quality assurance of medicines. Engagement of WHO consultants for guidance on pre-qualification process. Training of staff on pre-qualification process. Audit of laboratory facility by May &amp; Baker (a WHO pre-qualified pharma industry).</td>
</tr>
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</table>

Results

A proposal was submitted to a call for application by the MacArthur Foundation, and it won a grant of 950,000 dollars (Grant Number 11-97968-000-INP) to set up the Centre for Drug Discovery, Development and Production (CDDDP), University of Ibadan. Quantifiable and qualifiable outcomes in line with the stated objectives of the Centre are herein laid out:

**PDDD and MDDRP curriculum development**

A two-day retreat was held on 22–23 March 2013, where team members (investigators) drafted curricula for the Postgraduate Diploma in Drug Development (PDDD) and Master in Drug Development and Regulatory Pharmacy (MDDRP) in line with University of Ibadan guidelines.

The PDDD and MDDRP curricula were approved by the Postgraduate School Curriculum Committee in April 2013, ratified by the Faculty of Pharmacy Postgraduate Committee in June 2013, and approved by the Postgraduate School Board in June 2013. The curricula were thereafter approved by the university Senate. Table III captures a few of the topics covered in the two curricula. The two programmes run as ‘special postgraduate’ programmes. For the PDDD programme, face-to-face contact was for two weeks, twice a year, for a two-year period. This made four modules representing four semesters for the PDDD programme. The Master’s programme was designed to be five modules together with series of online interactive sessions with several time-bound assignments, assessments and term paper submissions. The Masters programme runs for two and a half years.

Table III: Selected titles of developed courses in the CDDDP curricula

<table>
<thead>
<tr>
<th>Course</th>
<th>MDDRP curriculum</th>
<th>PDDD curriculum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality management, audits and inspections in the pharmaceutical industry</td>
<td>Quality management, audits and inspections in the pharmaceutical industry</td>
<td>Fundamentals of drug discovery</td>
</tr>
<tr>
<td>Active pharmaceutical ingredients and pharmaceutical solids</td>
<td>Active pharmaceutical ingredients and pharmaceutical solids</td>
<td>Drug development, regulatory and quality compliance</td>
</tr>
<tr>
<td>Development and registration of medical devices and diagnostic tests</td>
<td>Development and registration of medical devices and diagnostic tests</td>
<td>Drug manufacturing processes</td>
</tr>
<tr>
<td>Food and drug laws</td>
<td>Food and drug laws</td>
<td>Regulatory documents and generic drug approval submissions.</td>
</tr>
<tr>
<td>Intellectual property law in drug development</td>
<td>Intellectual property law in drug development</td>
<td>Basics of clinical trials and bioethics in drug development</td>
</tr>
<tr>
<td>Good regulatory practices in drug development</td>
<td>Good regulatory practices in drug development</td>
<td>Project</td>
</tr>
<tr>
<td>Biopharmaceutical and bioequivalence methods for abbreviated new drug application</td>
<td>Biopharmaceutical and bioequivalence methods for abbreviated new drug application</td>
<td>Project</td>
</tr>
<tr>
<td>Documentation in drug development</td>
<td>Documentation in drug development</td>
<td>Project</td>
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</tbody>
</table>

**PDDD and MDDRP graduates**

The PDDD programme was advertised, and 17 applicants were admitted in the 2013/2014 academic session. The PDDD was initially structured as a prerequisite for admission into the Master (MDDRP)
programme. Therefore, the Master’s programme only commenced after the second PDDD students graduated. The Master in Drug Development and Regulatory Pharmacy began with 18 students in the 2017/2018 session.

The maiden semester/module of the PDDD course was held from 19–30 May 2014. The Centre has since then graduated three sets of PDDD and two sets of MDDRP graduates. Appendices A, B and C are pictures of an instructor, a cross-section of the students and the first set of PDDD graduates. Figure 2 and 3 show the number of graduates, their gender distribution, and their occupational background. Four (4) of the MDDRP students were pioneer students of the Centre, who had previously acquired the PDDD degree. Below are testimonials from some of the students:

“My experience of the PDDD program can be summarised in three (3) words: Rigorous, Stimulating and highly expository…. looking forward to the third module, which I expect to be equally educating and stimulating”. E.U, Lecturer, Nnamdi Azikwe University, Awka, Nigeria

“This course succinctly addresses the development of requisite skill and manpower to achieve local development and manufacture of drugs for the African continent by Africans. The PGD course affords deeply personalised and interactive tutoring by seasoned and experienced professionals, in addition to tailored sessions which suit the working-class individuals. A combination of these features makes my participation in this course a very worthwhile investment of time and resources (and I definitely recommend the course to anyone with a passion for change in the drug development landscape in Nigeria and the African continent as a whole)”. Pharm. YB, Neimeth International Pharmaceuticals Plc.

Figure 2: Gender distribution of PDDD and MDDRP graduates

Figure 3: Occupational distribution of PDDD and MDDRP Graduates

**Staff capacity development**

Staff capacity has been strengthened with valuable training on drug development from various institutions within and outside Africa. All the training programmes have broadened the knowledge base of the local faculty. Some trainings include: i) Industrial Pharmacy Advancement Training programme at Kilimanjaro School of Pharmacy, Moshi, Tanzania; ii) Application of Nanomedicine in Drug Development, Pretoria, South Africa. The knowledge gathered was helpful in the development of a nano-delivery technique for drug delivery of antimalarial-quinine suppositories - which was one of the research projects adopted by CDDDP for development into a finished product; iii) Use of liquid chromatography-mass spectrometry (LC-MS) analytical technique for the assay of drugs in biomatrices. This was at the African Institute of Biomedical Science & Technology (AiBST) Harare, Zimbabwe; iv) Summer internship in drug discovery in Boston, Massachusetts, USA; v) Training on paediatric formulations of artemether, quinine and artemether-lumefantrine (fixed-dose combination) suppositories with special reference to the tropical environment at the Department of Biopharmaceutical Sciences, College of Pharmacy, Roosevelt University, USA; and (vi) Training on pharmaceutical quality control and good manufacturing practices at the United States Pharmacopeia (USP) sponsored Center for Pharmaceutical Advancement and Training (CEPAT) in Accra, Ghana. This training was specific for the capacity development of laboratory staff employed in the state-of-the-art analytical laboratory in the CDDDP.

**Workshops and conferences**

The Centre has successfully held four training workshops and two international conferences. In total, CDDDP has trained over 350 professionals in the
pharmaceutical sector through its training programmes. Table IV lists the themes for the workshops and conferences, collaborating partners, and the number of trained participants.

Table IV: Themes for workshops and short-training courses, collaborating partners and number of participants

<table>
<thead>
<tr>
<th>Year</th>
<th>Theme for the training</th>
<th>Collaborating partners</th>
<th>Number of participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>From Powder to Tablet</td>
<td>BASF, a chemical company</td>
<td>28</td>
</tr>
<tr>
<td>2013</td>
<td>International Conference on “Medicine Regulation of Claims”</td>
<td>Reckitt Benckiser, United Kingdom</td>
<td>150</td>
</tr>
<tr>
<td></td>
<td></td>
<td>National Agency for Food and Drug Administration and Control (NAFDAC)</td>
<td></td>
</tr>
<tr>
<td>2015</td>
<td>The Role of Pharmacogenetics in Drug Discovery</td>
<td>African Institute of Biomedical Science and Technology (AisBT)</td>
<td>40</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Harare, Zimbabwe</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Institute of Advanced Medical Research and Training (IAMRAT),</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>College of Medicine, University of Ilbadan, Nigeria</td>
<td></td>
</tr>
<tr>
<td>2015</td>
<td>Bioinformatics and Computer-Aided Drug Design (CADD)</td>
<td>Nnamdi Azikiwe University, Akwa, Nigeria</td>
<td>28</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Afe Babalola University, Ado-Ekiti, Nigeria</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>University of the Sciences in Philadelphia, USA.</td>
<td></td>
</tr>
<tr>
<td>2016</td>
<td>Molecular and Computational Methods for Emerging Pathogens</td>
<td>UK Medical Research Council/Department for International</td>
<td>29</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Development (MRC/DFID) sponsored African Research Leader</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Molecular Microbiology Laboratory, University of Ilbadan</td>
<td></td>
</tr>
</tbody>
</table>

*In attendance were policymakers from the National House of Assembly, Federal Ministry of Health, NAFDAC, health professionals, pharma industrialists, academia and the general public

**Translation of research findings to products**

One of the objectives of CDDDP was to translate research findings into finished products. Some of the Centre’s research outputs include a) Development and formulation of pediatric artemether, quinine, and artemether-lumefantrine (fixed-dose combination) suppositories with special reference to stability in tropical environments; b) Development and formulation of anti-fungi cream from Senna and Ocimum leaves; c) Development and formulation of anti-fungi cream from *Picralima nitida* bark; d) Synthesis of amodiaquine, as part of the development of artemisinin-based combination therapy using green chemistry technology; e) Development and formulation of teas from edible vegetables that have been documented in the literature to have nutritional benefits such as antioxidants, probiotics, and lipid-lowering potentials (Abarikwu et al., 2019; Diez-Echave et al., 2020; Njoku et al., 2019; Zhang et al., 2019). These teas were produced through processes that ensure minimal disruption of their chemical constituents. Dossiers are being developed for them as a prerequisite to their registration by the National Agency for Food and Drug Administration and Control (NAFDAC), which is the major drug regulatory agency in the country; f) In the wake of the ebola epidemic, CDDDP produced alcohol-based hand sanitisers that became adopted by the university for safeguarding the health of the university community. The hand sanitisers were produced in 70 ml handy and 500 ml packs (CDDDP, 2013); g) Activities during Covid-19 were hampered due to the severity of the pandemic. However, post Covid-19, CDDDP as a core-flex partner with the United States Pharmacopoeia under the United States Agency for International Development (USAID)-sponsored Promoting Quality of Medicines Plus (PQM+) program, has participated in both online webinar series and face-to-face workshops for personnel of pharmaceutical manufacturing industries across West Africa. Some of the topics taught include: ‘Essential Requirements for Developing Quality-Assured, Generic Active Pharmaceutical Ingredients and Finished Dosage Forms’, ‘Quality Risk Management’, and ‘Annual Product Quality Review’.

**CDDDP’s quality assurance laboratory**

Recognising the importance of a quality assurance laboratory to teaching and research and ensuring of quality of drugs in circulation, CDDDP established a state-of-the-art laboratory for the quality assurance of medicines. The quality assurance laboratory has anchored over one hundred and fifty graduate research projects from various departments within and outside
the University of Ibadan. It offers third-party analyses to pharmaceutical companies, has undergone auditing in preparedness for WHO pre-qualification, and has established standard operating procedures (SOPs) in line with global standards. WHO consultants have assessed the laboratory and its operations, and a strategic plan for the pre-qualification process has been designed. May and Baker Plc, one of the four pharma industries in Nigeria with WHO pre-qualified facilities, has been to the laboratory for auditing of its equipment and operational processes. The laboratory supports hands-on training for both graduate students of CDDDP and workshop participants. The quality assurance laboratory has served as a source of revenue generation for the Centre. Table III succinctly captures the Centre’s stated objectives and achieved milestones.

**Awards and recognitions for CDDDP**

Products of CDDDP displayed at the 2018 University of Ibadan Research Development (UIRESDEV) fair won First place position. In recognition of the efforts of CDDDP in the sub-region, in May 2014, the African Medicines Regulatory Harmonisation (AMRH) Programme under the New Partnership for African Development (NEPAD) elected CDDDP as a Regional Centre of Regulatory Excellence (RCOREs) in Africa for training in medicine regulation, thus giving the Centre a continental recognition (AUDA-NEPAD, 2022). With this award, the Centre bears oversight functions in training in regulatory science, clinical trials and medicine regulation in Africa. With the current trend and interest in the Centre’s programmes and the RCORE designation by NEPAD, CDDDP has become a reference point for training in drug discovery, development, and production processes. In addition to the postgraduate and RCORE programmes, CDDDP is developing need-based short courses for professionals in the medicine production and regulation sector.

**Grant application and sustainability plans of CDDDP**

The Centre continually seeks collaborations, developing and implementing initiatives that support its mission. The Centre has responded to various local and international calls for proposals. The MacArthur Foundation grant was for five years and ended in 2017. For sustainability, the Centre had attracted an educational grant from Reckitt-Benckiser, United Kingdom (2013), and in the capacity of a sub-recipient, together with the United States Pharmacopeia (USP) won a USAID cooperative agreement for Promoting Quality Medicine Plus (PQM+) in the sub-region (USP, 2019).

**Challenges faced**

As with the conceptualisation and establishment of any structured setting, CDDDP has also encountered some challenges.

The lack of a pilot facility for manufacturing active pharmaceutical ingredients (APIs), which form a core component of the training module, necessitated travelling the Centre’s students to the partner facility in Tanzania for hands-on experience with drug manufacturing. This translated to both travelling and living expenses for the two weeks duration of the programme in Tanzania. The project team succeeded in getting tuition-only sponsorship ($1,500 per student) from UNIDO for the first three sets of PDDD students, but subsequently, students had to make out-of-pocket funding. Grant applications and requests for funding for building a purpose-built facility for pilot manufacturing have been made but to no successful outcome to date.

Operational space for the commencement and daily running of CDDDP was initially carved out of limited office and laboratory spaces within the Faculty of Pharmacy, University of Ibadan. However, with the growing capacity of the Centre and for optimal achievement of the objectives, the Centre needs a purpose-built facility that will handle practical training sessions, drug quality assurance services in accordance with ISO17025 certification, space for bioavailability/bioequivalence (BA/BE) studies and clinical trials, dedicated lecture rooms equipped with multimedia equipment, facility for pilot manufacturing and administrative offices for the staff of the Centre.

It was initially challenging getting the full buy-in of staff/personnel of medicine regulators in Nigeria, namely NAFDAC, Pharmacy Council of Nigeria (PCN), and other nationals, especially in West Africa, to attend the Postgraduate Diploma in Drug Development course. This may be due partly to funding costs associated with the programme and the bias of going for a postgraduate diploma rather than a master’s degree programme. This bias initiated the move by the Centre to step down on the acquisition of the PDDD as a pre-requisite for admission to the master’s degree programme, which in turn has seen a gradual increase in the number of drug regulators attending the degree course.

**Discussion**

Good manufacturing practices (GMP) and oversight of medicines exercised by strict regulatory authorities are the basis for assuring the quality of medicines. Despite Nigeria hosting the largest number of pharma industries
on the West African coast, there is still a dearth of these skills and techniques (WHO, 2014). The goal, therefore in CDDD was to fill in this gap via structured North-South knowledge transfer. Partners from developed countries with robust industrial drug experiences from discovery up to product launch were engaged as key resource persons for designing, developing and teaching the postgraduate curricula. This innovation was to create an enabling environment (i.e. the University of Ibadan), and curricula that would allow for training under the same roof stakeholders within the pharmaceutical strengthening systems. This formed the triangular philosophy of CDDDP (Figure 1). The aim was for these stakeholders in medicine development to be exposed to the same curricula as pertain to drug processes, thereby appreciating the complementary roles they were playing in ensuring the production and circulation of good quality, safe and efficacious drugs. The curricula were aimed to provide professionals working within the pharmaceutical industry, drug regulatory agencies (DRAs), academia, and relevant professions with core knowledge of the scientific, regulatory, clinical, ethical, and social issues relevant to the discovery, development, production, evaluation, registration, and promotion of medicines. The programme targeted capacity building to enhance local manufacturing of medicines and the availability of pre-qualified facilities for drug manufacturing under internationally accepted regulatory guidelines. It was also to improve the quality of health care by developing and promoting skills that hasten the development and supply of new therapeutic agents and to assist in optimising the use of existing medicines and devices to maximise their benefits and minimise risks. An implementation committee was set up that collected data on current medicine development and pharmacy regulatory activities in Nigeria and subsequently assessed the professional development needs of personnel of these sectors (Abate et al., 2003; Pheage, 2017; Ekeigwe, 2019). In collaboration with foreign partners, the committee identified the topics to be taught and the areas in which target personnel lacked basic knowledge and practical skills. Also determined was the breadth and depth to which the topics should be taught and the number of hours of instruction per week, to ensure effective learning and transfer of knowledge to the students (International Pharmaceutical Federation (FIP), 2008; Schwartz et al., 2013).

The University of Ibadan runs a system of two semesters comprising 13 weeks of lectures. While the constraints of job requirements would not readily permit staff of pharma industries, drug regulatory agencies, and even academia to be given such extended leave of absence from work, the CDDDP team crafted a modified training format that would be suitable to the target students and still be within the confines of the academic system of the university. The goal of the Centre, through the development of the ‘special postgraduate’ curricula, was to strengthen the skills of people already working in the pharmaceutical industry, drug regulatory agencies and academia in medicine development and regulatory pharmacy (Hammer et al., 2010). The dearth of human resource development or capacity building has been identified as one of the main constraints to rapid implementation and success towards strengthening local pharmaceutical production (Kabene et al., 2006; WHO, 2012; Babapour et al., 2018).

The staff of CDDDP and faculty members of Pharmacy, under the capacity building objective of the Centre, were sponsored to receive valuable and relevant training on drug development from various institutions both within and outside Africa. These trainings strengthened faculty members’ skills in various research areas and equipped them with the experience and knowledge required to discharge their duties (Andurkar et al., 2010; Tomei et al., 2016). Partnership with the Northern mentoring institutions was an integral part of the implementation strategy of the Centre’s services. This was based on the assessment of the kind of strengths needed to support the success of CDDDP.

Organisation of workshops and short-training courses are important aspects of the Centre’s activities. CDDDP recognised the impact these trainings have in enhancing the capability and capacity of participants. The workshop style adopted was didactic lectures followed by corresponding hands-on training. This style is not often utilised in the local environment but is highly called for within the nation’s circle of healthcare and allied professionals. Workshop organisers often shy away from this style of training because of the high cost involved, the logistics challenges associated with its preparations, especially where laboratory space and consumables are required, and the unwillingness of projected participants to pay workshop fees. Most participants mainly make out-of-pocket payments for such training, which negatively impacts the number of participants who register and attend such training workshops (Idiegbeyan-Ose et al., 2015).

**Future plans of CDDDP**

With the current trend and interest in the Centre’s programmes and the RCORE designation by NEPAD, CDDDP has become a reference point for training in drug discovery development and production. In addition to the postgraduate and RCORE programmes, CDDDP is developing need-based short courses for professionals in the medicine production and regulation sector. Other projects in the pipeline are:

The Centre seeks to set up a bioavailability/bioequivalence (BA/BE) studies and clinical trials unit to
enhance NAFDAC’s regulatory activities by carrying out BA/BE studies of generic drugs circulating in the country – as a prerequisite for registration and as a means of detecting substandard and fake drugs. A proposal for the establishment of the unit has been submitted to the Nigerian Federal Ministry of Health.

Grant applications will be a continuum. The Centre is not relenting in the grant writing efforts. The Centre has responded to various local and international calls for proposals. The Centre has received some grants and submitted proposals to funding organisations such as The European & Developing Countries Clinical Trials Partnership (EDCTP), the Tertiary Education Trust Fund (TETFund), and Management Sciences for Health, Inc (MSH), to mention a few.

Conclusion
A centre for capacity building of Africans in drug discovery, development and production has been established and its model of training together professionals in the academia, pharmaceutical industry and drug regulatory agency is workable and resultant. North-South collaborations are important for continued knowledge transfer, and grant sourcing is a plausible means for funding and sustainability of similar projects.

Conflict of interest
The authors declare no conflict of interest.

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https://www.semanticscholar.org/paper/Excellence-in-Curriculum-Development-and-Assessment-Abate-Stamatakis/41f025c2ec126bb7e31d4615adbe7b1e3982de75


Appendix A: Prof Joseph Fortunak delivering lecture at one of the Postgraduate Diploma training at University of Ibadan in 2014

Appendix B: Cross section of first set (May, 2015) of PDDD students listening with rapt attention
Appendix C: Graduation ceremony for pioneer students of postgraduate diploma in Drug Development (December, 2015)