M-CERSI

Final Report from Degree Programs in Regulatory Science and Engineering
April 15, 2013

The M-CERSI conference on "Degree Programs in Regulatory Science and Engineering " was held April 15 at the University of Maryland College Park campus. The program was organized by Drs. Keith Herold and James Polli. Fifty registered with 45 participants attended from nine universities (24), FDA (15), the Vietnam Ministry of Industry and Trade, Maryland State government, IOM/NAS, NRC/NAS, and several companies (6).

Two goals of the conference were

a) to exchange information about on-going educational programs in regulatory science
b) to discuss core competencies of such programs.

Additional items for discussion included: educational/workforce/retraining needs; desirable types of degrees (e.g. certificate, MS, doctorate); curricular core competencies; and differences between regulatory science (e.g. creating methods, tools and standards) vs regulatory affairs.

The afternoon involved two parallel discussions.

Drugs and Biologics

The re-occurring theme from the discussion of "drugs and biologics" was the need for general abilities, such as: writing, verbal communication, soft skills, critical thinking, self-learning, project management, teamwork, professionalism/ethics, leadership, and negotiation. Technical abilities in "drugs and biologics" areas were: pathophysiology/pharmacology/biochemistry, CMC, preclinical science, clinical science, outcomes/access/public policy, and digital/ informatics. Other major discussions points were: organization of FDA and need for great proactive (vs reactive) design; need to address advanced technologies and re-visitation of review by product class; need to match core competencies and pre-requisites in academic programs; desirable types of degrees; need to focus academic programs on job training; need for international scope in training; potential benefits or externships at FDA (e.g. enhanced transparency); and use of case study learning method.

Devices and Diagnostics

The discussion on devices and diagnostics covered a wide range of topics. It was noted that intellectual property considerations are key to device commercialization and should thus be strongly represented in educational programs. It was noted that an understanding of the expectations of the FDA is needed to enable proactive thinking on the part of medical device companies. FDA use cases, being developed by Francis Kalush and her group at FDA, are expected to provide some of this understanding. The role of human factors analysis in the regulatory process was

noted as an often mis-understood element – which should be represented in educational programs. The discussion highlighted the interdisciplinary nature of device regulation/device innovation. One related aspect is the observation that preliminary data for submissions is often generated offshore. Thus, an international perspective is necessary and inherent in the enterprise.

Summary of Presentations

Leslie Wheelock – FDA

The Federal workforce is central to the delivery of services to the American public, and the FDA staff of about 14,500 consists of seven scientific occupational groups: medical and public health (about 5271 staff), Biological sciences (about 1911 staff), physical sciences (about 1215 staff), mathematics and statistics (about 424 staff), engineering (about 405 staff), veterinary medicine (about 124 staff), and social sciences and psychology (about 77 staff). There are two FDA human capital challenges that are related to regulatory science. The first, the need to recruit a well-qualified workforce, is a result of retirement eligible FDA staff and Congressionally mandated hiring surges. For example in fiscal year 2013, there are 212 scientists and 26 scientific leaders eligible to retire. The second challenge, training and development, includes the time to train a new employee which is about 2-3 years and the need for scientists to keep current. The current hiring and training practice of the FDA is to hire scientists with degrees in a scientific field and then train them in regulatory science. Academic programs in Regulatory Science could potentially benefit the FDA, Industry and Academia by preparing scientists prior to them being hired which could potentially result in less time needed to be trained. Additionally, scientists who have academic preparation in regulatory science would be current in both their scientific field as well as regulatory science. In developing regulatory science educational programs, Academic organizations should consider hands on experience to include interactions with the FDA and Industry's experience with product approval. Because of limited FDA resources, educational strategies such as case studies would allow students to learn about regulatory decision making.

Univ. of Maryland

Jianghong Meng , JIFSAN, – Food safety. JIFSAN was established about 17 years ago. Most of the work is with Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM). They have 6 different programs. They focus on food production; most of the training is done in-country. They support collaborations between faculty on campus and FDA. They have a unique undergraduate training program wherein they work in a laboratory environment. Many of the Good Agricultural Practicies (GAP) are in south America. They understand the need for safe food supply globally and are working to establish

collaborative centers in several countries – spices in India; fresh produce in Mexico; aquaculture – Bangledesh; etc. This is how they will expand their influence.

They support food safety risk analysis courses by traveling to many countries – they send instructors.

They established a PPP with Waters Corp., to build a laboratory training program to provide hands on laboratory training experience, not "in-country", but here in College Park. They bring people from around the world to understand the processes and practices (thus far from 15 different countries). Laboratory training is very expensive and there are so many different topics; the FDA helps define what is needed, along with EPA.

Jim Polli – drug development and evaluation. Went over the courses for the MS in Regulatory Science. Courses include Drug, Biologic and Device Regulation; Drug Discovery; Drug Development; Clinical Research; Regulated Products in the Marketplace.

Keith Herold – M.Eng. More focus on devices. Certificate first…first course on regulatory affairs. Starting out in-class. Case studies will be included. Make it practical…link the academic viewpoint. Francis Kalush who is also here is helping to generate case studies.

Eunjoo Pacifici – PharmD and now in International Center for Regulatory Science, USC

Regulatory Science is an emerging discipline that is in the process of being defined and developed. Prior to the availability of a formal education in this field, regulatory training took place primarily "on the job," was often narrowly focused, and left significant knowledge gaps. USC's International Center for Regulatory Science is located on the Health Sciences campus along with the Keck medical school, pharmacy school, Norris Cancer Hospital, and the LA county hospital. More information can be found at regulatory.usc.edu.

The program was started in 2001 with MS in Regulatory Science and has since expanded to include Certificate Programs (2005), Doctorate Program (2008), MS in Management of Drug Development (2012), and MS in Health Care Decision Analysis (2013). Students are offered the flexibility to choose among 5 certificates, 3 MS, and a DRSc according to the individual student's goals and aspiration. Each MS curriculum, composed of required and elective courses, emphasizes a specific segment within the product development flow scheme in order to cover the full "Bench to Bedside" process.

Courses are held on weekends to accommodate working professionals as well as fulltime students with the option to enroll as a distance student if it is too far to travel. Students in the doctorate program are accepted into a cohort every two

years. The doctoral curriculum includes advanced courses with emphasis on executive, global, and strategic topics followed by thesis research in a diverse range of regulatory issues.

Todd Brinton, Stanford

BioDesign – medical device development. It is part of BioX. Educate. Collaborate. Innovate. Not to develop technologies, but rather to train individuals. Dr. Brinton is an interventional cardiologist. The Stanford program is about mechanical and electrical engineering; not biopharma. "MedTech Mecca" is between university at Stanford and a variety of organizations and individuals. Real world mentors – are executives, CEOs, clincians, etc. They have two main programs – Fellows and a graduate program. Biodesign teams – comprised of different types of people (e.g. biologist, surgeon, mechanical, electrical engineers). Identify the need, invent some new solutions, then select the best invention and part of this is runs through regulatory issues. The BioDesign Book (text) is about to release a second edition. They start with a "boot camp", starting in August, it runs a month. Basic lectures in engineering, the science for that year's program, team building. They have a clinical immersion program – not a detailed class by class effort. They have a certificate that results from this Immersion program. Different components are: Needs finding; Needs Screening and Specification (verify and validate – rank one versus another opportunity – don't get trapped by your own invention); Now Invent (brainstorm) and do Concept Development (this is where regulatory science gets embedded). Here they need to find 4 different ways to satisfy this issue – select based on IP, regulatory process hurdles, what is best for patient?, if you can't build a business around it (regulatory and reimbursement) then it won't go anywhere.

Then, we need to deal with Business/Project Planning. They have built an entire ecosystem.

Ken Dretchen. Ira Shoulson Georgetown – CERSI

They created a track in Regulatory Science in the MS in Clinical and Translational Research. Flexible format, several faculty from Georgetown, FDA, other institutions. Includes both didactic instruction and on-line. They are looking for students who hold medical or related degrees. The core curriculum is 23 credits; 10-credits of electives; 4 credits in a Capstone project. Regulatory Science Electives – Analytic Aprpoaches for Regulatory Science…several others. Capstone project is tailored to the students who are part of the program. Started Fall '12 with an Intro to Regulatory Science course that distinguished between regulatory science and regulatory affairs. They had an open course. MS students took it, PhD students took it, FDA folks took it, it was taken by many – included non-degree seeking options.

Admissions includes resume, cv., a statement of purpose, recommendation letters, etc. They will run the course again this fall. The course is 6-7:30 in the evening. This made it accessible.

Thomas Colonna – Johns' Hopkins – Center for Biotechnology Education

MS Regulatory Science … on line (2007). They are now 100% online. Two courses are given at any time. Less than 25% are within the DC area. Faculty from Govt and private industry (MedImmune, Merck, FDA, SAIC, etc.). Students are typically working professionals – lawyers, engineers, pharmacists, etc. There are two courses that are in class. Prerequisites – 3.0 GPA, undergrad in science / engineering, etc. Program was conceived in 2004 – includes 10 courses, 7 required, 3 electives.

Students are from every continent. They participate on line with amazing time differences. The courses that are required and electives are listed in the slides. They have research opportunities for students – as an Independent Study that consists of three tracks, that includes an academic mentor, or an industry mentor (this enables a workplace transition), and a few FDA mentors (as internships). There is a Thesis option. Mentors often overestimate what a part-time student can really accomplish in a one-semester internship. If they go long, they make it a Thesis.

Jay Gandy, U. Arkansas –

Proposed a Regulatory Sciences Program at UAMS in 2006. Will work with NCTR. Population of students comes mainly from pharmacology, toxicology, etc. Post-docs on campus and within NCTR like the idea of a Certificate. The purpose of the program is to round out the individuals' basic sciences strengths with regulatory science insights. How their science has applicability in industry/society.

Brief overview of learning objectives:

- Give broad understanding of how FDA works, regulations, its structure and mandates, etc. The individuals already have good critical thinking skills.
- Develop understanding of types of data needed.
- Risk assessments
- GLPs, GCP, GMP, or (GSP), Good regulatory Practices, etc.

Courses – 4 in initial certificate. Ten countries represented. Many of the students have as a goal to return to country of origin. It might actually send concepts back to the home countries.

They will be expanding the program this fall. There are many courses that are delivered as blended courses (blackboard). The courses will be evolving so that 90% will be on-line this year and eventually 100% on line in a couple years. They are going to try to develop tracks in three areas – less emphasis on the broad base – resulting in MS programs and perhaps an MPH program. The three tracks might be

food safety and preclinical drug development, clinical trials track, and pharmaceutical quality compliance. Each of the tracks has about 4 core courses.

Bob Meyer, UVa, What Does Industry want in Regulatory Science?

Will describe from Pharma perspective. At Merck, they looked for people with advanced (doctorate) degrees. This is not an uncommon resource in science based companies such as Merck.

Merck had its own internal "university" or institute. They had significant training on regulatory affairs with a focus on tactical aspects. He went from FDA to Merck about 5 years ago and found Merck had relatively little understanding of how FDA actually works. This reflects a lack of effective interchange; public meetings provide for a formal structure but limited quality time for informal dialogue. Training could be focused on enhancing the effective interactions between FDA and industry, in part through case studies.

Merck had some Pharm D internships; people would rotate through regulatory affairs offices. What is not sufficiently available is a broad-based experiential training component. Gather how regulatory folks at FDA work and apply regulations through case studies, direct internships, etc. A curriculum that imparts the "fun" of problem solving to affect an efficient, high POS global development strategy.

His experience at Merck was that most entry level RA personnel were female. On the executive table, however, most were male. This represents an opportunity to provide leadership training to RA individuals in companies. Need good regulatory workforce, this is critical for an innovative and exciting industry that his healthy. He mentioned that indeed it does take 2-3 years to understand FDA, even while at the FDA. How does academia help the FDA impact this as well as its loss due to top level retirements that are coming down the road?

How are we dealing with the "Science of Regulation (not just applying regulations to new science)"? This is an area of opportunity here.

Judy Britz, Maryland Biotechnology Center

Gov. O'Malley pledged 1B investment in 2007. Judy will talk about needs of companies from the perspective of the MBC – connecting different groups to enhance the state in the fields regulated by the FDA.

Examples of Maryland efforts. Lonza produces stem cells, which are significant. Genome sciences. Companies in Maryland were listed. There are 500 companies in Maryland that have an average number of 10. Most are in drug development and vaccines; devices and diagnostics; CROs and Research Tools Companies. The individuals have salaries of around 90K; produce 10B in revenues.

The vast majority of CEOs of Maryland companies are the inventors or scientists. Bob Gallo, Margaret Heckler (HHS), announced there would be an AIDs test within six months. What makes products fly through? Great Science.

Regulatory Science all over the Nation will help elevate the science to build standards in parallel with product development. Regulatory science could help by creating new trials with fewer people since the drug might be targeting a limited population (link via genetics). This will lower cost.

When I talk to scientist/CEOs….What is your vision for your final product? What is your regulatory strategy? Do you have the end in mind? I don't need a quality system right now, my product is years away. We need to have knowledge outside the US.

Certificate programs are very good as many people don't have time to enroll in a full degree program.

There is a Maryland Innovation Initiative (MII, 10.8 M) for new inventions in the universities.