



The PhD scientist's pathway into regulatory affairs

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Making a transition from a life and health science research scientist to a regulatory affairs professional can be challenging. It is difficult to gain the requisite experience in an academic or industry research setting. However, the combination of an advanced science degree, transferable skills, and professional experiences can make this transition attainable.

Intellectual curiosity is often the impetus for pursuing a doctorate degree (PhD). The desire to learn a subject at a deep level often motivates scientists to dedicate years of their lives to becoming experts in their field. Graduate degree programs are well suited to train scientists to continue in academia, become postdoctoral fellows, and eventually, professors. However, it is increasingly common that these scientists seek opportunities beyond academia after their graduation. Once deemed “alternative careers” the nonacademic career path is now becoming the norm. For the first time, in 2019, the percentage of science and engineering PhDs employed in the private sector (42%) was nearly equal

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the percentage employed at educational institutions (43%).¹ Owing to decreasing academic funding, a greater number of PhD graduates, and an increased awareness of nonacademic careers, graduates are now working across the public and private sectors. Many prospective employees and employers are recognizing that the skills honed during one's graduate career are a good fit for the pharmaceutical industry. Project management, teamwork, initiative, perseverance, analytic thinking, attention to detail, and communication are ideal competencies for success in the pharmaceutical industry. One field of particular interest is regulatory affairs (RA).

Regulatory affairs

Within the US product development industry, the regulatory affairs profession is responsible for ensuring that food, cosmetics, drugs, biologics, and devices are appropriately developed from origination to distribution so that these products meet federally mandated standards for human use. Although the US Food and Drug Administration (FDA) has the ultimate responsibility to ensure the safety of these products, the expertise of the RA professional is instrumental in ensuring compliance with federal regulations and ensuring the products we use are safe and effective. RA professionals may work for biotechnology firms, pharmaceutical companies, contract research organizations (CROs), academic institutions, and even within government agencies such as the FDA.² For the purpose of this article, the various regulated industries such as pharmaceuticals, medical devices, or biotechnology companies with RA professionals will be termed "industry."

Within those organizations, the role of the RA professional can include:

- Preparing and submitting documents to regulatory agencies,
- Consulting with external clients on new laws or regulations,
- Making strategic business decisions regarding a product's future, or
- Working with pharmacovigilance for pre- and postmarket safety reporting.

These tasks require constant communication and collaboration with other departments such as quality assurance, clinical, nonclinical, product development, pharmaceutical development, and pharmacovigilance.

Although a PhD is not a prerequisite, more than half of all RA professionals have an advanced degree, with about 20% holding a PhD.³ The first step to this transition for a research scientist is to recognize that the skills obtained during their graduate career make the PhD-holding scientist well suited for a career in RA.

Transferable skills

Throughout their graduate career, PhD scientists develop significant skills that are advantageous for a career in RA. Some of the most transferable skills include meticulous attention to detail, strong oral and written communication skills, sophisticated analytic and strategic thinking, and the ability to work collegially across disciplines.

Detail oriented

By the end of their graduate career, PhD scientists have often developed a keen attention to detail through the interpretation and validation of research data. This skill is easily transferred to industry and can be demonstrated through a thoughtful CV presentation. Not only should the CV effectively communicate critical experience and articulate attention to detail, but the CV itself must be free from grammatical and formatting errors. An RA scientist will need to apply their detail-oriented skills as they author and review documents that include key scientific data, as well as read and interpret nuances in the regulations.

Communication skills

A PhD scientist is expected to present research not only to the scientific community, but to the general population as well. PhD scientists have gained experience in authoring and presenting data throughout their graduate careers, culminating in their dissertations. The experience of receiving constructive feedback from peer-reviewed manuscripts further improves these skills. Exemplary oral and written skills are vital in industry. An RA professional should speak with authority while explaining scientific rationales, concisely clarifying regulations and regulatory guidance for internal teams and clients, as well as senior management. For all these activities, an RA professional must have strong communication skills.

Analytic skills

PhD students spend years discovering, troubleshooting, and problem-solving. Along the way, they develop strong analytic skills as they creatively and critically evaluate their research results. The ability to quickly assess the regulatory environment, efficiently review large volumes of data, identify the optimal pathways for a given product and situation, and provide clear rationales supporting the solution are paramount in the RA industry. Fast-paced projects require complex information to be digested in a short amount of time, so an RA scientist's ability to gather and interpret these data are essential. An RA professional must be able to use these analytic skills to distill large amounts of data and assimilate disparate concepts into a coherent whole.

Teamwork

In academia, many research projects require collaboration with external labs or institutions as well as those within the internal academic research team. PhD scientists are responsible for training and managing more junior research assistants and negotiating the pathway for their project with the principal investigator. The ability to work effectively with fellow researchers, delegate tasks appropriately, and take initiative to accomplish a common goal is essential to being a productive scientist. Almost every project in industry is managed by a multidisciplinary team. A scientist will need to have professional and efficient interactions with outside stakeholders such as regulatory authorities, sponsor companies, and third-party vendors. They will also be responsible for training and helping develop experienced colleagues, reaching agreement with other stakeholders to ensure discipline-specific goals are met for a project, while also

ensuring an efficient and successful regulatory pathway. It takes skilled RA professionals working well and effectively with others to be successful.

Experience

In addition to key skills garnered in graduate school, there are other opportunities of which PhD scientists can take advantage in order to transition into a career in regulatory affairs. Joining professional organizations, such as the Regulatory Affairs Professionals Society (RAPS) and the Society of Clinical Research Associates (SOCRA), will help aspiring RA scientists network with experts in the field and learn more about the profession. Through connections made in these organizations, PhD scientists can even conduct informational interviews with industry professionals to learn about potential jobs or training opportunities.

The best way to acquire a job as a regulatory scientist is to first gain industry experience. Most regulatory scientist positions require several years of experience, but many entry level jobs will enable scientists to get a “foot in the door.” Organizations may hire scientists for positions such as regulatory associate, study start-up specialist, and regulatory coordinator, and often offer on-the-job training for individuals with limited regulatory knowledge. Academic institutions often have regulatory affairs offices that can also provide entry-level job opportunities. These positions can help scientists develop an understanding of and familiarity with clinical trials, which can be a useful experience for an RA professional. After a few years of work in the field, one can also obtain a Regulatory Affairs Certification (RAC) through RAPS, which demonstrates that the holder understands global product development regulations and how to apply them. This exam is administered in three windows throughout the year.⁴ This certification, in addition to work experience, will help advance a career in RA. In addition, a PhD scientist may consider starting off as a research and development scientist within a company. This introduction into industry starts with participating in the development efforts and continues by learning what it takes to bring the product fully to market. Over time, PhD scientists could transition from research and development into the RA field within a company.

Internships

Another way to gain experience in RA is through an internship. A PhD scientist may choose to offer their time as an unpaid, short-term intern to get a basic understanding of the profession or take advantage of a formal internship that exist through their graduate school or within industry.

The National Institutes of Health (NIH) has recognized that PhD scientists need immersive training opportunities for careers outside of academia and has introduced a grant to encourage innovative approaches to address workforce challenges.⁵ The agency has stated “that traditional research-intensive positions are not the only means by which PhD graduates can meaningfully contribute to the biomedical research enterprise.” It has created a funding source for graduate students in the biomedical research space, termed Broadening Experiences in Scientific Training awards, also known as the BEST awards.

The Strengthening Biomedical Research Workforce program issued awards starting in September of 2014 and has provided graduate students and postdocs the opportunity to gain career experience through a formal internship. This five-year funded research program was initially awarded to seven institutions.⁶ During the program, the various universities investigated the efficacy of the internships over the course of the BEST awards and tracked career outcomes. Numerous publications were written analyzing the skills and experiences of the trainees of this grant.⁷ The findings showed that internships were seen as effective career exploration and self-development vehicles that influenced participants' long-term career goals. Graduate students and postdocs reported gaining transferable knowledge and skills, in addition to receiving valuable industry mentoring and networking opportunities.⁸

Although the initial funding of the BEST award has since ended, the participating universities have been able to secure alternative funding to continue the internship program by integrating this training opportunity into their institutional infrastructure and culture. In addition, the institutions have also provided guidance to other universities wanting to start similar programs.⁹

Since the inception of this NIH grant program, CATO SMS, a CRO based in Research Triangle Park (RTP), NC, has offered internships to more than 20 recipients of the NIH BEST grant. This grant provided a mutually beneficial opportunity for the scientists to work within industry part-time for 8 to 10 weeks. The interns received exposure to educational seminars and work projects in clinical strategy, chemistry manufacturing and controls, nonclinical safety, and RA. Throughout this experience, the interns worked closely with project teams and were involved in producing key deliverables for products across all stages of development, often taking full ownership of the work. This experience was invaluable to these scientists, showing them firsthand what the day-to-day work life could be like for a PhD scientist in industry, and to help them determine whether a private sector position might be a good fit for them in the future. After completion of the internship, the scientists were able to enter the market in a more competitive position. Analysis of their eventual place of employment showed that almost 90% of past-CATO SMS interns are now working in the drug development industry.

In addition to the RTP office, CATO SMS also offers internships to master's level students to match the requirements for the university programs in its Amsterdam, Netherlands, location. For the past 3 years, it has provided internships to students from various Dutch universities and has accommodated different programs, from science and business to science and management tracks. These internships last about 6 months, with the initial focus on establishing a sound research question. They are organized and managed by the consulting team within CATO SMS and are designed to reach students at an earlier stage in their graduate studies, helping them develop their thesis with real-world oncology clinical trial data. Recent theses topics have included cancer immunotherapy, adaptive trial designs, and digitalization of clinical trials. These experiences help prepare the intern for a career in industry even before they

might consider a shift away from academia. More than 75% of the interns at the Amsterdam location were offered positions in the drug development industry.

A number of other internships are available within industry and at the FDA. Genentech provides students with hands-on biotechnology experience along with learning and networking opportunities as they work alongside biotech experts at three of the company's California locations its Hillsboro, OR, location.¹⁰ Johnson & Johnson provides interns with practical, industry-specific, scientific and analytic experience to students enrolled in a PhD program in a science-related field.¹¹ At the FDA, a medical device summer fellowship program was previously available to learn more about the FDA regulation of medical devices.¹² Although funding for that program is not available in 2021, there continues to be numerous student opportunities at the agency.¹³

Fellowship programs in industry

A PhD scientist may also seek out entry level programs offered within industry that provide on-the-job training in RA.

The Integrated Product Development Associate program is available at Rho, a CRO based in Durham, NC.¹⁴ Rho recruits recent PhD graduates who aspire to enter the pharmaceutical industry. This 2-year program offers both clinical and regulatory exposure by first introducing trainees to all documents prepared as part of the product development process. The program is structured to impart an overall understanding of the complete product development process with classroom lectures and workshops. Given the 2 years of experience trainees acquire, they are encouraged to achieve their RAC at the end of their training program.

GSK, also located in Durham, NC has collaborated with leading US academic institutions through sponsorship of joint fellowship programs. Currently, their 2-year programs focus on medical affairs, RA, pharmaceutical outcomes research, and product information. Most graduates of these programs have gone on to successful industry or academic careers. In addition, a number of fellowship opportunities are available at the FDA for graduate and postgraduate students seeking experience in regulatory science.¹⁵ Fellowships allow for PhD scientists to enhance their careers through close exposure with leading authorities in health-related research.

Since 1989, the Cato Research [now CATO SMS] Fellows program has provided the opportunity for graduates of some of the world's most highly regarded programs to facilitate a transition in their careers from academia into drug development. The program provides rigorous, comprehensive, cross-disciplinary training in clinical research and product development. Fellows participate in course work, interactive learning, on-the-job training, and discussions in diverse areas such as regulatory and medical writing, clinical trial monitoring, and drug development strategies. At the start of the program, fellows are assigned a mentor who provides guidance, insight, coaching, and support. CATO SMS scientists and industry experts also guide and interact with the fellows throughout the 12-month training program. Fellows also receive extensive on-

the-job training and are strategically assigned to projects from early drug discovery to phase 3 or 4 clinical trials to maximize their exposure to clinical research and drug development. Project work includes various activities such as drug development plans, protocol design, regulatory strategy development, FDA-meeting preparation, project plan development, and clinical trial management.

Research to regulatory

There is no “typical career path” from graduate scientific research to RA, however, there are plenty of PhD scientists who have successfully made this transition, including the two featured here:

- **Sheila Plant, PhD, MHS, RAC**, senior director of regulatory affairs at CATO SMS, received her PhD in neurobiology from the University of North Carolina at Chapel Hill. Following a postdoc in the Duke University Medical Center’s Division of Neurology, she enrolled at Duke University and obtained a master’s in health sciences (MHS) from the Clinical Research Training Program. While in the MHS program as a clinical research fellow at Duke University, Plant was able to author protocol-related documents and design and execute clinical research within the division of neurology. She moved onto a position as regulatory coordinator in the Duke University Medical Center for Gastrointestinal Oncology, where she was able to submit initial investigational new drug reports for oncology investigator sponsored trials as well as coordinate all regulatory and start-up activities for those clinical trials. That position prepared her for entry to the industry as a regulatory and start-up specialist at Quintiles (now IQVIA), where she specialized in informed consent forms and study start-up activities. Shortly afterward, Plant joined Cato Research (now CATO SMS) as a regulatory scientist, authoring and reviewing various regulatory, clinical, and scientific documents. For the past few years, in addition to managing new drug marketing applications, she has contributed significantly to the scientific and analytic discussions and reports related to her drug, biologic, or device projects and is a well-seasoned regulatory affairs professional.
- **Robert McNeill, PhD, RAC**, made the transition into industry by taking advantage of the NIH BEST funding. While obtaining his PhD from the University of North Carolina at Chapel Hill, McNeill was selected as an ImPACT Scholar (the BEST award-Immersion Program to Advance Career Training). He was placed into CATO SMS for an 8-week internship in which he assisted in authoring an FDA application for a fast track designation and developing regulatory document templates, reviewed published manuscripts, authored summary tables, and participated in internal and sponsor meetings. Shortly after the culmination of his internship, McNeill was hired by CATO SMS as a fellow and eventually became a clinical strategy scientist and ultimately, director of clinical strategy before moving to Kowa Research Institute, as the associate director of regulatory affairs.

Conclusion

Making a transition from research scientist to regulatory affairs can be challenging; however, the skills and training a PhD scientist receives in their graduate studies prepares them for a career in the RA industry. Candidates

should demonstrate initiative to obtain industry experience, which may include an unpaid, short term internship to get a basic understanding of the profession. The combination of transferable skills and experience provides a solid foundation of critical characteristics that can help facilitate the shift into a productive career in RA. Once in the field, the PhD RA scientist can leverage their innate inquisitiveness, the dedication to detail, and RA experience in complex regulatory environments to chart a product's optimal path to market. A career dedicated to ensuring the safety and availability of new therapeutics and devices can be a meaningful way to transfer the graduate school experience beyond the academic setting.

Abbreviations

CRO, contract research organization; FDA, Food and Drug Administration; MHS, master's in Health Sciences; NIH, National Institute of Health; RA, Regulatory Affairs; RAC, Regulatory Affairs Certification; RAPS, Regulatory Affairs Professionals Society; RTP, Research Triangle Park; SOCRA, Society of Clinical Research Associates.

About the author

Laura DiMichele, PhD, RAC, CCRP, is vice president of clinical strategy and principal scientist at CATO SMS. She has more than 19 years of clinical and translational research experience, with 12 years' experience in regulatory affairs. She received her doctorate in cellular and molecular pathology from UNC Chapel Hill. She holds the RAC from the Regulatory Affairs Professionals Society, as well the Certified Clinical Research Professional (CCRP) from SOCRA. She can be contacted at Laura.DiMichele@cato-sms.com

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References

1. Langin K. In a first, US private sector employs nearly as many PhDs as schools do. <https://www.sciencemag.org/careers/2019/03/first-us-private-sector-employs-nearly-many-phds-schools-do> Published online 12 March 2019. Accessed 15 April 2021.
2. Joubert S. Working in regulatory affairs: Careers, salaries, and trends. <https://www.northeastern.edu/graduate/blog/working-in-regulatory-affairs-careers-and-trends> Published online 8 July 2020. Accessed 15 April 2021.
3. Schomisch J. Profile: Regulatory Affairs Professionals Society (RAPS). <https://onlinelibrary.wiley.com/doi/pdf/10.1002/qaj.102> Qual Assur J. 2001;5:53-6. Accessed 15 April 2021.
4. Regulatory Affairs Professionals Society website. How to apply for the RAC. <https://www.raps.org/rac-credential/applyrac/how-to-apply-for-the-rac> Accessed 15 April 2021.
5. National Institutes of Health website. NIH announces awards to strengthen the biomedical research workforce. <https://www.nih.gov/news-events/news-releases/nih-announces-awards-strengthen-biomedical-research-workforce> Published online 23 September 2013. Accessed 15 April 2021.
6. National Institutes of Health: Common Fund Programs. Strengthening the biomedical research workforce. <https://commonfund.nih.gov/workforce/fundedresearch> Last reviewed 4 January 2018. Accessed 15 April 2021.
7. National Institutes of Health: Common Fund Programs. Publications search by programs. <https://commonfund.nih.gov/publications?pid=33> Last updated 2 February 2021. Accessed 15 April 2021.
8. Chatterjee et al. Exploring the impact of formal internships on biomedical graduate and postgraduate careers: An interview study. <https://www.lifescied.org/doi/full/10.1187/cbe.18-09-0199> Published online 10 May 2019. Accessed 15 April 2021.
9. Lara LI, Daniel L, Chalkley R, eds. Implementing career development activities for biomedical research. Academic Press; 2020.

10. Genentech website. Internships and co-ops. <https://www.gene.com/careers/university-and-early-career/interns-co-ops> Accessed 15 April 2021.
11. Johnson & Johnson website. Careers: 2021 research and development summer internship. <https://jobs.inj.com/jobs/7432200131?lang=en-us> Accessed 15 April 2021.
12. Food and Drug Administration. Medical device fellowship program: Opportunities. <https://www.fda.gov/about-fda/medical-device-fellowship-program-physicians-engineers-scientists/medical-device-fellowship-program-opportunities> Current as of 3 March 2018. Accessed 15 April 2021.
13. USAjobs website. www.usajobs.gov Accessed 15 April 2021.
14. Rho website. https://www.rhoworld.com/?gclid=Cj0KCQjwo-aCBhC-ARIsAAkNQivYEclQ8Wl8Pa6GDcmF_1q9Z3jfHSZk23jatCfxqfMaW7it2w7E2QYaAlpfEALw_wcB Accessed 15 April 2021.
15. Food and Drug Administration. Scientific internships, fellowships/trainees, and non-US citizens. <https://www.fda.gov/about-fda/jobs-and-training-fda/scientific-internships-fellowships-trainees-and-non-us-citizens> Current as of 24 January 2021. Accessed 15 April 2021.