After-action Review of a U.S.-based M.S. Degree Program Delivered in Kilimanjaro, Africa: Challenges and Opportunities for Future Consideration

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Abstract

In the world of pharmaceuticals, regulatory science is an emerging field that has goals of developing tools, drugs, devices, and practices to increase benefit and lower risk concerning safety, quality control, and effectiveness. The dangers of having a subpar, or non-existent, regulatory science practice can be costly at best, or lethal at worst. Formal education at the graduate level to train professionals is a relatively new field. Research has been conducted on the practice of regulatory science, and on the institutions educating these scientists. The University’s investment, in particular, has the ultimate goal of getting sustainable medicine to Africa. The collaboration of the University’s Biotechnology Innovation and Regulatory Science program with the Kilimanjaro School of Pharmacy is helping to provide good regulatory practices in Africa.

This is the third in a series of three papers discussing the details of curriculum, administration and now, lessons learned with challenges and opportunities for future program delivery consideration.

The first paper addressed designing an applicable, theoretically sound and pragmatically implementable curriculum. The second paper focused on the risks of attending class through war torn territories, lack of information technology infrastructure, language, cultural implications, and the payment of tuition and fees as perhaps the most administratively challenging, of the challenges and opportunities documented and presented. The second paper focused on the many non-curriculum challenges and opportunities of delivering a U.S.-based M.S. degree in Kilimanjaro, Africa; a program individuals risked their lives to participate in.

This paper reviews the entire program; its design, development, delivery and student evaluations. The focus of this paper will be on the many lessons learned, identifying challenges and opportunities for future consideration and potential inclusion in yet another program offering in collaboration with the Kilimanjaro School of Pharmacy in Kilimanjaro, Africa. Challenges and opportunities will be presented such that others’ considering comparable international program offerings may benefit from these findings.
Curriculum Context

Springer, Terruso, Speer, Ekeocha, Byrn & Clase [1], previously documented many of the considerations for program content, duration, format and administration. A brief summary of this paper, predominantly focused on curriculum design and development is described below.

The collaboration of the Purdue University Biotechnology Innovation and Regulatory Science program with the Kilimanjaro School of Pharmacy is helping to provide good regulatory practices in Africa. This prompted the need to perform benchmarking activities comparing and contrasting the University’s program to both domestic and international certifications and degrees.

The methodology employed to assess the potential list of resources was to make an exhaustive list (as possible, since higher education is constantly changing) of graduate and post-baccalaureate institutions that provide certification in regulatory science fields. First, the categories of cost, availability, and curriculum needed streamlining for comparison purposes. Then, best practices needed to be identified, for both domestic and international programs. Common themes of coursework in the life sciences, biotechnology, and policy/ethics were identified. Often, programs would require or prefer a bachelors in health science, life sciences, or engineering with common requirements of the advanced degree mandating courses in tissue engineering, stem cell engineering and related disciplines. The international programs focused more on global processes than domestic ones. In addition, there was a common trend, both domestically and internationally, that pharmaceutical sciences background/employment experience was preferred and the programs were designed to be part-time so the degree/certification could be earned while remaining employed (some required a project be completed at the student’s place of employment). The most typical degree earned in this field was a Master’s degree and while ranging in cost from $23,000 - $100,000 in the domestic programs, the cost was typically much less expensive in the international programs.

The Biotechnology Innovation and Regulatory Science (BIRS) program transitioned to Purdue University’s Polytechnic Institute in the fall semester 2014, after 12 successful years as the Regulatory and Quality Compliance program in the University’s College of Pharmacy. This transition allowed the program to expand its pharmaceutical regulatory science and quality offerings to include medical devices & diagnostics, combination drugs and biotechnology innovation.

This paper’s science-based program is a 33 credit hour MS that includes 21 required hours and 12 elective credits. The curriculum aligns with identified key competencies for regulatory science programs and also prepares the student for further study if desired. Included in the required hours is a directed project. The directed project is an independent study course that allows the student to apply the program learnings to a project that proves to be value added within their company.
In the final analysis, it was determined the best approach to administering an MS program in Kilimanjaro, Africa, would be a distance-hybrid delivery model; with the face-to-face component being on-site in Kilimanjaro. The administrative organization for the program was/is the Purdue University Polytechnic Institute’s Center for Professional Studies in Technology and Applied Research (ProSTAR).

There was a need to perform a benchmarking study to compare the existing University program and the programs offered by others throughout the world in order to identify strengths and potential gaps in the University BIRS Program, specifically associated with global regulatory science education. A comprehensive literature review yielded an exhaustive list of institutions with graduate degrees and certifications in fields related to Regulatory Science (some less descriptive – like Biotechnology or Biomedical Engineering; some more descriptive – like Management of Drug Development) and the specific results were compiled. Further investigation was performed on each institution, looking at cost, availability, and curriculum.

The methodology employed encompassed a time-phased set of inter-related activities as described below.

- A compare and contrast was performed by identifying and normalizing categories of cost, availability, and curriculum
- Program offerings, nationally and internationally, were mapped to the normalized data for cost, availability and curriculum
- A compare and contrast was performed by characterizing and normalizing best practices, nationally and internationally, across identified programs
- Comparison of normalized data (other identified programs) to the University data was performed to determine criteria of preeminence; considering such factors as cost, mode of delivery and curriculum

Figure 1 graphically depicts the time-phased activities performed over a sixteen week period.

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Figure 1 – Time-Phased Research Activities

**Curriculum Cross-University Comparisons**

1 To maintain anonymity, the names of researched universities have been changed to University A, B, C… The authors maintain the mapping and bibliography for future research purposes and reference.
Through the above research, it was determined institutions offering elements of programs in regulatory science were distributed throughout the United States. There were western schools in Arizona, California, and Washington; mid-western schools in Minnesota, Illinois, and Wisconsin; eastern schools in Pennsylvania, Maryland, Massachusetts, and Washington, D.C.; southern schools in Georgia. Of the twenty two domestic institutions researched, fourteen included terms in their degree title (or, at least their degree’s concentration) that were clearly describing the regulatory science field. Of the ones that did not use the term “regulatory” or “regulatory science” explicitly, the degrees were in more peripheral disciplines, such as biotechnology, however, their curriculum indicated that the program goals aligned with regulatory science. University B, for example, offers a Master’s in Biotechnology, and specific course offerings include: Development of Vaccines to Infectious Diseases, Pharmacokinetics and Drug Design, and Molecular Targets of Drug Discovery. The course titles suggest that the content may include some topics peripherally related to regulatory science. While these courses are important, courses found within specific regulatory science degree programs were more focused in regulatory science content and its applications. An example of this category and representative course included, University C Clinical Research Management degree with a Regulatory Science concentration: Fundamentals of Regulatory Affairs course that is an overview of the role of ethical clinical research in new product development; or, Medical Device Development and Regulation course, that explores the regulatory framework for the design, development, approval, and marketing of medical devices.

It should also be noted that certain programs, such as University D and University E, that have more general degrees, such as Biotechnology/Biomedical Engineering, in addition to a separate Masters in Regulatory Science, also had a wide range in price. For example, at University E, a full-time, in-person graduate degree in Biotechnology or Biomedical Engineering costs a student over $70,000. A Regulatory Compliance graduate degree provided in the evening costs $37,521. It also appeared that most regulatory science programs across the country cater to working adults. Very few regulatory science programs are full-time and in-person, with the only institution being University E and two of its master’s degrees: Biotechnology and Biomedical Engineering.

Many of the other programs offer in-person and online hybrids (or solely online), evening and weekend classes, and the option of part-time or full-time. Depending on the institution, cost (tuition only, no extra fees, books, or living expenses were included in these amounts) could vary significantly. Some were as low as approximately $20,000 for the whole degree (University C’s fully online program) and some were as high as $84,000 (University F). It was difficult to compare course requirements in regards to units, since some institutions only had “8 units” (University B) and others were required “168 units.” The time to complete the degree was comparable and suggests that overall, the course expectations were similar. Most degrees can be completed (if enrolled full-time) in a span of two years.
Many programs were similar to Purdue’s 33-credit hour requirements. Those which were closest to the approximate $33,000 Purdue University program cost are: University G ($30,420), which is offered entirely online; University D’s Master’s in Regulatory Affairs, which offers six concentrations ($28,440) and is offered part-time and online; University E’s Regulatory Compliance Master’s degree ($37,521) which is offered full-time evening courses; University H’s Master’s in Regulatory Affairs ($29,250), which is offered entirely online; University I’s Master’s in Advanced Studies in Clinical Research ($30,000), which is offered in-person late afternoons and early evenings; and University J’s Master’s in Regulatory Science ($28,000) which is offered online and part-time. University K’s Master’s degree in Biomedical Regulatory Affairs is the only institution that included a single cohort of students progressing together throughout the program for two years, going full-time, and meeting in-person in the evenings. The cost is also comparable to Purdue ($32,400), lasting two years.

In addition to master’s programs, some institutions offer certificates as well. These are all post-baccalaureate, but some are prior to a master’s degree, while others are obtained after a master’s degree. The certificates are more similar than the graduate degrees, as far as cost, length of program, and availability. The nine institutions are distributed throughout the country, east coast, west coast, mid-west, and south. The cost range for these certificates ranges from $6500 (for a 3-course certificate at University K) to $19,500 certificate at University L. The courses are relatively comparable with titles like “Clinical Research for Regulatory Affairs” (University G), “Practical Quality Management” (University E), “Current Good Manufacturing Practices” (University J), and “Managing the Guidelines for Quality” (University M).

As for international programs that specified Regulatory Science, rather than a general Biotechnology or Pharmacy degree, their coursework lists were similar to those of the domestic institutions. However, graduate certificates were more common than the master’s degree and the requirements of the international graduate certificates were comparable to a master’s degree. TOPRA in conjunction with the University N offers a master’s degree with courses like “Regulatory Control of Clinical Operations” and “Strategic Planning in Regulatory Affairs” that costs the equivalent of $19,500. University O, Toronto, Ontario, offers a Regulatory Affairs Postgraduate Certificate, which costs approximately $7000 for domestic students and $21,000 for international students. This appears higher than the certificates offered in the states, but is more rigorous, covering three semesters and 14 courses.

Curriculum Findings

When comparing the other domestic institutions to the University’s BIRS master’s and certificate programs, there are some best practices that surface.

- Worker-friendly administration of the programs. Due to the applied nature of this field, many individuals are working while earning the degree or the certificate. Most of the
institutions offer some kind of flexibility (including the University), whether it’s online, in-person on the evenings or weekend, or some hybrid combination.

- **Program Cost** – the University is very cost competitive with most of these degrees. There are a few that are less expensive, but the ones that provide a similarly styled program, curriculum and/or delivery, are comparably priced.

- **Program delivery** – the benefits (contact and cost) of a distance-hybrid style of program delivery appears to be a best practice when delivering a program outside of the U.S. The face-to-face element of the University’s program delivery model provides the dual benefit of personal contact and efficiency of delivery; yet, never compromising on effectiveness.

In the final analysis, the University’s global regulatory science program, delivered internationally in Kilimanjaro, Africa, benefited significantly from the collective understanding gained from the market research performed. The findings support that the program cost is economical and the flexible program delivery and program administration that aligns with the schedule of working professionals helps contribute to long term success and sustainability, both nationally and internationally.

**Non-Curriculum Administrative Challenges**

Springer, Terruso, Speer, Byrn & Clase [2], previously documented the non-curriculum components attendant to information technology infrastructure, cultural and language barriers, tuition assessment and collection, and, risk of attending classes in a war torn area of Africa; all of which forms the underlying basis for non-curriculum administrative challenges.

The Biotechnology Innovation and Regulatory Science (BIRS) program, as administered in Kilimanjaro, Tanzania, Africa, required a distance education component, aside from the above referenced face-to-face component. The distance education component required the technology to support uploading and downloading of assignments and required electronic components of the program from the Learning Management Systems used by the university. The tangential and most widely used component of this program, required extensive use of information technology through web-based applications and services; such as Google for research searches and other scholarship-based archives.

While distance education and information technology in general is not typically a topic of conversation in the United States, it very much becomes a topic of concern when in Africa.

The distance-hybrid delivery model; with a face-to-face component being on-site in Moshi, Tanzania was an asset for these professional students. The majority of these professional students travel from other countries such as India and China as well as to remote rural areas within Africa. This could hinder access to the course management site, where course lectures and assignments were housed, due to unreliable internet connection. Students especially would find the internet connection unreliable during the rainy season (March – May). At times,
students would need to access their courses when they entered an area where the internet reception was better. It became apparent that it was necessary to spend additional time covering semester specifics during the 2 weeks’ face-to-face time to better prepare students for upcoming assignments found on the course management site. Reminder emails were increased throughout the semester to heighten communication.

Besides the course management system, WebEx technology was used for follow-up meetings, live lectures, question and answer sessions, etc. Again, being dependent on internet access, lectures were recorded and placed on the course management site so the lectures could be reviewed at a time better suited for the students. A call-in number was always available for those students that could utilize that feature. The time difference, while agreed to by the students, often posed a problem even though it was always set as New York time. This in part was due to the students’ travel schedules.

There are several thousand different societies or ethnic groups in Africa. Generally, they can be recognized by a common culture, religion or language.

In regards to language, Africa is noticeably diverse with an estimated 1500-2000 African languages in four main groups: Afro-Asiatic, Nilo-Sharaian, Niger-Saharan, and Khoisan, which are divided primarily by geography [3]. Most of the people living in Sub-Saharan Africa speak at least one of the six hundred Bantu languages, along with the European language of the former colonial ruler [5]. Education is complicated and varies widely in Sub-Saharan Africa due to the lack of wealth the country faces. From 1999-2012, pre-primary education increased by 2.5 times, but still is extremely low with an average gross enrollment ration of only 20%, which ranges from 2% in the country of Mali to 100% in Ghana, Mauritius, and Seychelles [4]. More than 50% of school-aged children globally who are not enrolled in school live in Sub-Saharan Africa.

A total of 43 students represented six African countries – Nigeria, Kenya, Uganda, Tanzania, South Sudan, and Zimbabwe. English is a primary language for these countries, but there were still difficulties in communication that became apparent during the application phase. Well-known documents that are referred to as transcripts and diploma in the United States were soon discovered to be referred to by a different name. This miscommunication created delays in the admission process as multiple documents would be submitted while missing documents were not received. Revised wording was quickly added to the application instructions to improve communication. ‘Official transcripts’ quickly became “An official transcript bears the original signature of the registrar and/or the original seal of the issuing institution. A transcript is an official report supplied by a school on the record of an individual student, listing subjects studied, grades received, etc.” In addition, “A diploma is a document given by an educational institution conferring a degree on a person or certifying that the person has satisfactorily completed a course of study. (Known as Academic Certificate in Tanzania).
Interestingly, but not surprisingly, in Sub-Saharan Africa payments for nearly all purchases are made in cash; only a small population of upper-class households have the ability to use credit cards, online banking, and the like. Kenya, for example has 90% of retail transactions done in cash and based on a Gallup survey of eleven countries in sub-Saharan Africa, more than 80% of adults’ bills are paid in cash [6].

The participants in this instantiation of the BIRS program were funded in total by corporate funding. While this eased the student burden, it made the university process somewhat cumbersome and difficult to manage. From a corporate perspective, it was not good practice for a corporation in Kilimanjaro, Africa, to be viewed as showing preferential treatment from other residing corporations. This may give the appearance of impropriety. This misgiven perception had to be balanced with the greater good of providing world-class education to the attending African population.

In the end, the university managed to anonymously provide the student tuition through a corporate grant; which, subsequently, was not considered a grant subject to university revenue sharing. This allowed the entirety of the grant to be applied to the benefit of the student tuition and the greater good toward the country of Africa.

Another issue that arose in the application process was the use of credit cards for the application fee. Many African applicants did not have a credit card and the University Graduate School only accepts credit cards for the application fees. Students used friends’ and relatives’ credit cards in order to pay the fee. Administratively, great care was taken to adhere to university policies and procedures. Moving forward, greater awareness and experience is expected to ease this process.
Relative to program risks, nearly 50% of Africa’s 53 countries are in conflict of one kind or another [7].

This is the story across much of Africa, where nearly half of the continent’s 53 countries are home to an active conflict or a recently ended one. Quiet places such as Tanzania are the lonely exceptions; even user-friendly, tourist-filled Kenya blew up in 2008. Add together the casualties in just the dozen countries that I cover, and you have a death toll of tens of thousands of civilians each year. More than 5 million have died in Congo alone since 1998, the International Rescue Committee has estimated.

...Even if you could coax these men out of their jungle lairs and get them to the negotiating table, there is very little to offer them. They don’t want ministries or tracts of land to govern. Their armies are often traumatized children, with experience and skills (if you can call them that) totally unsuited for civilian life. All they want is cash, guns, and a license to rampage. And they’ve already got all three. How do you negotiate with that?

Africa’s constant state of turmoil causes risk of life or limb just by moving across these many countries; even if the purpose is for education or continuing education.

The African students made the journey to Kilimanjaro, Tanzania all four semesters of their educational studies. Students’ journeys differed depending on their country and location to Tanzania. Approximately 15 African countries were in civil war [8]. On occasion, “security issues” or “unrest in the country” would be brought to the attention of the US professors and/or administrators by the students. Each situation was reviewed individually to determine if assignment extensions or other interventions were needed so not to penalize the student.

Findings and Opportunities for Future Program Offering

Previous literary works, as described above, provide rich description of challenges and opportunities for future consideration when implementing programs in Africa, as well as any other country outside of the United States. These prior documented findings, coupled with extensive student surveys provide an enhanced perspective on future challenges.

Below highlights the many opportunities for improvement and consideration.

After reflecting over the past several years, there have been many successes of this program and opportunities that can grow from it. Overall, the impression made by Purdue University at Kilimanjaro School of Pharmacy was very positive. Continuing education is instrumental for Africa to begin developing their own medicines as outlined by Byrn, Ekeocha, and Clase [10]. Students who participated in the academic program, have also been involved in a regulatory
workshop hosted by the University’s Biotechnology Innovation and Regulatory Science (BIRS) Center. The strong turnout and positive reflections speak to the quality of the program and is a positive indicator that the Kilimanjaro School of Pharmacy will become self-sufficient in these endeavors, which has been a goal from the start. Future opportunities include:

- Offer additional non-credit workshops in specific areas, such as technology, quality, leadership and strategy in Tanzania based on past experience and processes previously set by program experience
- Maintain collaboration among industry and academia to provide relevant educational topics
- Recruit mentors who have experience to provide guidance to program alumni

Some issues that the program has faced have been beyond anyone’s control and some allow for adjustments and improvement that can be embraced by faculty and administrators. Common complaints students made involved bandwidth capabilities, and personal financial costs required by the students. The usefulness of the internet for higher education coursework directly impacts the students’ feelings on the course [9]. However, due to a strong reliance on internet capabilities to complete coursework, the complaints of the internet being an unreliable medium for learning proves difficult to reconcile. Adding the sheer distance between instructor and student can make learning even more difficult. Flexibility and understanding are both crucial for making these students successful, along with quality on-site instruction. Additionally, method of payment and accommodations also had room for improvement, according to students.

As a result of this program, there is better awareness of the challenges. Some of the challenges and possible solutions are highlighted here:

- Internet challenges could be overcome by recording and posting meetings, lectures, and assignment instructions in a course management site to allow students access to materials when they have a good internet access connection.
- Establish early and tentative deadlines for assignments due to internet challenges to allow the student more time if they are unable to meet the deadline due to technology issues.
- A blended delivery model provides a venue for clarifying instructions, assignments, or assisting with technology challenges to enable students to stay on task.
- Provide additional time for the application process to allow students’ greater success in supplying the necessary funds/materials requested by the university; as university policies and procedures cannot be changed from a program perspective.
- Frequent and concise communication is vital throughout the program.
- Funding is important as students would comment that cost alone would prevent their studies.
The uniqueness in both location and demographics of this student population creates an exciting experience for both student and faculty. As mentioned, if controllable burdens can be eased for the student, the likelihood of success will grow. Learning from previous students and putting forth resources and effort to relieve some of the obstacles these students face will have a global impact in regulatory practices on the African continent. Addressing these challenges by making reasonable adjustments can make the inflexible challenges easier to bear. Growing a cohort of faculty and staff who understand the challenges has been paramount to the success of the program and is reflected in positive feedback from course evaluations. The main categories that received increasingly positive feedback as the program grew were:

- Quality of instruction
- Quality, clarity, and ease of understanding materials
- Preparedness of instructors
- Quality and number of group exercises; and use of technology.

Bibliography


