



Regulatory Science Education as a Foundational Health Policy

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■ Executive Summary

Regulatory science serves as the scientific backbone of modern healthcare regulation, ensuring that medical products are safe, effective, and accessible. As technological advancements and global health rapidly evolve, the demand for a workforce trained in regulatory science has become a strategic imperative. The Life Sciences sector has the potential to create a growing number of jobs over the next 10 years, with digital and computational skills, statistical literacy, leadership, and inter-disciplinary working essential to its continued success (ABPI, 2020).

This white paper examines the critical role of regulatory science education in addressing educational challenges, emphasizing its contributions to public health, workforce development, and innovation. Drawing from recent workforce data and international policy initiatives, the paper highlights the need for structured, competency-based education programs spanning undergraduate to doctoral levels. It identifies gaps in awareness, curriculum standardization, and faculty development, while underscoring the importance of global alignment and interdisciplinary learning.

The authors propose coordinated actions among academia, industry, and regulatory agencies to foster experiential learning and align education with emerging regulatory trends. Regulatory science education is not only a tool for professional development, it is a foundational policy priority essential to sustaining healthcare innovation and ensuring public health readiness in a complex global landscape.

■ Introduction

Regulatory science is a multidisciplinary field that integrates scientific, legal, and policy expertise to ensure the safety, efficacy, and quality of products in regulated industries, particularly pharmaceuticals, biotechnology, and medical devices. As the pace of healthcare innovation accelerates, the demand for a well-trained regulatory science workforce has become not only a professional imperative but a public health priority.

This brief examines the critical role of regulatory science education in strengthening national and global health systems. It highlights how targeted educational investments can advance workforce development, enhance public safety, foster innovation, and support the evolution of responsive, aligned regulatory systems worldwide.

■ The Evolving Role and Scope of Regulatory Science

Regulatory science is not merely a compliance function; it is the scientific foundation for evidence-based decision-making throughout the lifecycle of medical products (Succar, 2024; Church, 2023). Regulatory scientists play pivotal roles in: Designing and evaluating clinical trials; assessing the safety and efficacy of new therapies; setting and updating standards and policies for product development and manufacturing; monitoring post-market safety and effectiveness; and facilitating communication among industry, regulators, and the public.

As science and technology rapidly evolve, so too does the scope of regulatory science. Once seen as focused on its

impact on regulatory affairs, today regulatory science touches almost every aspect of therapeutic development and regulation. Advances in genomics, personalized medicine and biomarkers, artificial intelligence, and the use of real-world evidence are shaping the field. Focus areas identified by the US Food and Drug Administration (FDA) include oncology, rare diseases, public health preparedness, and the expansion of regulatory science education and training (FDA, 2016; FDA, 2022).

Similarly, the international momentum is growing. The 2024 European Medicines Agency (EMA) draft Concept Paper on the European Platform for Regulatory Science Research (EMA, 2024) calls for expanded academic partnerships and strategic investments to address emerging regulatory science research needs (EMA, 2024). Building on its 2020 strategic priorities (EMA, 2025) the EMA's 2024 update (EMA, 2024) underscores the urgency of advancing clinical trial science and modernizing regulatory science systems to keep pace with scientific innovation.

To meet these challenges, regulatory frameworks and organizations must adapt, requiring a new generation of professionals who are not only scientifically literate but also adept at navigating increasingly complex regulatory systems. These professionals must be equipped to operate with agility, integrate advanced technologies, and engage in international alignment efforts, all while upholding the highest standards of public health protection (Vigilare, 2025; FDA website).

■ Core Competencies in Regulatory Science Education

Recent workforce analyses underscore the urgent need for targeted skills devel-



**Regulatory science is not optional—
it's the scientific backbone of public
health and innovation.**

opment in regulatory science. For example, priority skills gaps in advanced medicines discovery—including immunology, genomics, and clinical pharmacology, particularly in digital and data skills, have been identified as critical barriers to sector growth (ABPI, 2020). In parallel, frontline employees cite comfort with change, critical thinking, and advanced data analysis as the most important skills for future success (Dukart, 2020).

A foundational element of regulatory science education and workforce development is the adoption of structured, competency-based teaching frameworks. Leading organizations such as the Regulatory Affairs Professionals Society (RAPS; www.RAPS.org), the Joint Task Force for Clinical Trial Competency (JTF; **Home - Joint Task Force for Clinical Trial Competency**), and the World Health Organization (WHO; www.who.int) have each articulated models that specify the knowledge, skills, and behaviors essential for effective regulatory practice (**Table 1**). These frameworks are organized along two complementary dimensions:

1. Proficiency Levels

- Competencies are distributed across progressive levels of professional responsibility and autonomy:
- o Level I (Foundational)
 - o Level II (Intermediate Skills)
 - o Level III (Advanced Understanding)
 - o Level IV (Expert Leadership)

2. Domain Areas

- Core competency domains encompass the full spectrum of regulatory activity:
- o Regulatory Frameworks & Strategy

- o Product Development & Registration
- o Post-Approval & Post-Market
- o Business Acumen
- o Scientific & Health Concepts
- o Leadership in Regulatory Practice
- o Ethics in Regulatory Practice

These competencies can guide curriculum development, ensuring alignment with industry needs and accreditation standards, supporting workforce development and career advancement. By embedding competencies spanning biostatistical data analysis, decision-theory methodologies, advanced IT applications, and regulatory policy navigation into academic curricula and professional development programs across proficiency levels and domains, this framework approach ensures that graduates emerge not only with task-based knowledge but also with the analytical rigor, strategic insight, and technical versatility required by industry and agencies to meet the multifaceted challenges of modern regulatory practice (Adamo, 2015; Moghissi, 2020).

■ Educational Pathways and Program Diversity

The 2024 RAPS Global Regulatory Affairs Professionals Workforce Report (RAPS, 2024) shows that the field of regulatory

affairs continues to attract highly educated professionals: 63% hold a master’s degree or higher (49% master’s, 14% doctorate), while 34% report a bachelor’s as their highest credential. Despite the advanced education levels, only 9% of professionals studied regulatory affairs directly; most entered the field from life sciences (47%), engineering (19%), business and finance (13%) or clinical science (12%). This underscores both the interdisciplinary appeal of regulatory science and the need to accelerate acquisition of core competencies through formal education.

Regulatory science programs now span undergraduate minors, graduate degrees, professional certifications, and fellowships. And while RAPS surveys highlight the important role of regulatory affairs, in the United States, a growing number of institutions, including pharmacy schools and public policy programs, offer specialized fields aligned with regulatory affairs and shaped by regulatory science (Succar, 2024; Church, 2023; Institute of Medicine, 2012).

RAPS maintains a comprehensive database of US and international schools and universities that offer training in the regulatory sciences. Created in collaboration with the USC DK Kim International Center for Regulatory Science, this resource (available at [Academic Programs | RAPS](#)) catalogues more than 90 aca-

Table 1.
Regulatory Competency Frameworks

Organization	Framework Focus
Regulatory Affairs Professionals Society (RAPS; www.RAPS.org)	Comprehensive regulatory competencies and career progression
Joint Task Force for Clinical Trial Competency (JTF; Home - Joint Task Force for Clinical Trial Competency)	Clinical trial competencies and workforce standards
World Health Organization (WHO; www.who.int)	Global regulatory and public health competencies

demographic programs across countries including the U.S., Ireland, Canada, Korea, Egypt and Australia.

These programs vary in structure (online, in-person, hybrid), length, and disciplinary alignment, enabling learners to tailor their education to individual goals. Many include experiential components, such as internships, fellowships, case-based learning, and simulations, that translate theory into practice (Succar, 2024; FDA website). Alignment with regulatory agency priorities and roadmaps strengthen their practical relevance.

■ The Impact of Regulatory Science Education

Enhancing Public Health and Safety

Regulatory science education ensures that professionals are equipped to evaluate and manage the risks and benefits of medical products, directly impacting patient safety and public health outcomes. Competency-based education fosters a deep understanding of regulatory frameworks, scientific principles, and ethical standards, ultimately to prevent errors, expedite the development and authorization of innovative therapies, and maintain rigorous post-market surveillance (Succar, 2024; Church, 2023).

Supporting Innovation and Industry Competitiveness

Trained regulatory professionals improve time-to-market for safe and effective medical products by navigating complex, evolving regulations and proactively engaging with health authorities. Their contributions are critical to driving innovation and ensuring international compliance (Moghissi, 2020; NAS, 2016).

Strengthening Workforce Sustainability

Formal education pathways support



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career advancement and professional recognition, while reducing attrition in a growing field. Programs that incorporate active learning, simulation, and interdisciplinary collaboration prepare graduates for leadership roles and foster lifelong learning (Church, 2023; FDA website; Adamo, 2015; Institute of Medicine, 2012). However, the availability of graduate-level training programs in regulatory science remains limited across U.S. universities, raising concerns about long-term workforce readiness and institutional capacity to meet demand (Richmond, 2020).

The 2024 RAPS Global Regulatory Affairs Professionals Workforce Report (RAPS, 2024) provides robust data supporting the value of formal education and professional development in the regulatory field. The global regulatory affairs workforce in the RAPS report 111,635 professionals, with the highest concentrations in Europe (45,201), North America (34,473), and Asia (31,961). With 44% of respondents citing “keeping up with regulatory changes” as their top professional challenge, the need for ongoing, structured learning and skills development has never been greater.

Bridging Gaps and Promoting Global Alignment

Education also bridges regional disparities by aligning competencies, improving collaboration, and addressing global health challenges. Programs that incorporate international policies and guidelines (e.g., ICH, IMDRF, WHO) and emerging topics

Policy Recommendations

To position regulatory science education as a national and global priority, we propose the following strategic and operational actions:

Strategic Policy Initiatives

- **Government:**
 - Develop and fund a sector-based skills policy, from schools and apprenticeship standards through to re-skilling (ABPI, 2020). This approach ensures a robust pipeline of regulatory professionals and addresses skills gaps across all career stages.
 - Allocate targeted funding for academic program development, faculty recruitment, and student training in regulatory.
 - Provide competitive grants and fellowships to support the education and advancement of future regulatory professionals.
 - Encourage legislation and policy frameworks that integrate regulatory science education into national workforce and health innovation strategies.
- **Legislative and Regulatory Alignment:**
 - Integrate regulatory science education into regulatory modernization initiatives, national public health preparedness strategies, and international harmonization efforts.
- Involve regulatory authorities in co-developing education programs and curricula to ensure real-world relevance.
- **Academia:**
 - Institutionalize regulatory science education at undergraduate, graduate, and continuing education levels.
 - Invest in faculty development, including dual-discipline training in science, law, business, communication and regulation.
 - Align programs with international competency frameworks to support both national and global workforce readiness.
- **Industry:**
 - Partner with academic institutions to co-develop curricula, offer internships, fellowships, and cooperative education (co-ops), and share real-world case studies.
 - Contribute funding and mentorship for student engagement and faculty support.
 - Engage in standard-setting efforts to ensure curricula meet evolving regulatory needs.
 - Increase investment in employee reskilling initiatives. Currently, only a third of companies have launched reskilling efforts, with investments lagging far behind tech companies (Dukart, 2020). Closing this gap is essential to maintain industry competitiveness and ensure the workforce is prepared for technological transformation.
- **Resource Allocation Needs:**
 - Support centers of excellence and regional consortia to drive innovation and alignment in regulatory science education.
 - Expand funding through national research and education agencies, as well as through international development bodies, to build institutional capacity.
- **Accreditation and Standardization:**
 - Promote adoption of internationally recognized regulatory science competency frameworks (e.g., RAPS, WHO, JTF).
 - Encourage development of national and international accreditation standards to ensure curriculum consistency and quality.
 - Support mutual recognition of regulatory education credentials across jurisdictions.

like AI, real-world data, and personalized medicine prepare professionals to operate across borders (Vigilare, 2025). For example, Asia Pacific Economic Cooperation (APEC) Regulatory Harmonization Steering Committee regulatory science-based training programs exemplify how coordinated education can foster harmonized oversight across diverse regions (Thakkar, 2023).

Similarly, Ireland's NIBRT and the UK's Cell and Gene Therapy Catapult are updating their training programs to address gaps in process and product technologies, especially cell and gene therapies (CGTs), further illustrating the global momentum towards harmonized, skills-based training (IPQ, 2021).

Regulatory Science Education and Clinical Trials

Regulatory science education is essential for clinical trial professionals because it equips them with the core competencies required to design, conduct, analyze, and monitor clinical trials in compliance with evolving regulations and scientific standards. As clinical trials become more complex, especially with the rise of innovative therapies such as CGTs, and digital therapeutics, formal, competency-based education ensures that professionals can navigate the increasing demands for safety, efficacy, and quality in innovative medical products. A deep understanding of regulatory science enables professionals to interpret and implement regulatory guidelines, ensuring that clinical trials meet the stringent requirements set by regulatory authorities. This knowledge is vital for protecting participant safety, maintaining data integrity, and achieving regulatory approvals, which are all critical for bringing new therapies to market, through high-quality clinical trials (Succar, 2024).



Despite high education levels, regulatory science remains underrepresented in formal training.

■ Educational Strategies and Innovations

Competency-Based and Active Learning

Modern programs emphasize competency-based, experiential instruction over didactic lectures. Active learning strategies—such as simulation workshops, case-based learning, and team projects—move students beyond simplistic learning by improving engagement, enhancing critical thinking, and fostering practical decision-making, ultimately leading to deeper knowledge retention and more effective memory recall (Succar, 2024; Church, 2023; Moghissi, 2020; FDA website; NAS, 2016). For example, simulation-based curricula allow students to role-play as investigators, patients, regulators, statisticians, or ethics committee members, providing hands-on experience in protocol development, trial management, and regulatory decision-making (Succar, 2024; Church 2023).

Integration at the Undergraduate Level

Introducing regulatory science early—through minors or embedded coursework, or participation in regulatory science research projects—cultivates awareness and interest among science, engineering, and pharmacy undergraduates (Church, 2023). Early engagement in hands-on research not only builds enthusiasm but also helps students connect classroom learning to real-world regulatory practices. For example, USC's Pharmacy Undergraduate Program offers minors in regulatory science, providing

students with a strong foundation for advanced study and opening pathways to diverse careers in the biomedical industry beyond traditional pharmacy roles (Church, 2023).

Flexible and Modular Program Design

Given the diverse backgrounds and evolving career goals of regulatory professionals, educational programs must be flexible, modular, and responsive to learner needs. Many institutions now offer part-time, online, or hybrid formats to accommodate working professionals (RAPS, 2024; Institute of Medicine, 2012). Certificate programs provide targeted training for those seeking to enter the field or develop specific competencies, while master’s and doctoral degrees offer opportunities for advanced study and research (RAPS, 2024). The University of Southern California’s Department of Regulatory and Quality Sciences, for example, offers a suite of interdisciplinary graduate programs, including Regulatory Science, Regulatory Management, Management of Drug Development, Medical Product Quality, Clinical Trial Management, and Progressive Master’s option, each designed to integrate academic rigor with practical experience through internships and accessible learning formats. Similarly, institutions such as Temple University, Johns Hopkins, and Northeastern University offer flexible learning options that accommodate the needs of working professionals.

Experiential and Interdisciplinary Learning

Experiential learning remains a cornerstone of effective regulatory science education, offering students real-world experience and valuable networking opportunities through internships, fellowships, and industry partnerships (**Table 2**). Interdisciplinary curricula that draw from pharmacy, medicine, law, engineering, and business reflect the multifaceted nature of regulatory science (Adamo, 2015; Institute of Medicine, 2012). Incorporating resources from regulatory agencies, such as the FDA’s pilot case study programs on science-based drug approval decision-making, can enhance the practical relevance of regulatory science education (FDA website).

■ **The Future of Regulatory Science Education**

The future of regulatory science education will be shaped by ongoing scientific innovation, globalization, and the increasing complexity of healthcare products (**Table 3**). We believe that curricula will need to adapt to key trends such as:

- **Integration of Real-World Evidence:** Regulatory professionals must be adept at leveraging real-world data to support regulatory submissions and

Table 2.
Strategic Roles in Advancing Regulatory Science Education

Sector	Key Actions
Government	Fund education pathways, support faculty training, create legislation embedding regulatory science in policy
Academia	Create formal degree programs, align with global competencies, develop interdisciplinary faculty
Industry	Offer internships, co-develop curricula, support reskilling, fund academic partnerships
Accreditation Orgs.	Develop and adopt standards, promote mutual recognition of credentials

post-market surveillance (Vigilare, 2025; FDA website; Thakkar, 2023).

- **Adoption of Advanced Technologies:** Training in artificial intelligence, machine learning, and digital health will become essential as these technologies are integrated into regulatory processes (Vigilare, 2025; Moghissi, 2020; Ronkowski, 2025; Papadopoulos, 2021). Beyond technical training, AI-driven role-play tools and online platforms could also help democratize access to regulatory science education, providing interactive practice and specialized resources to learners worldwide.
- **Precision Medicine and Companion Diagnostics:** Curricula will need to address the regulatory challenges of precision medicine therapies and sophisticated diagnostic tools (Institute of Medicine, 2012; NAS, 2016).
- **Global Alignment:** As regulatory requirements both converge and diverge internationally, educators must prepare professionals to operate in a global context, understanding the nuances of different regulatory systems (FDA, 2022).

■ Priority Actions for Implementation

To address immediate barriers and ensure quality, relevance and scalability of regu-



The talent crisis isn't coming— it's already here. U.S. universities are struggling to meet demand.

latory science education we recommend:

- **Standardizing Core Competencies:** Implement recommendations coordinated by the Association of Graduate Regulatory Educators (AGRE) (<https://www.agreglobal.org/>) to develop and adopt standardized, competency-based curricula, while maintaining flexibility for institutional strengths and regional contexts (Succar, 2024; Adamo, 2015; Moghissi, 2020).
- **Fostering Cross-Sector Collaboration:** Encourage collaboration between academia, industry, and regulatory agencies to share faculty, develop course materials, and offer joint training experiences (Adamo, 2015).
- **Expanding Experiential Learning:** Increase access to real-world learning opportunities, including internships, agency rotations, simulations exercises, and case-based coursework, to bridge the gap between theory and practice (Succar, 2024; Institute of Medicine, 2012).
- **Promoting Lifelong Learning:** Develop

Table 3.
Future Curriculum Focus Areas

Emerging Area	Why it Matters
Real-World Evidence	Supports post-market analysis and regulatory submissions
Artificial Intelligence and Digital Tech	Used in drug safety, trial management, and decision-making
Precision Medicine and Diagnostics	Requires new regulatory frameworks and case-based learning
Global Harmonization	Develop and adopt standards, promote mutual recognition of credentials

and promote continuing education and professional development to help the current workforce keep pace with scientific and regulatory advances (Institute of Medicine, 2012).

■ Conclusions

Regulatory science education is the foundational driver of public health, innovation, and global regulatory preparedness. As the medical product landscape becomes increasingly complex, driven by technological innovation, global collaboration, and shifting health priorities, there is an urgent need to invest in comprehensive and accessible education for the next generation of regulatory professionals.

The evidence is clear: well-trained regulatory scientists improve public health outcomes, accelerate innovation, and support global alignment efforts. To sustain this momentum, regulatory science must be recognized and supported as a strategic health policy priority. This requires coordinated investment in competency-based curricula, faculty development, and experiential learning opportunities at all levels of education.

Going forward, academia, industry, and government must work together to scale education programs, harmonize core competencies, and ensure equitable access to regulatory training across regions. Only through sustained collaborative commitment can we build a resilient, future-ready regulatory workforce prepared to meet the challenges of tomorrow's healthcare ecosystem.

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