by Taren Grom

Regulatory Science & REGULATORY AFFAIRS

As the FDA continues to implement its strategic plan for regulatory science, the role of regulatory affairs becomes ever-more important.

Regulatory professionals are more indispensable than ever. They play key roles in all aspects of bringing medical innovations to market, and uniquely combine strong expertise in medical science, regulation, business, and strategy.

Regulatory affairs groups play a pivotal and ever-expanding strategic role in the success of compounds, brands, and companies, according to a report from Cutting Edge Information (CE).

Regulatory teams enable organizations to navigate an increasingly complex, global healthcare landscape amid the growing array of regulatory bodies, different and constantly updated guidances, and often struggling product pipelines.

Skilled Regulatory Affairs Professionals

From a sponsor perspective, having a skilled workforce well-versed in understanding the complexities of regulatory science cannot be underestimated.

In fact, the Regulatory Affairs Professionals Society's (RAPS) 2012 Scope of Practice & Compensation Report for the Regulatory Profession, found that regulatory professionals are highly valued by companies in the life-sciences and healthcare products sector.

Because regulatory professionals are performing varied, vital work they are being rewarded with increased compensation. According to the study, regulatory professionals' base salary and total compensation grew in the United States, Canada, and some European countries despite a tough global economy and workforce cutbacks in areas such as pharmaceuticals. In North America, base salaries increased by 4%, and total compensation grew by an average of 3%. Over the past decade, total compensation has grown by 29%.

"While many life-sciences companies have downsized, the results of this study show that regulatory professionals are more indispensable than ever," says RAPS Executive Director Sherry Keramidas, Ph.D. "They play key roles in all aspects of bringing medical innovations to market, and uniquely combine strong expertise in medical science, regulation, business, and strategy. The fact that compensation continues to rise shows employers recognize their value."

The work of regulatory professionals has evolved over the past decades and has shifted from an emphasis on compliance to a more varied scope of practice that includes involvement in the full product lifecycle from product development through submission, manufacturing and postapproval, including business and regulatory strategy.

According to a recent CE report, the most important factor contributing to coordination with a regulatory agency is the experience of the regulatory affairs team. A number of surveyed companies point out that experience is becoming a necessity and nowhere is the benefit of experience more evident than when dealing directly with regulatory agencies.

The need for experienced regulatory affairs professionals will continue to grow particularly as the FDA continues to implement its strategic plan for regulatory science, which was put into place two years ago.

A Planned Approach to Regulatory Science

The initiative identifies eight priority areas essential to the continued success of the FDA's public health and regulatory mission. The plan is wide-ranging, with its target areas including personalized medicine, food safety, and medical countermeasures to protect against threats to U.S. health and security.

Critical to this plan is gaining acceptance around the term regulatory science, which provides the evidence that the FDA needs to know that products such as drugs, medical de-

DR. SHERRY KERAMIDAS
RAPS Executive Director

Writing the Book on Drug Promotion

The Regulatory Affairs Professionals Society (RAPS) has published a new book that covers the regulation of pharmaceutical marketing and promotions by the FDA. The book, FDA Requirements for Prescription Drug Promotion, by John Driscoll, addresses topics such as fair balance, material facts, off-label promotion, and Internet and social media communications.

"The book is really intended both for those who are new to the field as well as experienced regulatory professionals," Mr. Driscoll says. "For those with only limited experience or those who are involved in other related areas of the industry, for example marketing and medical affairs, I think the book can serve as a comprehensive curriculum for learning FDA's requirements for prescription drug promotion. For established regulatory affairs professionals, the book is primarily intended to serve as a go-to reference for all the publicly available information on these topics."

FDA Requirements for Prescription Drug Promotion is available from the RAPS Store both in print and as an e-book for $44.95 for RAPS members, or $54.95, plus shipping, for nonmembers.

vices, vaccines, cosmetics, and foods are safe for consumers. Regulatory science makes it possible for the FDA to evaluate the safety and effectiveness of advancing technology, and to get innovative products to consumers as quickly as possible. According to FDA officials, it is difficult to count the number of ways in which this research affects the daily life of the average American consumers.

Regulatory science is about developing the knowledge, tools, standards, and approaches for the FDA to do its job better.

According to Douglas Throckmorton, M.D., deputy director of the Center for Drug Evaluation and Research (CDER), regulatory science is an important part of developing new medicines for diseases, such as Alzheimer's, cancer, and diabetes.

"First, regulatory science helps us identify what patients are likely to benefit from the uses of new medicines and helps us identify those benefits earlier with better precision," he says.

Dr. Throckmorton adds that regulatory science also provides insights into who is going to benefit from the uses of new medicines leading to the approval of those medicines.

One recent example of the impact of regulatory science led to the FDA approving the first genotyping test for patients with the hepatitis C virus.

The FDA based its approval of the Abbott RealTime HCV Genotype II, in part, on the assessment of the test's accuracy in differentiating specific HCV viral genotypes compared with a validated gene sequencing method. The FDA also reviewed data from investigators demonstrating the relationship between HCV genotype and effectiveness of drug therapy.

The Abbott RealTime HCV Genotype II, which can differentiate genotypes 1, 1a, 1b, 2, 3, 4, and 5, using a sample of an infected patient's blood plasma or serum, will aid healthcare professionals in determining the right approach to treatment. Because the various HCV genotypes respond differently to drug therapies, knowing the type of HCV a person is infected with can result in better patient outcomes.

"Second, regulatory science is giving us new tools to predict the safety of drugs earlier, so that adverse events don't happen to patients and if they do they can be treated more quickly," Dr. Throckmorton says.

According to Stephen Spielberg, M.D., Ph.D., the FDA's deputy commissioner for medical products and tobacco, the growing understanding of the human genome has opened new horizons for understanding the mechanisms of disease, for developing new diagnostic tests to uncover the cause of individual patient symptoms, and for developing new medical products targeted to specific causes of illness.

"This is the heart of personalized medicine — the right dose, the right medicine for the right indication for the right patient," he says. "Regulatory science helps us convert therapeutic innovation into practical approaches to speed the development of new products, to assure the safety and efficacy of those products, and to improve the diagnosis and treatment of all patients." PV

VIEWPOINTS

BHASKAR SAMBASIVAN
VP and Head of Life Sciences
Cognizant

Technology Opens Up New Avenues

As the pharma business model is moving toward an integrated influencer model involving patients, payers, consumers, and pharmacies from the traditional physician-focused model, many organizations are increasingly using social, mobility, analytics, and cloud computing technologies to build new types of innovation ecosystems to gain insights, ideas, and inspiration from both employees as well as external sources, including customers, partners, and even competitors. Whether its utilizing insights and analytics to identify the personalized and most cost-effective therapy or using social media to engage with customers, new modes of technology will continue to play a significant role. For life-sciences companies, this opens up new opportunities to connect with consumers, to communicate the value proposition throughout a product's lifecycle, and to improve health delivery and patient outcomes.

CHRISTOPHER JOCK
VP, Global BPO Practice Lead
Kelly Outsourcing and Consulting Group

New Organizational Models Needed

Organizations from different parts of the healthcare industry are faced with the challenge to provide a more efficient system as the proliferation of new technologies become more complex and products become more specialized. In order for the industry to realize the savings these technologies will provide, healthcare is embracing innovative organizational models designed to create environments where complexities can be reduced. These organizational models will catalyze the industry to a more productive status and cause a paradigm shift in attitudes and behaviors.