

RESEARCH ARTICLE

Efforts at building capacity for manufacturing and testing the quality of medicines in Sub-Saharan Africa: Historical evidence from the BIRS programme

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Abstract

Background: Some countries in sub-Saharan Africa combat the proliferation of substandard medicines using anti-counterfeiting devices. An alternative measure involves advanced pharmaceutical education. The Biotechnology Innovation and Regulatory Science (BIRS) educate students in pharmaceutical Good Manufacturing Practices (GMP) and quality control (QC). **Objective:** This study assessed the African BIRS programme's efforts to initiate and sustain the manufacturing of quality medicines. **Method:** Qualitative case studies were used to assess the impact of the BIRS professional training intervention. A convenient purposeful sample of alumni students working in pharmaceutical manufacturing and quality control (QC) participated. Quantitative parametric methods were used to test the hypothesis that participants would significantly increase over the years if the programme met its objectives in the region. **Results:** Alumni from ten countries implemented and sustained projects in Good Manufacturing Practice (GMP) and QC. Participants from 2016 (17 males, 8 females) and 2018 (14 males, 8 females) increased in year 2020 (31 males, 22 females), p -values < 0.05, $\alpha = 0.05$. **Conclusion:** Advanced education has improved efforts in maintaining quality healthcare in the region.

Introduction

The prevalence of substandard, spurious, falsely labelled, falsified, and counterfeit (SSFFC) medical products remains a grave challenge, especially in lower resource global settings. To proactively build capacity for manufacturing and testing quality medicines in the region, some entities have developed and implemented short courses and training focusing on technical skills and knowledge. With these efforts, countries can build the capacity to develop and sustain the manufacturing of quality medicines and reduce their dependence on importing these essential health commodities. For sustainable change, course participants need leadership opportunities, such as adapting material to teach back and sharing with peers and professionals within their organisation and beyond.

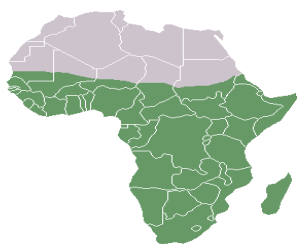
This study investigated the specific impacts of an educational intervention that provides both technical skills and competencies integrated with opportunities to practice leadership "in-house" and "in Africa" through training peers with specialised education in analytical and manufacturing sciences in their own regulatory agencies and companies.

In the past, efforts have been made to improve the development of healthcare infrastructure in this sub-region. However, considering the World Health Organisation (WHO) reports, the average life expectancy in sub-Saharan Africa, unlike other developed countries, has not significantly improved from the twentieth to the twenty-first century (Jong-Wook, 2011; World Health Organisation, 2012). This phenomenon is attributable to the prevalence of disease burdens from HIV/AIDs, malaria, and tuberculosis in the region (Tshikuka Mulumba *et al.*, 2012). Although some African countries

made efforts to provide universal health coverage for their citizens at an affordable cost, those projects were inundated with enormous economic challenges (Wong, 2015). An example of such unfortunate incidents occurred when some countries tried to achieve lower health costs without corresponding measures to maintain quality assurance, contributing to the prevalence of SSFFC medicines (Pisani, 2019). To combat this menace, some of these countries employed reactive efforts such as using the Raman and Near Infra-red spectroscopy anti-counterfeiting devices, while others also used SSFFC-detecting test kits, such as Minilab, Mobile Authentication Services (MAS), and the TruScan device (Khuluza *et al.*, 2016; Spink, Moyer & Rip, 2016; Aminu & Gwarzo, 2017; Petersen, Held & Heide, 2017; Walker *et al.*, 2018). However, despite these initiatives, the percentage of counterfeit medicines in Africa seems to be on an upward trend, as 70% of total medicines in circulation in some areas may fall under SSFFC (Aminu *et al.*, 2017). Also, over 70% of oxytocin and other maternal health-related products were of poor quality (Anyakora *et al.*, 2018). Similar incidences of poor-quality medicines in these low-income economies have also been reported (Bassat *et al.*, 2016; Ozawa *et al.*, 2019).

To address this trend, the WHO recommended proactive measures to ensure safe and effective medicines in sub-Saharan Africa (Figure 1). The WHO advocacy provided guidelines for scaling up training for healthcare workers. Furthermore, it has emphasised the quality, not just quantity, of the training modules to employ to build competencies for these professionals (World Health Organization, 2013).

To achieve this goal of improving public health outcomes in the region, some non-profit organisations engaged in making advanced regulatory science education available to some university graduates in Africa (Byrn, Ekeocha & Clase, 2017). These efforts align with an old proverb by a past African leader, Nelson Mandela, who emphasised the importance of education to empower the region (Suen, 2013). Therefore, this study was initiated to assess current efforts to improve medicine manufacturing and quality control in sub-Saharan Africa.



Source:
https://upload.wikimedia.org/wikipedia/commons/thumb/6/65/SubSaharan_Africa_definition_UN.png/220px-Sub-Saharan_Africa_definition_UN.png

Figure 1: Countries in sub-Saharan Africa

Past efforts at building capacity for health sector personnel in sub-Saharan Africa

Literature searches revealed that some institutions made efforts to implement WHO recommendations for building capacity in sub-Saharan Africa by training healthcare professionals in the region ("Health care", 2011; Appiah-Denkyira *et al.*, 2013; Wilmshurst *et al.*, 2016). One such initiative, the African Paediatric Fellowship Programme, at a University in Cape Town, South Africa, trained paediatric healthcare experts. A study reported that trainees who completed the six-month to two-year mentorship programme returned to their home countries and replicated the skills acquired to improve healthcare delivery (Wilmshurst *et al.*, 2016). Despite these historical efforts, with several of them being targeted at training medical professionals, the literature search conducted by the authors of this work could not find training sessions specific for workers in medicine manufacturing and quality control.

Additionally, a study assessed training for health services and systems research in Sub-Saharan Africa. Expectedly, it concluded that the numbers of graduate-level trainees in the region are insufficient to drive the much-needed health system strengthening and innovation (Guwatudde *et al.*, 2013). This study highlighted the need for training programmes to equip professionals whose roles impact the quality of medical products. The regulatory functions of these health professionals in sub-Saharan Africa are similar to those of their counterparts in the United States Food and Drugs Authority (FDA). In performing its mandate, the US FDA makes decisions based on the best available scientific data provided at all stages of product development to protect consumer health (US FDA, 2011). Therefore, this inquiry suggests regulatory sciences as a core training for building capacity in Africa if the region aims to manufacture quality medicines.

Capacity building initiative of the Biotechnology Innovation and Regulatory Science (BIRS) Masters' programme

To develop the capacity to manufacture and test quality medicines in sub-Saharan Africa, a US-based University started the Biotechnology Innovation and Regulatory Science (BIRS) MS programme. The initiative utilised an approach similar to how the American Pharmaceutical Association controlled counterfeit medicines in the 1860s (Higby & Stroud, 2005). In describing the BIRS' approach for equipping Africans to manufacture quality medicines for Africa and beyond, an excerpt from a paper co-authored by the programme director stated that:

"The strategy involves collaboration among industry scientists and academic faculty to share current best

practices and hands-on laboratory skills with education in Good Manufacturing Practices... WHO Prequalification of Medicines documents, and other documents used to substantiate and assure the quality of (generic) medicines production" (Byrn, Ekeocha & Clase, 2017).

Additional goals of the BIRS programme include directing student projects so that they positively affect the manufacturing and testing of medicines in Africa (BIRS, 2019).

The BIRS programme transitioned from a prior initiative, the Industrial Pharmacy Advanced Training (IPAT), founded by Sister Zita Ekeocha, an African missionary who had a burning desire to see Africans manufacture quality medicines in the sub-region. Together with Professors Stephen Byrn, 2008, and Joseph Fortunak, 2009, she started teaching the first set of IPAT certificate courses. The IPAT programme was later metamorphosed into BIRS in 2014 (Byrn, Ekeocha & Clase, 2017). At the time of this study, the African BIRS community had about 140 graduates of the IPAT certificate and master's programme, in addition to professors and industry and regulatory leaders who have taught in the programme since its inception in 2008 (Clase et al., 2019).

Considering the need for capacity building for health professionals, this study sought to evaluate the impact of BIRS MS training in sub-Saharan Africa, with an emphasis on manufacturing medicines and laboratory controls. It also tested an initial hypothesis that if the programme achieves its objectives, student enrolment will increase in over the years. This assumption is based on the postulate that BIRS MS graduates will recommend the training to other African colleagues. Alternatively, the projects implemented by attendees will form evidence to motivate enrolment for the MS programme.

Therefore, this paper is a current effort to evaluate advances achieved by the BIRS MS programme in the areas of pharmaceutical manufacturing and quality control in sub-Saharan Africa.

Assumptions of the study

The study population consisted of alumni who work in pharmaceutical manufacturing and quality control. This study assumed that current responses reflect those of alumni in other fields, such as regulatory, academia, and private practice. Another assumption was that student enrolment would increase over the years if the programme had a positive impact on the sub-region. Short email responses were requested from the participants, who were trained professionals expected to deliver clear and concise assessments of the programme.

Methods

Setting and significance

The objective of this case study was to find out about the novel pharmaceutical manufacturing and quality control projects that African BIRS alumni initiated after their Master's (MS) degree. Furthermore, this study quantitatively evaluated the programme's acceptance from the inception of the African MS programme in 2014. This study was conducted to give more in-depth insight into areas where African alumni have utilised knowledge and skills acquired through the programme. Secondly, it addressed how the BIRS MS programme influenced participants' career experiences. Finally, this study explored the programme's acceptance within the sub-Saharan African community.

Research questions

Question 1 (Q.1) What effect did BIRS training elicit on African alumni's professional organisation in pharmaceutical manufacturing and laboratory quality control space?

Question 2 (Q.2) Was the programme acceptable to the sub-Saharan African community?

Q.1 was qualitatively evaluated using email responses and interviews with human subjects (programme Alumni). The study quantitatively determined if the programme gained acceptance after its inception in 2014 to address Q.2. The study hypothesised that the programme's acceptability would be associated with an increase in the population of African student enrolment from 2014 to 2020. The null hypothesis was that the number of BIRS MS participants would be the same over the years; that is, there would be no changes.

$$H_0: \mu_1 = \mu_2 = \mu_3,$$

where μ_1 , μ_2 , and μ_3 represent the number of participants in the years: 2016, 2018, and 2020 respectively

$$H_1: \mu_1 \neq \mu_2 \neq \mu_3,$$

The assumption was that the student population would increase over the years if the programme had a positive impact on the sub-region. A significance level of 5% ($\alpha = 0.05$) was used because this education mode and technology transfer was novel in Africa. Therefore, the study could not benchmark a similar programme. The student population indices were assessed over three years of graduates, 2016, 2018, and 2020.

Research design

The mixed method research using literature review and evaluative studies was applied to assess the impact of a professional training intervention.

The qualitative approach employed in this study was described as a form of applied research where the worth of a programme or process is evaluated by collecting evidence or data to make informed decisions (Patton, 2015). For this research, the case investigated a bounded system consisting of the African cohort of BIRS MS alumni. The study sampled alumni who work in pharmaceutical manufacturing and quality control to understand the impact of BIRS training in these areas. This procedure was similar to the two-tier sampling described by Merriam and Tisdell (2015).

Additionally, the quantitative aspect of this study tested the hypothesis that there will be a significant increase in the student population in successive years if the programme has a positive impact in sub-Saharan Africa.

Institutional Review Board (IRB) approval

The research involved human subjects; IRB approvals IRB-2020-698 and IRB-2019-818 were obtained from the US-based host University.

The first author in this study is an Alumnus of the BIRS programme and currently undertaking a doctorate at the same University. From her experience, she used the BIRS MS training she received as the basic framework to develop some laboratory quality system improvements, as cited in this study. She assumed that the programme might have elicited the same impact on other attendees. Therefore, she sought to conduct this study to establish whether the data would be congruent with her assumptions.

The study applied a multi-stage selection of students who graduated from the African MS programme in 2016, 2018, and 2020. To further narrow its focus, the study employed a non-probabilistic purposeful sampling of alumni who conducted their master's thesis in pharmaceutical manufacturing and laboratory quality control. Accordingly, emails were sent to that group of students to obtain testimonials about the programme's impact. They were requested to chronicle how they utilised knowledge from the BIRS training to improve their workspace. Their responses were expected to reflect insider views, as described by some qualitative researchers (Merriam & Tisdell, 2015). Hence, this study sought to get emic perspectives on the BIRS initiative. Congruent to the description of Merriam and Tisdell of purposeful sampling (2015), this research selected the alumni group that can provide the most valuable information on the effects of the programme on manufacturing and quality control in sub-Saharan Africa.

Data collection

For Q.1, the semi-structured asynchronous interview method was used to collect the study data through emails

to participants, consistent with the description of online interviews as a means of collecting qualitative data in research (Ruddock, 2015). This form of data collection facilitated interviewing multiple respondents across Africa. The strength of this approach was elaborated by Merriam and Tisdell (2015).

An oral interview was conducted with one alumnus who did not respond via email to enrich the rigour and depth of the data gathered from the study group. The one-on-one discussion was carried out using an online platform, during which the respondent answered questions related to her experiences with the BIRS MS programme.

Data for Q.2 was collected from the BIRS programme repository.

Data analysis

Qualitative: The study data collected eight email responses and one transcribed interview; these were coded at two levels, open and axial, to obtain common themes that described the experiences for Q.1.

Quantitative: The student population indices were assessed for 2016, 2018, and 2020 cohorts. Analysis of Variance (ANOVA) was used to test the null hypothesis that all the group means are the same or that the number of participants did not change over the years at a 95% confidence interval and $\alpha = 0.05$. Chi-square contingency tests with simulation-based p-value and robust to small cell counts were carried out, comparing all cohorts. A Bonferroni correction was also included to account for inter-year comparisons in Q.2. All statistics in this study were computed using Microsoft Excel 2010 edition and R studio (RStudio Team, 2019).

Results

Q.1 What effect did BIRS training elicit on African alumni's professional organisation in pharmaceutical manufacturing and laboratory quality control space?

Students participated in several course segments addressing quality manufacturing and laboratory controls through a formal MS graduate programme. Modules included an emphasis on analysis and testing of medicines utilising a range of analytical instruments following the International Conference on Harmonization (ICH) Q2 procedures of method validation to provide advanced pharmaceutical education in analytical and manufacturing sciences for personnel in the healthcare sector: national regulatory bodies, pharmaceutical industries, and academia.

This study reported some experiences obtained from a literature search on BIRS MS training activities. Also, it

discussed responses of alumni as case studies, using verbatim quotes and words gleaned from their emails and a transcribed oral interview. This approach aligned with the recommendations of Patton, an expert in descriptive inquiry and a researcher in applied social science. He described qualitative data as "direct quotations from people about their experiences, opinions, feelings, and knowledge". According to Patton, qualitative data can be obtained using excerpts, quotations, or entire passages extracted from documents or interviews (Patton, 2015). Therefore, the following paragraphs will highlight the results from a review of existing literature, BIRS MS alumni email responses, and one oral interview.

1. Literature-based evidence of BIRS training in sub-Saharan Africa

a) Small-scale pharmaceutical manufacturing under cGMP

The Industrial Pharmacy Advanced Training (IPAT) programme initiated in 2008 metamorphosed into the BIRS programme in 2016. Interestingly, since 2009, students have been exposed to hands-on Good Manufacturing Practices (GMP) training in pharmaceutical manufacturing. For example, the 2014 students' laboratory sessions (Figure 2) covered small-scale API synthesis, tableting, and coating of efavirenz, an anti-retroviral medicine. This practical training was done in a laboratory facility located in Tanzania, East Africa.



Figure 2: African students of the IPAT/BIRS MS programme training in small-scale manufacturing to initiate and maintain quality medicines in sub-Saharan Africa

b) Analytical method development and laboratory improvement

In 2015, the BIRS centre global development team (GDT) comprised some US-based professors and undergraduate students who worked with some African MS students from the BIRS programme. The group developed a universal method to assess the quality of commonly used medications in the East-

Africa region. The project's universal method aimed to eliminate the financial and time loss associated with switching equipment parameters when analysing individual drug products. The high-pressure liquid chromatography (HPLC) was chosen by the group because it offers better performance and versatility in pharmaceutical analysis in comparison to liquid and other classical chromatography (Ahuja & Dong, 2005). The method used water, acetonitrile, methanol, and potassium phosphate, combined at different proportions, as the solvents for the HPLC analysis of ten medicine products. The ten moieties studied selected from the WHO list of essential medicines were acetaminophen, amitriptyline, amoxicillin, ciprofloxacin, haloperidol, hydrochlorothiazide, loratadine, lumefantrine-artemether, mefloquine, and quinine sulphate tablets (World Health Organisation, 2015). Then, the group analysed and compared the quality of the different brands of these medicines. It concluded that the methods developed were suitable for detecting SSFFC medications in the region (Maize et al., 2017).

The GDT project also developed capacity for the African MS BIRS students in the validation of analytical methods. Subsequently, students applied linearity, accuracy, and precision tests to validate the universal method for acetaminophen tablets. The project also provided maintenance support for the operational HPLCs used for the manufacturing course for the BIRS programme at the training location in Tanzania. It also developed a document for the general procedure used for some HPLC analyses (McCord et al., 2015). The GDT group's effort was similar to that of universal methods developed for 19 antimalarial agents; here, the group optimised the methodology for three of the studied moieties (Debrus et al., 2011).

2. BIRS Alumnus projects: Themes gleaned from email responses of BIRS MS alumni

The document for the qualitative aspect of this study consisted of email responses from eight alumni of the BIRS MS programme. Contents of the IRB-approved email and testimonials of respondents are found in the Appendix section. Table I summarises some verbatim quotes from each script. These were used to generate open codes that categorised experiences described in the email responses. After that, the second level of the axial coding scheme (Table II) re-classified these broader categories into themes that richly describe respondent experiences.

Table I: Level 1 open coding conducted to generate general themes from the BIRS alumni email responses

Open Codes (level 1)	Examples of verbatim responses obtained	Total number of respondents with experience
Proposals for process improvement	"I presented a model risk-based approach for scheduling GMP inspections at National Drug Authority for consideration" Pharm. B.	3
Training on risk-based GMP	"I was able to polish my training skills..... to conduct regular GMP training for staff" Pharm. C.	4
Conducted Hands-On training	"The hands-on laboratory demonstrations offer very practical knowledge on where I teach" Pharm. H.	4
Improved Critical thinking skills	"This gives us a common understanding of such topics from a more enlightened perspective," Pharm. H.	2
Implemented process improvement measures	"The BIRS course coincided perfectly with the adoption of Common Technical Document (CTD) in Uganda. time for dossier preparation was greatly shortened" Pharm. C.	5
Improved Leadership Skills	".... We have demonstrated that leadership without authority is possible" Pharm. H.	5
Improved knowledge base for workplace	"Awareness and understanding of Global GMP Guidelines and Regulations" Pharm. E.	2
Advocacy skills	".... to help build capacity in the local pharmaceutical manufacturing industry" Pharm. G.	1
Capacity building through mentorship	"I also consult for other industries and help upgrade their quality management systems. Additionally, I teach pharmacy students using the information from the program" Pharm. H.	2

Table II: Second-level coding generated emergent themes surrounding participant's experiences with the BIRS MS programme

Open codes (level 1)	Axial codes /Themes (level 2)
Training on risk-based GMP	Capacity building through training
Conducted Hands-On training	
Implemented process improvement measures	Organisational Process Improvement Initiatives
Proposals for process improvement	
Improved Critical thinking skills	Improved organisational Problem-solving capacity
Improved knowledge base for workplace	
Advocacy skills	Leadership and quality culture
Capacity building through mentorship	
Improved Leadership Skills	

3. Capacity building through training

The results further indicated that alumni from ten countries have implemented and sustained projects in pharmaceutical GMP and laboratory analysis. They conducted teach-back sessions to build capacity for other medicine regulators and manufacturers in their home countries. The testimonials of study participants, who are alumni of the programme, can be found in Appendices B and C. The following paragraphs

summarise the contents of responses provided by these BIRS alumni.

The first was Dr GM, who conducted several human capacity development sessions in countries in the East-African Communities (EAC) region. He has organised and delivered training on topics ranging from principles of Risk Management to current Good Manufacturing Practice (cGMP), Data Integrity, and others (Appendix B). One alumnus, Pharm. B. conducted training for

other regulators in Uganda to help them optimise the use of limited funds and prioritise areas of risk in assessing the GMP of manufacturing companies (Appendix C).

b) Organisational Process Improvement Initiatives

Some alumni's projects facilitated improvements in laboratory processes. One such project, by Pharm. M.O. improved quality control tests carried out at different stages of pharmaceutical manufacturing, which generated quantitative data. This BIRS graduate developed spreadsheet calculators to address inconsistencies in manipulating quantitative analysis of laboratory data (Appendices F and G). The spreadsheets were developed and validated for use in several quality control processes to ease data handling,

maintain inter-personnel consistencies in quantitative data analysis, and thus improve data integrity (Okezue, Clase & Byrn, 2018b). The same alumnus designed a system to monitor equipment performance using statistical process charts (SPC) and control limits. Her efforts assessed the process capabilities of laboratory equipment, similar to other authors who also described the use of SPC in monitoring processes (Montgomery, 2013; Jones-Farmer, Ezell & Hazen, 2014). The control charts developed by this alumnus checked whether laboratory equipment was in a state of compliance or required corrective actions (Figures 3 and 4). The impact of this project facilitated the ISO17025 accreditation of a laboratory for Nigeria's National Medicines Regulatory Authority, NAFDAC (Okezue, Clase & Byrn, 2018a; Okezue *et al.*, 2020).

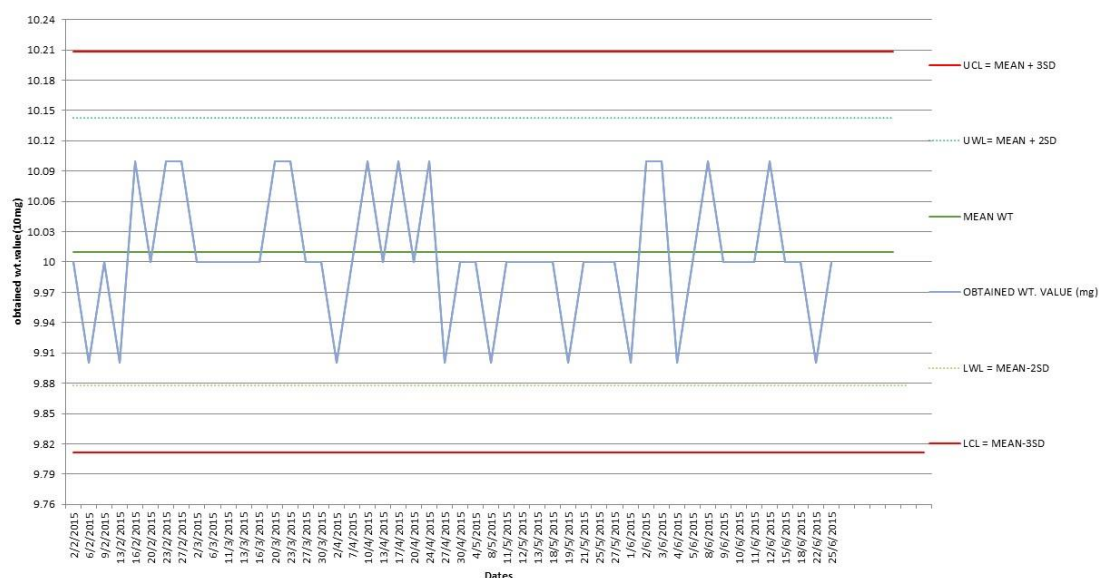


Figure 3: Statistical control chart for process monitoring of analytical balance

c) Advancements in manufacturing capabilities and facilities monitoring

Additional alumni from Botswana, the Democratic Republic of Congo, Ghana, Kenya, Tanzania, South Sudan, Rwanda, and Zimbabwe mentored manufacturing companies and continue to provide the leadership needed to bring the required transformation in pharmaceutical manufacturing in the sub-region. Pharm. S., who works in a pharmaceutical company in East Africa, applied the knowledge from her BIRS education and achieved improvement in the company's manufacturing efforts. She also initiated a monitoring system for the company's heating, ventilation, and air-conditioning systems, which are crucial for the quality of medicine production (Appendix H). Similarly, another alumnus, who works as a quality control manager in one

of the leading indigenous pharmaceutical manufacturing companies in West Africa (Medtrack, 2017), used the knowledge gained through his BIRS training and improved several processes in the company. The company achieved better product performance indices and higher customer satisfaction through the process improvement efforts of Mr. DM and two of his colleagues, who also graduated from the BIRS MS programme in Africa (Appendix I). A BIRS alumnus from Zimbabwe, Pharm. P., implemented internal audits to strengthen the quality management systems of her company through her learning and knowledge sharing (Appendix J). Likewise, an alumnus from Nigeria, Pharm. M., mentored a start-up pharmaceutical company in skills to develop Standard Operating Procedures and established the expertise needed for their GMP document as part of her MS project (Appendix L).

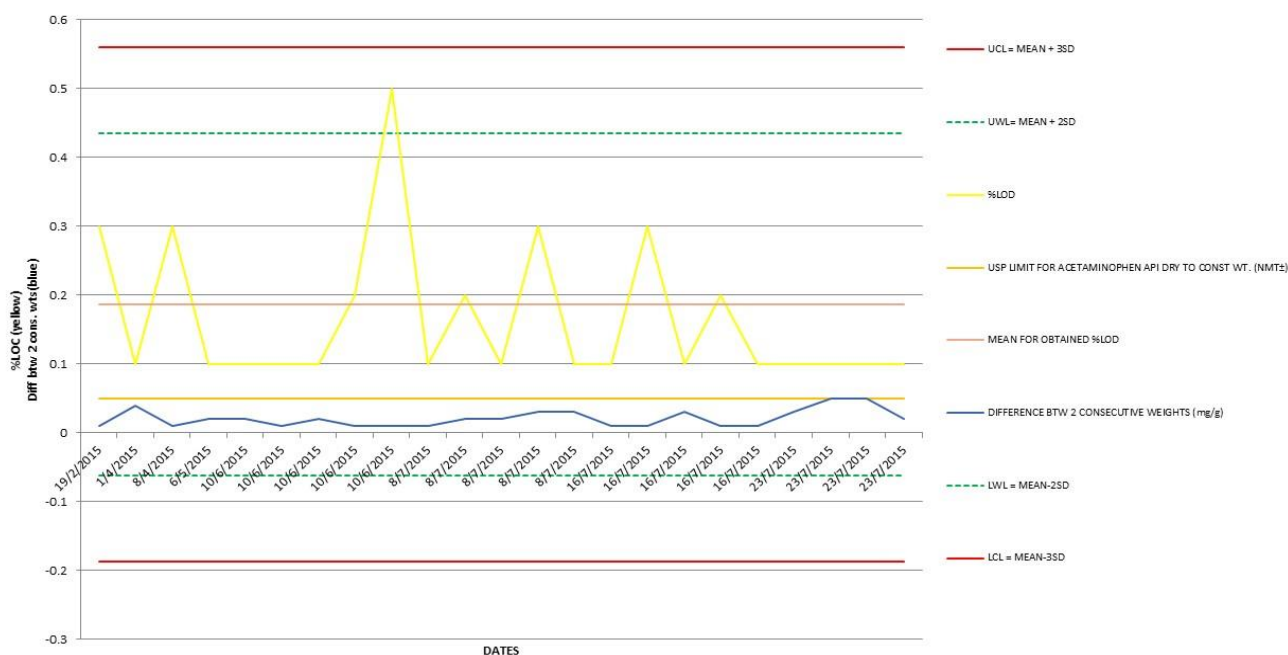


Figure 4: Statistical control chart for process monitoring of loss on drying using hot air oven

d) Leadership and quality culture

Harmonisation efforts in Africa have faced many challenges. Examples are the difficulties in achieving consensus encountered by the countries in sub-Saharan Africa under the New Partnership for Africa's Development (NEPAD) (Shittu, 2016). These countries pursue sustainable science and technological growth, similar to Asia-Pacific-Economic-Cooperation for regulatory dialogue (Lin, Lin & Chern, 2009). The BIRS MS programme provides a platform where the main stakeholders, regulators, industry, and academia from different African countries learn in classrooms together (Springer *et al.*, 2016), thereby establishing networks that will enhance partnerships between these countries, congruent with the goals of the NEPAD initiative.

The BIRS programme builds relationships and networks between sub-Saharan African regulators. Three alumni of the programme, Pharmacists F, G, and H (Appendices K, L, and M), described how their MS training greatly enhanced their leadership, mentoring, and advocacy skills. These are very useful tools required by professionals in the region, even as groups in sub-Saharan Africa strive towards harmonisation of regulatory standards.

These sustainability efforts are a means for improving the quality systems of organisations that play critical roles in maintaining public health in these low-income countries.

3. Oral Interview with a BIRS MS participant

A qualitative researcher described interviews as a means through which a researcher discusses questions with a respondent to gather information related to a study (DeMarrais & Lapan, 2003). Since this case study aimed to explore novel projects related to pharmaceutical manufacturing and quality, a one-on-one interview with an alumnus discussed her experiences with the BIRS MS programme to gain more perspective. The respondent, Pharm. K, is the quality assurance manager for a national regulatory authority for food and drugs in West Africa.

This participant showed much enthusiasm in discussing the topic; she seemed to understand the objective of the BIRS programme in Africa. The interviewer reported being passionate about her narratives and experiences as an MS student of the BIRS programme. Furthermore, she described the impact her colleagues, who are alumni of the programme, had elicited in their workplaces. Verbatim quotes and the main themes that emerged from her responses are shown in Table III.

Table III: Themes and quotes gleaned from one-on-one interview of a BIRS MS alumnus

Themes	Examples of quotes around each theme
Concept of "train the trainers."	"... Each time they go and come back from the program, you know, the ideas and training they shared with us because they actually shared some training with us, also helped, you know, to enlighten us and educate us more on areas, especially laboratory areas, and even things we thought we knew, they taught us better and that actually excited you."
The program builds capacity in laboratory and manufacturing	"... Then the issue of out of specification, knowledge gained helped us improve our existing processes. The knowledge gained helped us make our procedures fit for purpose and more robust."
Developed leadership skills and traits	"... That attitude of giving, you need to give knowledge, you need to give yourself, build a succession plan to impact other people's lives."
Laboratory process improvements and institutionalizing a quality culture	"Other aspects of the laboratory have also been impacted, like the areas of QMS too. As everyone being responsible, and not just the quality manager and the quality team."

The results obtained from this qualitative approach indicated that alumni from some countries in the region had implemented projects that improved the manufacture and quality control of medicines. Through their MS training, they acquired tremendous capacity-building prowess that is positively transforming their current workspaces.

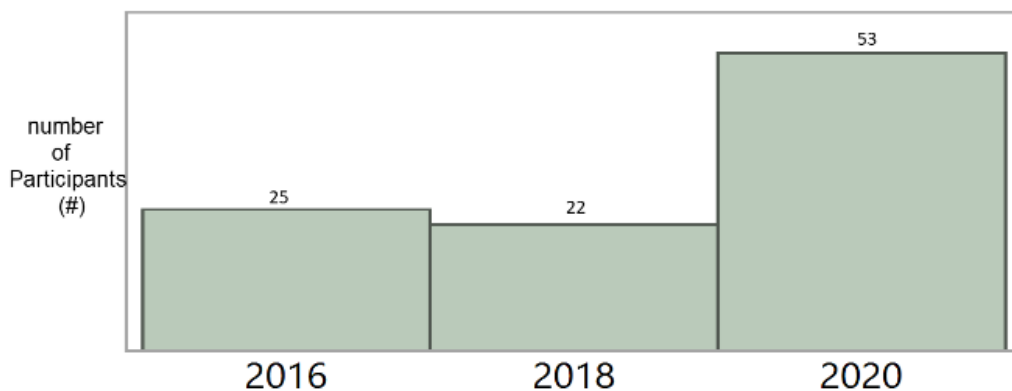
Q.2 Evaluate if the program is acceptable to the sub-Saharan African community?

The analysis of variance (ANOVA) was used to evaluate the differences between the number of participants across the years 2016, 2018, and 2020 and test the hypothesis that participants will significantly increase over the years if the programme meets the set objectives. At the time of this report, the trend from the student enrolment showed that the programme had

trained one hundred (100) MS students in Biotechnology Innovation and Regulatory Sciences (Figure 5).

These participants were from ten countries (Figure 6); East Africa had the highest number of alumni. The programme trained personnel from regulatory, industry, academia, and other work areas (Figure 7). Some of these MS students who implemented and sustained projects in pharmaceutical GMP and laboratory quality control formed the alumni respondents for this study.

Compared to females, a higher number of males participated in the programme in the three cohorts (Figure 8): 2016 (17 males, 8 females), 2018 (14 males, 8 females), and 2020 (31 males, 22 females). However, the number of female participants increased over the years.



The number of participants increased in 2020.

Figure 5: Year of graduation and associated frequencies of alumni

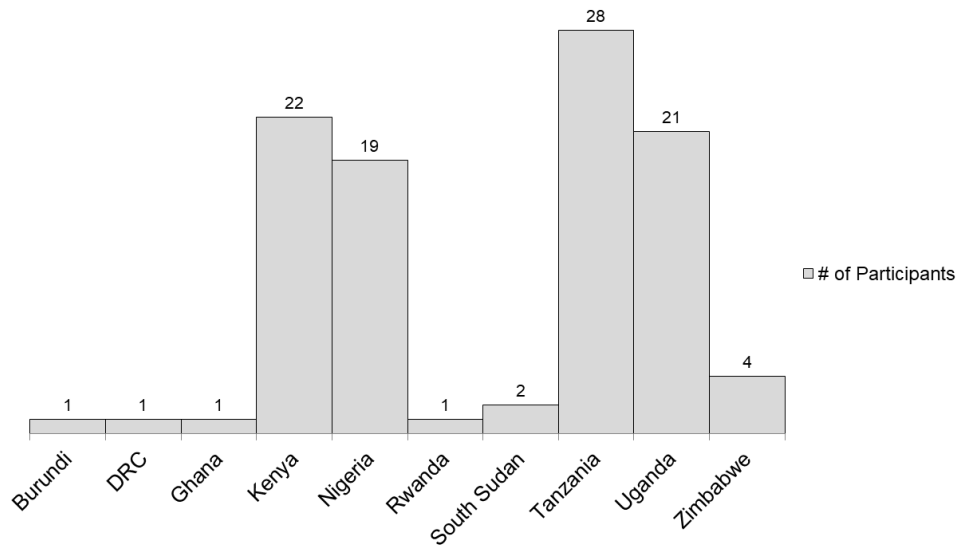
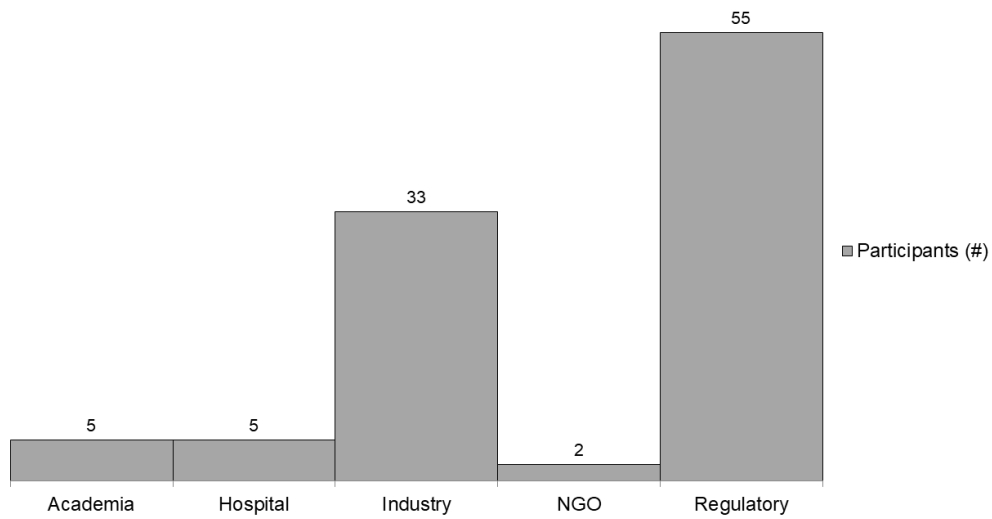
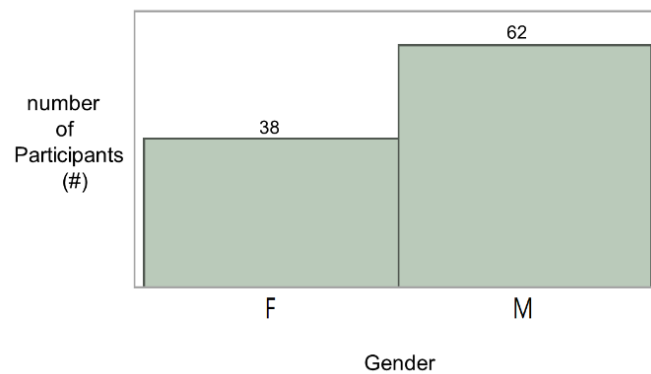


Figure 6: Participating countries and counts for the BIRS MS programme 2016-2020



The programme has trained more regulators in sub-Saharan Africa

Figure 7: Participants by work area (2016-2020 cohorts)



More males participated than females

Figure 8: The BIRS MS participants by gender (2016-2020)

The one-way ANOVA showed a significant increase in the mean number of participants (high programme acceptance in sub-Saharan Africa) in the BIRS MS

programme from 2016 to 2020 ($F_{1,4} = 39876.4$, $p = 3.77E-09$) (see Table IV).

Table IV: ANOVA Summary of students' participation in the BIRS MS programme 2016-2020

Source of variation	SS	Df	MS	F	p-value
Between Years	5908353	1	5908353	39876.4	3.77E-09
Within Years	592.6667	4	148.1667		
Total	5908945	5			

Chi-square contingency tests with simulation-based p-value and robust to small cell counts were carried out comparing the total number of participants between the years 2016 vs 2018, 2018 vs 2020, and 2016 vs 2020 to further investigate in which graduation years this significance existed. The results of these comparisons, (Table V) revealed that the decrease in the number of

participants from 2016 to 2018 was not significant ($\chi^2 = 0.19149$, $p = 0.7715$, $\alpha = 0.05$); However, the increase in student participation from 2016 to 2020 was significant ($\chi^2 = 10.051$, $p = 0.0024$, $\alpha = 0.05$). Similarly, there was a significant increase in participants from 2018 to 2020 ($\chi^2 = 12.813$, $p = 0.0005999$, $\alpha = 0.05$).

Table V: Chi-squared test with simulation, compared the number of BIRS MS participants

Number of participants	χ^2	p (2-tailed)
Pair 1: 2016-2018	0.19149	0.7715
Pair 2: 2018-2020	12.813	0.0005999*
Pair 3: 2016-2020	10.051	0.0024*

Note: significant p-values when the number of participants year (2020) was paired with 2016 and 2018, respectively. Non-significant p-value was obtained for the 2016- and 2018-years comparison.

*p is significant < 0.05. Bonferroni corrected significance level for alpha = 0.5 is $0.05/3 = 0.0167$

Discussion

The purposeful sampling method used in this study provided an in-depth understanding of the milestones the BIRS MS training has achieved within the scope of the research in manufacturing and quality control. This approach aligns with Patton's argument that the power of the qualitative study is increased when information-rich cases are sought from individuals who form a core selection that can give accurate accounts relevant to the inquiry or research question (Patton, 2015). Other researchers supported a criterion-based sample selection method, where the researcher first determines attributes that will best answer the research question and then selects elements that will satisfy those (LeCompte & Schensul, 2010). This opinion supports the authors' choice of getting feedback from BIRS alumni who have initiated projects that can sustain the manufacturing of quality medicines in sub-Saharan Africa (Agu et al., 2021; Apiyo et al., 2021; Emma Mbabazi et al., 2021; Lubowa et al., 2021; Ogodo et al., 2021; Okezue, Clase & Byrn, 2021; Uche et al., 2021; Usai et al., 2021). This study also provides evidence from other participants who have contributed significantly to improved laboratory quality controls (Okezue, Clase & Byrn, 2018a; Costantine et al., 2021;

Mukungu et al., 2021; Okezue, Clase & Byrn, 2021; Okezue, 2022).

The overall themes that described the experiences of alumni in pharmaceutical manufacturing and laboratory control included the following: The BIRS MS programme increased their capacity-building skills; all respondents were involved in several forms of cascading training for their peers and other professionals within their workspace. They also initiated various organisational improvement projects; some led to accreditation status, e.g., the ISO 17025 recognition for the national regulatory authority in Nigeria, NAFDAC, following improvements in laboratory processes (Okezue, Clase & Byrn, 2018a). The respondents also admitted that the BIRS training improved their organisational problem-solving capacity; Pharm. P stated that: "the programme increased awareness and understanding of Global GMP Guidelines and Regulations". Her assertion is similar to the findings of a paper that analysed how regulatory knowledge is defined and translated into regulatory decisions with potential for international market gains (Hauray, 2017). Furthermore, from the testimonials of alumni, some organisations in the sub-region have experienced advancement in leadership skills and quality culture. Pharm. NI and other respondents

described how their leadership potential has increased after completing the BIRS MS programme. They have instituted quality culture initiatives required for improved quality metrics in pharmaceutical manufacturing (Morris, 2014; Schniepp, 2015; Tomic & Brkic, 2017).

Congruent with the BIRS alumni experiences described in this study, Wilmshurst and colleagues (2016) discussed the impact of fellows from a similar capacity-building effort in sub-Saharan Africa. The authors employed attendees' interventions, collaborations, and ability to influence policies as indices to measure the success of their training (Wilmshurst *et al.*, 2016). Following the success of their training model, the paper also reported that 33 centres in 13 African countries were using the training template. In a similar trend to the BIRS MS training programme, a few academic institutions in Africa are making efforts to develop graduate health sector personnel. Web-based information indicates that the University of Ibadan, Nigeria, West Africa, focuses on a programme for drug discovery and pharmaceutical development and production (University of Ibadan, 2020). Also, Muhimbili University in Tanzania received funding for capacity building for pharmaceutical scientists (MedicoPress, 2018). These novel efforts in pharmaceutical sciences further support the need identified by this study to evaluate the impact created by an already established programme such as the BIRS MS course.

Furthermore, the experiences of the BIRS MS alumni discussed in this paper provide some evidence for the progress achieved in the landscape of medicines in sub-Saharan Africa regarding pharmaceutical manufacturing and quality control. This study did not consider other alumni's contributions to advancing their regulatory landscape (Mashingia *et al.*, 2021; Musa *et al.*, 2021; Sopein-Mann *et al.*, 2021). However, this study has highlighted the need for more manufacturing and quality control participants who will use the knowledge acquired in their BIRS MS training to initiate and sustain the desired goal of quality medicines in sub-Saharan Africa. Pharm. NI identified funding as the main challenge that hinders students' participation.

Finally, with an overall significant increase in the number of participants enrolled in the BIRS MS programme, there is enough evidence to reject the null hypothesis that the number of students remained the same over the years, suggesting that the sub-Saharan African countries are recognising the impact of the programme and supporting student participation.

Limitations

This study focused only on alumni who work in pharmaceutical manufacturing and laboratory quality control sectors. The results from the quantitative assessment show that the programme has trained more regulatory personnel than other areas of practice, which accounts for the low number of alumni eligible to participate in this study. Although participation email invites were sent to the most eligible BIRS alumni, responses were not received from some who had conducted their MS-directed projects in the areas of pharmaceutical manufacturing and laboratory quality controls. Therefore, the details of this study do not provide a holistic overview of the programme's current impact in that area. Also, the use of semi-structured questions, which required the respondents to give a brief narration, may have hindered describing other experiences.

Conclusion

This study described the current efforts of a US-based university in combating the menace of fake and substandard medicines through building the capacity to manufacture quality medicines in sub-Saharan Africa. Course modules that emphasised pharmaceutical manufacturing following Good Manufacturing Practices (GMP) also impacted capacity in organisations, in addition to other quality assurance principles that enable analytical and manufacturing laboratories in the sub-region to attain international standards.

The literature reviewed highlighted small-scale manufacturing hands-on demonstrations as a principal component of the BIRS MS training. The programme also elicited projects related to pharmaceutical quality control that improved laboratory procedures. This study richly described the experiences of some alumni of the BIRS MS programme and provided evidence of leading improvement indicators of manufacturing and quality control of medicines in the region. The results from this qualitative approach indicated that alumni from ten countries in sub-Saharan Africa had implemented projects that enhanced the manufacture and quality control of medicines. Through their MS training, they acquired tremendous capacity-building prowess, positively transforming their current workspaces.

The participants also displayed dexterity in providing several process improvement initiatives and improving problem-solving capacity in their organisations. Finally, the programme was shown to have gained acceptance

in sub-Saharan Africa, as the number of participants has significantly increased over the years.

Conflict of interest

Mercy Okezue (MO) earned an MS and doctorate in the BIRS programme and is currently a Post-Doc researcher at Purdue University, West Lafayette, Indiana, United States.

Stephen Byrn (SB) is a professor and academic advisor to MO in her Ph.D. programme. SB and Zita Ekeocha (ZE) are team members in the Purdue University BIRS programme.

Ethics approval and consent to participate

Study IRB approval was received from Purdue University, West Lafayette, Indiana, USA: IRB-2019-818 and IRB-2020-698. In line with the IRB approval, a letter of invitation was sent to all respondents who are alumni of the Purdue BIRS MS programme. The letter communicated that their participation was voluntary and the data would be published. The participants answered the email request in written and provided testimonials of the impact of their BIRS MS training. The contents of the IRB-approved email and the respondents' written statements are provided in the appendices section of this manuscript.

The authors confirm that all methods were carried out under the relevant guidelines and regulations in the Purdue University IRB approvals for this study.

They also confirm that informed consent was obtained from all subjects per relevant guidelines and regulations in the Purdue University IRB approvals for this study.

Authors' contributions

MO conceived study ideas and received IRB approvals. MO designed, collated, and analysed the data. SB and ZE contributed to writing the manuscript. All authors read and approved the final manuscript.

Institutional Review Board Approval

Purdue University, West Lafayette, Indiana, United States. IRB-2020-698, IRB-2019-818. Efforts at building

capacity for manufacturing quality controls of medicines in sub-Saharan Africa; historical evidence from the BIRS Programme (Parts 1 & 2).

Consent for publication

Not applicable

Availability of data and materials

The datasets used and/or analysed in this study are available from the corresponding author upon reasonable request.

Source of funding

The authors did not receive any funding.

List of abbreviations

BIRS: Biotechnology Innovation and Regulatory Science

GMP: Good Manufacturing Practice

HPLC: High-pressure liquid chromatography

IRB: Institutional Review Board

NAFDAC: National Agency for Food and Drug Administration and Control

NEPAD: New Partnership for African Development

MS: Masters

SSFFC: Substandard, Spurious, Falsely Labelled, Falsified, and Counterfeit

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Mukungu, Pharm. Sandra Lanyero, Pharm. Portia Kampota – Munhuweyi, Pharm. Monica Agu. and Pharm. Collete Ifudu.

References

Agu, M., Ekeocha, Z., Byrn, S., & Clase, K. (2021). The Impact of Mentoring as a GMP Capability Building Tool in The Pharmaceutical Manufacturing Industry in Nigeria. Retrieved from <https://docs.lib.purdue.edu/cgi/viewcontent.cgi?article=1003&context=birsafriatcr>

Ahuja, S., & Dong, M. (2005). Handbook of pharmaceutical analysis by HPLC (Vol. 6): Elsevier

Aminu, N., & Gwarzo, M. S. (2017). The Eminent Threats of Counterfeit Drugs to Quality Health Care Delivery in Africa: Updates on Consequences and Way Forward. *Asian Journal of Pharmaceutical and Clinical Research*, *10*(7), 82-86. <https://doi.org/10.22159/ajpcr.2017.v10i7.18384>

Aminu, N., Sha'aban, A., Abubakar, A., & Gwarzo, M. S. (2017). Unveiling the Peril of Substandard and Falsified Medicines to Public Health and Safety in Africa: Need for All-Out War to End the Menace. *The Journal of Medicine Access*. <https://doi.org/10.5301/maapoc.0000023>

Anyakora, C., Oni, Y., Ezedinachi, U., Adekoya, A., Ali, I., Nwachukwu, C., Esimone, C., Abiola, V., & Nwokike, J. (2018). Quality medicines in maternal health: results of oxytocin, misoprostol, magnesium sulfate and calcium gluconate quality audits. *BMC pregnancy and childbirth*, *18*(1), 44. <https://doi.org/10.1186/s12884-018-1671-y>

Apiyo, E., Ekeocha, Z., Byrn, S., & Clase, K. (2021). Improving Pharmacovigilance Quality Management System in the Pharmacy and Poisons Board of Kenya. Retrieved from <https://docs.lib.purdue.edu/cgi/viewcontent.cgi?article=1011&context=birsafriatcr>

Appiah-Denkyira, E., Herbst, C. H., Soucat, A., Lemiere, C., & Saleh, K. (2013). Towards Interventions in Human Resources for Health in Ghana: Evidence for Health Workforce Planning and Results. *World Bank Publications*. <https://doi.org/10.1596/978-0-8213-9667-4>

Bassat, Q., Tanner, M., Guerin, P. J., Stricker, K., & Hamed, K. (2016). Combating poor-quality antimalarial medicines: a call to action. *Malaria Journal*, *15*, 302. <https://doi.org/10.1186/s12936-016-1357-8>

BIRS. (2019). Sustainable Medicines in Africa – Biotechnology Innovation and Regulatory Science (BIRS) Center – Purdue University. Retrieved from <https://www.purdue.edu/discoverypark/birs/css/Article%20Publications.php>

Byrn, S. R., Ekeocha, Z., & Clase, K. L. (2017). An Education Strategy to Respond to Medicine Inequality in Africa. *Journal of pharmaceutical sciences*, *106*(7), 1693-1696. <https://doi.org/10.1016/j.xphs.2017.02.027>

Clase, K., Ekeigwe, A., Ekeocha, Z., Byrn, S.R., & Shivanand, P. (2019). Human Capacity Building in Africa – The BIRS Model.

BIRS Faculty and Staff Creative Materials. Paper 2. Retrieved from <https://docs.lib.purdue.edu/birsfcm>

Costantine, A., Ekeocha, Z., Byrn, S., & Clase, K. (2021). Quality of Sample Testing in the Laboratory Unit: Current Situation and Strategies for Improvement. Retrieved from <https://docs.lib.purdue.edu/cgi/viewcontent.cgi?article=1013&context=birsafriatcr>

Debrus, B., Lebrun, P., Kindenge, J. M., Lecomte, F., Ceccato, A., Caliaro, G., Mbay, J. M., Boulanger, B., Marini, R. D., Rozet, E., & Hubert, P. (2011). Innovative high-performance liquid chromatography method development for the screening of 19 antimalarial drugs based on a generic approach, using design of experiments, independent component analysis and design space. *Journal of chromatography*. *A*, *1218*(31), 5205–5215. <https://doi.org/10.1016/j.chroma.2011.05.102>

DeMarrais, K. B., & Lapan, S. D. (Eds.). (2003). Foundations for research: Methods of inquiry in education and the social sciences. Routledge. New York. <https://doi.org/10.4324/9781410609373>

Emma Mbabazi, K., Ekeocha, Z., Byrn, S., & Clase, K. (2021). Standardisation of Staff Training to Increase Efficiency. Retrieved from <https://docs.lib.purdue.edu/cgi/viewcontent.cgi?article=1001&context=birsafriatcr>

Guwatudde, D., Bwanga, F., Dudley, L., Chola, L., Leyna, G. H., Mmbaga, E. J., Kumwenda, N., Protsiv, M., Atkins, S., Zwarenstein, M., Obua, C., & Tumwine, J. K. (2013). Training for health services and systems research in Sub-Saharan Africa—a case study at four East and Southern African universities. *Human resources for health*, *11*, 68. <https://doi.org/10.1186/1478-4491-11-68>

Hauray, B. (2017). From Regulatory Knowledge to Regulatory Decisions: The European Evaluation of Medicines. *Minerva*, *55*(2), 187–208. <https://doi.org/10.1007/s11024-017-9323-3>

Health care: An African solution. (2011). *Lancet (London, England)*, *377*(9771), 1047. [https://doi.org/10.1016/S0140-6736\(11\)60417-0](https://doi.org/10.1016/S0140-6736(11)60417-0)

Higby, G., & Stroud, E.C. (2005). American Pharmacy (1852-2002): A Collection of Historical Essays (Vol. 21): American Institute of the History of Pharmacy

Jones-Farmer, L.A., Ezell, J.D., & Hazen, B.T. (2014). Applying Control Chart Methods to Enhance Data Quality. *Technometrics*, *56*(1), 29-41. <https://doi.org/10.1080/00401706.2013.804437>

Jong-Wook, L. (2011, 2011-08-02 13:38:00). WHO | Speech to the Fifty-sixth World Health Assembly. WHO. Retrieved from https://www.who.int/dg/lee/speeches/2003/21_05/en/

Khuluza, F., Kigera, S., Jahnke, R.W.O., & Heide, L. (2016). Use of thin-layer chromatography to detect counterfeit sulfadoxine/pyrimethamine tablets with the wrong active ingredient in Malawi. *Malaria Journal*, *15*(212). <https://doi.org/10.1186/s12936-016-1259-9>

- LeCompte, M.D., & Schensul, J.J. (2010). Designing and conducting ethnographic research: An introduction. (2nd ed.). Lanham and New York: AltaMira Press
- Lin, C.-H., Lin, B.B., & Chern, H.-D. (2009). APEC Pharmaceutical Evaluation Report (PER) Scheme: A Regional Solution for Global Drug Development. *Drug Information Journal*, **43**(3), 305–309. <https://doi.org/10.1177/009286150904300309>
- Lubowa, N., Ekeocha, Z., Byrn, S., & Clase, K. (2021). Pharmaceutical Industry in Uganda: A Review of the Common GMP Non-conformances during Regulatory Inspections. Retrieved from <https://docs.lib.purdue.edu/cgi/viewcontent.cgi?article=1009&context=birsaficatr>
- Maize, H., Mavity, M., McCord, J., Schramm, S., Stepanovic, M., & Wintczak, D. (2017). Method to improve drug safety in Africa: a pharmaceutical learning module. *The Journal of Purdue Undergraduate Research*, **7**(1), 3. <https://doi.org/10.5703/1288284316392>
- Mashingia, J., Maboko, S., Mbwiri, P.I., Okello, A., Ahmada, S. I., Barayandema, R., Tulba, R., Byomuhangi, E., Ekeocha, Z., Byrn, S., & Clase, K. (2021). Joint Medicines Regulatory Procedure in the East African Community: Registration Timelines and Way Forward. Retrieved from <https://docs.lib.purdue.edu/cgi/viewcontent.cgi?article=1002&context=birsaficatr>
- McCord, J., Mavity, M., Damayo, S.A., & Wintczak, D. (2015). Universal HPLC analysis for counterfeit medication: A partnership of Purdue University and the Kilimanjaro School of Pharmacy. *Purdue Journal of Service-Learning and International Engagement*, **2**(1), 7. <https://doi.org/10.5703/1288284315692>
- MedicoPress. (2018). MUHAS professor and team win nearly Sh400million for drug discovery, design. Retrieved from <https://medicopress.media/2018/05/25/muhas-professor-and-team-win-nearly-sh400million-for-drug-discovery-design/>
- Medtrack. (2017). Emzor Pharmaceutical Industries Ltd Medtrack Company Profile. Emzor Pharmaceutical Industries Ltd Medtrack Company Profile. Available at: <https://www.emzorpharma.com/about-emzor/>
- Merriam, S.B., & Tisdell, E. J. (2015). Qualitative research : a guide to design and implementation (Fourth edition). John Wiley & Sons
- Montgomery, D.C. (2013). Introduction to statistical quality control (7th edition). John Wiley & Sons
- Morris, W. (2014). Large industry cross-section contributes to PDA quality metrics recommendations: PDA works with FDA to create pharmaceutical quality metrics. *Pharmaceutical Technology Europe*, **26**(2), 27-29
- Mukungu, A., Ekeocha, Z., Byrn, S., & Clase, K. (2021). Evaluating and Understanding the Reason for an Increase in Nonconformances in the Laboratory. *BIRS Africa Technical Reports*. Paper 1. Retrieved from <http://dx.doi.org/10.5703/1288284317430>
- Musa, P., Ekeocha, Z., Byrn, S., & Clase, K. (2021). Knowledge Sharing in Organisations: Finding a Best-fit Model for a Regulatory Authority in East Africa. Retrieved from <https://docs.lib.purdue.edu/cgi/viewcontent.cgi?article=1003&context=birsaficatr>
- Ogodo, M.O., Ekeocha, Z., Byrn, S., & Clase, K. (2021). Defects Analysis and Root Cause Robustness of Product Labels of an Acaricide Product in East Africa. Retrieved from <https://docs.lib.purdue.edu/cgi/viewcontent.cgi?article=1008&context=birsaficatr>
- Okezie, M.A. (2022): Developing Multipronged Models to Enhance Effectiveness of the Management System of Quality Control Laboratories. Additional Focus on Synthesis and Characterization for 5 New Salts of Bedaquiline. *Purdue University Graduate School*. Thesis. <https://doi.org/10.25394/PGS.19620642.v1>
- Okezie, M.A., Adeyeye, M.C., Byrn, S.J., Abiola, V.O., & Clase, K.L. (2020). Impact of ISO/IEC 17025 laboratory accreditation in sub-Saharan Africa: a case study. *BMC health services research*, **20**(1), 1065. <https://doi.org/10.1186/s12913-020-05934-8>
- Okezie, M.A., Clase, K.L., & Byrn, S. (2018a). Instituting Process Control Mechanisms in a Quality Control Analytical Chemistry Laboratory. BIRS Symposium. Retrieved from <https://docs.lib.purdue.edu/cgi/viewcontent.cgi?article=1003&context=itbs>
- Okezie, M.A., Clase, K.L., & Byrn, S.R. (2021). An Effort at Improving Reliability of Laboratory Data in Titrimetric Analysis for Zinc Sulphate Tablets Using Validated Spreadsheet Calculators. *International Journal of Pharmacological and Pharmaceutical Sciences*, **15**(5), 182-189. <https://publications.waset.org/10012043/pdf>
- Okezie, M.A., Clase, K.L., Byrn, S.R., & Shivanand, P. (2021). Disparities versus Similarities: WHO GPPQCL and ISO/IEC 17025: 2017 International Standards for Quality Management Systems in Pharmaceutical Laboratories. *International Journal of Pharmacological and Pharmaceutical Sciences*, **15**(12), 341-353. <https://publications.waset.org/10012373/pdf>
- Okezie, M., Clase, K.L., & Byrn, S. (2018b). Use of Excel Spreadsheet Calculators in Handling Data Generated From UV- Spectrometer. BIRS Symposium. Retrieved from <https://docs.lib.purdue.edu/cgi/viewcontent.cgi?article=1004&context=itbs>
- Ozawa, S., Evans, D.R., Higgins, C.R., Laing, S.K., & Awor, P. (2019). Development of an agent-based model to assess the impact of substandard and falsified anti-malarials: Uganda case study. *Malaria journal*, **18**(1), 5. <https://doi.org/10.1186/s12936-018-2628-3>
- Patton, M.Q. (2015). Qualitative research & evaluation methods: integrating theory and practice (Fourth edition): Thousand Oaks, California : SAGE Publications
- Petersen, A., Held, N., & Heide, L. (2017). Surveillance for falsified and substandard medicines in Africa and Asia by local organizations using the low-cost GPHF Minilab. *PloS one*, **12**(9), e0184165. <https://doi.org/10.1371/journal.pone.0184165>
- Pisani, E. (2019, 2019-09-04). How moves towards universal health coverage could encourage poor quality drugs: an

- essay by Elizabeth Pisani. *BMJ (Clinical research ed.)*, **366**, 15327. <https://doi.org/10.1136/bmj.15327>
- Rstudio Team. (2020). Rstudio: Integrated Development for R. Rstudio, PBC, Boston, MA URL <http://www.rstudio.com/>
- Ruddock, U. (2015). E-Interviews. A Review of Janet Salmons' Qualitative Online Interviews (2nd edition). *The Qualitative Report*, **20**(3), 356-358. <https://doi.org/10.46743/2160-3715/2015.2276>
- Schniepp, S. (2015). An update on the quality metrics initiative. *BioPharm International*, **28**(5), 40-41
- Shittu, R. (2016). Africa and The Philosophy of the New Partnership For Africa's Development (NEPAD). *Acta Universitatis Danubius : Communicatio*, **10**(2), 117-134
- Sopein-Mann, O., Ekeocha, Z., Byrn, S., & Clase, K. (2021). Medicines Regulation in West Africa: Current State and Opportunities. Retrieved from <https://docs.lib.purdue.edu/cgi/viewcontent.cgi?article=1010&context=birsafriatr>
- Spink, J., Moyer, D.C., & Rip, M.R. (2016). Addressing the risk of product fraud: a case study of the Nigerian combating counterfeiting and sub-standard medicines initiatives. *Journal of Forensic Science & Criminology*, **4**(2), 1-13. <https://doi.org/10.15744/2348-9804.4.201>
- Springer, M., Terruso, L., Speer, M., Ekeocha, Z., Byrn, S., & Clase, K. (2016). Administration of a U.S based MS program in Kilimanjaro, Africa- a global benchmarking in regulatory science. Paper presented at the ASEE 2016 International Forum
- Suen, S. (2013). The education of women as a tool in development: challenging the African maxim. *Hydra: Interdisciplinary Journal of Social Studies*, **1**(2), 60-71
- Tomic, B., & Brkic, V.S. (2017). Quality culture. *Quality Progress*, **50**(7), 16-21
- Tshikuka Mulumba, J.G., Atua Matindii, B., Kilauzi, A.L., Mengema, B., Mafuta, J., Eloko Eya Matangelo, G., Mukongo Bulaïmu-Lukeba, A., & Jerry, I.L. (2012). Severity of outcomes associated to types of HIV coinfection with TB and malaria in a setting where the three pandemics overlap. *Journal of community health*, **37**(6), 1234-1238. <https://doi.org/10.1007/s10900-012-9559-7>
- Uche, C., Ekeocha, Z., Byrn, S., & Clase, K. (2021). Retrospective Study of Inspectors Competency in the Act of Writing GMP Inspection Report. Retrieved from <https://docs.lib.purdue.edu/cgi/viewcontent.cgi?article=1012&context=birsafriatr>
- University of Ibadan, O.S.N. (2020). The Centre for Drug discovery, development and Production (CDDDP). Retrieved from <https://pharm.ui.edu.ng>
- UNSD. (2020). Methodology: Standard country or area codes for statistical use (M49). Retrieved from <https://unstats.un.org/unsd/methodology/m49/>
- US FDA. (2011). Advancing Regulatory Science at FDA: A STRATEGIC PLAN. United States: US FDA Retrieved from <https://wayback.archive-it.org/7993/20170404215759/https://www.fda.gov/downloads/ScienceResearch/SpecialTopics/RegulatoryScience/UCM268225.pdf>
- Usai, J., Ekeocha, Z., Byrn, S., & Clase, K. (2021). Herbal Medicines Registration Process for Zimbabwe Overview of the Process. Retrieved from <https://docs.lib.purdue.edu/cgi/viewcontent.cgi?article=1007&context=birsafriatr>
- Walker, E.J., Peterson, G.M., Grech, J., Paragalli, E., & Thomas, J. (2018). Are we doing enough to prevent poor-quality antimalarial medicines in the developing world?. *BMC Public Health*, **18**(1). <https://doi.org/10.1186/s12889-018-5521-7>
- Wilmshurst, J.M., Morrow, B., Du Preez, A., Githanga, D., Kennedy, N., & Zar, H.J. (2016). The African Pediatric Fellowship Program: Training in Africa for Africans. *Pediatrics*, **137**(1). <https://doi.org/10.1542/peds.2015-2741>
- Wong, Joseph. (2015). Achieving universal health coverage. *Bulletin of the World Health Organization*, **93** (9), 663 - 664. World Health Organization. <http://dx.doi.org/10.2471/BLT.14.149070>
- World Health Organisation. (2012). WHO:International shortfall inequality in life expectancy in women and in men, 1950-2010. WHO. Retrieved from <https://apps.who.int/iris/handle/10665/271171>
- World Health Organisation. (2015). Essential Medicines: WHO Model List. Retrieved from https://www.who.int/medicines/publications/essentialmedicines/EML_2015_FINAL_amended_NOV2015.pdf?ua=1
- World Health Organisation. (2013). Transforming and scaling up health professionals' education and training: World Health Organization guidelines. World Health Organization. Retrieved from <https://www.who.int/publications/i/item/transforming-and-scaling-up-health-professionals'-education-and-training>

Appendix

Appendix A: Purdue IRB approved email invite sent to study participants

Hello all,

We are gathering data for a proposed paper publication: **Efforts at advancing capacity for manufacturing quality medicines in sub-Saharan Africa; historical evidence from the BIRS Program**

All participants are past/current Purdue BIRS MS student; your participation is voluntary.

Could you provide a brief document, describing the impact BIRS training you received, improved your place of work as regards manufacturing / laboratory?

You can also include the abstract of your BIRS masters thesis if you implemented it in your area of practice.

Please include your full contact details at the end of your write-up and send it as an attachment in response to this email.

Your contributions will be acknowledged in the final paper.

If you have any questions, please contact me using details provided below.

Thank you

Appendix B : Email response from a BIRS alumnus, Dr. A

Quality Infrastructure Improvement through Training

Purpose:

Prompt quality culture in pharmaceutical manufacturing through training on quality assurance topics/GMP in the East African region (GMP training).

Pass the learned knowledge and experience to the next generation of quality leaders.

Outcome:

Improvement of the pharmaceutical products' quality and efficiency and effectiveness of the process.

Improved compliance to cGMP requirements.

Regional (East Africa) GMP training missions successfully conducted to date:

- a. Risk management, Qualification and Validation, 7th -9th July 2015 in Kigali Rwanda.
- b. Regional Incubation Workshop for Federation of East Africa Pharmaceutical Manufacturers (FEAPM)-Academia Internship Programme for Pharmacists held in Nairobi, Kenya held on 4th-15th December 2015. Topics covered:
 - Good Manufacturing Practices for Finished Pharmaceutical Products

- Deviation Management, CAPA and Change Control Management
 - Good Practice in Production
 - Introduction to Inspection and the Role of an Inspector
- c. Train of Trainers, 27th – 29th June 2018 in Nairobi, Kenya
 - d. Train of Trainers, 2nd – 4th July 2018 in Kampala, Kenya
 - e. Training in a workshop on Good Documentation Practices and Data Integrity workshop held in Kampala from 30th July-1st August 2019, covering six presentations, namely:
 - Documents Relevant to GMP
 - GMP Compliant Documentation
 - Batch Documentation
 - Standard Operating Procedures
 - Data Integrity: Introduction
 - Data Integrity Requirements-ALCOA and ALCOA-plus
 - f. Training on Quality Risk Management unit in QC and Production Equipment Preventative Maintenance Course held in Nairobi from 6th – 9th May 2019.

Purpose:

Promoting a culture of quality in pharmaceutical manufacturing through training on quality assurance topics/GMP in the East African region. In other words, I am passing the knowledge learned and my experience to the next generation of quality leaders.

Appendix C: Email response from a BIRS alumnus, Pharm. B**Follow on actions to the BIRS directed project**

I conducted a directed project titled, "Risk-based approach in Scheduling GMP Inspections: A case study of Uganda National Drug Authority". The directed project examined the existing bottlenecks in the process of scheduling GMP inspections of pharmaceutical manufacturers by Uganda National Drug Authority with a view of designing a risk-based approach to address the challenges. The major observations made in the study included;

1. An average delay of 6 months to conduct re-inspections of pharmaceutical manufacturers after expiry of their GMP certificates which cost the institution approximately 200,000 USD every year

2. An abnormally high cost of inspection man-days required to inspect all manufacturers on time.
3. It takes a long time to review the systems of high-risk manufacturers.

I presented a model risk-based approach for scheduling GMP inspections to the management of Directorate of Inspectorate & Enforcement at National Drug Authority for consideration.

I also trained GMP inspectors on a risk-based approach in scheduling GMP inspections in an Advanced GMP training for GMP inspectors in the East African Community (EAC) Region that was held in Kampala on 10th November 2017. In the same training, I presented a hands-on practical exercise on using the risk-based model and the EAC members appreciated the value of the tool and promised to adapt and implement it. I have continued advocating for a need to adopt a risk-based approach to scheduling inspections during GMP peer review committee meetings.

A recent WHO Global Benchmarking audit of the National Drug Authority which was conducted in November 2019 also revealed a need for a risk-based approach in scheduling GMP inspections. Management has committed to addressing all recommendations made including implementing a risk-based model for scheduling GMP Inspections.

Advanced Good Manufacturing Practice Training Course on Quality Risk Management and Data Integrity for GMP Inspectors, 6th to 10th November 2017

Friday 10 th November 2017	
08:00-09:00	Risk based inspection planning: <ul style="list-style-type: none"> • Tools and models available • Knowledge and information needed
09:00-10:30	Risk Management in Scheduling GMP Assessments Hand on exercise: Risk based national inspection plan
10:30-11:00	Coffee break
11:00-11:30	Quality assurance of the reporting of and standardisation of risk: <ul style="list-style-type: none"> • Deficiency in writing and standardisation • Recommendations and certificates • Recording recommendations from the inspectors and acting upon them
11:30-12:00	Workshop on writing, classifying and referencing deficiencies. Examples of poor and good deficiency writing. Clarity in defining the problem. Root cause and consideration of likely effective CAPA
12:00-1:00	Case study
13:00-14:00	Lunch
14:00-16:00	Assessment in the form of a test
16:00-17:00	Closing Ceremony & Cocktail Officiating closure of training

Appendix D: Spreadsheet calculator for Uniformity of dosage units (UDU) stage 1

DOCUMENT TITLE: UNIFORMITY OF DOSAGE UNIT CALCULATIONS				
Prepared by/date:	Issue No.: 01	Originating Directorate:XXX-YYY- Drug Lab		
HOU:14-06-2014		Doc Ref. No.:	XXX-CHEM-100-00	
Reviewed by/date:	Approved by/Date:	Effective Date:	20-06-2014	
QAU:17-06-2014	HOL:19-06-2014	Review Due Date:	20-06-2017	
Page 1 of 2				
DATE	21/07/2014			
ANALYST NAME	OLUWO <4>			
NB REF NO:	LS-DL-AN-171			
SAMPLE LAB NO:	YB/DRN/6187/2014			
SAMPLE NAME:	Celactone (Spironolactone 25mg)			
BATCH NO	20140214			
METHOD USED	BP 2013			
CPU USED	LAB 2			
BALANCE ID/CAL	YB-AB-04 / 02-15			
STAGE 1B: UNIFORMITY OF DOSAGE UNIT (WEIGHT VARIATION)				
DOSE AND RATIO OF DRUG SUBSTANCES				
AVERAGE WT(g)	0.15427			
DOSE(mg):	25			
RATIO(%):	dose(mg)* average wt(mg)	100=	16.20535425	
CALCULATION OF CLAIMS FOR WEIGHT VARIATION				
S/NO	WEIGHT(g)	% claim	STAGE 1B	DETERMINATION OF ACCEPTANCE VALUE (AV)
			REFER TO TABLE 2 <905> USP/NF FOR AV EQUATION	M=98.5% AV= 98.5-Xbar + k*s
			Since $X_{\text{bar}} < 98.5\%$,	98.5
			AV=105.4-101.5+(2.4*0.9995085)	
			AV=3.9+2.3988204	
			AV=8.466 (Satisfies limit for L1 =NLT 15)	
			AV=	8.5
			STATUS: Uniformity of Dosage Unit :	
			Analyst Signature =	
			Supervisor Signature=	
1	0.1549	92.486154		
2	0.156	93.142931		
3	0.1542	92.068205		
4	0.1528	91.232307		
5	0.1549	92.486154		
6	0.1557	92.96381		
7	0.154	91.948791		
8	0.1556	92.904103		
9	0.1515	90.456116		
10	0.1531	91.411428		
TOTAL WT OF 10 TABLETS	1.54	NA		
AVERAGE WEIGHT	0.15427	NA		
MEAN(X_{bar}) OF % CLAIM	N/A	92.11		
STD OF % CLAIM	N/A	0.8648017		

Appendix E: Spreadsheet calculator for Uniformity of dosage units stage 2

DOCUMENT TITLE: UNIFORMITY OF DOSAGE UNIT CALCULATIONS				
Prepared by/date:	Issue No.: 01	Originating Directorate:xx-yy Drug Lab		
HOU:14-06-2014		Doc Ref. No.:	AAA-CHEM-100-00	
Reviewed by/date:	Approved by/Date:	Effective Date:	20-06-2014	
QAU:17-06-2014	HOL:19-06-2014	Review Due Date:	20-06-2017	
Page 3 of 4				
STAGE 2C: UNIFORMITY OF DOSAGE UNIT (WEIGHT VARIATION)				
CALCULATION OF CLAIMS FOR WEIGHT VARIATION				
1	WEIGHT(g)	% claim	STAGE 2C	DETERMINATION OF ACCEPTANCE VALUE (AV)
			REFER TO TABLE 2 <905> USP/NF TO DETERMINE EQUATION FOR AV	
			Since $98.5 \geq X_{\text{bar}} \geq 101.5\%$	M=Xbar (AV = K* S)
			M =	0
			Xbar =	0
			K=	2
			s=	0
			AV=	0
			AV=	0.00 (Doesn't Satisfy limit for L1 =NLT 15)
			STATUS: Uniformity of Dosage Unit :	Unsatisfactory
			STAGE 2	Where L= 25 M= 98.5
			MINIMUM=	(1-(0.01*L2))*M
			MINIMUM=	73.875
			MAXIMUM=	(1+(0.01*L2))*M
			MAXIMUM=	123.125
			STATUS:	Uniformity of Dosage Unit = Unsatisfactory
			Analyst Signature =	
			Supervisor Signature=	
1	0.1094	72.145		
2	0.1388	91.534		
3	0.169	111.449		
4	0.142	93.644		
5	0.1409	92.919		
6	0.199	131.233		
7	0.1409	92.919		
8	0.1376	90.742		
9	0.1908	125.826		
10	0.1404	92.589		
11	0.1094	72.145		
12	0.1388	91.534		
13	0.169	111.449		
14	0.142	93.644		
15	0.1409	92.919		
16	0.199	131.233		
17	0.1409	92.919		
18	0.1376	90.742		
19	0.1908	125.826		
20	0.1404	92.589		
21	0.1094	72.145		
22	0.1388	91.534		
23	0.169	111.449		
24	0.142	93.644		
25	0.1409	92.919		
26	0.199	131.233		
27	0.1409	92.919		
28	0.1376	90.742		
29	0.1908	125.826		
30	0.1404	92.589		
TOTAL WT OF 30 TABLETS	4.53	NA		
AVERAGE WEIGHT	0.15088	NA		
MEAN(X_{bar}) OF % CLAIM	N/A	99.5		
STD OF % CLAIM	N/A	17.32042382		

Appendix F: Email response from a BIRS alumnus, Pharm. C

Impact of BIRS training

Workplace

- Received Hands on experience in tableting which was particularly helpful because my company is planning to expand our production lines to include tableting of which will definitely be an invaluable resource.
- Elements of Lean manufacturing such as correction, overproduction, waiting, and inventory which I have since implemented and led to improved employee efficiency, realised cost savings, and increased competitiveness.
- Enhanced problem-solving skills. I am capable of getting to the root cause of the problem using various techniques taught during the course. For example the five WHY's and fishbone. This was especially useful, because in manufacturing, a number of problems will come up and having the requisite problems solving skills helps in the identification of the root cause of the problem so that recurrence is avoided. This inevitably ensures the manufacture of good quality medicines as well as saves time and money. I have applied problem-solving skills when developing Corrective and Preventive Action (CAPA) plans following an audit or problem identification.
- Common Technical Document (CTD) compilation. The BIRS course coincided perfectly with the adoption of CTD in Uganda. As the Pharmacist, it is my responsibility to prepare dossiers. Initially, it was a nightmare because I didn't have adequate prior training with the result that all submitted dossiers were rejected because their format was unacceptable or had lots of missing pertinent information. This all changed following the hands-on training that we received during the BIRS course. The result was that the time for dossier preparation was greatly shortened from up to six months to one-two months which means Medipharm's list of registered products is now growing faster. I am now the focal person for CTD compilation in my organisation.
- I have access to Purdue libraries for research which is particularly useful during dossier compilation.
- I was able to polish my training skills. In my position as the Supervising Pharmacist of a

manufacturing facility, one of my responsibilities is to conduct regular GMP training for staff. The skills picked up during the BIRS course as well the literature shared (books and slide presentations) has made me a much more effective trainer. In addition to staff, I also train over 30 pharmacy intern students annually. All of whom are directly benefiting from the excellent training received from Purdue.

Personal

- Polished my presentation skills
- Developed networking skills
- Access to a vast network of professionals with whom we get to share ideas and experience
- I am a much better leader thanks to BIRS and get better results from my team by applying emotional intelligence.

Appendix G: Email response from a BIRS alumnus, Mr. J

The impact of biotechnology innovation and regulatory sciences (BIRS) education

The following are some of the impacts the BIRS education has made in the Quality Control Laboratory operations and Manufacturing in Emzor Pharmaceutical Industries Ltd, Lagos, Nigeria:

I have carried out formal training/knowledge sharing on the following topics among the different levels of the hierarchy of Emzor Pharmaceutical Industries Ltd, especially in the Quality and Production departments.

Training topic	Date	Participants
cGMP Systems (The Six systems)	14/05/2014	Operation Managers
Quality Risk Management (QRM)	14/05/2014	Operation Managers
Production Controls	26/05/2014	Production, QA/QC Staff
Cleaning Validation	14/07/2016	QA/QC Staff
Organizational Health	22/05/2017	HODs/Directors
Process Validation (with QA & Production)	12/04/2018	Production, QA/QC Staff
Analytical method Validation	16/08/2018	QC Analysts

The impact of the above training and the implementation of the Pharmaceutical Quality Control Laboratory Elements as outlined in my MS Directed Project Thesis on the Quality Control Laboratory Operations and manufacturing are as follows:

Period Parameters	Before 2014-2016	From 2014-till date
Speed		
Average analytical cycle time of finished products.	1 hour 30mins	1 hour
Microbial results of Clean In Place (CIP) samples	24 hours (minimum) using the traditional plate culture method	40-60 seconds using instrumental Luminometer technology
Accuracy		
Average monthly OOS/OOT results due to the Laboratory	10	1 – 2
Average monthly OOS/OOT results due to Processing	15	3
Average Annual Product Failure		
Due to Microbial contamination	5	Nil
Due to processing error	10	2
Improved manufacturing facilities	Terrazzo flooring, Air conditioning in controlled processing areas	Epoxy flooring HVAC in controlled processing areas
Improved laboratory technologies	Two HPLC systems NO FTIR NO Raman Spectrometer	Eight HPLC systems Two FTIRs One Raman Spectrometer
Improved Regulatory Compliance		
NAFDAC/PCN/SON Audits	QC = 11 (Major & Minors)	Three (Minors)
Average Non-Conformities (NCs)	QC = 11 (Major & Minors)	Three (Minors)

OOS- Out of Specification; OOT- Out of Trend; HVAC- Heating, Ventilation, and Air Conditioning; FTIR - Fourier-transform infrared spectroscopy; SON- Standards Organisation of Nigeria and PCN- Pharmacists Council of Nigeria.

Project management : Three of us from Emzor Pharmaceutical Industries Ltd who are graduates of the MS BIRS are highly involved in the various Plant/facilities construction projects going on in our company.

Appendix H : Email response from a BIRS alumnus, Pharm. E.

Impact of the BIRS programme

The knowledge and practical skills that have been impacted by experts from Purdue and industry and regulatory leaders from global organisations have given the students the following opportunities:

- Awareness and understanding of Global GMP guidelines and regulations.
- Ability to ensure continuous improvement in our organisation's Quality Management Systems and cGMP.
- An opportunity to keep abreast with the latest technologies and systems and thus opening our minds to a broader picture and seeing opportunities that can be applied to the African Pharmaceutical industry.
- Formation of an expert network and pool, intra-Africa and Internationally, where we can continuously share ideas.
- Most importantly, priceless leadership skills that will enable us to lead the African Pharmaceutical Industry to sustainably make quality medicines for Africans and beyond.

Organisation/Personnal:

- Have enabled us to compile quality product dossiers for submission to different National Medicines Regulatory Authorities (NMRAs) in the region faster.
- Continual improvements of the QMS, cGMPs, and Good Laboratory Practices (GLP) through internal quality audits by highly knowledgeable personnel.
- Training – I share the training materials I got from the programme.

Appendix I: Email response from a BIRS alumnus, Pharm. F.

Highlights of the Purdue Master of Science programme at the KSP Moshi Tanzania

The programme was designed to address the knowledge gap in manufacturing and regulatory science in African Professionals/Practitioners in the continent, especially in sub-Saharan Africa. Significant insight and clarity were provided in the areas of regulatory science, manufacturing, leadership, and project management amongst others.

Manufacturing:

The series on Good manufacturing practices was impactful. Specifically, the systems approach was an

eye opener as it brought to the fore the inter-relationships within the organisation. Some specific aspects included process validation, concepts of Process Analytical Technologies (PAT), and continuous process monitoring. The series on Product Development was a major high point in the training from topics such as “Drug Development Pathway: A Comparison - Drugs, Biologics, Devices, Diagnostic Devices” which gave an overview of regulatory requirements as part of development strategy.

Introduction to the International Conference on Harmonization (ICH) series in particular ICH Q8(R2) the elements of pharmaceutical development such as Quality target profile, critical quality attributes, risk assessment in product development Linking Material Attributes and Process Parameters to Drug Product Critical Quality Attributes (CQAs), Quality by design, design space amongst others were very helpful in my outlook at product development as being more systematic in approach.

Statistics play a significant role in the application of GMP. When beginning the development of a new product, several important processes are involved such as; combinations of excipient levels, mixing and granulation methods, drying methods, temperatures, compression forces, spray rates, and Design of Experiments (DOE): provides a wealth of information from a manageable number of experiments. Otherwise, experimenters run a great number of trials where they change only one variable at a time. Great deal of time, people, and material resources are expended and little to show for it unless they are very lucky. At the same time, the One Factor At a Time (OFAT) approach was also noted which could also be used. Statistics helps to elevate our conversations from positions of subjectivity and opinion to ones of objectivity and data. These formed some of the high points of the programme.

Appendix J: Email response from a BIRS alumnus, Pharm. G.

Impact of the BIRS programme on my career /life goal

BIRS programme took me back to the basics- the science of pharmaceutical development, manufacture, and regulations from a global perspective. The programme is one of its kind, coming from visionary leaders (Sister Zita Ekeocha, Prof. Stephen Byrn, and Prof. Kari L. Clase amongst others), who are driven by the passion to raise leaders from the African continent with the capability to re-engineer the pharmaceutical manufacturing industry and regulations with the sole

aim of giving patients in Africa Quality, Efficacious and Safe medicines.

This programme resonated with my personal life goal of giving back to society from the wealth of knowledge and experience I have garnered by God’s grace. This programme is a dream come true for me to see that Africa produce medicines with quality that measure up to the requirements of the most stringent regulatory authorities in the world, I wrote an article inline with this in the maiden publication of African Pharmaceutical Forum of FIP in 2007 titled, “Accelerating access to quality medicines in Africa”. In this article, I appealed to Multinational Pharmaceutical Manufacturing companies to help build capacity in the local pharmaceutical manufacturing industry since these are the ones who will weather the storm in the economy, having no other home to run to when the going gets tough.

The BIRS programme is the answer to my appeal coming many years after. I am grateful for the learnings from this programme which will enable me to join hands with other experts to groom our local pharmaceutical manufacturing industry, helping it grow up and cease to remain an infant in the scheme of pharmaceutical manufacturing worldwide. The faculty, comprising of experts from Purdue university, multinational pharmaceutical companies and leaders who worked for stringent regulatory authorities in the world, impacted in us expert experiential knowledge filled with real life examples that paint pictures that aided our understanding.

Not only were our eyes opened to the technical knowledge, but also the learnings of business planning using the business model canvass, project charter and conduct of research are tools that have taught us best practices that are necessary for success. In view of all that, I also received sponsorship in this programme through the benevolence of Bill and Melinda Gates Foundation for my project which will focus on how to build capacity in the Pharmaceutical Manufacturing Industry. Hence, I chose to work on the project with the title: “The Impact of Mentoring as a Capability Building Tool in the Pharmaceutical Manufacturing Industry in Nigeria”. This topic is borne out of the desire to find innovative ways to complement the capacity building strategies currently being used in the industry to bring about faster development in the Pharmaceutical manufacturing industry in Africa. I believe my colleagues and I have the privilege to be the ones to make this happen. I implore all of us to light our candles and put them on the lampstand to shine light for others to see. Let us give back and lead without authority. I know we can do it, let us rise and make it happen.

Appendix K: Email response from a BIRS alumnus, Pharm. H.*Efforts at advancing capacity for manufacturing quality medicines in sub-Saharan Africa; historical evidence from the BIRS programme*

I really enjoyed the diversity of the topics shared especially the audits and inspections, also the statistics which has enabled me to appreciate the metrics that we need to use and actually make use of the enormous data that we generate in order to improve our quality system. I have received very helpful content from the lecturers regarding a broad range of industrial and regulatory topics. I was able to understand these topics from experts who have done the activities. Whenever I learn something new, I share it with my colleagues at work and they are always grateful for the content. This gives us a common understanding of such topics and enables all of us to tackle work related issues from a more enlightened perspective.

Content from this course is unique as it enables me to understand what regulators are looking for, both during audits and dossier review. I recently had to make use of this knowledge during the five audits that I had in three months, all by seasoned regulators. I have had an opportunity to relate with regulators across Africa and Europe. This is a great opportunity for me to keep abreast with current regulatory expectations across the world which has been vital to ensure that our procedures are aligned with those expectations.

The course approaches all content from a quality leadership perspective. Leadership is a very pivotal topic for an industry. Part of the lessons I have learned is to freely share the knowledge I have gained. My lecturers call it "paying forward", which I do by influencing decisions within my company even though I don't have authority, a technique that has been passed on to me during the course. Through doing this, I am continuously influencing my colleagues to have the courage to initiate positive change from any position that they hold. We have demonstrated that leadership without authority is possible.

This course has instilled in me the concept of systems thinking which is hinged on the principle that every activity in a system impacts another and for any intervention to have a lasting impact, it should be synchronised with all other activities in the system. Solutions that are to be implemented in silo are never sustainable. This knowledge has streamlined my assessment of corrective and preventive actions (CAPAs); we ensure that all proposed preventive actions are synchronised to our system of work, which makes them sustainable. This approach has improved the success rate of our responses to regulatory audit reports.

I also consult for other industries and help upgrade their quality management systems. Additionally, I teach pharmacy students using the information from the programme. The hands-on laboratory demonstrations offer very practical knowledge on the key principles in manufacturing and analysis. I intend to also pass on these knowledge to others.