The Evolving Role of the Regulatory Affairs Professional

By Preeya Beczek - Independent Regulatory Affairs Expert

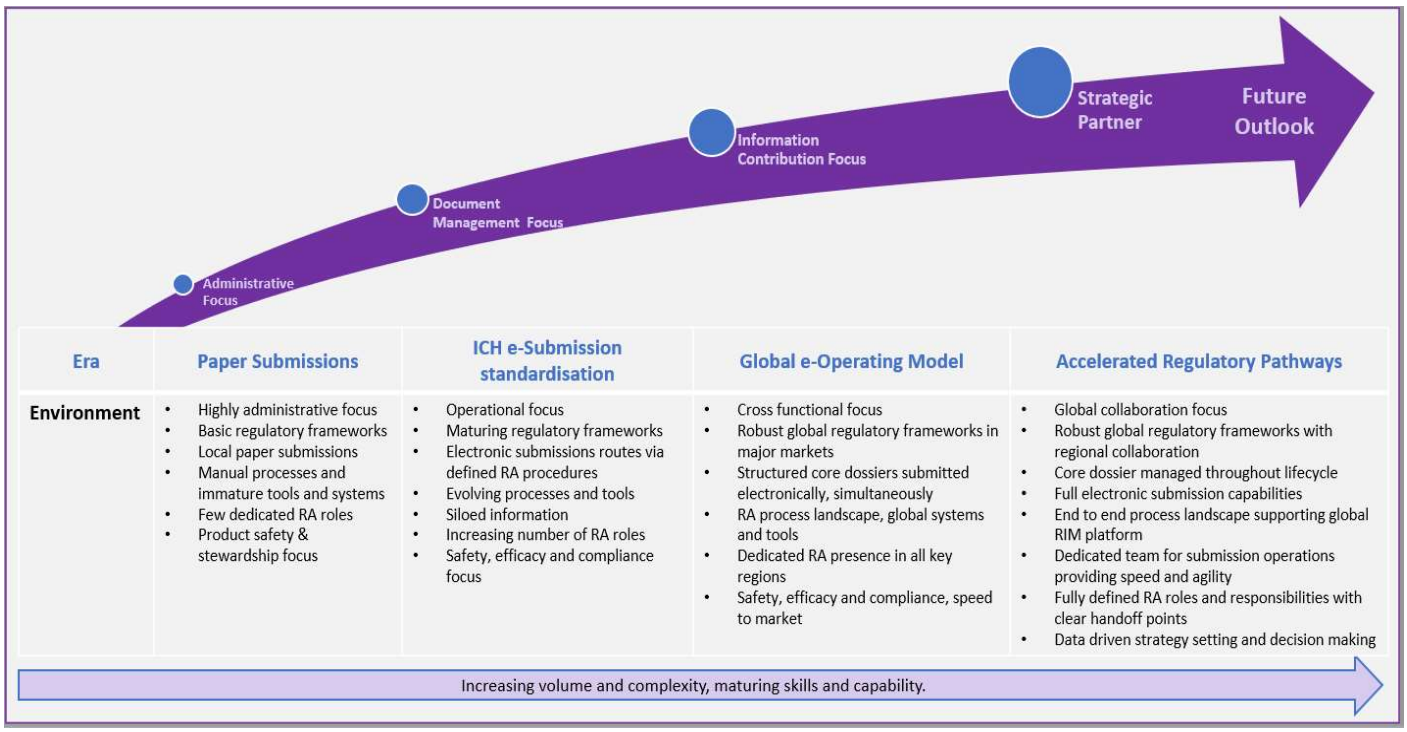
The Regulatory Affairs (RA) function is increasingly being viewed as a strategic partner from research and development through post approval. It is no longer just about submission strategy and operations, policing compliance, and registration management. Most RA professionals are evolving their skills and knowledge to continually grow and advance in a global environment with increasing complex regulations and strategy considerations.

Companies are continuously navigating complex regulations in an increasingly globalised market, governed by continually changing regulations. Collaboration between industry and authorities is growing, more licensing deals are struck, and companies have an ever-pressing need to navigate the regulatory paths quickly. Additionally, science itself has never been so advanced, diverse and exciting. The types of medicinal products and devices currently in development are bursting with advanced technology, patient lead research hubs[1] and artificial intelligence[2] making this corporate landscape highly competitive and interesting!

With all of this, one could argue that the current role of the RA professional needs to be 'firing in all cylinders', executing turnkey operational activities, collating and assessing key information while being a trusted strategic partner.

In fact, the RA role has evolved through some fundamental eras to arrive to where it is today. Along the way, the profession has built up a solid foundation of key skills and qualities by working through the environments each era has presented.

Typical Eras and Environments for the RA Professional



Era	Paper Submissions	ICH e-Submission standardisation	Global e-Operating Model	Accelerated Regulatory Pathways
Environment	• Highly administrative focus • Basic regulatory frameworks • Local paper submissions • Manual processes and immature tools and systems • Few dedicated RA roles • Product safety & stewardship focus	• Operational focus • Maturing regulatory frameworks • Electronic submissions routes via defined RA procedures • Evolving processes and tools • Siloed information • Increasing number of RA roles • Safety, efficacy and compliance focus	• Cross functional focus • Robust global regulatory frameworks in major markets • Structured core dossiers submitted electronically, simultaneously • RA process landscape, global systems and tools • Dedicated RA presence in all key regions • Safety, efficacy and compliance, speed to market	• Global collaboration focus • Robust global regulatory frameworks with regional collaboration • Core dossier managed throughout lifecycle • Full electronic submission capabilities • End to end process landscape supporting global RIM platform • Dedicated team for submission operations providing speed and agility • Fully defined RA roles and responsibilities with clear handoff points • Data driven strategy setting and decision making

Increasing volume and complexity, maturing skills and capability.

Additionally, through these eras, there has been a deepening dependence on what the RA function should deliver and thereby dictating the myriad of skills the RA professional would have to possess. The pathway to career progressions and advancement in RA is similar for people in any job by making yourself indispensable by contributing insightful ideas and advice that offer a material difference to the team and organization.

However, the increasing demands on RA professionals can result in an up-hill climb for career progression. There are key skills and qualities the RA professionals should have, or will gain, over the course of their career. These are common requirements in most RA job specifications, indicative of a truly demanding role in industry today.

Key skills and qualities of a RA professional

Key RA skills as an Operational Resource

The career of an RA professional often starts with undertaking certain operational tasks. It presents a good way to learn about types of submissions, country level requirements and key soft skills to successfully execute a submission through collaboration with key contributors.

In this space the RA professional typically creates and maintains a repository for all documents, assembles, validates, and submits documents to Health Authorities for review and approval while ensuring compliance with all regulations and guidelines. It is this type of role the majority of skills shown in Figure 2 are initially accomplished. Operational roles include RA submission managers, publishers, information and data managers. Often, purely operational tasks are outsourced or there is a mix of in-house personal and outsourced contingent workers. This is common across mid to large size companies. In fact, the global regulatory affairs outsourcing market size is expected to reach $13.9 billion by 2026.[3]

Key RA skills as a Business Leader

A successful career in RA necessarily has its foundations in a thorough understanding of regulations governing product development, registration, manufacturing and marketing. However, it does not end there. Life sciences organisations need RA professionals capable of participating in and influencing some of the most significant business decisions they make in the life of a product.

As such, they need to develop the analytical skills to identify both opportunities and pitfalls, the ability to share their knowledge and communicate positions clearly, plus the confidence to provide guidance to the highest levels within organisations. RA professionals who do this will elevate themselves to strategists and business leaders. As a business leader the RA professional undertakes regular tasks such as:

- Detecting trends and changes in the external regulatory landscape
- Conducting impact assessments
- Identifying and addressing changes that have an impact on the business
- Maintaining and updating records on regulations
- Developing and providing easy reference regulatory intelligence tools to aid key business decisions
- Informing the organisation of impact, changing and providing ongoing, localised communication and training
- Developing the appropriate regulatory strategy and recommendations
- Directing operational teams to execute the regulatory strategy via relevant submission and notification activities
- Maintaining professional relationships with health authorities and external bodies.

Often, RA business leaders can also be engaged in internal initiatives and continuous improvement programs. Therefore, business process ownership and leadership are skills that RA professionals are adding to their repertoire. Over the last decade more companies have been engaging in process optimisation and digitalisation.[4] The RA professional can find themselves at the heart of these programs, owning and leading change programs that span across the RA value chain.

Key RA skills as a Strategic Partner

Perhaps the most encouraging news is that in most situations and organisations, RA is no longer viewed as an obstruction to achieving the company's goals, but rather as a strategic partner in the business. Leadership generally recognises that guidance; recommendations and oversight provided by RA can play a critical role not only in speeding and smoothing the filling and approval process, but also in ensuring successful development outcomes and product licensing.

Regulatory Affairs is seen as a trusted partner in reducing risk, and improving the efficiency of multiple processes along the product lifecycle. Inherently, they need to have a deep understanding of the product they support in order to really add value. So, what are those 'added value' skills and qualities?

- A solid understanding of the overall business – its products, processes, challenges and commercial environment
- Strong communication skills - sufficient to explain to senior management the impact of regulation on the product and business, as well as to be able to make and justify recommendations. Moreover, business leaders tend to appreciate RA professionals who willingly educate others
- Negotiation and persuasion skills - to effectively work with cross-functional teams and regulatory authorities to address 'grey areas' and resolve issues
- Analytical and interpretive skills - to identify areas within regulations that are open to interpretation in a way that may serve the business's interests and smooth the regulatory path
- Project management skills - to oversee complex projects having multiple, simultaneous workstreams and involving global, matrixed teams.
- Data organisation and ownership skills – keeping up with technology that houses product and registration level data. Ensuring data quality and using authoritative sources to report product information in a way that influences strategy setting and decision making.

With these skills, RA professionals will find themselves contributing strategically on a day to day basis to activities across the development lifecycle, such as:

- Offering input into early stage development products and contributing to go/no go decisions based on competitive situation and established precedents.
- Identifying any restraints and requirements that would influence the direction of development and quantify associated risks
- Developing road maps of how best to navigate through the clinical trial process to support a successful marketing approval application
- Recommending ways to ensure that the research will meet the registration requirements of the greatest number of markets.
- Providing essential regulatory intelligence information for accelerated product authorisation pathways along with potential risks and mitigation options.

These activities are certainly indicative of a demanding but perhaps a very interesting day at the office. Working across global boundaries and functions towards a common goal – scientific breakthroughs and saving lives.

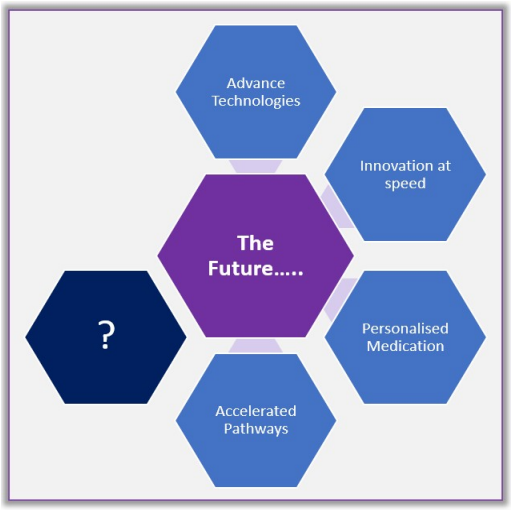
Speaking from Experience

There has certainly been a shift in the culture and reputation of RA professionals. Although the RA role has evolved and will continue to do so, there are some skills that should remain at the core:

Share knowledge - Adopt the role of an educator. Do not assume that others have the same knowledge and understanding of the regulations and procedures as you.
Anticipate requirements and be proactive - Understand the businesses goals and consider what it will need to be successful. Tell the team what you know and be prepared to share your thoughts and ideas.
Think in terms of risks - Be prepared to explain the risks associated with every recommended step. One key contribution is helping companies foresee and avoid potential problems that could derail or delay its commercial plans. However, it's good to delineate between a regulatory risk and what may be a wider a business risk.
Remain objective - Remain credible to both internal stakeholders and regulatory bodies, RA professionals must deal in facts and avoid appearance of being personally invested in the outcomes of a decision. Giving examples to demonstrate key points can be of great value.
Speak in business terms - Especially when communicating the strategic and commercial implications of regulatory decisions and changes, use terms that business leaders can understand and appreciate in context.
Learn continually - Ask questions, shadow experienced peers on projects and participate in lessons learnt upon completion of projects. Tap into professional organisations for conferences, courses and certification programmes to accommodate ongoing education.
Become an ambassador - Realise that it is not enough to know what to do and how to do it within your function; you need to be able to explain your activities and rationale to others.
Increase your exposure - Volunteer, to present at team meetings, write articles, or conduct a training session on an area of your expertise. Take part in external consultations and lobbying.

Closing Remarks

The role of the RA professional is ever evolving across industry. One could argue that what lies ahead is already known to a large extent.



Advanced technologies for automation - there is active interest amongst large companies for automated document generation, meta data population and extraction for interfacing systems. [4]
Breakthrough thinking and speedy innovation in response to epidemics and pandemics – through 2020 organisational teams and health authorities have had to demonstrate unprecedented approaches to deliver fast, effective and safe vaccination options for COVID-19 – this is ongoing.
Personalised medication - practiced more widely over the last decade, the current approaches to regulatory oversight, will have to be redefined and restructured.[5]
Accelerated pathways – e.g. rare diseases, an area where there are gaps between policy and practice across countries, indicating that there is still some way to go in terms of accelerated regulatory pathways.[6]

The notion that RA is 'the place to be' presupposes that professionals in the field are equipped to add value beyond performing operational tasks. Those who develop a strategic mindset and demonstrate that they can contribute in meaningful ways to business goals do stand to advance within the organisation with a great career ahead of them.

The Author – Preeya Beczek is a Director with over 23 years' experience across life sciences, chemical and fast-moving consumer industry. She has led regulatory projects across the entire product lifecycle in various therapeutic areas / product platforms. Preeya has extensive industry experience and insights to lead and support teams across regulatory and compliance functions as an operational consultant and subject matter expert /advisor.

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