2020 GLOBAL CONFERENCE ON REGULATORY SCIENCE

MACHINE LEARNING AND DATA SCIENCE

Oct 20-21, 2020 | 10am - 3:30pm ET | Virtual Meeting

WORKING GROUP TIMES
10/20 11am-12:30pm &
10/21 11am-12:30pm
(EST)

***W*orking Group:** Education in Regulatory Science

Workgroup Goal: To consider state-of-the-art methods to prepare and continually maintain a workforce equipped to maximize the application of regulatory science.
Workgroup Objectives: Identify the issues confronting training and continuing education in regulatory science as scientific advances occur more rapidly and more broadly. Propose mechanisms for addressing these issues during the group discussions.:

Regulatory Science History

During the past two decades the FDA has made great strides in strengthening the breadth and rigor of its regulatory science activities. Such achievements have been motivated in part by challenges that the Agency has faced and recommendations stemming from a 2007 report by the FDA Subcommittee on Science and Technology that followed closely upon the Institute of Medicine's report on the Future of Drug Safety. One consequence of this report was a joint undertaking by the FDA, the Defense Advanced Research Projects Agency and the National Institutes of Health that was launched in 2010 to promote research in the field of regulatory science. The overarching goal of this collaborative Regulatory Science Initiative is to foster the development, evaluation and availability of new or improved tools, methods, standards, and applied science that support a better understanding and improved evaluation of product safety, quality, effectiveness, and manufacturing throughout the product life cycle.

Role of Training and Professional Development

The complexity, and rapidity of change, in the life sciences makes regulatory science training and professional development all the more important. Many new areas of medical product development, and indeed, entire fields of scientific inquiry, ranging neuroprosthetics to digital therapeutics to the use of cellular organelles to target human disease, pose novel challenges to regulators working to safeguard the health and well-being of the public while expeditiously bringing patients the advances being translated from being the sciences fundamental to medicine through the application of scientifically sound regulatory activities. The key challenge and opportunity facing educators is to develop and maintain currency in a workforce that is equipped to maximize the promise of regulatory science in rapidly evolving disciplines.

Select Examples of Innovations Posing Challenges to Regulators

- Omics
- Gene and gene-editing therapies
- Cellular therapies
- RNA-based therapies
- Mobile health technologies/wearables
- Digital therapeutics
- Mitochondrial and other cellular organelle gene therapy
- Exosome therapies
- Neuroprosthetics
- Nanomedicine
- Microbiome
- AI/machine learning (e.g., software as a medical device)
- Biomarkers
- Decentralized clinical trials
- Real world evidence

Queries for Exploration

1. What are the principal means that are currently used to provide individuals with training in regulatory science?
2. What core competencies should be reinforced through regulatory science education?
3. Is there an art, as well as the science, of regulation, and if so, how can this best be imbued among trainees and early-stage professionals?
4. How can training and professional development initiatives help to counter many forces that may infringe upon the professional activities of scientists? (OR … remain true to scientific principles and not deleteriously impacted by political, social, perverse economic or other inappropriate incentives?)
5. How can training and professional development initiatives remain up to speed with the rapid pace of scientific change?
6. What methods can be used to ensure that training and professional development activities are as impactful as possible?
7. What strategies can be used to maximize the degree to which training programs incorporate and reflect the experiences and views of diverse stakeholders?

References

1. Mission Possible: How FDA Can Move at the Speed of Science. Report of the Science Looking Forward Subcommittee. Prepared for FDA Science Board. September 2015. Available at https://www.fda.gov/media/93524/download. (Accessed Oct 5, 2020).

2. Institute of Medicine. The Future of Drug Safety: Promoting and Protecting the Health of the Public. Washington, DC: The National Academies Press; 2006 Sep. Available at https://www.fda.gov/media/77173/download .(Accessed Oct 5, 2020).

3. Hamburg MA. Advancing regulatory science. Science. 2011; 331:987.

4. Food and Drug Administration Safety and Innovation Act of 2012. Available at: https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/food-and-drug-administration-safety-and-innovation-act-fdasia (Accessed Oct 5, 2020).

5. Joan E. Adamo, Erin E. Wilhelm, and Scott J. Steele. Advancing a Vision for Regulatory Science Training. Clinical and Translational Science. 2015; 8(5):615-618

6. Alexandra J. Greenberg-Worisek, Katherine E. Cornelius, Luz Cumba Garcia, Felicity T. Enders, Nilay D. Shah and Anthony J. Windebank. Translating innovation in biomedical research: Design and delivery of a competency-based regulatory science course. J Clin Transl Sci. 2020 Feb; 4(1): 8–15.

***Discussion Summary*: Education in Regulatory Science Working Group**

The Education in Regulatory Science Working Group convened during the 2020 Global Conference on Regulatory Science (Oct 20-21). The group was composed of thought leaders from academia, industry and regulatory agencies, representing both the European and US perspectives *(membership list attached)*. The participants had lively conversations around regulatory science education, best practices for training, and learning barriers. The group proposed recommendations to ensure the development of a workforce that is equipped to maximize the promise of regulatory science in rapidly evolving disciplines.

The guiding questions and discussion points are presented below.

1. What are the principal means that are currently used to provide individuals with training in regulatory science?

- *Formal training*: courses, seminars/lectures, Certificate, MS or PhD programs
- *Experiential learning*: internships, rotations, work in multidisciplinary teams, participation in meetings between sponsors and regulatory agencies, on the job
- *Others*: audit of advisory meetings, incorporation of regulatory science elements in trainees' research projects, develop or utilize case studies

2. What core competencies should be reinforced through regulatory science education?

- Build competencies across the continuum of health product development
- Adaptability and flexibility are key characteristics to an agile workforce

3. Is there an art, as well as the science, of regulation, and if so, how can this best be imbued among trainees and early-stage professionals?

- Implementing regulation has aspects of both art and science
- The art dimension is reflected in the interpretation of regulations
- Science generates evidence for updating guidelines and regulatory processes
- Best practices for training in the science and art of regulation: teach the current gold standard (regulatory guidance) accompanied by case studies which illustrate how innovation creates opportunity for guidance updates

4. How can training and professional development initiatives help to counter many forces that may infringe upon the professional activities of scientists? (OR … remain true to scientific principles and not deleteriously impacted by political, social, perverse economic or other inappropriate incentives?)

- Provide context for the role of science in broader public policy making
- Teach history/legacy of regulatory science and the political and economic forces that shape its evolution
- Introduce bioethics training and link to discussions on pharmaco-economics

Training Considerations

Barriers

- Lack of awareness about regulatory science as a discipline
- Hard to reach and provide incentives for mid-career and later stage professionals

Solutions

- Integrate regulatory science elements in curricula starting at undergraduate level
- Help scientists reframe their projects from the regulatory science perspective
- Co-localize junior and senior professionals

- Teach what creativity and flexibility means in policy making and implementation
- Educate and engage the public

5. How can training and professional development initiatives remain up to speed with the rapid pace of scientific change?

- Horizon scanning: identify emerging technologies and innovations, and develop training for different stakeholders involved in product development and regulation
- Bring together subject matter experts who know the technology well and people who understand the process of innovation and the principles of regulation
- Consider formal continuing education programs (and eventually possible certification)
- Learn by cross-pollination with other disciplines in which technologies and innovations are more mature in order to advance core competencies in regulatory science
- Disseminate information through seminars and newsletters

Training Resources

- https://www.edx.org/course/prescription-drug-regulation-cost-and-access-curre
- https://www.urmc.rochester.edu/research-alliances/regulatory-science.aspx
- https://www.csa-stars.eu/About-STARS-50.html

6. What methods can be used to ensure that training and professional development activities are as impactful as possible?

- Start regulatory science training at the undergraduate level
- Integrate regulatory science elements in existing training programs and specialities
- Identify mentors with a combination of didactic and real-world experience, able to provide a framework for the regulatory decision-making process

7. What strategies can be used to maximize the degree to which training programs incorporate and reflect the experiences and views of diverse stakeholders?

- Identify where the knowledge is and integrate the views of multiple stakeholders
- Incorporate patient voices in scientific, non-clinical training to ensure that their ideas are integrated during the early stages of health products development
- Immerse trainees in experiential learning in multiple fields
- Include a diverse cadre of teachers to reflect multiple perspectives

Implementation Ideas

- *Short courses*
- *Online courses*
- *Compendium of regulatory science case studies*
- *Central repository for regulatory science training materials and curricula*
- *Regulatory science "Train-the-Trainer" workshop*
- *Student exchange, mini-sabbaticals*
- *Cross-professional conferences and training opportunities*

Working Group Membership

Moderators:

Caleb Alexander, Professor of Epidemiology and Medicine, Johns Hopkins Bloomberg School of Public Health
Michael Rosenblatt, Chief Medical Officer, Flagship Pioneering

Members:

Catherine Dubreuil, Director Therapeutics Education, I-Hub, Harvard Medical School
Johanna Gutlerner, Associate Dean for Graduate Education, Harvard Medical School
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Marisa Papaluca, Professor, Imperial College London, Former EMA Senior Scientific Advisor
Sarah Potter, PhD candidate, Harvard Medical School
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Scott Steele, Associate Professor, Director of Regulatory Science Programs, Clinical and Translational Science Institute, University of Rochester Medical Center