Welcome Back!

By Frances J. Richmond

We seem to be constantly in evolution...a good thing. As many of you know, we have been spending our last few years transitioning in the same way as the rest of the regulatory community, from a largely national to a truly global organization. This newsletter will try to help you to understand this evolution, that we believe will offer much more to our students and alumni in terms of 21st century learning experiences.

Time does seem to fly. Can you believe that we are in our 7th year of our “new” doctoral program and already have more than 10 graduates with this appellation? That we are doing our first MS course based in China to examine GMPs from a more global point of view? Of course all of this would not be possible without the continued support of a host of committed speakers and alumni, whose stories allow us to live vicariously in many different environments. Thank you for all of your help. We will need it even more as we grow and try to keep up with the changes in regulatory systems. We are riding a fast-moving horse together.

RECORD NUMBER OF APPLICANTS

After receiving a record number of applications for all the Regulatory Science programs the admissions committees are pleased to welcome 42 new students to the MS and Certificate program and 14 new students to the fourth cohort of doctoral students. Good luck to all!

Summerfest at USC!

What is “summerfest” you ask? It was two months of exciting opportunities for the Regulatory Science students and faculty. Summerfest 2014 was kicked off with the International Regulatory Science Symposium (IRSS) on June 19th as we hosted experts from all over the world to discuss ways to collaborate and innovate within the regulatory space. We were honored to host senior officials from the European Medicine’s Agency (EMA), including Executive Director, Dr. Guido Rasi and Dr. Hiroshi Yamamoto, Chief Safety Officer at Japan’s Pharmaceutical and Medical Devices Agency (PMDA). Dr. James Leong from the Singapore Health Sciences Authority as well as Regulatory Science professors from Japan and Dr. Robert Pacifici, CSO of Cure Huntington’s Disease Initiative (CHDI), all shared their unique perspectives on the future of the biomedical industry.

REGULATORY CONSULTING CENTER

The consulting service has been working closely with an investigator to seek clinical approval for Fecal Microbiota Transplant (FMT) - a novel, experimental therapy, to treat Ulcerative Colitis (UC). The Investigational New Drug (IND) application was recently approved by the FDA and the clinical site will start to enroll the first subject soon.
Our Summer Scholars!
By Eunjoo Pacifici, PhD

The International Center for Regulatory Science was pleased and honored to welcome faculty and students from China, Taiwan and South Korea to the Regulatory Science program for the month of July. Representing the Chinese Pharmaceutical University (CPU), China Medical University (CMU) and Sungkyunkwan University (SKKU) these students participated in a series of special lectures prepared by the faculty in preparation for them to attend class days for the summer course offerings available during their stay. In addition, they partook of the many cultural activities in Los Angeles and surrounding areas.

Inaugural International Regulatory Science Symposium
By Shannon Bondy

The International Regulatory Science Symposium theme of “Collaborate, Innovate, Globalize” was emphasized during Dr. Robert Pacifici’s keynote presentation entitled “Collaboratively Enabling Drug Discovery”. During his address he highlighted the importance of nonprofit foundations collaborating with larger pharmaceutical companies in order to advance a drug from bench to market. As Dr. Pacifici noted “although many want to ‘leave no stone unturned’ in drug discovery, taking this exhaustive drill approach is not physically possible”. Furthermore, he commented that institutions have different motivations. One example Pacifici gave described how pharmaceutical companies are profit motivated and desire a drug that has $1 billion fifth year peak sales; disease foundations are selfish, and although they are not financially driven, they desire a drug only for their rare disease; academic institutions strive to work only on their compound; and biotech companies seek a drug that leverages their technology.

“\textit{There is nothing more valuable to a drug hunter than an observation made in the population you seek to treat!}”

With these conflicts, researchers must consider how to collaborate and globalize. In taking this collaborative approach, researchers must work on a disease that is ready for drug discovery and translational effort. Yet, as Dr. Pacifici remarked, there are three reasons for why a drug might fail: chemistry or compound related issues, clinical or trial related issues, and biology or target related issues. Researchers must think outside the box and innovate around target tractability and “drugability” in order to translate an entity that will help the target population. Dr. Pacifici concluded his presentation by discussing how his company Cure Huntington’s Disease Initiative (CHDI) collaborates with other institutions dedicated towards discovering a drug for Huntington’s disease.

Keynote Speaker Robert Pacifici, PhD of the CHDI Foundation
Regulation – The Bridge between Innovation and Access

By Aimee Greco

In another one of the focus sessions, Dr. Hans-Georg Eichler, Senior Medical Officer for the EMA, spoke about international innovation and developments in drug regulation and what thoughts on best practices in good quality regulatory decisions and evaluations. He also elaborated on the roles of stakeholders and efforts they can apply to improve not only decision making in Regulatory Science but also how those decisions ultimately affect agencies, industry and patients globally.

Ultimately, regulatory frameworks and the basis of their decisions used by many regulatory agencies is based on benefit and risk analysis. Such approaches assess whether a medical product’s benefit outweighs the risks. While Dr. Eichler notes that the agency’s priority is to protect public health, their mission also includes supporting patients to have medical access for proper medical care. Such balance, notes Dr. Eichler, results in practices in good decision making, defined process, constant assessment and consistent scientific benefit risk analysis. “...good decision processes should not be pursued solely by regulatory agencies. Effective decision making on the part of industry results in the construction of a logical and well-documented dossier as well.”
Update from Japan

By Theresa Ryan Stueve

Operating in this new era of global drug development, many of the speakers at the International Regulatory Symposium spoke of the desire for harmonized regulatory frameworks among regulatory agencies and stakeholders with global reach. In particular, several of the speakers from Japan presented trends in that country’s healthcare, demographics, and regulatory environment highlighting the need for increased participation in clinical trials (GCT) and changing perspectives at the Pharmaceuticals and Medical Devices Agency (PMDA) may be integral in solutions to avert a national healthcare crisis.

Known for its industriousness, ability to innovate, and regionally healthy workforce, Japan has been a preeminent force in the global marketplace since the Second World War. Among South East Asian countries, Japan was first to adopt western marketing strategies and values that hastened its entry into the global marketplace. In terms of healthcare however, Japan has historically fared much better than many of its western business partners by sticking with regional practices. For instance, Japanese frequent doctors’ offices more often than Europeans, spend half as much as much on healthcare as do Americans, and live longest. However, Japan’s population is aging and shrinking, and its economy has suffered bouts of stagnation.

At the Symposium, a charismatic and distinctly empathic Dr. Tatsuo Kurokawa, of Keio University, opened the session with figures indicating there are now 1/3 fewer doctors per capita in Japan than most western countries, and the incentives for new doctors, mostly funded by a state recovering from unprecedented man-made and natural disasters, are diminishing. Japanese doctors have very little time to consult patients, especially in rural areas. Drs. Shinji Miyake and Dr. Hiroshi Yamamoto in subsequent sessions described Japan’s increasing participation in GCTs and changing perspectives at the PMDA as critical elements.

Japan is aging faster than any other nation in the world, and Dr. Kurokawa noted that nearly a quarter of its population is over 65. Given the combination of rapid demographic shifts and a shrinking healthcare workforce, Dr. Miyake explained Japan’s increased participation in Global Clinical Trials (GCTs), while Dr. Yamamoto presented the PMDA’s five-year strategy for reviewing GCT data underpinned by a keen awareness of ethnic differences in pharmacokinetics and respect for good clinical and laboratory practices. In 2007 the Ministry of Health, Labor, and Welfare published GCT guidelines that have resulted in large increases in new drug approvals, yielding 42 GCT-based new drug approvals from 2007-2012. More than 13.4% of drugs approved in 2012 in Japan brought to market from GCT-based approvals. With recent development of the bionic pancreas, it is conceivable that changing paradigms at the PMDA may spur innovation in monitoring and interventional medical devices that support Japan’s aging population and alleviate practitioners’ healthcare burden simultaneously.
International Regulatory Science Symposium
Date: Saturday, November 1, 2014
Time: 9am – 5pm

Exploring China
“Legal, Regulatory, and Cultural Aspects”

COMING EVENTS

Good Research Practices (GRP) Symposium
Date: Thursday, October 30, 2014
Time: 9 am – 5 pm
Aresty Auditorium

ATTENTION: Reg Sci Alumni
We are planning a “Back to School Happy Hour” for the Fall...stay tuned and make sure we have your current contact info!

COLLABORATE WITH COBRA
Dr. James Leong from Singapore HSA, one of the Health Authorities which participate in the COBRA consortium (along with Health Canada, SwissMedic and Australia’s Therapeutic Goods Administration), presented the need for a universal benefit-risk assessment framework for regulatory approvals of new drugs. The need for such a framework has to include all stakeholders, global regulatory agencies alike, to not only improve the quality of the decision but be able to communicate what was considered in the decision, making it more transparent and less arbitrary to outsiders.