



## **Administering A U.S. Based M.S. Degree in Kilimanjaro, Africa – A Global Benchmarking in Regulatory Science**

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Dr. Springer currently serves as the Executive Director for Purdue University's Polytechnic Institute located in West Lafayette, Indiana. He has over 35 years of theoretical and industry-based practical experience from four disciplines: Software Engineering, Systems Engineering, Program Management and Human Resources. Dr. Springer possesses a significant strength in pattern recognition, analyzing and improving organizational systems. He is internationally recognized, has contributed to scholarship more than 150 articles, presentations, books and reviews on software development methodologies, management, organizational change, and program management. Dr. Springer sits on many university and community boards and advisory committees. He is the recipient of numerous awards and recognitions; most recently he was awarded the Purdue University, College of Technology, Equity, Inclusion and Advocacy Award.

Dr. Springer received his Bachelor of Science in Computer Science from Purdue University, his MBA and Doctorate in Adult and Community Education with a Cognate in Executive Development from Ball State University. He is certified as a Project Management Professional (PMP), Senior Professional in Human Resources (SPHR & SHRM-SCP), in Alternate Dispute Resolution (ADR), and, in civil and domestic mediation. He is a State of Indiana Registered domestic mediator.

**Dr. Kari L. Clase, Purdue University, West Lafayette**

Kari Clase is an Associate Professor in the Department of Technology Leadership and Innovation in the Polytechnic Institute and the Department of Agricultural and Biological Engineering in the College of Agriculture at Purdue University. Dr. Clase is also the Director of the Biotechnology Innovation and Regulatory Science (BIRS) Center. The mission of the BIRS Center is to develop global programs to ensure sustainable access to medicines for Africa and developing nations, and to advance discovery in manufacturing technology, quality of medicines, and rare disease research. This mission is accomplished through innovative knowledge-based programs in STEM areas with an emphasis on interdisciplinary collaboration. Dr. Clase teaches multiple courses covering topics in biotechnology, bioinformatics, biological design and drug discovery to engineers, scientists and technologists. Her currently funded projects include collaborators from multiple disciplines and an impact that spans K-12 to graduate education.

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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 done on the practice of regulatory science, but not on the institutions educating these scientists. Purdue's investment, in particular, has the ultimate goal of getting sustainable medicine to Africa. The collaboration of Purdue's 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 Purdue 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.

## **Overview**

The Biotechnology Innovation and Regulatory Science (BIRS) program transitioned to the Purdue Polytechnic Institute in the fall semester 2014, after 12 successful years as the Regulatory and Quality Compliance program in the Purdue 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 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.

A Biotechnology Quality and Regulatory Compliance graduate certificate program is also available. It is comprised of 4 courses (1 course per semester) and compliments bachelor, MS or Ph.D. degrees.

These programs are designed to offer an education that fits the busy working professional. Students have flexibility in registering for courses and can enroll in 1 to 3 courses per semester. Courses are offered in a blended format. Basic information is presented online and the advanced material, including difficult concepts and group projects, are presented on weekends (3 weekends per semester) on the Purdue University campus located in West Lafayette, IN. The program welcomes students to enter fall, spring or summer semesters.

## **Program Administration**

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 Polytechnic Institute's Center for Professional Studies in Technology and Applied Research (ProSTAR).

On June 11, 1998, the Purdue University College of Technology initiated the process for University, and subsequently, Indiana Commission for Higher Education, approval of a non-traditional delivery medium, fee-based weekend alternative to Purdue's traditional campus tuition-based Master of Science with a major in Technology degree<sup>1</sup>.

On October 13, 2000, the Indiana Commission on Higher Education (ICHE) approved the University request for delivering a hybrid distance-based alternative to traditional classroom-only programs. The entire process from conceptualization to full final approval took two years

and four months. Noteworthy, from the proposal excerpt, the concept of evaluation was integral to the program concept from the onset.

In the fall of 1998, the COT's Department of Industrial Technology took a lead role in implementing, pursuant to authorization, the first weekend master's program (WMP) in Technology on the campus of Purdue University in West Lafayette, Indiana. The original offering was cohort-based and it employed a weekend format; meeting from Friday through Sunday. The cohort met three times a semester, twice in the summer semester, for a total of five semesters (Fall, Spring, Summer, Fall and Spring). Because of its non-traditional approach, the state's authorization included the establishing of a different fee structure than normal classes which resulted in a cost that was higher than conventional campus-based instruction.

The Center for Professional Studies in Technology and Applied Research (ProSTAR) was approved by Purdue University under the College of Technology as an academic Center in February 2009. At that time, the underlying foundation for ProSTAR's professional education activities was a Master of Science degree with a primary focus in technology leadership and innovation skills including tools for process improvement and quality management.

As well, the program incorporated other innovations beyond its delivery system, schedule and fee structure. To be consistent with its goal of developing practical skills and knowledge immediately, or at least quickly, applicable to business and industry, its plan of study<sup>2</sup> incorporated a base of essential core studies, flexible and easily tailored courses to insure relevance to emerging technologies, and a guided, industry focused applied research and development project called simply the Directed Project (DP). The latter DP was deliberately designed to require work commensurate to what is typically expected of a master's degree thesis<sup>3</sup>.

ProSTAR is entirely self-funded from fee-based programs. It offered its first 100% distance program in 2010.

The initial on-campus distance-hybrid offering in the fall of 1998 spawned a comparable off-site instantiation of this sole program in 2005. The 2005 instantiation was delivered in an on-site format at the location of the target corporate partner. This industry- and corporate-specific instantiation provided for the first time, significantly increased enrollments outside of the main campus and the prior and on-going on-campus distance-hybrid baseline program. Figure 1.0 below depicts the suggested first wave of increased enrollments.

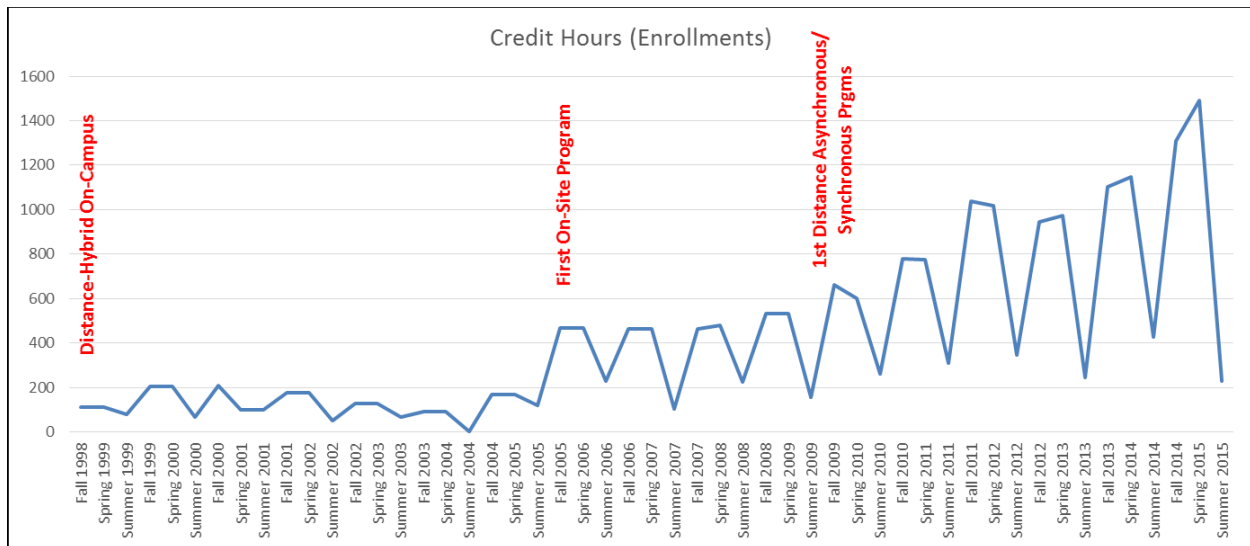


Figure 1.0 – Delivery Induced Enrollment Growth

The geographical limits of on-campus programs, even taking into consideration the distance-hybrid aspects of the program, created a self-imposed constraint. Moving the programs to a customer’s location, geographically distant from the main campus program, spurred enrollment growth, but it too created enrollment limitations based on corporate sponsorship and geographical specificity.

In 2010, ProSTAR, in collaboration with the academic departments, entered the distance education market with three 100% distance programs. Distance offerings created a significantly greater market, one not bounded by geography. Most growth to-date has been the result of distance offerings. It is further anticipated that most future growth providing the greatest opportunity for sustainment of an on-going administrative organization will materialize through distance delivery models.

The 2010 offering of distance programs came in two noticeably different delivery methodologies: namely, synchronous and asynchronous. Synchronous delivery of a given distance program implies the recipient of the instruction is receiving the instruction in real-time as the instruction is being provided. While this methodology supported the distance element thereby not requiring the student to attend class on the university campus or, in a previously discussed format, at an employer’s location, it still limited student participation by requiring a set time by which the instruction was to be given and therefore a set time by which the student must be available and prepared to receive said instruction. This concept created yet another limitation to full enrollment possibility or potential for maximum enrollment opportunities.

Distance programs offered through the latter delivery mode of asynchronous delivery, fixed, or removed, the barriers other predecessor program delivery models created.

While the on-campus distance hybrid, on-site distance-hybrid, and 100% distance asynchronous delivery models still exist in multitude of program offerings, the 100% distance asynchronous delivery model creates the greatest promise for maximum enrollments; only limited by the desire to obtain the offered degree program.

Figure 2.0 below depicts the delivery modes employed and their respective limitations.

Delivery Mode	Limitations		
	Geographical	Employment	Real-Time
1998 Distance-Hybrid; on campus			
2005 Distance-Hybrid; on-site, off-campus			
2010 Distance Synchronous Programs			
2010 Distance Asynchronous Programs			

Figure 2.0 – Enrollment Limitations by Delivery Mode

## Methodology

There was a need to perform a benchmarking study to compare the existing Purdue program and the programs offered by others throughout the world in order to identify strengths and potential gaps in the Purdue 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 Purdue University data was performed to determine criteria of preeminence; considering such factors as cost, mode of delivery and curriculum

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

Activities Performed	Weeks							
	1-2	3-4	5-6	7-8	9-10	11-12	13-14	15-16
Criteria Identification and Normalization								
Program Identification and Mapping to Criteria								
Identification of Best Practices								
Comparison of Normalized Data								

Table 1.0 – Time-Phased Research Activities

## Findings<sup>1</sup>

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

<sup>1</sup> 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.

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.

## Conclusions

When comparing the other domestic institutions to Purdue’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 Purdue), whether it’s online, in-person on the evenings or weekend, or some hybrid combination.
- ❑ Program Cost - Purdue 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 Purdue program delivery model provides the dual benefit of personal contact and efficiency of delivery; yet, never compromising on effectiveness.

In the final analysis, the Purdue University 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.

## References

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