Proposal: Regulatory Science Training Consortium (RSTC)

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Context/Need

• To foster the development of a robust education and training environment in regulatory science
  – Address gaps in traditional academic programs
  – Provide continuous learning opportunities for academic, industry and regulatory scientists
  – Prepare the future regulatory science workforce
Advancing Regulatory Science for Public Health— A Framework for FDA’s Regulatory Science Initiative, *FDA, October 2010*

III. Scientific excellence, professional development, and a learning organization

FDA will support a culture of and capacity for continuous scientific learning and professional development of our scientific staff. The agency will explore several approaches:

- Access to cutting-edge, continuing education and professional development for FDA staff — through universities and government agencies, for example — as well as policies and resources that support these activities

- Scientific exchange programs with academic and governmental institutions and with international regulatory counterparts
Enormous potential for academic programs involving regulatory science

• There are a growing number of regulatory science training/degree programs in the US but most are based on regulatory affairs and not necessarily on the science of regulation or topics and tools used in medical product development or evaluation

• There is currently little coordination among academic programs concerning regulatory science or with FDA specifically
Key Opportunity

• Collaboration involving all stakeholders is essential to creating an infrastructure to build regulatory science competencies and to more efficiently turn discoveries into medical products that benefit public health.
Program Areas

Curriculum Development
- Blended learning, online modules, case studies made available to stakeholders

Academic Exchanges
- Training in industry, academic and regulatory environments

Sabbaticals
- Opportunities for senior and mid-level faculty to train within FDA

Fellowships
- Therapeutic area and discipline specific training for post-graduates and early career professionals
REGULATORY PATHWAYS FOR MEDICAL DEVICES: CHOOSING THE RIGHT ONE

This fictionalized case study is the first in an educational series published by the U.S. Food and Drug Administration.

For 35 years, Henry Neyhardt had practiced pediatrics in this 1970s beige brick building. When he first opened his doors, the building seemed hip and modern—a fresh start. Exactly what he needed. After his residency, he had taken a detour in his career and founded a medical device company, combining his love for medicine with his drive for invention. Where others saw problems, he saw solutions. But turning his ideas into reality eluded him. He struggled to get his business off the ground, and funds ran out before his products reached the market. He closed the company and opened his medical practice. Neyhardt was a gifted pediatrician, and his patients and practice thrived. And yet, almost daily, a medical instrument or piece of equipment disappointed him. He knew he could do better. At night, on his own time and with his own resources, he tinkered.

All in all, Neyhardt had filed more than 20 patents for medical devices over the years. Each time, he was beaten to market by competitors who were more savvy about product development and marketing. He was forced to redevelop the device, sometimes more than once. It burned off his capital, and the devices never reached the patients he was trying to help.

Neyhardt’s latest invention: an insulin infusion pump. The device could deliver insulin at preset rates with simple user features, allowing patients to adhere to their regimens with increased compliance. Although the device was intended for adults with diabetes, his ultimate goal was to improve the care of pediatric patients. This time, Neyhardt thought, would be different. He would design the device right the first time.

He had reached a crossroads in its development; its key features could be designed to operate electronically or mechanically. Both were appealing. But which design would make it smoothly through the regulatory process to the marketplace? Which one would succeed?

The Protégée

A wiry, energetic young woman with short brown hair stuck her head in his office. Sten Laws. Neyhardt had hired her to prepare a business plan and help recruit investors for the development and manufacturing of the insulin infusion device. Laws was finishing business school at the end of the month and had jumped at the chance to get a new venture off the ground. With her was Rush Mooney, a tall, thoughtful engineering student about to graduate from the same university.
Alzheimer's Disease Fellowship
a FDA/RUF/AA Pilot Program
FDA/Harvard/Boston U Partnership

Pilot Course in Statistical and Quantitative Methods for Pharmaceutical Regulatory Science
Potential Training Areas

Develop training modules to support regulatory science education in key areas including:

– CMC, phamtox, clinical pharmacology, statistics
– clinical trial design and analysis methods to support the development of biologics, drugs and medical devices
– PRO development, endpoints to support the development of biologics, drugs and medical devices
– subtopics of rare diseases
– pediatrics, elderly, and other vulnerable populations
– drug-device interactions
– investigator responsibilities (regulatory, legal, ethical)
– microbiological, chemical and analytical methods to support food safety
Initial Phase

• Establish a Coordinating Committee comprised of multiple stakeholders to:
  – assess regulatory science education gaps in the existing academic programs
  – identify and prioritize training needs critical to establishing an effective regulatory science workforce
  – understand the range of regulatory science educational content that is available
  – develop metrics to assess the usefulness of the consortium approach to address regulatory science training needs
Thank you
Discussion Questions

1) What are the strengths and weaknesses of this proposal?
2) What do you see as priority areas of focus for regulatory science education?
3) Do you envision a role for the CERSIs in this effort? If so, what would be the role?
4) Of the four activity streams proposed (curriculum development, academic exchanges, sabbaticals, fellowships), which area presents an opportunity for quick wins?