

Q&A: The role of regulatory affairs

With James Ottinger, Vice President of Regulatory Affairs and QA for Premier Research Group.

NGP. What do you see as the role of regulatory affairs in the pharmaceutical industry?

JO. Virtually every process in the pharmaceutical industry is regulated in some way. The industry attracts top scientific talent with expertise across an array of disciplines, including chemists, toxicologists, statisticians, physicians and business leaders, which form the drug development team. The role of regulatory affairs is twofold. One is to develop and execute a regulatory strategy to ensure that the collective efforts of the drug development team results in a product that is approvable by global regulators but is also differentiated from the competition in some way. The second is to ensure that the company's activities, from non-clinical research through to advertising and promotion, are conducted in accordance with the regulations and guidelines established by regulatory authorities. This broad remit covers activities beginning in the non-clinical laboratories, and continuing throughout the entire clinical development phase, marketing and lifecycle of a product.

NGP. Given the broad remit you describe, how can a regulatory professional be able to maintain expertise in so many areas?

JO. The goal is not to become an expert in each area, but to be knowledgeable to the extent that one knows how they interrelate and fit together in the regulatory puzzle we call the NDA, which is the ultimate deliverable of the drug development process. All companies – big pharma or small virtual companies – have either internal experts or external consultants that drive the science behind drug development. However, it is often the case that the individual experts have no idea how their work can affect the entire process and impact labeling. It is up to the regulatory professional to lead the team in this area to ensure that all of the pieces fall into place and meet the expectation of the company and the regulators.

NGP. You mention both big and small companies, does the role of the regulatory professional change with company size?

JO. The overall role of the Regulatory Affairs as a function does not change; we all must meet the same basic requirements because the FDA does not alter its regulatory positions based on company size or finances. However, the role of the individual regulatory professional may change dramatically. At most large companies, the regulatory function is very broad but the individual staff responsibilities are very narrowly focused in specific areas such as CMC, nonclinical or clinical development, advertising and promotion, international or regional regulatory affairs, operations versus regulatory strategy, investigational versus marketed product support, and so forth. There is really



no limit to the ways you can slice and dice the function when delivering regulatory affairs at a global level. Conversely, in small companies, a single individual or a small team may have total 'cradle to grave' coverage of the drug product.

NGP. You have worked both on the sponsor side of the industry at Wyeth Research and now on the service side of the industry at Premier Research. How do you compare the regulatory affairs role in each?

JO. It is entirely the same in many aspects but completely different in others. It is the same as the rules and regulations governing drug development effectively mean one focuses on the same goals; for example, a 'pre-IND meeting' is a 'pre-IND meeting' so the work required to prepare for one is similar. The regulatory professional simply replaces a pharmaceutical company's 'project team' with a CRO's 'clients'. A big difference on the service side is the scope of the responsibility and the breadth of the experience encountered in a small period of time. There is an insurance company slogan *Life comes at you fast* and I think this describes the difference to a certain extent. On the service side of the business, clients need regulatory services for all types of drugs, devices and combination projects in the entire universe of indications. The diversity can be challenging but also exhilarating. Another huge difference can be the lack of bureaucracy on the CRO side, which is quite refreshing.



James Ottinger

NGP. What are your views on outsourcing regulatory affairs in the pharmaceutical industry?

JO. Functional outsourcing of regulatory affairs is currently done by many companies, and it is growing. For small or virtual biopharmaceutical companies it is a method to bring extensive regulatory experience into an organization in a cost effective manner. For companies with a single or a limited number of projects, recruiting and hiring full time regulatory support can be both difficult and expensive. Outsourcing to a CRO can provide a small company with a wealth of regulatory experience at limited costs. We find that we can assign a 10 or 20 year regulatory veteran to the task of developing and executing the regulatory strategy for a company for a fraction of the cost that it would take to hire a similar individual internally. This cost effectiveness and the ability to provide a therapeutic focus in areas such as CNS, analgesia and oncology drives the outsourcing model for us. ■