

INTRODUCTION

The regulatory profession has evolved in many ways over the past few decades.

First, many embraced the profession with scientific or clinical background with no formal regulatory education or systematic training in regulatory affairs. Therefore, most have learned on-the-job. While many have become very successful regulatory professionals, having gained important knowledge and profound experience and made significant contributions to industry, lack of formal training has limited the entry of new professionals and presented a steeper learning curve. Over the past decade, many universities have begun training programs in regulatory affairs and quality assurance, offering accredited diplomas and degree programs.

Second, the role of the regulatory professional has been refined from an operational one to a strong, visible and strategic leadership function, to address the changes in and add value to the pharmaceutical industry. Many regulatory professionals have evolved with this changing expectation and business landscape; however, a number of industry regulatory team members have not fully grasped this strategic expectation that regulatory is now a necessary business partner in industry. A clear definition of the regulatory professional's role, required competencies and expected goals will enable thoughtful recruitment strategy and will significantly improve the contribution of the regulatory professional.

Third, as the biopharmaceutical industry pursues high-quality therapies to address increasingly complex medical needs, it faces a set of challenges arising from globalization in a heterogeneous world, an evolving regulatory landscape and the expectations of multiple stakeholders. There is a strong need and sense of urgency for products that are acceptable and commercially successful across global regulatory systems, thus understanding and planning for regulatory challenges, and leveraging regulatory opportunities simultaneously across global systems, provides competitive advantage.

Regulatory assessments have become more stringent as existing alternative therapies modify the regulatory approval threshold and the speed of information flow among regulatory authorities influence regulatory decisions. Multiple stakeholders determine new product market entry and patient access, including regulators, payors, physicians and patients. Each group has become increasingly demanding for product differentiation and value-added from existing products. Like the biopharmaceutical industry, these groups are focused on the patient and are equally determined to provide favorable benefit-risk ratio from the products. These business imperatives and the focus on expedient patient access for unmet medical needs underscore the need for the regulatory professional to become an integral, strategic contributor and business partner, while ensuring rigorous product assessment for success in the current environment.

Note: In order to provide the most up-to-date information, some of the facts provided in *Global Regulatory Systems: A Strategic Primer for Biopharmaceutical Product Development and Registration* were obtained from individual regulatory agency web sites. The strategic applications provided are from my professional experience.

Dr. Henrietta Ukwu, MD, FACP, FRAPS