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Current scenario of Drug regulatory affairs

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Abstract:

Regulatory affairs (RA) professionals play critical roles in a pharmaceutical industry Because it is concern about the healthcare product lifecycle, it provide strategic, tactical and Operational direction and support for working within regulations to expedite the development And delivery of safe and effective healthcare products to individuals around the world.

The Role of regulatory affairs is to develop and execute a regulatory strategy to ensure that the Collective efforts of the drug development team results in a product that is approvable by Global regulators but is also differentiated from the competition in some way and also is to Ensure that the company's activities, from non-clinical research through to advertising and Promotion, are conducted in accordance with the regulations and guidelines established by Regulatory authorities.

Regulatory Affairs is an attractive career choice for graduate students From a scientific background who enjoy communication and team work, are comfortable with Multi-tasking and are eager to expand their knowledge in the wide realms of the Pharmaceutical world. Regulatory Affairs is a rewarding, intellectually stimulating and highly Regarded profession within pharmaceutical companies.

INTRODUCTION

Regulatory Affairs (RA), also called Government Affairs, is a profession within regulated Industries, such as pharmaceuticals, medical devices, energy, and banking. Regulatory Affairs Also has a very specific meaning within the healthcare industries (pharmaceuticals, medical Devices, Biologics and functional foods) most companies, whether they are major multinational Pharmaceutical corporations or small, innovative biotechnology companies, have specialist Departments of Regulatory Affairs professionals[1-4]. The current Pharmaceutical Industry is well Organized, systematic and compliant to international regulatory standards for manufacturing of Chemical and Biological drugs for human and veterinary consumption as well as medical Devices, traditional herbal products and cosmetics. Stringent GMPs are being followed for blood And its derivative as well as controlled manufacturing for Traditional Herbal Medicines, Cosmetics, Food and Dietary products which was otherwise differently a century before. Each Regulatory system had faced certain circumstances which led to current well-defined controlled Regulatory framework. This has resulted into systematic manufacturing and marketing of Safe, efficacious and qualitative drugs. With the growth of industry, the legislations from each Region have become more and more complex and created a need for regulatory professionals [2]. To understand the chronological development of the modern era of pharmaceutical industry And regulatory framework, we will glance through the historical evolution of regulations in USA, Europe and India

Fig.1

Objectives of Regulatory Affairs

- How and why the pharmaceutical industry and drug regulations have developed in USA
- Major Regulations of USA
- Framework of EU and its regulatory
- "The Rules Governing Medicinal Products in the European Union"
- Pharmaceutical Legislations of EU
- Indian Pharmaceutical Industry & Drug Regulations development in different Era
- Types of Marketing Authorization Procedure in EU Market
- Major Rules and Act of India
- Roles of Regulatory Affairs Professional in Health Authorities as well as Pharmaceutical

Functions of Drugs regulatory affairs.

Department :

Provide regulatory and technical inputs for product Development. Prepare, review and submit different regulatory Submissions. Act as interface between internal department of Organization. Review and submit Annual drug reviews, Adverse Drug experience, recall coordination activities and Different regulatory guidelines. Answer and negotiate with the Drug regulatory Authorities on various issues on drug registration.

Apply for the various certifications and arrange for The audit and also work on their renewal & many more.

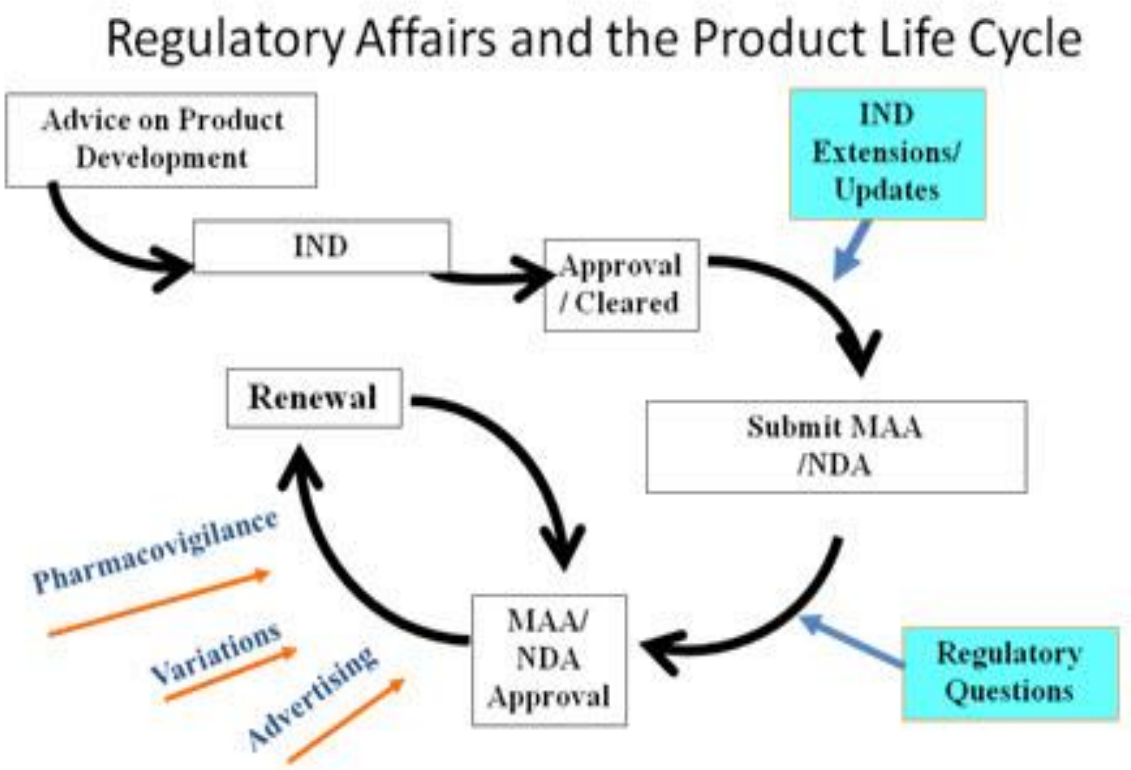

Fig .2

Scope

- Regulatory Affairs is a comparatively new profession which has developed from the desire of governments to protect public health, by controlling the safety and efficacy of products in areas including pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines ..
- Drug regulatory affairs deals with pharmaceutical products.
- Ensuring compliances with regulations and laws pertaining to their business.
- Availability of safe ,effective and quality pharmaceutical products.
- It is dynamic and challenging field in pharmaceutical industries.
- It is an affair between competent authority and an applicant to manage lifecycles of products .
- In present regulatory scenario , company requires experts in regulatory activities to manage to product life cycle
- RA experts are qualified professionals to provide right solution to the technical problems under the light of laws regulations.
- Regulatory affairs plays a critical role in the pharmaceutical industries and is involved in all stages of drug development and also after drug approval and marketing .
- Pharmaceutical companies use all the data accumulated during discovery and the development stage in order to register the drug and the market the drug.
- Throughout the development stages , pharmaceutical companies have to abide by and array of strict rules of guidelines in order to insure safety and efficacy of the drug in humans.
- Regulatory affairs professionals are employed in industries ,government regulatory authorities and academics .The wide range of regulatory professionals including these areas :
- Pharmaceuticals
- Medical devices
- In vitro diagnostics
- Biologics and biotechnology
- Nutritional products
- Cosmetics

Historical overview

During 1950s, multiple tragedies i.e. sulfanilamide elixir, vaccine tragedy and thalidomide tragedy have resulted in substantial increase of legislations for drug products quality, safety and efficacy. This has also resulted into stricter norms for Marketing Authorization (MA) and Good Manufacturing Practices (GMPs). Let us see what happened in USA, Europe and India.

Needs of regulatory affairs

Drug development and commercialization is highly regulated the path to drug registration Marketing Approval) is paved with good intention but can be complicated Things change constantly.

Parameter of regulatory affairs

- Design =Development Plan
- Co-ordination= Writing/reviewing, supervising
- Construction= Assembling & Submission Management
- Testing= Where are the weakness
- Drug regulations
- National Laws (e.g. UK – Medicines Act, US- CFR)
- Regional Laws (EC directives)
- National and Regional Guidelines
- International Guidelines (ICH)

Regulatory affairs trends in 2020

1. **The Evolution of Medical Device Regulation:**

The European Union is in the process rewriting all its medical device regulations (MDRs), which Will significantly impact the work of regulatory professionals.

"The evolution of MDRs will fundamentally change how device manufacturers develop, market, and gain regulatory approval of their products," Amato remarks. "For example, healthcare practitioners can interact with implants such as pacemakers and insulin delivery devices through Bluetooth or the cloud, so now cybersecurity is a concern because those devices could be hacked. The FDA and regulatory agencies around the world are developing regulations that will guide manufacturers in complying with new data security standards."

2. **Changes to Biopharma Approval Processes :**

In December 2016, the U.S. Congress determined that the FDA will consider real-world evidence from off-label drug use in regulatory approvals. The resulting effects of this legislation, however, are just now being implemented.

"There's a public policy debate raging about whether this is helping or hurting the drug approval process," Amato says. "This is a mechanism for the FDA to approve new drug products sooner, but as part of that approval, they're asking manufacturers to continue to collect data by observing how the drug is being used in clinical practice. One of the driving factors in collecting this real- world evidence is that it enables a more rigorous safety profile."

3. Clinical Trials

Amato says the FDA and other regulatory agencies are now using patient-reported outcomes

(PROs) more frequently in the drug approval process.

"Historically, agencies relied on lab tests such as blood panels and urinalysis instead of what the patient felt," Amato notes. "There's legislation in the works to collect PROs and use these to determine if a drug is approved or not. If you look at insomnia medications, for example, what really matters to the patient is whether they fall asleep at night, so PROs are really important and can affect regulatory decision making."

Amato says industry professionals should remain cognizant of these changes and how they may impact their day-to-day responsibilities and the industry as a whole moving forward.

Regulatory affairs as a profession

The (healthcare) regulatory affairs profession is still an emergent profession but has four major international professional membership organizations:

- Drug Information Association, DIA.
- The Regulatory Affairs Professionals Society, RAPS.
- The Organization for Professionals in Regulatory Affairs, TOPRA.
- Vietnam Regulatory Affairs.
- Association of Regulatory Affairs Professionals :

Which offer education and training, professional development, competence certification and codes of ethics.

The regulatory professional typically has a background relevant to the business in which they work, i.e., science, medicine, or engineering.

Qualities of good RA Profession

- Authoritative
- Team Player
- Decisive
- Resourceful
- Good Communication Skill
- Analytical Skill- Ability to evaluate the strengths and weakness of the technical and legal options open to a company.
- Good Informational Technology skills
- Negotiating Skills

- Able to reapply scientific and regulatory principles
- Ability to work with other disciplines
- Flexible- Always willing to learn

Regulatory functions

- Regulatory Affairs is actively involved in every stage of development of a new medicine and in the post-marketing activities with authorized medicinal products.
- Regulatory Affairs professionals can play a key role in guiding drug development strategy in an increasingly global environment.
- Regulatory professionals ensure that the information and data to be conveyed and discussed with the regulatory bodies are presented in the right way and form.
- They develop the regulatory strategy, arrange agency meetings, prepare and compile the questions and briefing documents; they attend the meetings and manage all communication with the agencies. Since the regulatory environment is constantly changing the regulatory team provides advice on necessary adaptations to development plans and target product profiles.
- Many aspects in India are not regulatory intensive, these may lead to supply of poor quality pharmaceutical agents to the patients. There is no way to check the quality of drugs after 4 years from the date of first introduction in India
- During this 4-year period the drugs will be under ―new drug¦ category and they require bioequivalence and if necessary clinical studies are conducted.
- Those drugs which are called ―old drugs¦ after this 4-year period, need not be subjected to bioequivalence studies and they can be permitted to market without these stringent requirements as compared to new drugs.
- Evolution of regulatory system changes the industry in any country and encourages people to do more to discover and invent new drugs for emerging diseases. India is rich in biodiversity and plants with high medicinal values.
- The USFDA is responsible for giving rise to the most competitive pharmaceutical• industry in the world. They set standards so that doctors and patients are not afraid of using new drugs.

The Present Scenario

Pharmaceuticals are considered as the most highly regulated industries worldwide. The regulatory body ensures compliances in various legal and regulatory aspects of a drug. Every country has its own regulatory authority, which is responsible to enforce the rules and regulations and issue the guidelines to regulate drug development process, licensing, registration, manufacturing, marketing and labelling of pharmaceutical products.

Regulatory Approval in India

The drug approval process in India has faced challenges in recent years, some around compulsory licensing of patents, government price control and narrow standards for patentability. Other issues have also occurred in the clinical trials area, which, despite India's high treatment-naïve population and emerging economy, have reduced pharmaceutical sponsors' interest in India as a priority area which to conduct clinical studies. The international regulatory organizations play essential role in all aspects of pharmaceutical regulations related to drug product registration, manufacturing, distribution, price control, marketing, research and development, and intellectual property protection.

DRUG APPROVAL PROCESS IN INDIA

It is given in THREE phase

First phase:

1) Applicant is filling the application of IND (Investigational New Drug) with their informational studies to CDSCO headquarters.
2) All the information is examined by new drug division.
3) Then detailed review by IND committee

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4) With proper information of CDSCO Recommendation to DCGI (Drug Controller General Of India).
5) Then IND application is approved

Second phase:-

1) Application is given one copy of IND information to ethical committee with application.
2) Then ethical committee report the application of IND.
3) This process taken within 12 Weeks.

Third phase:-

1) In 1 phase, IND application is approved and in 2 phase, ethical committee report is positive then 3 phase is started.
2) In 3 phase, clinical trials is started.
3) Then again give application for new drug registration to CDSCO.
4) Then finally review by DCGI
5) If Review is positive or complete then LICENSE IS GRANTED
6) If Review is not complete then refused to grant license (4,5,6).

Pharmaceutical Drug Regulatory Affairs.

This department is responsible for knowing the regulatory requirements for getting new products approved. They know what commitments the company has made to the regulatory agencies where the product has been approved. They also submit annual reports and supplements to the agencies. Regulatory Affairs typically communicates with one of the Centers (e.g., Center for Drug Evaluation and Research) at the FDA headquarters, rather than the FDA local district offices. Gimps do not directly apply to Regulatory

Affairs; however, they must understand and evaluate changes to drug manufacturing and testing activities to determine it.

And when the FDA must be notified. Regulatory Affairs is a comparatively new profession which has developed from the desire of governments to protect public health, by controlling the safety and efficacy of products in areas including pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines. The companies responsible for the discovery, testing, manufacture and marketing of these products also want to ensure that they supply products that are safe and make a worthwhile contribution to public health and welfare. Regulatory Affairs professionals, with their detailed knowledge of the regulations and guidelines, are frequently called in to advice on such matters.

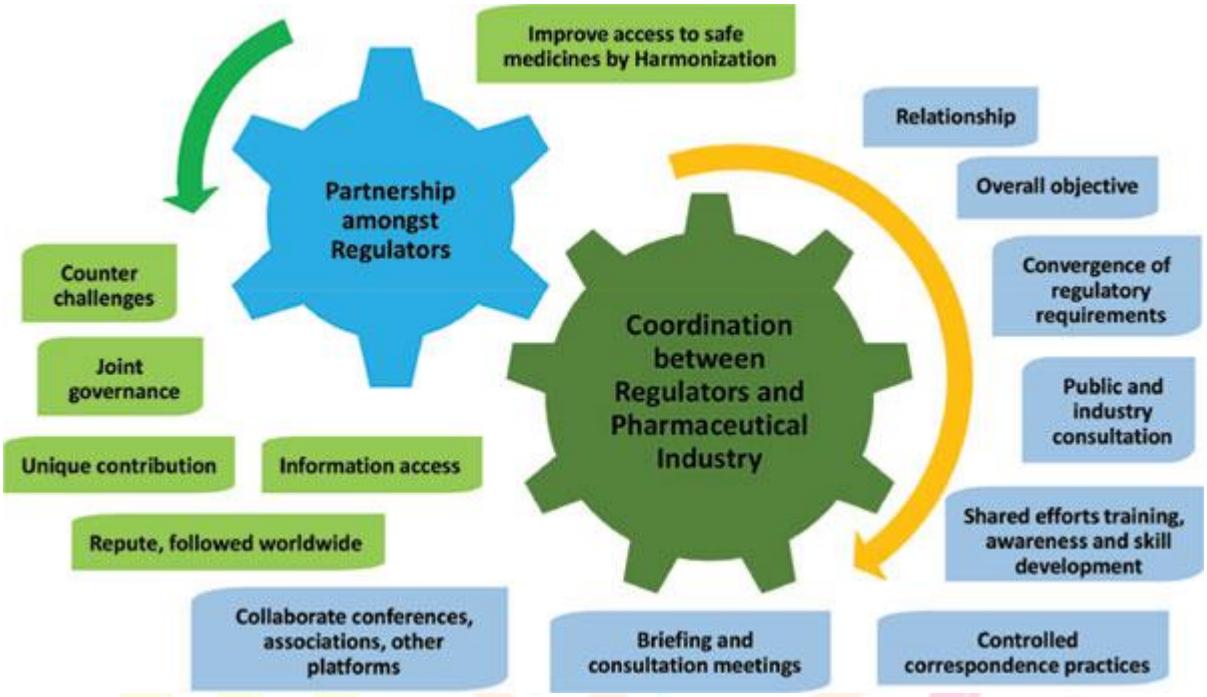

fig.3

Challenged to regulatory affairs

GMP ensures that quality is built into the organization and processes involved in the manufacture of the products and all those operations should be carried out strictly according to cGMP. Current Good Manufacturing Practices, formal regulations contained in statutes and agency policies and concern the design, monitoring and control of manufacturing processes and facilities. GCP (Good Clinical Practice) is an international ethical and scientific quality standard for the performance of a clinical trial on medicinal products involving humans. GCP includes all aspects of a clinical trials. Regulatory affairs is a comparatively new profession which developed from the desire of governments to protect public health by controlling the safety and efficacy of products in areas including pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines

- Sterile pharmaceutical or biological medicinal products.
- GMP regulations.
- Regulatory requirement of pharmaceutical products.
- Health care regulatory affairs.
- Clinical safety data management.
- Clinical investigation of medical devices.

The Responsibilities of the Regulatory Affairs

- Keep in touch with international legislation, guidelines and customer practice.
- Keep up to the date with a company's product range
- Ensure that a company's products comply with the current regulations.
- The Regulatory Affairs professional's job is to keep track of the ever-changing legislation in all the regions in which the company wishes to distribute its products. They also advise on the legal and scientific restraints and requirements, and collect, collate, and evaluate the scientific data that their research and development colleagues are generating.
- Formulate regulatory strategy for all appropriate regulatory submissions for domestic, international and/or contract projects.
- Coordinate, prepare and review all appropriate documents for example dossier and submit them to regulatory authorities within a specified time frame in conjugation with the organization.
- Prepare and review of SOPs related to RA. Review of BMR, MFR, change control and other relevant documents.
- Monitor the progress of all registration submission.
- Maintain approved applications and the record of registration fees paid against submission of DMF's and other documents.
- Respond to queries as they arise, and ensure that registration/ approval are granted without delay.
- Impart training to R&D, Pilot plant, ADl and RA. Team members on current regulatory requirements.
- Advising their companies on the regulatory aspects and climate that would affect proposed activities. i.e. describing the "regulatory climate" around issues such as the promotion of prescription drugs and Sarbanes-Oxley compliance.
- Manage review audit reports and compliance, regulatory and customer inspections.
- Regulatory Affairs professionals help the company avoid problems caused by badly kept records, inappropriate scientific thinking or poor presentation of data. In most product areas where regulatory requirements are imposed, restrictions are also placed upon the claims which can be made for the product on labelling or in advertising.

Regulation and Regulatory Affairs:

India is home to about 10,500 manufacturing units and over 3,000 pharma companies, and exports all forms of pharmaceuticals from APIs to formulations, both in modern medicine and traditional Indian medicines. Everything from drug development and regulation to commercialization is highly regulated in the country. Every drug must undergo rigorous scrutiny and clinical trials before getting the market approval to ensure its quality, safety, and efficacy. In India, these standards are set by regulatory authorities or the Drug Control Authority (DCA). Regulation impacts all aspects of the pharmaceutical domain, from pharmaceutical companies and independent innovators to regulatory or administrative bodies and patients.

The regulatory department holds a crucial link between drug products, companies, and regulatory authorities in determining the chances of drug development and the product to enter the market. Regulation involves a broad and extensive evaluation of a particular drug to ensure the protection of public health, drug registration, marketing authorization, pharmacovigilance, import, export, and distribution of the product. Regulatory Affairs is a blend of science and management that helps achieve the commercial goal of the drug-development organizations. RA takes care of everything from the development plan to supervising/reviewing of the submission guidelines in the drug development and authorization process

The Roles of current scenario of drug regulatory affairs

- RA as profession is broader than registration of products , they advise companies both strategically and technically at the highest level.
- There role began rights from development of product to making marketing and post marketing
- They advise at all stages both in terms of legal and technical requirements and restrains help companies save a lot of time and money in developing the product and marketing the same.
- They have a major contribution in companies success both commercially and scientifically
- Their main role is to comply with safety and efficacy of the product as per regulation laid down by the government.

Regulatory Affairs Profession

The (Healthcare) Regulatory Affairs Profession is still an emergent profession but has two major international professional membership societies:

The Regulatory Affairs Professionals Society, RAPS,

The Organization for Professionals in Regulatory Affairs, TOPRA,

In Canada, the major professional membership society is: The Canadian Association of Professional Regulatory Affairs, CAPRA,

- **Major Regulatory Authorities In Difference Countries**

1.Country Regulatory Authority

2.India Central Drugs Standard Control Organization Drug controller general of India (DCGI)

3.US Food and Drug Administration (US FDA)

4.UK Medicines and Health care products regulatory Agency (MHRA)

5.Australia Therapeutic Goods Administration (TGA)

6.Japan Japanese Ministry of health, Labour and Welfare (MHLW)

7.Canada Health Canada

8.Brazil Agency Nacional degradation Vigilancia Sanitaria (ANVISA)

9.South Africa Medicines Control Council (MCC)

10.Europe **European Directorate for Quality of Medicines (EDQM)**

European Medicines Evaluation agencies (EMEA)

Regulatory Strategy

The role of regulatory affairs is to develop and execute a regulatory strategy to ensure that the collective efforts of the drug development team results in a product that is approvable by global

Regulators but is also differentiated from the competition in some way and also is to ensure that the company's activities.

Importance Of Drug Regulatory Affairs

- In today's competitive environment the reduction of the time taken to reach the market is critical to a product's and hence the company's success. The proper conduct of its Regulatory Affairs activities is therefore of considerable economic importance for the company.
- Inadequate reporting of data may prevent a timely positive evaluation of a marketing application. A new drug may have cost many millions of Euros or dollars, pounds, to develop and even a three- month delay in bringing it to the market has considerable financial considerations.
- Even worse, failures to fully report all the available data or the release of product bearing incorrect labeling, may easily result in the need for a product recall .
- Either occurrence may lead to the loss of several millions of units of sales, not to mention the resulting reduction in confidence of the investors, health professionals and patients.
- The Regulatory Affairs department is very often the first point of contact between the government authorities and the company.

Regulatory Affairs in Product Management

- The key role of RA professional is broader than registration of products, they advise companies both strategically and technically at the highest level.
- Their role begins right from development of a product to making, marketing and post marketing strategies.
- Their advice at all stages both in terms of legal and technical requirements help companies save a lot of time and money in developing the product and marketing the same.
- For countries that do not have their on regulations the World Health Organization guidelines on health matters and World Trade Organization on trade regulations between nations is followed.

The Regulatory Affairs in R & D

- The regulatory affairs personnel work hand in hand with marketing and R&D to develop, innovative products that take advantage of new technological and regulatory developments to accelerate time to market.

- With new products expected to add significant revenues to the company's bottom lines, small decreases in time to market equate to large material gains in revenue and profit.

- Employing adaptive clinical trial strategies, obtaining quick approval from regulatory authorities and avoiding pitfalls in processes can accelerate development of new products and help to reduce costly errors and time lags.

: Current Scenario

- Currently, regulatory responsibilities are divided between CDSCO and SDRAs.
- CDSCO is responsible for granting approvals for clinical trials, new drugs and specialized medicinal products (vaccines, parenteral, and other high risk products) and authorizations for import and export.
- SDRAs are responsible for granting manufacturing, distribution and sale licenses and for inspections, sampling and testing and overall quality control of medicinal products (including investigating violations and launching prosecutions).
- The lack of uniformity in legal interpretations of the DCA, and in regulatory decision making between CDSCO and SDRA, is a continuous challenge in ensuring harmonized application of drug regulatory standards throughout the country.
- The DCA Bill, 2015 has sought to address this issue by expanding the functional mandate of the CDSCO to include 17 new categories of products for which manufacturing and sales licenses will be granted by it.
- Almost all the regulatory officials from Kerala said that there is limited interaction with the CDSCO except for the DCC meetings (attended only by the SDC) and joint inspections.
- The 59th Parliamentary standing committee reported that due to some ambiguity on the powers of the SDRAs, some SDRAs have issued manufacturing licenses for.
- As per the law, a product is deemed to be a new drug when two or more drugs, already approved individually, are combined for the first time in an FDC.
- Fig No . 2 Organization Chart Of Regulatory Affairs
- Too many pharmaceutical companies make the common mistake of starting with the organizational a different mind-set and spread that new way of thinking as they develop employees to fill changing roles in the organization.
- Senior leaders must clearly define desired skills and experience and ensure that these skills are aligned with the organization's mission; failing to do so can result in poor hiring decisions, low-impact training, and incentives that do not align with the desired mission.
- Making this shift requires a completely different talent profile. GRA organizations have two options: develop the needed people internally, or hire a new crop of employees.
- People already in the organization may also be a good fit for other roles under a new structure.
- To identify promising internal candidates, GRA organizations can map potential career paths by defining the knowledge, skills, and attitudes required to move from one role to another, whether upward to more senior positions or laterally to different functions.
- GRA organizations must also update their recruiting practices to attract individuals with the right skills.
- For example, so-called "behavior event interviewing"—asking candidates to explain situations or experiences from previous positions— can help recruiters gauge if a candidate has exhibited a strategic mind-set in the past and screen out prospects whose qualifications on paper may be impressive but who would not meet the behavioral expectations of a strategic GRA organization.
- In addition, these interviews can help GRA executives assess an individual's ability to be a network leader 3 and to engage effectively with both internal and external stakeholders— a critical skill in regulatory affairs today.

Report

- ISR interviewed 13 experience regulatory affairs professionals at 11 of the top 50 pharmaceutical companies to better understand the regulatory affairs function .
- ISR has design this report to be use as a bench marking tool for companies to compare there regulatory affair functions to those of other organizations . key take a ways include :
- Identifies how your companies approach to regulatory affairs may be different from a typical industry approach and the benefits and drawbacks that may result

- Gather information on unique regulatory affairs structures and based practices employed by other organizations , which may be used to improve or stream line the function
- Compare your companies regulatory affairs department size , structure, resources and approach to those of other companies.

Conclusion

The Indian regulatory system for drugs can be described as a classic command and control regime, wherein technical standards are set which the regulate is expected to follow and the regulator then undertakes inspections to supervise compliance. Most other drug regulatory systems also follow the same pattern. There are certain aspects of a command and control system which aligns itself with the objectives of drug regulation. Established standards ensure clarity of what is expected from regulates and also make it relatively easier to identify breach of such standards. However, there are certain prerequisites to ensure success of such a regulatory structure. First, standard setting is expertise driven and requires considerable investment in accessing technical knowledge. Second, adequacy of staff and infrastructure is important to ensure quality and regularity of inspections. Third, as put forth by Kagan (1994), command and control norms are easier to enforce in the case of big and easily identifiable regulates rather than smaller firms. The Indian regulatory system has been suffering from critical shortfalls in regulatory resources (personnel and other infrastructure like drug laboratories), thus undermining its capacity to ensure effective enforcement. The division of regulatory responsibilities between the Centre and states, without any single agency being made responsible for the holistic enforcement of law has led to fragmentation and undermined effectiveness. This is also to underline that the analysis presented in this study is not only based on perception, but is based on hard facts. For all these reasons, we hope that this study is widely read by all stakeholders as it holds a clear mirror to the present challenges confronting the drug 49 regulatory system. We hope that this study will help contribute to the current discussions of regulatory reform of the Indian drug regulatory system.

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