Evolution of the regulatory intelligence profession

Daanish Ashraf, PharmD, and Kirsten Messmer, PhD, RAC

Regulatory intelligence has gained significant importance with increasingly global considerations for product development, clinical trials, and submissions to ensure market access in key regions. The regulatory intelligence profession, tasked with providing strategic input to ensure regulatory compliance, has evolved to fulfill the additional needs of various departments within the company and by senior leadership by strategically analyzing relevant regulations and product competitive landscapes. The increased complexity of products and implementation of technological innovations is again changing the demands on the regulatory intelligence professional. This article provides an overview of the evolution of the regulatory intelligence profession over the past 2 decades and examines its possible trajectory during the next 5-10 years.

Introduction

Emerging technologies and systems for monitoring regulatory requirements need to be implemented to address the challenges created by the rapid regulatory developments. The scale and complexity of those developments have outpaced the ability of in-house teams of regulatory affairs professionals, which are typically small, to effectively manage compliance. Next generation

regulatory intelligence systems and technologically advanced solutions have become an immediate need.

Artificial intelligence (AI), a maturing technology, is increasingly explored for its application to regulatory compliance and intelligence monitoring. The implementation of AI into state-of-the-art regulatory intelligence monitoring presents unique opportunities for surveillance, for example, of new regulatory information and formal and proposed regulations. This AI-enabled surveillance provides strategic advantages, allowing the regulatory professional to develop proactive strategy and make more efficient proactive compliance modifications, thereby reducing the burden of reactive compliance adjustments.[1]

In the current environment, regulatory intelligence is generally the monitoring, gathering, and analyzing of publicly available and experience-based regulatory information needed to develop a strategy for time- and cost-saving drug development. Regulatory intelligence is not just information and knowledge management. There is a need to put the "intelligence" into the collected regulatory information by conducting an impact analysis and efficiently disseminating findings to build strategies. Regulatory intelligence adds value to the information and can also help shape the environment to create a competitive advantage.

> *An organization's ability to learn and translate that learning into action rapidly is the ultimate competitive advantage.*
> Jack Welch, PhD, former chairman and CEO of General Electric[2]

Information overload, caused by the evolution of information technology, is a common phenomenon experienced by regulatory intelligence professionals – there is just too much information becoming available at an ever-increasing speed. The increasing volume of information released by health authorities, databases, social media, internet resources; and the necessity to develop globalized strategies addressing increasing numbers of jurisdictions contribute to the pressure on regulatory intelligence professionals to work through this information effectively. Regulatory intelligence professionals serve as filters for this information overflow, capturing and analyzing the pertinent information based on business priorities. Regulatory intelligence professionals can support business success in many ways, for example, by developing robust strategies through regulatory landscape knowledge (including precedent and surveillance), aligning understanding of regulatory requirements through education, reducing the risk of noncompliance, and analyzing the impact of regulatory requirement changes to ensure continued compliance. In addition, regulatory intelligence professionals are in a unique position to influence the external environment, including regulatory agencies and policy makers through interaction, advocacy, and providing comments in response to new guidance and/or policy documents issued by regulatory agencies.

Regulatory intelligence professional survey, 2019
Methodology
The fourth iteration of a web-based, industry-wide survey on the regulatory intelligence profession was conducted from 12 March to 15 April 2019.

(Previous surveys were in 2002, 2007, and 2013) Participant solicitation was used to ensure there was only one participant per company to obtain a cross-section of the industry and avoid multiple respondents from the same company distorting the data. Respondents accessed the 32-question survey through Google forms. It included an optional question and allowed for free-form feedback. Limitations of the survey include that the questions and participants changed during the period the surveys were conducted.

Findings

Participant metrics. There were 38 participants in the 2019 survey, reflecting a steady increase over the previous surveys (7 participants in 2002; 14 in 2007; and 29 in 2013). Most of the 2019 respondents (71%) worked in companies with more than 1,000 employees, although smaller companies, with fewer than 100 employees, were also well represented (21.1%).

Respondents indicated the number of regulatory affairs employees at their companies remained small, with more than half (55.3%) saying there were fewer than 100 regulatory affairs professionals at their company (**Figure 1**). The number of regulatory intelligence professionals within regulatory affairs departments was even smaller, with 52.6% of respondents indicating there were only 1-3 employees focused on regulatory intelligence at their company. Only 7.9% of respondents said there was no regulatory intelligence function, suggesting that even smaller companies recognize the importance of the regulatory intelligence function. However, the regulatory intelligence profession is likely still not sufficiently represented because only 15.8% of respondents indicated their company had more than 10 employees fulfilling regulatory

Figure 1. Participant metrics
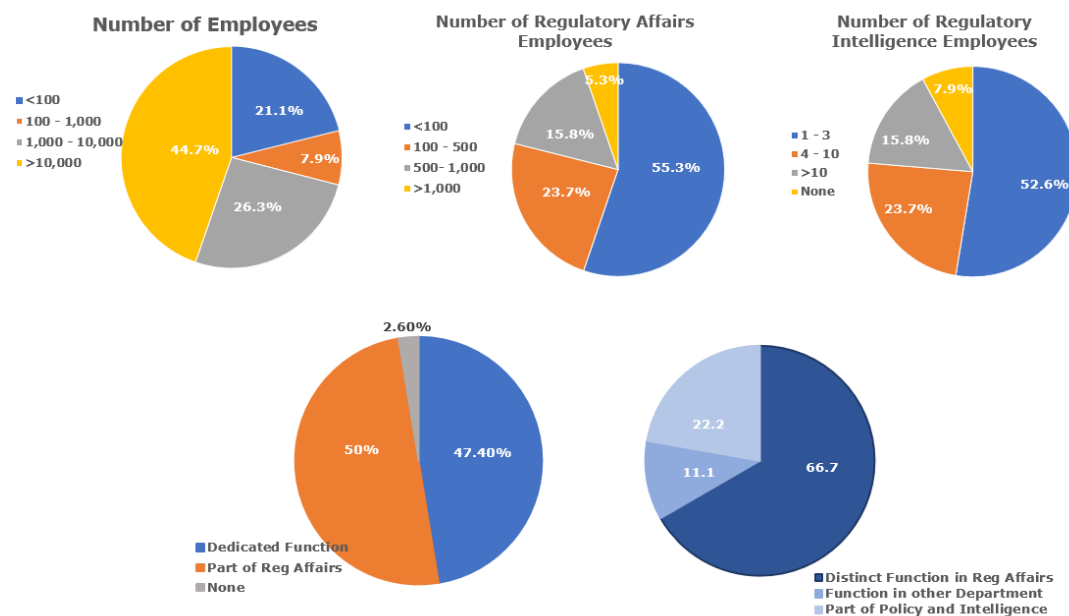
intelligence tasks. The size of the regulatory intelligence function has remained largely unchanged over the last 2 decades, with about half of the respondents indicating their company had fewer than 5 employees in the regulatory intelligence function.

About half the respondents indicated that regulatory intelligence is a dedicated function, meaning that the professional performs regulatory intelligence tasks as a full-time position rather than part of other position duties. Half the respondents said their regulatory intelligence responsibility was in addition to their normal regulatory affairs responsibilities. The majority of companies (66.7%) have regulatory intelligence as a dedicated function (regulatory intelligence tasks only) within the regulatory affairs department. According to the respondents, 11.1% of companies included the regulatory intelligence function in a department other than regulatory affairs. Shaping the external regulatory environment is becoming increasingly important with the constant flux of new policies and regulatory requirements. Almost a quarter of respondents (22.2%) indicated that regulatory intelligence was part of the company's policy (which often includes advocacy) and intelligence group, reflecting the growing importance of external engagement.
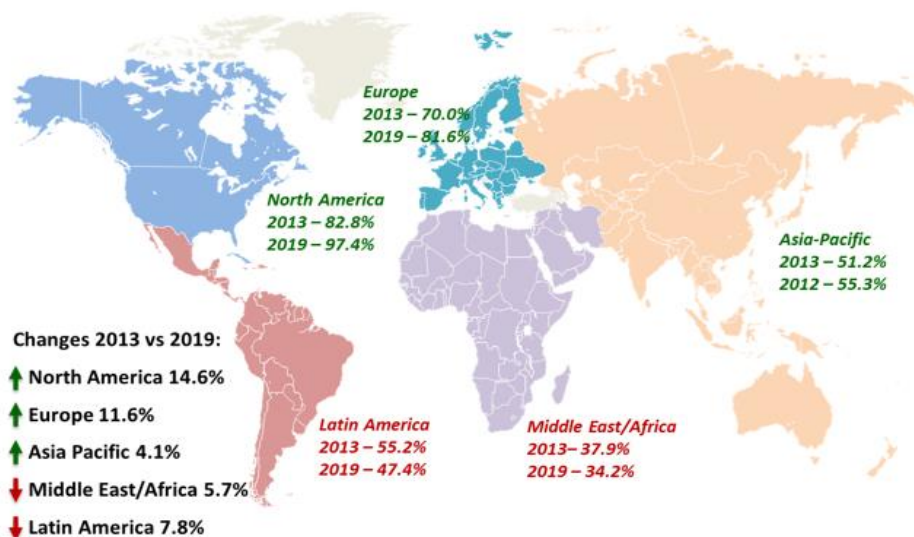
Globalization of regulatory affairs. The slogan, "Thinking with the end in mind," is becoming increasingly applicable to a range of situations in regulatory affairs. For regulatory affairs, and regulatory intelligence in particular, it is becoming increasingly important to determine at the outset of a product development program which countries should be targeted for obtaining approval for marketing and commercialization. Although there are multiple harmonization efforts under way, regulatory requirements across countries and regions remain varied and can sometimes differ significantly. It is part of the regulatory intelligence professional's responsibility to determine regulatory requirements across the different regions and to form a cost- and time-efficient strategy for program development with the support of other departments as necessary.

The 2019 and 2013 findings on global regulatory intelligence coverage by regulatory intelligence professionals and colleagues within regulatory affairs were compared. In 2013, respondents indicated they provided intelligence coverage mostly for North America and Europe (82.8% and 70.0%, respectively), with 51.2% covering Asia-Pacific and 55.2% and 37.9% focusing on Latin America and the Middle East/Africa, respectively (**Figure 2A**, p. 5). Data from the 2019 survey indicated an increase in regulatory intelligence coverage in North America (97.4%) and Europe (81.6%), with Asia-Pacific coverage relatively steady at 55.3% and decreases in coverage of Latin America (47.4%) and the Middle East/Africa (34.2%).
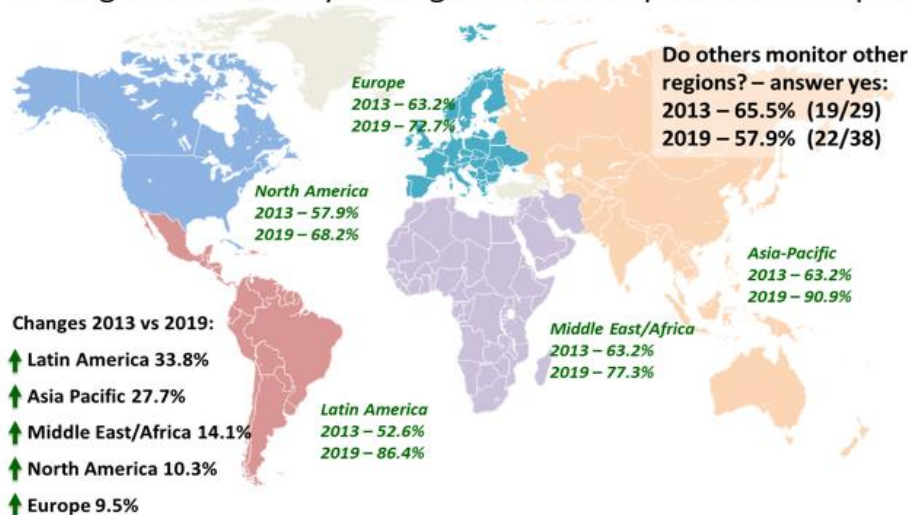
However, the responses showed there was extensive use of colleagues within the same company to supplement regulatory intelligence for various regions, suggesting a need for the expansion of regulatory intelligence teams within the company or use of regulatory affairs colleagues globally. In 2013, between 52.6% and 63.2% of participants said colleagues within their company provided information for regions outside of the respondent's region (**Figure 2B**, p. 5).

Figure 2. Geographic regulatory intelligence coverage by respondents and colleagues

A – Regions covered by survey respondents

Europe
2013 – 70.0%
2019 – 81.6%

North America
2013 – 82.8%
2019 – 97.4%

Asia-Pacific
2013 – 51.2%
2012 – 55.3%

Changes 2013 vs 2019:
▲ North America 14.6%
▲ Europe 11.6%
▲ Asia Pacific 4.1%
▼ Middle East/Africa 5.7%
▼ Latin America 7.8%

Latin America
2013 – 55.2%
2019 – 47.4%

Middle East/Africa
2013 – 37.9%
2019 – 34.2%

B – Regions covered by colleagues within respondent's company

Europe
2013 – 63.2%
2019 – 72.7%

Do others monitor other
regions? – answer yes:
2013 – 65.5% (19/29)
2019 – 57.9% (22/38)

North America
2013 – 57.9%
2019 – 68.2%

Asia-Pacific
2013 – 63.2%
2019 – 90.9%

Changes 2013 vs 2019:
▲ Latin America 33.8%
▲ Asia Pacific 27.7%
▲ Middle East/Africa 14.1%
▲ North America 10.3%
▲ Europe 9.5%

Middle East/Africa
2013 – 63.2%
2019 – 77.3%

Latin America
2013 – 52.6%
2019 – 86.4%

In 2019, that percentage increased by about 10% for Europe, to 72.2%, and North America (68.2%); and about 14% for Middle East/Africa, to 77.3%. Those percentages jumped by close to 34% for Latin America, to 84.6%, and by almost 30% for Asia-Pacific, to 90.9%.

Background and skillset. Regulatory intelligence professionals require a combination of knowledge about the industry and its history and soft skills. There are no hard-and-fast rules about how many years of experience a new hire would need in regulatory affairs and the pharmaceutical and/or medical device industries. However, a good rule of thumb for entering the regulatory

intelligence profession is that a minimum of 5 years of industry and 3 years in regulatory affairs should be required for entry-level positions. The required number of years of experience will increase with the seniority of the position.[3]

The survey revealed that the number of years' experience in industry has increased particularly over the last 10 years. In the 2002 and 2007 surveys, the majority of respondents – about 60% – had 5 to 10 years' experience in industry, compared with about 65% of 2013 respondents and 75% of 2019 respondents having more than 10 years of industry experience.

Similarly, regulatory intelligence professionals' experience in regulatory affairs also increased between 2013 and 2019, with 55.3% of 2019 respondents having more than 10 years of regulatory affairs experience, compared with 41.4% of respondents in 2013. Of note is that there was a decline from 2002 to 2019 in the percentage of respondents having worked for a regulatory affairs agency (57.1% and 10.6%, respectively).

The regulatory intelligence function can have many applications within regulatory affairs and across different departments within the company but plays a key role in informing regulatory strategy. The 2019 participants were asked if they thought the regulatory intelligence function became more operational or more strategic over the last 5 years; 44% responded it had become more strategic, with only 12% indicating an increase in operational functions and 27% saying they observed no change (**Figure 3**).

Participants were asked to rank soft skills according to their importance for the regulatory intelligence professional. The top 5 most important skills on a scale of 1 (lowest value) to 8 (highest) were negotiation, being an influencer, collaboration, communication, and, tied in fifth pace, leadership and broad industry knowledge. The rankings were very close, ranging from 3.8 to 3.3, with self-motivation and strategic/critical thinking ranking lowest at 3.1 and 3.0,

Figure 3. Is regulatory intelligence becoming more strategic or operational?
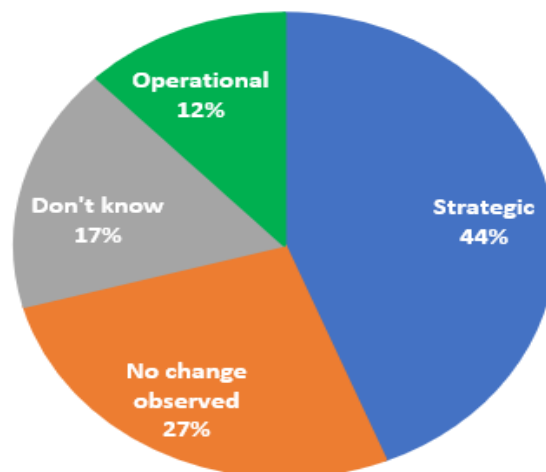
respectively. The closeness of the rankings suggests the value of each soft skill likely depends on personal preference and/or need during work performance.

Negotiation and influencing go hand-in-hand. For example, if an regulatory intelligence professional notes changes in the regulatory landscape that would render an approved strategic plan more time- and cost-intense than previously thought, the team will need to be convinced of the benefits of developing a new strategy and altering the current development plan accordingly. Interactions with regulatory agencies also may require negotiation on timelines and/or requirements. In addition, as noted previously in this article, policy and advocacy are becoming increasingly important in influencing and shaping the regulatory landscape.

Once the regulatory intelligence has been developed, it must be communicated to the teams. The ability to communicate clearly, precisely, and using the appropriate vehicle is of utmost importance since members from diverse functional teams within and outside of regulatory affairs, as well as with colleagues at various levels within the organization might need to receive pertinent information.

It was surprising that leadership was ranked as less important. Many regulatory intelligence tasks require input and collaboration from a team and some tasks cannot be done alone, making good leadership skills and working well with others important attributes for a regulatory intelligence professional. It is important to note that leadership is not dependent on an individual's hierarchical status within an organization or the size of the team. Leadership requires collaboration, negotiation, and empowering others to achieve a common goal, and therefore requires a combination of many other skills.

Regulatory intelligence scope. The survey also measured the scope of regulatory intelligence by asking participants which areas of pharmaceutical development they monitored. Regulatory intelligence professionals must cover a range of topics for which they need in-depth knowledge of the entire drug development process. In this survey, 71% of respondents said the pre-approval space and "specific therapeutic area" were the most common areas of focus for regulatory intelligence professionals. The full listing of the focus areas showed the extent of coverage needed in regulatory intelligence and included: specific product type; post-marketing; chemistry, manufacturing, and controls; competitor regulatory intelligence; pharmacovigilance; and quality (**Figure 4**, p. 8). For each area of focus, at least 50% of the respondents stated it was under their purview. These results were in line with those of previous surveys.

Deliverables, cross functionality, and key performance indicators (KPIs). There was a surprising amount of diversity regarding the deliverables for which regulatory intelligence professionals are responsible. Almost 75% of respondents stated they were responsible for developing and submitting comments on regulatory guidance documents/guidelines, providing regulatory

Figure 4. Key areas monitored by regulatory intelligence professionals
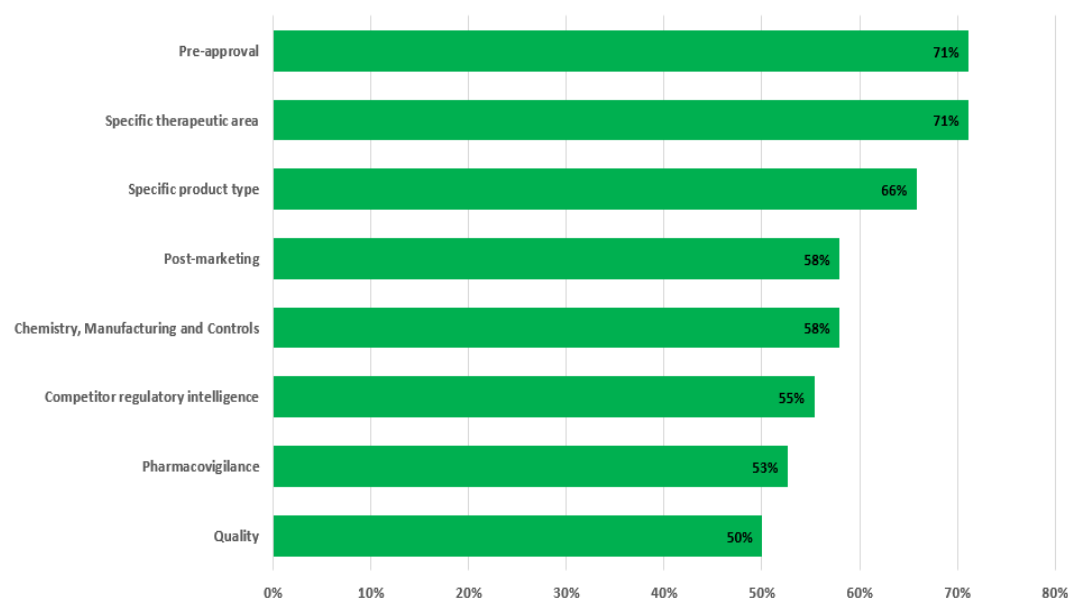
insights on changes to the regulatory environment, educating internal groups on key regulatory topics, and contributing to the development of regulatory strategy. These results paint a disparate picture of the work done by regulatory intelligence professionals. In particular, the large percentage of respondents saying they comment on regulatory guidance documents/guidelines was a break from previous survey trends and points to policy work becoming a greater part of a regulatory professional's duties.

Respondents were asked with whom or with which departments they interacted outside of the regulatory group but within their company. The most common response was senior leadership, which points to the importance of regulatory intelligence within a company. Other groups, including clinical, pharmacovigilance, nonclinical, and marketing/commercial, were also noted and indicate that regulatory intelligence professionals frequently work cross-functionally.

One organizational tool that does not seem to have been embraced by regulatory intelligence groups is the use of key performance indicators (KPIs), which measure the success or achievement of an organization or a person toward an operational and/or strategic goal. Most survey respondents stated that KPIs weren't used within their regulatory intelligence group.

Sources and communication. Regulatory intelligence sources differ across companies. Larger, better resourced companies can purchase licenses to paid subscription services such as Cortellis or Tarius, whereas smaller companies have to rely on public sources of regulatory intelligence. The survey respondents indicated that the most popular source of regulatory intelligence was regulatory authority websites, which is understandable because they are the best source of regulatory information. It is interesting to note that the 2019 survey results

indicated less usage of subscription services compared with findings in the previous iterations of the survey. That might point to there being more free information available on the internet, which reduces the need to pay for quality regulatory intelligence.

Respondents were also asked about their use of social media as regulatory intelligence resources, and the most common source mentioned was professional association discussion forums, such as the RAPS RegEx platform. Surprisingly, the least-used resource was Twitter. Twitter can be difficult to use as its functionality and user interface differs from more commonly used social media sites. However, Twitter is a remarkably useful tool for competitive analysis. Frequent Twitter users can be exceptional at dissecting company press releases and highlighting key takeaways.

Information distribution and new tools. Gathering regulatory intelligence is only part of a regulatory intelligence professional's role. Distributing it effectively is as important. Preferred communication methods were identified by survey respondents as daily newsletters and seminars, each selected as such by 45% of the respondents. Newsletters are a common communication tool throughout the regulatory intelligence profession but can be difficult and time intensive to generate. There are vendors that create regulatory intelligence newsletters, but they tend to be expensive. This was reflected in the findings showing that most respondents generated their newsletters internally.

A slight majority of respondents stated their group had used new tools and technology, such as Sharepoint-based information management systems.

Regulatory intelligence of tomorrow
Over the past decade, the availability of regulatory information has significantly increased, and online search engines have become more efficient. Simultaneously, availability of large amounts information creates the challenge to analyze and meaningfully arrange this information for effective dissemination. Most regulatory professionals do not have sufficient time and/or technology resources. Rapid and streamlined approaches to collating regulatory and legislative data through emerging technology, such as AI, will be needed to support regulatory intelligence professionals. Adaption to, and implementation of, new tools is inevitable amid the challenges in regulatory strategy and compliance. Development of AI applications and tools in regulatory intelligence is an evolving field. It is envisaged to support life sciences companies in efficiently managing modern world complexities of business overall and the regulatory environment in particular. The regulatory intelligence profession of tomorrow will continue to shift into data analytics and informatics for surveillance of the regulatory landscape. However, interpretation of insights and developing effective strategies will remain a key function of regulatory intelligence and continue to require human analysis and skills.

Conclusion
Although the increase in availability of information is generally embraced, it also creates challenges around timely uptake and appropriate dissemination of

information. Generally, industry has reacted by assigning increased numbers of regulatory intelligence professionals full or part time to monitor and inform regulatory strategies. With the increase in information availability and growing complexity, the need for using developing technology – particularly artificial intelligence, natural language processing, and machine learning – becomes more prevalent. Despite this increased need, the regulatory intelligence function currently remains small, independent of company size, which underpins the need for implementation of evolving technology to support the regulatory intelligence team.

About the authors

Kirsten Messmer, PhD, RAC, is a senior research analyst and contributes to the research and development of content for Agency IQ. Before joining Agency IQ, she was a principal regulatory affairs specialist at PPD, providing global regulatory intelligence to support efficient, compliant, and successful clinical research and drug development for biopharmaceuticals and advanced therapies. Messmer has a doctorate degree in neuroscience from the University of Sheffield (UK) and a biology diploma from the Eberhard-Karls University (Tübingen, Germany). She is a RAPS member and holds a Regulatory Affairs Certification (RAC) in US regulation. Messmer is an author of the third edition of *Regulatory Intelligence 101*, published by RAPS. She can be contacted at kmessmer@agencyiq.com.

Daanish Ashraf, PharmD, is the regulatory intelligence lead at Biogen. He previously worked in regulatory intelligence and strategy roles at Allergan and Astellas and was an adjunct professor at St. John's University College of Pharmacy. He received his doctorate in pharmacy from University of Illinois at Chicago College of Pharmacy. Ashraf is a co-editor and lead author of the third edition of *Regulatory Intelligence 101*, published by RAPS. He can be contacted at Daanish.Ashraf@biogen.com.

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