

The Importance of Building Regulatory Competencies to Address a Broadening Skills Gap

The global life sciences industry is expected to reach >£1.4 trillion in gross value by 2023 (approximately \$1.6 trillion today)¹. In 2014, the European pharma sector generated 19.8% of global pharma sales² and the EU-5 is set to grow by 25% between 2017–2022, accounting for 69% of the European pharma market in 2022³. In the coming decades, healthcare spending is expected to outgrow the economy in Organisation for Economic Co-operation and Development (OECD) member countries by 3.3% versus 2% compound annual growth rate (CAGR), creating a sustainability challenge for healthcare systems and new opportunities for life sciences industry growth⁴. This has huge potential for the pharmaceutical industry and, with significant industry changes taking place over the coming years, it is critical to support the regulatory workforce that will be charged with navigating through this period of rapid development and regulatory uncertainty.

The regulatory profession is a relatively new profession, having been established just a few decades ago, and people still tend to enter the field from other related disciplines. The most recent Scope of Practice and Compensation Survey of the Regulatory Profession conducted by the Regulatory Affairs Professionals Society (RAPS) found that more than 88% of respondents began working in other specialties before moving into regulatory and generally originated from the bench sciences or engineering fields.

The regulatory workforce broadly includes either those who possess plenty of experience having performed roles in other areas of the pharma sector, or graduates and younger recruits who simply enter the industry from other career fields. These recruits are entering the profession with excellent academic qualifications (around 99% of those who took part in the 2016 survey hold a university degree

and more than 42% have achieved a master's degree) but possess little to none of the practical competencies required in the role. With a growing proportion of many experienced professionals reaching retirement age, this poses a skills gap issue. As a result, this skills gap is becoming more noticeable just as the role of regulatory professionals is becoming increasingly important within a broader strategic business model.

In addition, in response to the increasing evolution of global industry regulations, more dynamic product and technological development and changing business models, the role of regulatory professionals in the pharmaceutical sector has had to adapt.

Today, there is a greater reliance on the strategic support of regulatory professionals on more complex issues. Regulatory has also become a much more formalised career path, helped by the increase in dedicated training and educational support.

Closing the Skills Gap

The relationship between the regulatory professionals in the pharmaceutical industry and healthcare professionals (HCPs) and healthcare organisations (HCOs) plays a vital role in ensuring life-enhancing pharmaceutical products are safe and effective and reach the market efficiently. So what can companies do to support the regulatory workforce and lessen this skills gap?

Professional development organisations are ideally positioned to work with the pharma industry to help to bridge the gap and ensure a highly skilled and competent regulatory workforce. Continuous development is vital in an industry where change is so frequent. This is also true as the path to globalisation broadens and product portfolios grow in variety. Regulatory professionals have had to expand their range of skills to deal with

multi-geographical workloads across numerous product types on a global scale.

Demand for professional development support has surged over the last decade. Individuals are also recognising the importance of keeping up with industry- and sector-specific information, which has led to the development of the industry-recognised Regulatory Competency Framework (RCF) and the growing uptake of the Regulatory Affairs Certification (RAC), the only postgraduate certification in regulatory affairs. Professionals with RAC have proven that they possess the core competencies required to successfully operate in a progressively changing industry.

The Changing Role of Regulatory

So influential is the globalisation of the industry and product diversity that just 7.2% of participants in the RAPS survey reported that their role focused on a single country and nearly 75% were involved with multiple sites and variations of products.

As detailed above, the ever-increasing expectations for regulatory professionals to help guide and support a company's strategic focus has shifted the perception of the profession. Whereas previously, regulatory professionals were solely expected to submit and gain product approvals, they now play a part in shaping the wider strategic vision for the whole company.

As their role diversifies, they are required to take an active role in discussions across a multitude of departments, including research and development, manufacturing and quality, all the way through to marketing, sales, legal, finance and management, and sometimes even working in areas directly involving clinicians and consumers.

Furthermore, regulatory knowledge must extend beyond simply knowing



the regulations, to understanding their practical application and potential wider business implications. These professional networks for sharing information and best practices are more important now than ever. By tapping into a global network, a regulatory professional can benefit from the knowledge and expertise of the entire network in many different areas, including vital details about different regional and national regulatory systems. A shared body of knowledge benefits all stakeholders from recent graduates to experienced regulatory professionals, manufacturers, marketers and regulators. The rise of technologies that allow nearly unlimited communication with anyone around the world has made it possible for professional societies and associations with a global reach to connect professionals to specialised and regional know-how with increasing ease.

While it's not that easy to address experience as this comes with time, professional development programmes underpinned by clear competency frameworks are one way to assist the regulatory workforce. Training providers must continuously develop their programmes to meet the changing educational requirements of a workforce whose role is rapidly evolving. This also means that even those professionals with vast experience in

regulatory issues are recommended to commit to a professional development programme.

Final Thought

In order to address the skills gap, there is a real need for formal training and certification to become standard practice for regulatory professionals. Only then can they be best equipped to advance public health in the most efficient and compliant manner. A dedicated approach to professional development for this workforce, coupled with the industry's willingness and encouragement of knowledge-sharing, will no doubt ensure that regulatory professionals continue to strive to build their competencies. As the remit of a regulatory professional has diversified so much, this workforce can have a real impact on both their employers' businesses and the patients who ultimately benefit from the healthcare products.

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