Training needs in regulatory science for the biopharmaceutical industry

For regulatory affairs professionals as well as newly hired scientists, a solid grasp of regulatory science is needed to succeed in pharmaceutical R&D.

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The regulatory affairs professional not only must read and understand each regulation, but must have an appreciation of its place in the regulatory “milieu.” This requires that he or she have a thorough understanding of the history of the FDA and of a particular regulatory document, as well as an appreciation for the evolution of the regulatory process on a worldwide basis. It is imperative to have an understanding of not only the words contained in a regulatory document, but the intended result envisioned by the individuals who drafted that regulatory document. Also, in order to adequately interpret that regulatory document to colleagues, the regulatory professional must have a clear understanding of the organization, procedures, and resources of his or her own company.

How do regulatory affairs professionals attain the knowledge of the regulatory aspects of their job? When I started as a regulatory professional in this industry, the learning process was primarily one of “jumping into the deep end of the pool and learning how to swim.” This was greatly assisted if one could find, as I did, an outstanding mentor who had already learned the trade in a similar manner. Over the years, a number of organizations, such as the Regulatory Affairs Professional Society (RAPS), the Drug Information Association (DIA), the Food and Drug Law Institute (FDLI), and international organizations like the European Society of Regulatory Affairs, have taken an increasing role in providing educational meetings for the regulatory affairs professional.

As an alternative, one can attend a growing number of meetings presented by commercial training companies, such as Parexel-Barnett and the Pharmaceutical Education and Research Institute (PERI). A number of colleges and universities offer courses related to regulatory affairs. In addition, a few universities offer fully accredited degrees in regulatory affairs, including Temple University, Long Island University, San Diego State University, the University of Massachusetts, and starting this fall, the University of Southern California.

The newly hired scientist

On its web site, the California State University Program for Education and Research in Biotechnology (CSUPERB) has posted tables extracted from the Massachusetts Biotechnology Directory listing the many types of individuals who work within the pharmaceutical research and development arena. Besides regulatory affairs professionals, they include highly educated and trained professionals in a wide variety of disciplines: chemists, pharmacologists, toxicologists, clinicians, pharmacokineticists, biostatisticians, and process engineers, among others. Most have received an education in their particular specialty at a college or university, and have been hired based on their outstanding knowledge of these specialized areas. But unfortunately, these scientists have not been exposed to the basic regulatory concepts of Good Laboratory Practices (GLP), Good Clinical Practices (GCP), or current Good Manufacturing Practices (cGMP) as part of their scientific training. They do not comprehend that, through the workings of committees like the International Conference on Harmonization (ICH), these concepts are being standardized internationally. But once they join the company, they too must comply with the many laws and regulations as they fulfill their research or development responsibilities.

How do they learn how to do this? Currently, each department must have a series of standard operating procedures (SOPs) detailing all the key activities within that department. Individual members of the department must be trained regarding the application of and adherence to these SOPs. These SOPs often focus on the rigorous documentation of nearly every aspect of their daily activities. This level of documentation is an order of magnitude beyond that which the scientists learned and applied during their educational training.

When such a highly trained individual first joins a company, this high level of detail regarding procedures and documentation is often confounding and confusing. The SOPs are perceived as “unnecessary corporate bureaucracy”, with little or no value. They seem to get in the way of the
individual’s creative endeavors. In addition, the newly hired scientist, used to working alone to complete the research necessary to write his or her thesis, does not appreciate where he or she fits into the organization. It often takes a long time for these professionals to realize that research and development is a team activity. They do not immediately know the goals of that team, or how their work relates to these goals. Finally, they have no understanding of the scope of the regulatory restrictions that need to be satisfied, or the historical evolution of the regulatory process.

Without a clear understanding of the historical perspective of the regulatory process, the intent of each of these regulations, or even a clear understanding of their company’s organization, these highly educated and creative individuals often fail to comply with the SOPs, and thus the regulations governing the company’s activities. This can have a significant impact on the company, especially if FDA investigators audit the individual’s data or reports.

Back to school
So how can a newly hired scientist gain the understanding he or she needs regarding the regulations and their importance? Company training staffs and facilities are routinely overwhelmed with training new hires in basics such as cGMPs and new SOPs, and often they themselves do not have the training or understanding of the historical evolution or intent of these many required regulatory procedures.

Fortunately, a small number of colleges and universities are now offering degrees in regulatory affairs. Each has, as part of their degree curriculum, introductory foundational courses that outline the health care product research and development process and the regulatory oversight of that complex process. While the full degree program may only be appropriate for the individual in regulatory affairs, or contemplating a career move into regulatory affairs, one or two of these introductory courses will clearly benefit the newly hired scientist. They are routinely available to be taken individually through a university’s extended studies branch, and some courses are now becoming available as online, Internet-based, distance-learning presentations, and thus are accessible to the staff of companies who are remote from the

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<th>Resource</th>
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<tr>
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<td>San Diego State University, Master of Science in Regulatory Affairs</td>
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<tr>
<td>Temple University College of Pharmacy, Graduate Program in QA/RA</td>
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<tr>
<td>University of Southern California, Masters Program in Regulatory Science</td>
<td><a href="http://regulatory.usc.edu">http://regulatory.usc.edu</a></td>
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<tr>
<td>California State University Program for Education and Research in Biotechnology (CSUPERB), Massachusetts Biotechnology Council’s overview of biotechnology industrial jobs</td>
<td><a href="http://www.csuchico.edu/csuperb/MBC_JobsImages.html">http://www.csuchico.edu/csuperb/MBC_JobsImages.html</a></td>
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The existence of FDA guidelines and guidance to assist them in their daily work. All of this will lead to greater compliance with existing company SOPs and an appreciation for their contributions toward successful attainment of the team’s goals. Finally, adequate basic training of all new research and development team members in the basics and historical background of the regulatory process will facilitate future interactions with members of the regulatory affairs staff, making for more productive discussions about the inevitable new regulations.

Get a head start
Considering the importance to the young scientist headed for a career in biotechnology of some basic training in regulatory affairs, it seems imperative that undergraduate and graduate educators incorporate some of these basic concepts into their curriculum. The concepts of SOPs and adequate documentation should be an integral part of their laboratory training. And an elective course in basic regulatory affairs, exposing the students to the concepts of GLP, GCP, and cGMP, would be a valuable addition to the college or university’s offering. Although the expertise for such a course may not be readily found within your current faculty, there is a high likelihood that there is a regulated pharmaceutical, biotechnology, or medical device company nearby. They probably have a regulatory affairs professional who would be willing to design and teach a basic regulatory affairs course or two, as an adjunct faculty member. Such a course could provide a significant added value to your “product”—your highly trained scientists.