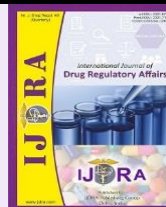
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### Review Article



## A Review on various aspects of Regulatory Affairs

Swaranjali Pore\*, Jeevan Deshmukh, Shivani Biskite, Snehal Jadhav, Akshata Moharekar, Ankita Gurav

Adarsh College of Pharmacy, Shivaji University Kolhapur, near MIDC Khambale, Vita 415311, Maharashtra, India.

### Abstract

In order to guarantee the efficacy, safety, and calibre of medications, medical equipment, and other healthcare supplies, Regulatory Affairs is essential. Anticipating future trends and difficulties in Regulatory Affairs is crucial as the healthcare sector changes due to technological breakthroughs, globalization, and new regulatory paradigms. This abstract examines the consequences of developing fields for regulatory frameworks, including gene treatments, digital health, artificial intelligence, and personalized medicine. It also covers the increased significance of real-world evidence, patient-centric approaches, and international harmonization in regulatory decision-making. In addition, it looks at the difficulties presented by supply chain interruptions, cybersecurity risks, and regulatory divergence in a world that is changing quickly. Stakeholders may effectively navigate the complicated regulatory landscape of the future by embracing innovation, collaboration, and adaptive regulatory methods facilitate the timely delivery of safe and effective healthcare products to patients worldwide.

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\*Corresponding author

### 1. Introduction

Regulatory Affairs an essential part of pharmaceutical research worldwide. Aspects such as Regulatory Affairs which deal with the legal prerequisites for marketing authorization for medicinal products are being impacted by digital disruption. Regulatory Affairs are sometimes known as government affairs. The government's efforts to protect and maintain public health by enforcing safety and efficacy regulations on goods such as pharmaceuticals, medical devices, veterinary care, cosmetics, agrochemicals, and complementary and alternative medicine have given rise to a relatively new profession.

This line of work involves obtaining, assessing, recording, and disseminating information on the advantages and risk assessment of all medical products to regulatory bodies and the general public worldwide. In general, RA is a vital link between the global drug regulatory agencies and the pharmaceutical industries. It serves as a mediator between the two of them. The healthcare sector is making significant efforts worldwide to transform fundamental practices and expedite better patient outcomes. Real-world evidence and newly developed technology are becoming increasingly important in today's world of data gathering, capture, and analysis. It is also advantageous for severe disease states and the discovery of new modalities. Every facet of RA

work is being expressed by this swift transition. Through the use of numerous techniques and technologies, RA is constantly expanding. (1,2)

The focus on data integrity and cyber security is growing daily as a result of the use of AI tools and RA to increase working productivity. Researchers are working to reverse the effects of new drugs or medications due to changes in people's habits or lifestyles for a variety of reasons, including an increase in diseases and syndromes. As a result, improving data collectively and promoting the information sent by the researcher won't happen quickly. The entire process will be pending, which causes a delay in the creation of new drugs. Therefore, in order to work more conveniently in the future, RA should make use of technologies that will increase productivity because they will undoubtedly result in earlier processing for subsequent steps. AI and block chain are examples of emergency technologies that can significantly enhance the regulatory process. Ra professionals are involved in product post-marketing surveillance as well. They keep an eye on unfavourable incidents and other product-related safety concerns, and they strive to make sure that the proper steps are done to resolve these problems. Ra's capacity to quickly adapt to shifting regulatory environments. The RA profession stays current on any modifications to their product and ensures that it satisfies all criteria.

The complexity of the regulatory environment has led to a major increase in the importance of Regulatory Affairs. This is brought about by the proliferation of rules, the growing need for responsibility and openness in the creation and promotion of medical products, and the internationalisation of several businesses. (1,2)

## 2. Objectives of Regulatory Affairs

The goals of Regulatory Affairs usually encompass keeping an eye on changes in laws and regulations and also merging trends and importance of artificial intelligence that impact the sector, getting product approvals, submissions to regulatory bodies and guaranteeing product safety and efficacy.

- To know about present aspects of Regulatory Affairs.
- To know the scope of Regulatory Affairs.
- To know the qualities and skills required in individual in Pharma sector.
- To know about future opportunities in Regulatory Affairs.
- To know the importance of Artificial Intelligence in Regulatory Affairs.

### Spectrum of RA:

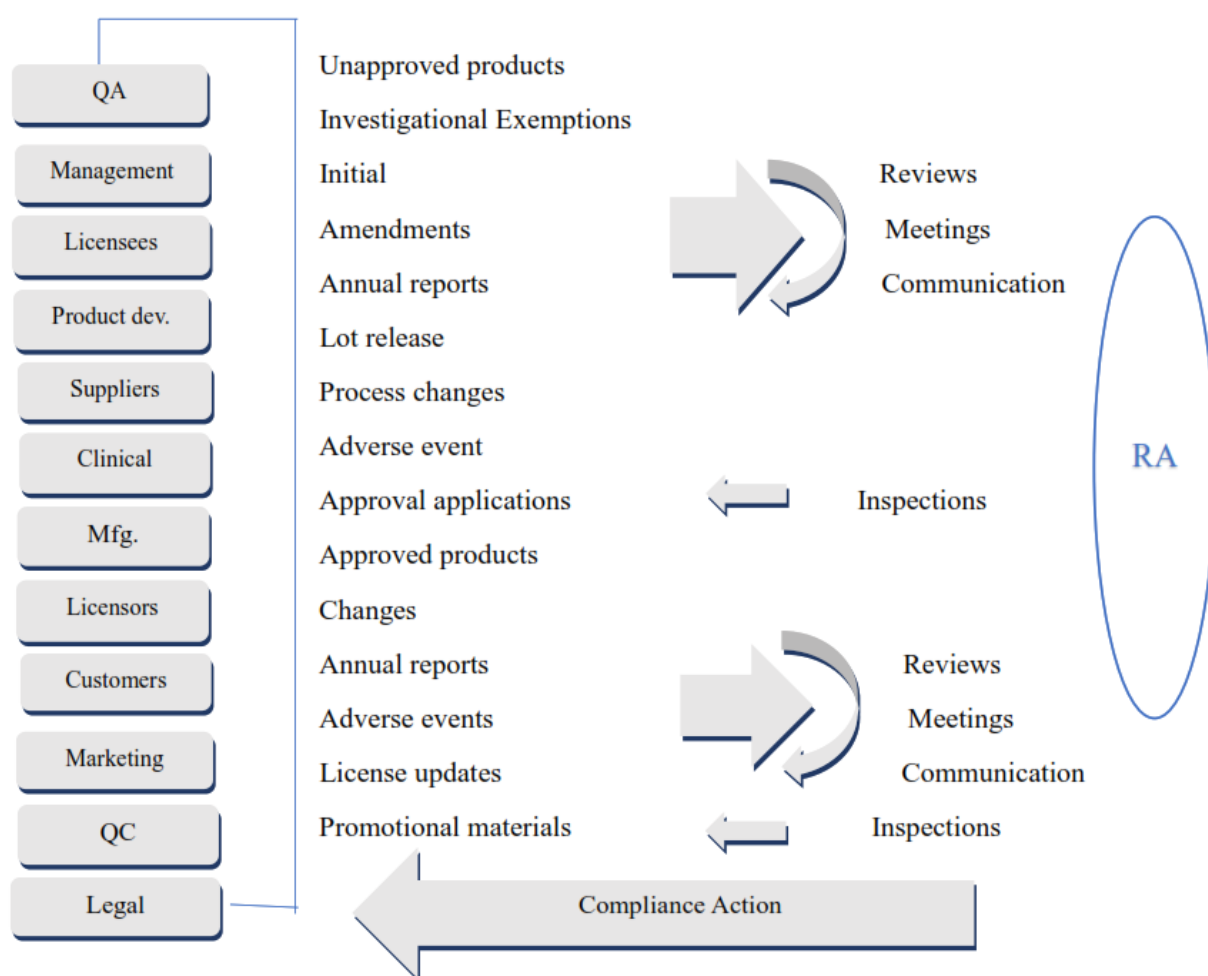


Figure 1. Spectrum of RA (2)

## 3. Scope of Regulatory Affairs

- Improved data analytics: It will be essential to use data analytics to spot patterns, foresee possible problems and make well-informed judgements.
- Globalised expertise: Due to the growing interdependence of markets, Regulatory Affairs specialists must be aware of several regulatory environments and have a worldwide viewpoint.
- Technological fluency: For work to be done effectively and efficiently, one must stay current on the newest tools and technologies related to regulations.
- Managing Clinical Trials: Careful planning and execution are necessary for clinical trial regulatory approval. Regulatory Affairs professionals play a critical role in ensuring that all ethical and legal standards are satisfied during the development and execution of clinical studies.
- Interacting with Regulatory Authorities: The primary point of contact for businesses with

regulatory bodies is Regulatory Affairs specialists. They guarantee a smooth clearance process by being open and honest in their communication, answering inquiries and providing clarifications.

- **Regulatory Submission Preparation:** This entails compiling comprehensive dossiers on the efficacy, safety and quality of products, which are then submitted to regulatory agencies for approval. This calls for meticulous attention to detail and strict adherence to formatting and content rules.
- **Developing Trust and Reputation:** A company's reputation and trust are enhanced by adhering to the law and this boosts market acceptability and brand loyalty.
- **Post-Market Surveillance:** The job doesn't end after a product is approved. Regulatory Affairs specialists are in charge of keeping an eye on how the product is selling, spotting any possible safety issues and notifying the appropriate authorities about them.
- **Creating and Maintaining Quality Management Systems:** Ensuring product consistency and regulatory compliance requires the implementation and upkeep of strong quality management systems. In this procedure, Regulatory Affairs specialists are vital. (3,4)

#### 4. Quality of Regulatory Affairs

Environmental, biotechnology, pharmaceutical and medical device industries are just a few of the sectors that heavily depend on Regulatory Affairs specialists. They guarantee that businesses abide with all rules and legislation relevant to their industry. Essential characteristics of proficient Regulatory Affairs specialists encompass

- **Knowledgeable:** They need to be extremely knowledgeable about the rules and regulations governing particular sectors and areas. Keeping up with changing legislation requires on-going learning.

- **Detail-Oriented:** Since Regulatory Affairs specialists are in charge of creating and examining comprehensive regulatory documentation and submissions, accuracy is essential.
- **Analytical Skills:** They must evaluate legal requirements and standards and comprehend how they relate to the goods and services offered by their organisation.
- **Strategic Thinking:** Experts in this area frequently participate in strategic decision-making, assisting in the development and implementation of regulatory plans that complement goals.
- **Communication Skills:** Interacting with regulatory agencies, preparing submissions, and informing colleagues of regulatory requirements all depend on effective written and vocal communication.
- **Problem-Solving Skills:** They frequently have to come up with innovative ways to satisfy legal standards without sacrificing the development of new products or corporate objectives.
- **Project Management Skills:** Good organisational and project management skills are necessary to oversee the preparation of regulatory filings and guarantee compliance initiatives are finished time.
- **Interpersonal Skills:** Success depends on establishing and preserving a good rapport with regulatory bodies and guaranteeing cross-functional cooperation inside the business.
- **Ethical Integrity:** To guarantee that all regulatory actions are carried out honestly and openly, Regulatory Affairs specialists must preserve the greatest standards of ethical behaviour.
- **Adaptability:** Since laws and policies can change suddenly, it's critical to have the flexibility to adjust to new demands in order to stay in compliance and keep access to markets.

These attributes help Regulatory Affairs professionals successfully navigate complicated regulatory environments and support their organisations' success and compliance. (5)

**Table 1.** Regulatory Agencies of few countries (6)

Country	Authority	Full Form
USA	USFDA	United states food and drug administration
UK	MHRA	Medicines and health care products regulatory agency
India	CDSCO	Central drug standard control organization
Canada	HEALTH CANADA	Health Canada
Australia	TGA	A Therapeutic goods administration
South Africa	MCC	Medicines control council
Brazil	ANVISA	Agencia Nacional de Vigilancia Sanitaria
European union	EMA	Europe, the middle east and africa
China	SFDA	Saudi food and drug Authority
New Zealand	MEDSAFE	New Zealand medicines and medical devices safety authority
Japan	MHLW	Ministry of health, labour and welfare
Korea	KFDA	Korean medical device regulator
Zimbabwe	MCAZ	Medicines control authority of Zimbabwe
Sri Lanka	MoH	Ministry of Health



**Figure 2.** Quality of Regulatory Affairs

## 5. Present Aspects

The field of Regulatory Affairs was born out of the governments' desire to safeguard public health by monitoring the efficacy and safety of products in a variety of industries, such as pharmaceuticals, veterinary care, medical devices, pesticides, agricultural chemicals, cosmetics and complementary and alternative medicine, as well as the companies in charge of product development, testing, manufacturing and marketing, who want to make sure their products are safe and contribute meaningfully to public. A new category of experts has emerged to manage these Regulatory Affairs on behalf of businesses. Regulatory issues include a wide spectrum of specialised knowledge and professions. In the best of cases, it consists of a group of individuals that serve as a

mediator between the potentially antagonistic domains of industry, government and consumers in order to ensure that marketed goods are secure and efficient when used in accordance with their promoted instructions. Regulatory Affairs professionals' mediate disputes between the market (consumers), the industries that are regulated (industry) and the regulators (government) in order to promote and maintain the sale of high-quality products while preventing the sale of low-quality ones. The process of working with project teams and communicating with regulatory health organisations, such as the FDA or the global conference on Harmonisation of Technical Standards for Registration of Pharmaceuticals for Human Use is overseen by Regulatory Affairs liaisons. Apart from roles involving regulatory relations liaisons. (7)

**Table 2.** Drug Regulatory body in India (8)

Sr. No.	Main Bodies
1	Central Drug Standard Control Organization (CDSCO)
2	Ministry of Health and Family Welfare(MHFW)
3	Indian Council of Medical Research (ICMR)
4	Indian Pharmaceutical Association (IPA)
5	Drug Technical Advisory Board (DTAB)
6	Central Drug Testing Laboratory (CDTL)
7	Indian Pharmacopoeia Commission (IPC)
8	National Pharmaceutical Pricing Authority (NPPA)

## 6. Future aspects of Regulatory Affairs:

- **Integration of Technology:** Automation, artificial intelligence and machine learning are just a few of the technologies that Regulatory Affairs will use more and more to improve data analysis, expedite procedures and guarantee compliance. This covers the application of big data analytics for pharmacovigilance, block chain for supply chain transparency and electronic submission systems.
- **International Coordination:** The trend to harmonise regulatory standards across regions will continue as pharmaceutical markets become more

globalised. The International Council for Harmonisation (ICH) and other initiatives will be crucial in bringing rules into line to make medication development and market access more efficient.

- **Patient-Centricity:** Including patient viewpoints in regulatory decision-making is becoming more and more important. To make sure that treatments satisfy patients' requirements and preferences in the real world, this entails involving patients at every stage of the drug development lifecycle from designing clinical trials to conducting post-market surveillance.

- **Real-World Evidence (RWE):** RWE which offers information on the efficacy and safety of treatments in a range of patient groups outside of carefully monitored clinical trial settings will play a bigger role in regulatory submissions. It's likely that regulators will keep improving the frameworks they use to assess RWE and make decisions.
- **Medical devices and digital health:** Medical devices and digital health technologies are developing quickly which brings both benefits and challenges for regulation. In order to maintain patient safety regulators will need to modify their frameworks to accept innovations like wearable technology, telemedicine platforms and AI-driven diagnostics.
- **The Agility of Regulation:** Regulatory bodies will have to improve their responsiveness and agility in order to stay up with the quickly changing scientific and technological landscape. This might entail implementing more adaptable regulatory frameworks, promoting creativity and quickening the approval procedure. (9)

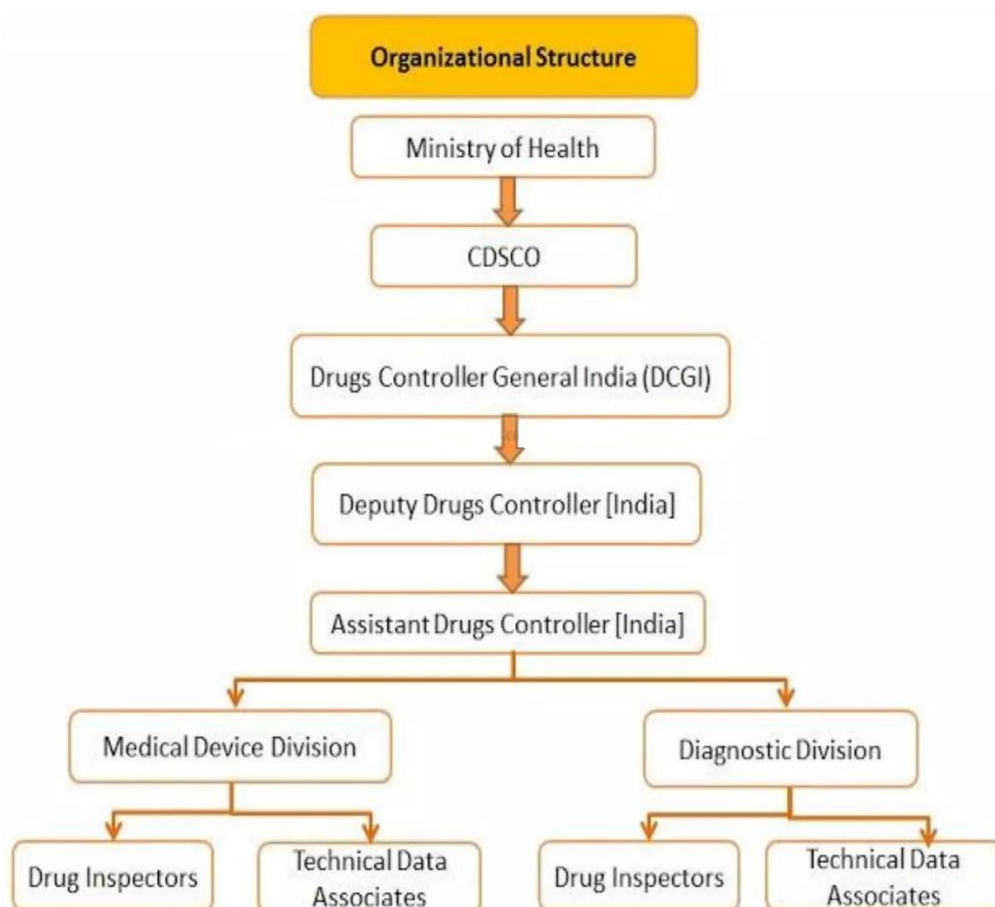


Figure 3. Organization Structure of Regulatory Body in India (10)

## 7. Importance of Artificial Intelligence in RA

- Artificial intelligence (AI) is a significant factor in Regulatory Affairs because it provides creative ways to increase compliance, optimise workflows and facilitate better decision-making. The following main ideas emphasise how crucial artificial intelligence is to Regulatory Affairs:
  - **Efficiency:** AI-powered solutions save regulatory professionals time and money by automating repetitive processes like document review, data analysis and compliance monitoring.
  - **Enhanced Compliance:** AI systems can scan through enormous volumes of data to find trends, abnormalities and possible threats. This allows for proactive compliance management and the resolution of legal problems.
- **Predictive Analytics:** AI models help businesses remain ahead of the curve by predicting compliance needs, predicting regulatory trends and evaluating the possible effects of regulatory changes.
- **Quality Assurance:** AI-powered quality control systems guarantee compliance with regulations by enhancing the precision and coherence of regulatory filings, minimising errors.
- **Decision Support:** AI systems help regulatory professionals make well-informed decisions in complicated regulatory contexts by giving them actionable insights and recommendations based on data-driven analysis.

- **Real-time Monitoring:** AI-driven monitoring systems keep tabs on news, updates and developments related to regulations, allowing businesses to quickly adjust to changes and stay compliant.
- **Risk Management:** Artificial intelligence (AI) algorithms evaluate and rank regulatory risks, enabling businesses to focus on high-impact areas and deploy resources efficiently to reduce vulnerabilities associated to compliance. (11)

## 8. Need of RA

India's economy is expanding quickly and more people are needed in the pharmaceutical field to meet the industry's demand for cures related to global concerns. Biotechnology and medical device pharmacy Investigation and creation these two industries have the strictest regulations worldwide. India's pharmaceutical industry is expanding at a very rapid pace. Professionals in regulatory relations serve as a bridge between the pharmaceutical industry and regulatory bodies. They have to know every rule inside and out. They must be knowledgeable about the rules, legislation, guidelines and directives issued by regulatory bodies. The pharmaceutical industry in India is expanding quickly, and companies need Regulatory Affairs professionals to help them compete on a global scale. The current topic addresses learning resources, regulatory education and its necessity, Course availability, curriculum and employment in Regulatory Affairs.

The pharmaceutical industry is growing more and more competitive worldwide and these observations highlight the importance of doing the work by understanding establishing guidelines akin to different activities serves as a guarantee that the procedure is governed. One of the businesses with the fastest regulatory changes is the pharmaceutical sector, which has the capacity to "handle Regulatory Affairs in a comprehensive manner."

The search and development biotechnology sector is one of the most strictly controlled in the nation of pharmaceutical scientific devices and science Given the rapid growth of the pharmaceutical industry in India, regulatory fairs specific lists are necessary to satisfy the needs of the industry in order to compete globally.

The pharmaceutical industry and worldwide regulatory agencies are connected by means of Regulatory Affairs specialists. They are required to possess a thorough understanding of the laws, regulations, directives and policies of regulatory bodies. For the benefit of pre-collegiate students and the college community, it is imperative that careers in pharmacy incorporate the most recent innovations into their traditional curricula. The current analysis looks at the need for academic resources, practical courses, regulatory education, route materials and job opportunities in Regulatory Affairs. The pharmaceutical industries are beginning to realise that the true struggle for survival is being able to carry out the work by seeing the associated suggestions. The number of tasks completed to give people confidence that the

procedure is below regulation as they move forward and become more.

In order to guarantee that laws and regulations are followed in a variety of industries, Regulatory Affairs are essential. Among the essential requirements for Regulatory Affairs are:

- **Compliance:** Making sure that, in order to reduce risks and preserve public safety, processes and goods meet legal requirements and standards.
- **Knowledge Management:** Keeping up with changing rules, policies, and industry standards to influence strategy and decision-making.
- **Strategic Planning:** Creating and putting into practice regulatory plans that minimise regulatory risks and ensure compliance with corporate goals.
- **Communication:** Encouraging efficient communication among internal groups, regulatory bodies and interested parties in order to resolve regulatory issues and hasten approvals.
- **Quality Assurance:** Setting up and keeping up quality systems to protect product integrity and regulatory compliance across the course of the product's lifecycle.
- **Risk management:** Recognising possible regulatory risks and creating plans to mitigate them in order to proactively handle problems and guarantee regulatory compliance.
- **Global Compliance:** Comprehending and manoeuvring through international regulatory frameworks to enable entry into markets and growth into international markets.
- **Advocacy:** Promoting regulations and rules that encourage innovation and safeguard public health and safety.
- **Technology Integration:** Using technological tools to improve productivity assure compliance and streamline procedures. Examples of these tools include data analytics and regulatory software.
- **Continuous Improvement:** Putting procedures in place for continuing Regulatory Affairs practice monitoring, assessment and improvement in order to adjust to changing industry trends and regulatory environments. (12,13)

## 9. Professional roles in Regulatory Affairs

Serving as a liaison with regulatory agencies is the responsibility of a Regulatory Affairs specialist. cGMP, ICH, GCP and GLP rules, regulations and laws that apply are prepared and adhered to the utmost care. In order to translate regulatory requirements into realistic, feasible plans, they are offering their experience and regulatory information. In the industry, regulators are involved in all phases of drug research as well as those that follow approval and marketing of the drug. To register and subsequently market a medicine, pharmaceutical companies use all of the data that was seen during the drug's discovery and development phases. Pharmaceutical

businesses must adhere to stringent regulations and rules during the development phase in order to guarantee the efficacy and safety of drug in human.

Regulatory experts are accountable for Keeping abreast of the constantly evolving laws in every area where a business wants to sell its goods recommending limitations and requirements in the fields of science and law gathering, organising and assessing scientific data submitting registration paperwork to regulatory bodies and conducting any further discussions required to secure or preserve the items' marketing authorization Providing strategic and technical guidance at the highest levels of their organisations, they significantly contribute to the commercial and scientific success of the business overall. Assisting the business in avoiding issues brought on by improperly maintained documentation, erroneous scientific reasoning, or inadequate data presentation.

It is the responsibility of the Regulatory Affairs specialist to stay up to date with the constantly evolving laws in every area where the business hopes to distribute its goods. Additionally, they make recommendations regarding the constraints and requirements imposed by law and science and gather, compile and assess the scientific data being produced by their research and development colleagues. They must or will be in charge of presenting registration paperwork to regulatory bodies and handling all follow-up talks required to keep the relevant products' marketing license. At the highest levels of their organizations, they provide strategic and technical guidance from the outset of product development, significantly contributing to the program's and the company's success from a commercial and scientific standpoint. (14)

#### **Essential knowledge and skill**

A bachelor's degree in chemistry, product safety, or a similar discipline is required for employment as a Regulatory Affairs expert. It will be helpful to have a solid understanding of both national and international rules. Those that are interested can apply to join trade associations such as the Society for Regulatory Affairs Professions. One of the most crucial competencies for Regulatory Affairs professionals is excellent analytical skills, as they must apply their regulatory expertise to guarantee that organisations are compliant. Strong communication abilities are essential for Regulatory Affairs professionals to work with others and communicate with suppliers, clients, or sales reps as needed. To effectively supervise regulatory activities, they need also possess a keen eye for detail.

The Regulatory Affairs team will be impacted by these advancements in medicine, healthcare and the pharmaceutical and medical device industries. With the advent of digital technologies and automation, the old heavy "task"-based workload will change and call for broader strategic leadership abilities. To progress in their careers, regulatory professionals must consequently possess the abilities, know-how and self-development mentality that will enable them to grow as individuals. Volatile, unpredictable, complex, and ambiguous (VUCA) is the term used to describe the modern work environment; the worldwide pandemic has created a "new

normal" in which these elements are exacerbated. The World Economic Forum has highlighted many crucial competencies for the workplace of the future, including complex problem-solving, active learning, analytical thinking and innovation and critical thinking and analysis.

Regulatory professionals should examine their individual competencies and identify any gaps before working with their managers to build a strategy for ongoing learning and professional development. To up skill, they might look for a combination of formal schooling, quick courses, micro credentials and unofficial learning opportunities. Working on short-term projects in many fields also contributes to expanding perspectives, strengthening connections and deepening expertise. This supports a solution-focused approach to work by aligning with a growth mind-set as opposed to a task perspective. Regulatory professionals can make sure they are regularly assessing trends that may impact their work in addition to receiving additional education and training to develop the necessary skills. One way to do this is by routinely reviewing the activities and outputs from international regulatory bodies like ICMRA, IMDRF, IPRP, ICH and WHO.

To determine future paths for regulatory agencies, regulatory professionals should evaluate modifications to law and strategy plans from regulators. It is important to consider the effects of significant policy changes, such the Pharmaceutical Strategy for Europe, as well as revisions to national medicines policies that are specific to each country, like the most recent revision to Australia's National Medicines Policy. Such policies may have effects that go beyond the borders of the nation or area taking part in the effort. Regulatory experts can better understand global discussions and the sources of different change drivers by reviewing such changes. Regulatory professionals should also be informed on pertinent government reviews that could have an influence on their industry and organisations. (15)

#### **10. Conclusion**

In the current competitive landscape, the appropriate execution of all Regulatory Affairs-related operations is considered for the company's financial significance. Future information regarding regulatory actions is necessary in order to make several adjustments that will impact the field's advancement. The regulatory landscape is changing and technological breakthroughs combined with globalization are driving exciting developments in the field of Regulatory Affairs. It will be essential to embrace advances while upholding strict standards in order to ensure patient safety, promote industry growth, and provide prompt access to cutting-edge therapies globally.

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## Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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