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Regulatory Science Education: The Need for Generalization

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Abstract

Ever since the beginning of regulatory science, the need for relevant education has been recognized. However, after the Food and Drug Administration (FDA) officially recognized regulatory science, several universities have developed educational programs. This paper provides the results of a study to evaluate the existing education programs on regulatory science. The study identifies the generic definition of regulatory science, consisting of applied version of various scientific disciplines used in the regulatory process. The study found that the educational programs in regulatory science largely dealt with compliance with FDA regulations. In many cases, the programs used the term "regulatory affairs" to describe the regulations and how to comply with them. Based on the experience at Georgetown University, the study provides an outline for regulatory science education. The proposed educational program consists of: 1) approximately 10 topics that are relevant to most, if not all, regulatory science disciplines; 2) a summary of various regulatory science disciplines; and 3) education in specific regulatory science disciplines.

Keywords: regulatory science education, regulatory affairs education

1. Introduction

Virtually all technical disciplines have routinely provided education dealing with various aspects under their purview. The evolution of regulatory science required the application of specific disciplines as the foundation of the decision process. For example, the evolution of regulatory science as it is used for medicine, occupational safety, and environmental protection required the application of toxicology. As described by Moghissi et al. [12], the term regulatory science was developed in the 1970s at the U.S. Environmental Protection Agency (EPA), and the first organization (Institute for Regulatory Science) with regulatory science in its title and mission was established in the early 1985. In order to simplify the discussion in this paper, the term science is used to include natural sciences, engineering disciplines, and other disciplines such as economics.

The first government agency that recognized regulatory science as a relevant scientific discipline was the U.S. Food and Drug Administration (FDA). Currently, the Office of Regulatory Affairs manages key elements of regulatory science at the FDA [23]. Recently, EPA published a proposed rule that addressed regulatory science and identified certain issues related to dose-response and models.

Regulatory science education must consider the needs of three communities. The first community is that of regulatory agencies needing individuals with scientific knowledge to implement legal requirements by developing, applying, and enforcing regulations. The second community consists of the scientific staff in the regulated community who must comply with regulations. Finally, the third community provides the regulators and regulated communities with relevant scientific information, performing research and developing scientific advances. All three communities need regulatory science education to ensure the availability of individuals with knowledge in regulatory science applicable to their needs.

1.1. Definition of Regulatory Science

Historically, many attempts have been made to define regulatory science, an evolving scientific discipline, leading to three key definitions:

- FDA Definition: "Regulatory science is the science of developing new tools, standards, and approaches to as-

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sess the safety, efficacy, quality and performance of all FDA-regulated products." [22]

- EPA Definition: "Regulatory science means scientific information including assessments, models, criteria documents, and regulatory impact analyses that provide the basis for EPA final significant regulatory decisions." [20]
- Generic Definition: "Regulatory science consists of the applied version of various scientific disciplines used in the regulatory process." [12]

This paper is a continuation of several previous studies performed by graduate students participating in a regulatory science program at Georgetown University. The study consisted of evaluating regulatory science (and regulatory affairs) educational programs, with the objective of identifying their current shortcomings and attempting to provide directions for the improvement of regulatory science education. The search primarily used the internet, followed by evaluation of the internet findings. Despite potential shortcoming of a far from systematic internet search, the search provided sufficient examples to evaluate the current status of regulatory science education in the U.S. and abroad. The study consisted of identifying degree programs pertinent to regulatory science and their relevant courses. The survey demonstrated the problem of describing the courses, notably the relationship between the title and the content of a course, as often the subject was too complex to be properly described in the title. Similarly, many universities provide elective courses that could improve the educational program in regulatory science, albeit to a greater or lesser extent depending on their content.

1.2. Three Phases of the Regulatory Process

Regulatory science education must consider the status of regulatory requirements. As described previously [11], there are three phases in the application of regulatory science in the regulatory process. During the initial phase, regulatory agencies must meet deadlines and use scientific information with various levels of maturity to promulgate regulations. Historically, regulators have used terms such as Best Available Information and Best Available Technology to indicate that they used their judgment in selecting the needed information. Subsequently, during the exploratory phase, experience with the promulgated regulations and new findings based on research and development are used to reevaluate the initial decision. During the third standard operating phase, information gathered in the second phase is used to reevaluate the initial regulatory decision.

2. Survey Results

Some of the first regulatory science programs identified in the survey were the four Centers of Excellence in Regulatory Science and Innovation (CERSI) funded by the FDA [21]. These centers perform relevant research and provide training in the form of workshops and lecture series designed to improve FDA's design and implementation of regulations. Currently there are four universities having a CERSI:

- John Hopkins University
- University of Maryland
- Stanford University in collaboration with the University of California at San Francisco
- Yale University in collaboration with the Mayo Clinic

The results of the survey are presented in three parts. The first part consists of regulatory science/regulatory affairs degree programs in the Unites States. The second part consists of one program at Georgetown University where the research leading to this paper was performed. The third part includes a few regulatory science/regulatory affair education programs at universities outside of the United States.

Arizona State University: MS in Regulatory Science
Core Courses: Medical Device Development and Regulation; Quality Assurance and Clinical Research; Responsible Conduct of Clinical Research; Fundamentals of Regulatory Affairs; Drug Discovery, Development and Regulations; Global Regulatory Affairs; Legal Aspects of Clinical Research; Translational Research in Drug Discovery and Development [1].

University of California, Berkeley Extension: Professional Program Certificate in Regulatory Affairs
Core Courses: Principles of Regulatory Affairs: Pharmaceuticals and Medical Devices; Biologics License Application/New Drug Application/Marketing Authorization Application (BLA/NDA/MAA) Submissions and Commercialization; Harmonization Across Worldwide Applications; Investigational New Drug/Clinical Trials Application(IND/CTA) Enabling Studies and Agency Interfaces; IND/CTA Preparation and Submission; Post-Approval Activities; Principles of Supply Chain and Manufacturing; Principles of Institutional Product and Process Development; Principles of Quality and Compliance; Chemistry Manufacturing and Controls (CMC); Regulatory Compliance for Pharmaceutical Products [24].

George Washington University School of Medicine and Health Sciences: MS in Health Sciences/Regulatory Affairs
Core Courses: Topics in Health Care Leadership; Issues and Trends in Health Systems; The Health Care Enterprise; Biostatistics for Clinical and Translational Research; Epidemiology for Clinical and Translational Research; Introduction to Global Regulatory Affairs; Regulatory Strategy in the Development of Devices and Diagnostics; Clinical Research for Regulatory Affairs; Regulatory Compliance; Leadership and Change in Regulatory Affairs [5].

George Washington University: MEng in Regulatory Biomedical Engineering
Core Courses: Biomedical Engineering Coursework and

Practicum; Regulatory Issues; Patent Law for Engineers [4].

Johns Hopkins University: MS in Regulatory Science/Drug Compliance
Core Courses: Biological Processes in Regulatory Affairs; Introduction to Regulatory Affairs; Translational Biotechnology; Introduction to Good Manufacturing Principles Compliance; Clinical Development of Drugs and Biologics; Food and Drug Laws; Practicum in Regulatory Science and Laboratory Science Disciplines [7].

Keck Graduate Institute of Claremont Colleges: MS in Bioscience with emphasis in Clinical Regulatory Affairs
Core Courses: Regulatory Affairs (RA) for Pharmaceuticals, Medical Devices, Biologics and Functional Foods; U.S. Food and Drug Law; Medical Device Regulatory Affairs; Biologics Regulatory Affairs; Drug Regulatory Affairs; Biopharmaceuticals Quality Assurance and Control; Clinical Trials Design; Conduct and Strategies for Medical Device Development and Market Release or Marketing Assessment; Risk Management Tools and Techniques [8].

Long Island University, College of Pharmacy: MS in Drug Regulatory Affairs
Core Courses: Biostatistics; Drug Regulatory Affairs; Pharmaceutical Labeling, Advertising and Promotion; Seminar in Social and Administrative Sciences; FDA Regulation of Over-the-Counter Drugs, Medical Devices and Dietary Supplements; Principles and Practices of Regulatory Compliance and Enforcement; Mechanics of Preparing INDs and NDAs; The American Pharmaceutical Industry [9].

University of Maryland, School of Pharmacy: MS and Graduate Certificate in Regulatory Science
Core Courses: Drug, Biologics, and Device Regulation; Drug and Biologics Discovery; Drug and Biologics Development; Clinical Research; Regulated Products in the Marketplace; Biological Processes in Regulatory Affairs; Introduction to Regulatory Affairs; Translational Biotechnology: From Intellectual Property to Licensing; Introduction to Current Good Manufacturing Practices (cGMP Compliance); Clinical Development of Drugs and Biologics; Food and Drug Law; Practicum in Regulatory Science [27].

Massachusetts College of Pharmacy: MS in Drug Regulatory Affairs and Health Policy
Core Courses: Law and Health Policy of Drugs and Devices; FDA and Regulatory Affairs; International Regulatory Affairs; Statistics in Clinical Research; Laws and Regulations Governing Human Health, Epidemiology; Advanced Topics in Regulatory Affairs; Data Analysis and Presentation Capabilities; Research in Regulatory Affairs [10].

Northeastern University, College of Professional Studies: MS in Regulatory Affairs for Drugs, Biologics, and Medical Devices
Core Courses: Clinical Research for Therapeutic Product Development: A Regulatory Overview; Medical Device Overview; Pharmaceutical and Medical Device Development and Law: Topics and Cases; Global Impact of Electronic Common Technical Document (eCTD) submissions; Clinical Trial Design Optimization and Problem Solving; Practical Applications in Biomedical Product Global Regulatory Affairs; Introduction to Food and Drug Administration (FDA) Pharmaceutical Regulation and Medical Device Regulation; Human Experimentation Methodological Issues Fundamentals; Medical Device Development and Law; Practical Applications in Biomedical Product; Global Regulatory Affairs; Regulatory Compliance Culture; International Regulations and Introduction to Australian, Asian, and Latin American Regulatory Affairs; Working in Multicultural Environments: Challenges and Opportunities; Operational Collaborative Approach; Strategic Regulatory Affairs Topics and Cases; Advanced Regulatory Writing: Medical Device Submissions [13].

Northwestern University, School of Professional Studies: MS in Regulatory Compliance
Core Courses: Quality Systems for Regulatory Compliance; Applied Research and Writing; Biostatistics; Risk and Decision Management; Foundations of Leadership; Capstone Course or Thesis Research [14].

University of Pennsylvania, School of Medicine: MS in Regulatory Affairs
Core Courses: Intro to Bioethics; Intro Clinical and Translational Research; Intro to Drug Development; Fundamentals of FDA Regulations; Clinical Study Management; Biopharmaceutical Science; Product Development; Post-Approval Maintenance of Drugs, Biologics and Devices; Required Capstone Mentored Project for Surveillance of Drug Reactions and Designing a Process Improvement [28].

San Diego State University: MS in Regulatory Affairs
Core Courses: Pharmaceutical, Biotechnology, and Medical Device Industries; Food and Drug Law; Medical/Scientific Writing for Life Science Professionals; Advanced Topics in Regulatory Affairs; Project Planning for the Biomedical Industries; Leadership for Change and Continuous Improvement; Current Good Manufacturing Practices - General Concepts; Post-Approval Activities, Including Advertising, Promotion and Labeling; Medical Device Regulations; Investigational and Marketing Applications for Drugs and Biologics; Clinical Trials: Issues in Design, Conduct and Evaluation; Quality Control and Quality Assurance: Pharmaceuticals, Biologics, Medical Devices; International Regulatory Affairs with emphasis on European Union; Ethics for Life Science Professionals; Effective Communication for Life Science Professionals; Research; Special Study [15].

University of Southern California: MS in Regulatory Science
Core Courses: Introduction to Medical Product Regulation;

Quality Assurance for Drugs and Biologics; Quality Assurance for Medical Devices & Combination Products; Quality Systems & Standards; Structure and Management of Clinical Trials; Quality Systems & Statistical Process Control; Introduction to Clinical Trial Design & Statistics; Regulation of Pharmaceutical and Biological Products; Regulation of Medical Devices and Diagnostics; Regulation of Food and Dietary Supplements; Introduction to Food Science and Toxicology; Medical Products and the Law; Biomedical Commerce [29].

St. Cloud State University: MS in Regulatory Affairs and Services

Core Courses: Special Problems Independent Study; Legal Basis for Medical Device Product; Regulatory Routes to Market: 510(k)s; Regulatory Routes to Market: Pre-market Authorizations (PMA's); International Regulatory Affairs: European Union, East Europe; Investigational Device Exemption (IDE) Regulations and Clinical Trial Design; Quality Systems for Regulated Industries; Regulatory Affairs Compliance; Health Policy and the Medical Technology Industry; Reimbursement and Cost Management for Medical Technology; Regulatory Affairs Internship; Regulation of Combination Products; Regulatory and Clinical Ethics Involving Medical Devices; International Regulatory Affairs: Japan, Other Asia, Latin America and Middle East; Advanced Reimbursement and Cost Management for Medical Technology; Capstone Culminating Project [16].

St. Thomas School of Engineering: MS in Regulatory Science

Core Courses: Design and Manufacturing in Medical Device Industry; Program/Project/Team Management; Engineering Leadership; Medical Device Regulatory Submission; FDA Medical Device Quality Systems; Medical Device Clinical Studies; Combination Products, Drugs and Biologics; International Regulatory Affairs for Medical Devices; Directed Study (Independent Research) [17].

Temple University, School of Pharmacy: MS in Regulatory Affairs and Quality Assurance

Core Courses: Drug Development; Food and Drug Law; Manufacturing Practices, Good Clinical Practices, Laboratory Practices, Advanced GMPs; IND/NDA Submissions or Quality Audit; Managing the Guidelines for Quality; Global Chemistry, Manufacturing, and Controls, (CMC) and Regulatory Dossiers; Risk Management and Safety Signaling of Healthcare Products; Regulatory and Legal Basis of Pharmacovigilance; Global Regulatory Affairs; Regulation of Dietary Supplements; Botanicals and Nutraceuticals; Food Law; Food Labeling and Regulatory Affairs; Clinical Aspects of Pharmaceutical Medicine; Industry Interactions with FDA/Health Authorities; Advanced Topics in Food and Drug Law [18].

University of Washington: MS in Biomedical Regulatory Affairs

Core Courses: Introduction to Biomedical Regulatory Affairs; Introduction to Clinical Trials; Skills for the Regulatory Affairs Professional; Product Development and Manufacturing Systems; Implementation and Conduct of Clinical Trials; Technical Writing for Biomedical Regulatory Affairs; Product Testing, Evaluation and Post-Market Issues; Project Management and the Business of Clinical Trials; Advanced Technical Writing for Biomedical Regulatory Affairs; Practicum; Year 2: International Regulatory Affairs; Medical Risk Analysis and Management; Practicum; Statistical Topics for Biomedical Regulatory Affairs Professionals; Practicum; Advanced Medical Products Regulation; Practicum. [30]

University of Copenhagen, Denmark: MS in Medicines Regulatory Affairs

Courses: Biopharmaceuticals Quality Development and Documentation; Clinical Development and Documentation; Drug Regulatory Science; Discovery and Development of Medicines; Global Pharmaceutical Policy Rationales and Stakeholders; Market Access for Pharmaceutical Products; Transparency and Trustworthiness in Drug Development; EU Regulatory Environment Procedures and Applications; The U.S. Regulatory Environment; Safety of Medicines; Quality - Drug Substance and Drug Product; Quality by Design in Pharmaceutical Development; Biopharmaceuticals Drug Development; Labelling as a Driver for Regulatory Strategy [25].

University of Hertfordshire, School of Life and Medical Sciences, United Kingdom: MS in Regulatory Science, Pharmaceutical and Devices

Core Courses: Human Physiology with Pharmacology; Fundamentals of Analytical Chemistry; Foundations of Pharmaceutical Chemistry, Biology and Biochemistry, Dosage, Form, Design and Manufacture; Pharmacology; Introduction to Epidemiology and Pharmacoepidemiology; Global Pharmaceutical/Devices Regulatory Requirements; Introduction to Health Technology Assessment (HTA), Clinical Development, Strategic Planning and Product Life Cycle Management; Management and Corporate Finance [26].

Donau University Krems, Austria: MS in European Union (EU) Regulatory Affairs Pharma-management

Core Courses: Introduction to Regulatory Affairs; Drug Regulatory Affairs; Medical Device Regulatory Affairs; Pharmaco-Economics and Decision-Analytics; Introduction to Regulatory Affairs in the EU; The Role of the Regulatory Professional; Pharmaceuticals: EU Regulations; Pharmaceuticals: Compliance and Audits; Pharmacovigilance; Medical Devices: EU Regulations; Medical Devices: Compliance and Audits; Medical Devices: Postmarket Surveillance; Good Clinical Practice (GCP); Regulation of U.S. and EU Biologics [2].

Humber College, School of Health Sciences, Canada: MS in Regulatory Affairs

Core Courses: Health Care Legislation, Regulation and Guidelines; Product Development-Premarket; Product Development-Chemistry, Manufacturing, and Controls (CMC); Medical

Products Safety Communication; Pathophysiology and Pharmacology; Management of Regulatory Submissions; Management of Global Regulatory Submissions; Regulation of Food Products and Agrochemicals; Medical Devices; Provincial Formularies and Reimbursement Policy; Emerging Biotechnology with Internship [6].

Georgetown University: MS in Biomedical Science Policy and Advocacy

At Georgetown University, regulatory science courses are part of a MS program in Biomedical Policy. These courses provide Introduction to Regulatory Science, Regulatory Science Tools, and inclusion of key scientific disciplines such as regulatory toxicology in regulatory science [3].

3. Discussion

It was difficult to summarize the results of the survey. The study chose not to include elective courses and many universities provided a few too many elective courses with variable relationship to regulatory science. The current regulatory science education in the U.S. largely consists of how to comply with FDA regulations. For the last several decades, those involved in public health issues have attempted to establish organizations to assist health professional to comply with relevant regulations, policies, and related requirements. Several organizations were formed with regulatory affairs in their title to accomplish this goal. Similarly, many universities use the term "regulatory affairs", apparently to imply that they follow requirements of the Office of Regulatory Affairs at the FDA. However, the title of a course or any other activity must be descriptive of its content. Precisely because of the significance of regulatory science, notably its impact on public communication, a renaming of the term Regulatory Affairs in these educational programs would be desirable. Regulatory affairs professionals might benefit from a revision of the title of their profession depending on its focus. For example, those educated to deal with medical issues might have a descriptive title of Medical Regulatory Affairs whereas those dealing with foods might have a descriptive title of Food and Nutrition Regulatory Affairs. This would open the way for educational programs to support EPA regulatory programs in Environmental Regulatory Affairs.

The current regulatory science education covers mainly compliance with regulations on drugs and medical devices, and, in some cases, foods. The study also identified four universities located in Austria, Denmark, the United Kingdom and Canada that provide curricula similar to those provided by the universities in the United States. Virtually every educational program covers requirements for regulating drugs, how to comply with drug-related regulations, and how to comply with regulations addressing medical devices. On occasion, courses are offered that describe relevant laws and how regulations are developed and implemented. In contrast, the coverage of basic science of toxicology and pharmacology is limited.

University websites describe curricular programs for learning regulatory competency and career skills necessary for managing the regulatory approval processes to commercialize products. Some of the regulatory affairs and regulatory service program descriptions indicate a specific design for the next generation of science graduates to become skilled in regulatory knowledge and capable of communicating with agency and corporate policy analysts about relevant concepts and terminology. Regulatory Science courses improve the employability of graduates to engage in leadership roles for in-demand professions in the medical device industry. Some programs match students to faculty who are industry experts with practical experience in the field, and focus on clinical affairs, quality systems, and health care reimbursement.

3.1. Fundamental Structure of Regulatory Science Education

Regulatory science education requires two parts. The first part provides generic topics common to regulatory science in virtually all disciplines. In contrast, the second part deals with specific regulatory science disciplines.

Key general topics of regulatory science are as follows:

1. Description of the nature of Regulatory Science addressing the historical overview; description of principles of the regulatory science discipline; classification of regulatory science claims and their reliability; and the desirability of exclusion of non-scientific subjects such as ideology in regulatory science
2. Application of peer review in regulatory science
3. Scientific assessment as a primary tool of regulatory science
4. Decision process in legislative, regulatory, and judicial branches of government, including how science is used in the three branches of government; the role of the Library of Congress; and the role of the National Academies of Science, Engineering and Medicine
5. Regulatory science ethics
6. Regulatory science transparency and communicability
7. Public and stakeholder participation and their roles in the decision process
8. Cost/benefit analysis
9. Metrology and its application in regulatory science
10. Mathematical models

3.2. Overview of Regulatory Science Disciplines

Regulatory science students would greatly benefit from learning how each scientific discipline is applied to the regulatory process. Key relevant disciplines include the following:

1. Regulatory Toxicology
2. Regulatory Ecology
3. Regulatory Pharmacology

4. Regulatory Microbiology
5. Regulatory Hydrology
6. Regulatory Occupational Safety
7. Regulatory Nutrition
8. Regulatory Waste Management
9. Regulatory Environmental Engineering
10. Regulatory Civil Engineering
11. Regulatory Economics, particularly cost/benefit analysis

3.3. Regulatory Advanced Degrees

The educational structure for advanced degrees would require specializing in one of the key areas identified in regulatory science disciplines.

4. Conclusion

Regulatory science is an evolving and expanding scientific discipline. Currently, regulatory science education covers mainly compliance with certain FDA regulations. Meanwhile, the EPA has initiated activities in regulatory science. In the United States there are many regulatory agencies, and their activities include application of science in their regulatory process. These agencies would benefit from recognizing the existence of regulatory science as a key scientific discipline that is applicable to their activities. The global community also would benefit from the development of educational programs that address not only specific regulatory science disciplines but also areas that are common to all of them.

Due to the predictive nature of regulatory science, there are various levels of uncertainties in its application. One of the key shortcomings in the application of regulatory science is the inclusion of societal vision, such as the use of ideology in science to be "protective" or "conservative". There appears to be a lack of recognition that being protective or conservative is part of the policy, and not science.

5. Declaration of Conflicting Interest

The authors declare no conflict of interest.

6. Article Information

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