



CODEN [USA]: IAJ PBB

ISSN : 2349-7750

INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES

SJIF Impact Factor: 7.187

<https://doi.org/10.5281/zenodo.17487377>Available online at: <http://www.iajps.com>

Review Article

INTER RELATIONSHIP BETWEEN RA, QA AND QC FOR REGULATORY AFFAIRS

Gunde Navitha*, Mrs. M. Mounika, Dr. D. Venkata Ramana.

Department of Pharmaceutical Regulatory Affairs, Holy Mary Institute of Technology and Science (College of Pharmacy), Keesara - Bogaram - Ghatkesar, Telangana -501301.

Abstract:

The regulatory affairs (RA) department of a pharmaceutical company is responsible for obtaining approval for new pharmaceutical products and ensuring that approval is maintained for as long as the company wants to keep the product on the market. There are different departments in pharmaceutical company such as Research and Development, Quality Assurance, Production, and Quality Control. RA officer having different roles in these departments. They are involved in the development of new medicinal products from the primary stage, preparing the dossier and documentation to till end stage, submitting the relevant regulatory dossiers to health authorities. In this review we discussed that the role of RA officer in different areas discussed. RA is also responsible for maintaining the appropriateness and accuracy of the product information. And its main role to act as a liaison with regulatory agencies, providing expertise and regulatory intelligence in translating regulatory requirement into practical workable plan, advising the company on regulatory aspects and climate that would affect their proposed activities for the purpose of regulatory submission.

Key words: Research and Development, Quality Assurance, Production, and Quality Control, regulatory submission.

Corresponding author:**Gunde Navitha***

Department of Pharmaceutical Regulatory Affairs,
Holy Mary Institute of Technology and Science (College of Pharmacy),
Keesara - Bogaram - Ghatkesar, Telangana.
Email Id- navitha1914@gmail.com

QR CODE



Please cite this article in press Gunde Navitha et al., *Inter Relationship Between RA, QA And QC For Regulatory Affairs*, Indo Am. J. P. Sci, 2025; 12(10).

INTRODUCTION:**Regulatory submission**

Regulatory submissions are packages of information and data needed by a regulatory agency to establish whether a regulated healthcare product can progress to clinical testing or whether it is safe and effective for marketing. A regulatory submission for a healthcare product includes any documentation or information submitted to a regulatory agency for review, for notification or in response to a request for additional information related to a healthcare product. The format can be paper or electronic, or both. The amount of information involved and its required complexity can vary significantly. A licensing application for a drug or biological product may contain hundreds of paper volumes whereas a response to an agency's question for a clarification may involve a single page.^{1,2}

Types of regulatory submissions

Types of regulatory submissions can include:

- Licensing applications for drug, biologics or devices
- Clinical trial applications
- Requests for orphan drug or fast-track designations
- Requests for protocol assistance
- Responses to agency questions that arise during the review; for example, clarifaxes, deficiency letter, requests for additional information
- Post-approval studies or commitments
- Amendment/variation applications or notification submissions

Planning for and preparing your regulatory submission

Before preparing any regulatory submission, identify the relevant regulatory requirements so that you can ensure your submission will comply. Note that the requirements for drug and medical device submissions are quite different.

Consider the following:

- Who is the regulatory agency and what is the review division for my healthcare product?
- What are the regulatory requirements that govern my submission?
- What kind of information should be included? Is there a guidance document available that details the format and content requirements of the submission?
- Where do I send the submission?
- How many copies should I submit?
- Should I submit the submission in an electronic format? Is that mandatory?
- For hard-copy submissions, are there requirements regarding binding

- For electronic submissions, what is the acceptable data format, file size and means for submission (CD-ROM, secure gateway, others)

Develop a standard format or style guide for managing submissions. Submission templates should have built-in styles for headers and footers, headings, table and figure titles, and so forth. Such templates should also identify the paper size as well as the margins (both portrait and landscape) for printing and binding purposes. This is particularly important if you plan to generate global submissions, as the information can then be printed on both letter size and A4 paper and permit proper binding.

As the submission should facilitate the regulatory review, organize the information so that it is easy to read and properly sectioned. Have it support navigation so the reviewer can quickly find what they need. Where applicable, consider using these elements:

- Cover letter
- Table of contents
- Volume and page numbers
- Clear headings and subheadings
- Table and figure numbers, with accurate references to them from within the text
- Tabs that aid quick finding of the submission sections
- Reader-friendly font sizes, types and colours

Ensure that content is clearly legible and that submissions are properly bound using binders acceptable to the regulatory agency. Lastly, if any source document is in another language, ensure you provide an appropriate translation. Generate electronic submissions in accordance with regulatory requirements. Once you have prepared your regulatory submission, examine it thoroughly to ensure it is accurate and complete (for example, no missing pages within a hard copy, no broken links within an electronic submission) before you submit it to the regulatory agency.

Goal of the Guidance

This guidance describes a comprehensive quality systems model, which, if implemented, will allow manufacturers to support and sustain robust, modern quality systems that are consistent with CGMP regulations. The guidance demonstrates how and where the elements of this comprehensive model can fit within the requirements of the CGMP regulations. The inherent flexibility of the CGMP regulations should enable manufacturers to implement a quality system in a form that is appropriate for their specific operations

The overarching philosophy articulated in both the CGMP regulations and in robust modern quality systems is:

Quality should be built into the product, and testing alone cannot be relied on to ensure product quality; This guidance is intended to serve as a bridge between the 1978 regulations and our current understanding of quality systems. In addition to being part of the FDA's CGMP initiative, this guidance is being issued for a number of reasons:

1. A quality system addresses the public and private sectors' mutual goal of providing a high-quality drug product to patients and prescribers. A well-built quality system should reduce the number of (or prevent) recalls, returned or salvaged products, and defective products entering the marketplace.
2. It is important that the CGMP regulations are harmonized to the extent possible with other widely used quality management systems, including ISO 9000, non-U.S. pharmaceutical quality management requirements, and FDA's own medical device quality system regulations.
3. This guidance serves as a first step to highlight common elements between the CGMP regulations and Quality Management Systems. With the globalization of pharmaceutical manufacturing and the increasing prevalence of drug- and biologic-device combination products, the convergence of quality management principles across different regions and among various product types is very desirable.
4. The FDA has concluded that modern quality systems, when coupled with manufacturing process and product knowledge and the use of effective risk management practices, can handle many types of changes to facilities, equipment, and processes without the need for prior approval regulatory submissions. Manufacturers with a robust quality system and appropriate process knowledge can implement many types of improvements. In addition, an effective quality system, by lowering the risk of manufacturing problems, may result in shorter and fewer FDA inspections.
5. A quality system can provide the necessary framework for implementing quality by design (building in quality from the development phase and throughout a product's life cycle), continual improvement, and risk management in the drug manufacturing process. A quality system adopted by a manufacturer can be tailored to fit the specific environment, taking into account factors such as scope of operations, complexity of processes, and appropriate use of finite resources.

Pharmaceutical Process Validation A CGMP Concept

The concept of validation was first proposed by two Food and Drug Administration (FDA) officials, Ted Byers and Bud Loftus, in the mid 1970's in order to improve the quality of pharmaceuticals. The first

validation activities were focused on the processes involved in making these products, but quickly spread to associated processes including environmental control, media fill, equipment sanitization and purified water production.

In a guideline, validation is act of demonstrating and documenting that any procedure, process, and activity will consistently lead to the expected results. It includes the qualification of systems and equipment. The goal of the validation is to ensure that quality is built into the system at every step, and not just tested for at the end, as such validation activities will commonly include training on production material and operating procedures, training of people involved and monitoring of the system whilst in production. In general, an entire process is validated and a particular object within that process is verified. The regulations also set out an expectation that the different parts of the production process are well defined and controlled, such that the results of that production will not substantially change over time.

Why Is Validate a process:-

The main reasons for validation are

1. **Quality assurance:** Quality cannot be assured by daily quality control testing because of the limitations of statistical samples and the limited facilities of finished product testing. Validation checks the accuracy and reliability of a system or a process to meet the predetermined criteria. A successful validation provides high degree of assurance that a consistent level of quality is maintained in each unit of the finished product from one batch to another batch.
2. **Economics:** Due to successful validation, there is a decrease in the sampling and testing procedures and there are less number of product rejections and retesting. This lead to cost- saving benefits.
3. **Compliance:** For compliance to current good manufacturing practices CGMPs, validation is essential.

Department Responsible:-

- Site validation committee (SVC): Develop Site master Validation plan, Prepare/execute/approve validation Studies
- Manufacturing department: Prepares the batches as a routine Production batch
- Quality assurance: Ensure compliance, see that documentations/procedures are in place, approves protocols and reports
- Quality control: Perform testing and reviews protocol and report as needed.

Responsible Authorities For Validation:-

The validation working party is convened to define progress, coordinate and ultimately, approve the entire effort, including all of the documentation

generated. The working party would usually include the following staff members, preferably those with a good insight into the company's operation.

- Head of quality assurance
- Head of engineering
- Validation manager
- Production manager

Specialist validation discipline: all areas Department

/Designation Responsibility

Manager Production Responsible for manufacturing of batches and review of protocol and report.

Manager QC Responsible for analysis of samples collected

Executive QC Responsible for samples collection and submission to QC Manager

Maintenance Providing utilities and engineering support Executive Production

Responsible for preparation of protocol and manufacturing of validation batches

Manager QA Responsible for protocol authorization and preparation of summary report.

Elements Of Validation:-

Qualification is pre-requisite of validation. The qualification includes the following:

1. Design Qualification (DQ):-

In this qualification, compliance of design with GMP should be demonstrated. The principles of design should be such as to achieve the objectives of GMP with regard to equipment. Mechanical drawings and design features provided by the manufacturer of the equipment should be examined.

2. Installation Qualification (IQ):-

Installation qualification should be carried out on new or modified facilities, systems and equipment. The following main points should be included in the installation qualification.

- Checking of installation of equipment, piping, services and instrumentation.
- Collection of supplier's operating working instructions and maintenance requirements and their calibration requirements.
- Verification of materials of construction
- Sources of spares and maintenance

3. Operational Qualification (OQ):-

Operational qualification should follow IQ, OQ should include the following:

- Tests developed from the knowledge of the processes systems and equipment
- Defining lower and upper operating limits,. Sometimes, these are called 'worst case' conditions.

4. Performance Qualification (PQ):-

After IQ and OQ have been completed, the next qualification that should be completed is PQ. PQ should include the following:

- Tests using production materials, substitutes or simulated product. These can be developed from the knowledge of the process and facilities, systems or equipment.
- Tests to include conditions with upper and lower limits

GMP in Pharmaceutical Industry

Medicines are perhaps as old as Mankind and the understanding how their quality has to be ensured has evolved gradually over the time. Unfortunate events have prompted the development of medicines regulations more than the evolution of a knowledge base. Drugs are not ordinary consumer products and in most of the instances, consumers are not in a position to make decisions about quality of the drugs, hence the production of medicines, their distribution and dispensing also requires special knowledge and expertise³. Since our ancestors began trading several years ago, counterfeit and substandard medicines have been a recurring problem, with history punctuated by crises in the supply of anti-microbial, such as fake cinchona bark in the 1600s and fake quinine in the 1800s. Unfortunately this problem persists, in particular bothering innocent patients in 'developing' countries. Poor-quality drugs contribute to a 'crevasse' between the enormous effort in therapeutic research and policy decisions and implementation of good-quality medicines.

Globalization of the pharmaceutical industry has the potential to rapidly spread poor-quality medicines worldwide before adequate detection and intervention are possible. There are two main categories of poor-quality medicines: substandard and counterfeit. Substandard products arise as a result of lack of expertise, poor manufacturing practices, or insufficient infrastructure, whereas counterfeits are the 'products' of criminals. Counterfeits may contain no active ingredient, incorrect ingredients, or toxins. The amount of active ingredient does not provide sufficient information to accurately determine if a medicine is counterfeit; inspection of the packaging is also required as mislabelling is a key part of the definition and counterfeits with fake packaging but the correct amount of active ingredient have been described. In many reports, it is unclear if poor-quality medicines are counterfeit or substandard, but it is important that they are correctly classified because they have different origins and different solutions. Inadequate enforcement, lenient penalties, corruption, 'spaghetti-like' trade arrangements, unregistered medicines, and ignorance of poor-quality medicines among the public and health workers worsen the situation. To

ensure that quality is consistently achieved in the drug product, Good manufacturing practices have to be followed. To obtain and maintain GMP compliance, every manager and supervisor should provide frequent, meaningful GMP reminders, train and develop all employees, and fully participate in formal, on-going training programs. Senior management must make it clear through their actions that following GMPs is the only way their company does business. If you want people to move toward regularly following GMPs, they have to know why the regulations came about and what's in it for all of us as consumers to see them followed. Most requirements were put in place as responses to tragic circumstances and to prevent future tragedies⁴.

WHO GMP Protocols:

World Health Organization GMP guidelines were instituted in 1975 in order to assist regulatory authorities in different countries to ensure consistency in quality, safety and efficacy standards while importing and exporting drugs and related products. India is one of the signatories to the certification scheme. The WHO-GMP certification, which possesses two-year validity, may be granted both by CDSCO and state regulatory authorities after a thorough inspection of the manufacturing premises.

Schedule M Compliance:

The requirements specified under the upgraded Schedule 'M' for GMP have become mandatory for pharmaceutical units in India w.e.f. July 1, 2005. Schedule M classifies the various statutory requirements mandatory for drugs, medical devices and other categories of products as per the current Good Manufacturing Practices (cGMP). Schedule M protocols have been revised to harmonize it along the lines of WHO and US-FDA protocols. These revised protocols include detailed specifications on infrastructure and premises, environmental safety and health measures, production and operation controls, quality control and assurance and stability and validation studies.ⁱⁱ Problems related to Schedule M compliance are mostly confined to small-scale pharmaceutical units as large-scale firms have shown greater willingness to comply with the revised norms in order to increase their competitiveness in the global arena.

The Central Drugs Standards Control Organization has, however, yet to compile data on the extent of Schedule M compliance by the firms. The Najma Heptullah Committee on Subordinate Legislation, which tabled its report in Parliament recently, is scheduled to compile data on extent of Schedule M compliance shortly. However, according to state regulatory sources, units in states like Gujarat, Karnataka, Maharashtra and Andhra Pradesh have achieved a high percentage of Schedule M compliance in comparison to units in other states.

International regulatory certification for Indian manufacturing units: A principal issue relating to good manufacturing practices is that WHO-GMP is no longer sufficient, particularly for exporting of drugs and related products to developed countries. Regulators from these countries visit Indian firms to carry out a thorough inspection of their manufacturing units before registering the concerned product. A large number of domestic players are seeking international regulatory approvals from agencies like US-FDA, MHRA UK, TGA Australia and MCC South Africa in order to export their products, mostly generics, in these markets. A large number of Indian firms are increasingly seeking at least WHO GMP approval in order to compete for exports to CIS countries and other Asian markets. India has the distinction of having the largest number of US-FDA approved manufacturing units, totaling 100, mainly for production of Active Pharmaceutical Ingredient (API), outside of the United States.

The scope of regulatory intelligence(RI) encompasses multiple sources; monitoring the regulatory landscape/environment; RI-Databases; and other regulatory sources to research questions on regulatory issues such as analysing, discussing of possible procedure types as well as its implementation in compliance with agency's requirements inclusively awareness of advantages/disadvantages of each single choice of procedure type selected.

The regulatory world is a living and evolving body. Therefore, it is crucial to understand the necessity of monitoring the regulatory environment and agencies' requirements as result of this evolutionary process.

RI provides the Regulatory Professional with Information to identify opportunities such as broader indications; roadmap to product approval; identify possible hurdles e.g. compliance issues; change in requirements for certain indication. In addition, RI helps Regulatory Professionals to predict Agency approval requirements as well as its review times.

The consequence of monitoring and gathering of RI will be finally the development of a regulatory strategy which leads to generate valuable advantages such as decrease in approval time, reduce of costs of drug development based on current information as well as maximizing of the target market(s).

For a global regulatory strategy, there is a necessity to keep abreast of worldwide regulatory information as a change in the global landscape can affect the global regulatory strategy in terms of pharmaceutical development, planning for the implementation of the Global Regulatory Strategy across multiple regions as well as identifying of development areas requiring special considerations

across various regions. Consequently this might result in achieving a widening of market corridors and thus serve the best commercialization of both newly and existing developed products.

Finally, as RI can identify competitive advantages in an increasingly complex regulatory landscape for the global development of drugs and so determine the regulatory pathway, a successfully implemented RI process can be considered as a powerful business driver.

RI can promote product lifecycle with regard to procedural, technical, scientific and strategic input. Key roles include general information gathering and tracking legislation, followed by information dissemination and utilization. For this purpose, identification and utilization of appropriate relevant information sources for gathering of respective data with reliable updates of the latter are of importance⁵.

Regulatory Affairs in Pharmaceutical Industry

Regulatory affairs Department (DRA) is a comparatively new profession which developed from the hankering of governments to protect public health by monitoring the safety and efficacy of products in areas including pharmaceuticals products, medical devices, pesticides, agrochemicals, cosmetics.⁶ The Pharmaceuticals companies responsible for the discovery, testing, manufacture and marketing of these products also want to confirm that they supply products that are safe and make a valuable contribution to public health and welfare. Role of RA officer increasing day by day in different departments of pharmaceutical industries Fig.1. RA officer playing a vital role in bringing new product to market, there are different responsibilities for them from primary stage to till end stage⁷.

Regulatory guidelines changes regularly, so its duty of the RA officer to update with new regulatory guidelines. This is the responsibility of RA officer that what they making in Pharmaceutical company complying with latest regulatory guidelines or not. RA officer will make sure that they making quality product as there is safety of the consumers is major concern. Its RA officer duty to ensure compliance with regulation in all regions in which a company wishes to distribute its drug. Working with Central, state and local regulatory agencies and personnel on specific issues affecting their business. Guiding companies on the regulatory aspects and climate that would affect their planned activities^{8,9}.

Regulatory Affairs officer role in Different Department

1. Raw material department

RA plays vital role in this department, for manufacturer a pharmaceutical drug, companies' required active pharmaceutical ingredient (API). For import and export of API Company has to take permission from regulatory authorities' state

regulatory authority or central authority. RA officer will take care of the documentation part for getting permission from these authorities. After getting the permission RA officer will verify the quantity of the API, Storage condition, approved or unapproved status of the API also will cross verify.¹⁰

2. Research and Development department

Research and Development department (R&D) having the responsibilities to bring a new drug to the market after lots of research and investigation, testing on different compounds. It is the duty of the R&D department to develop innovative products which beneficial and safe for public health. RA officer having the role in providing fast regulatory approval for test and analysis of the new drugs from State Food and Drug Control Administration (FDCA).^[5]

Company has to take approval in FORM 30 application and license in FORM 29 (Test licence is issued for the purpose of examination, test or analysis). Drugs those not approved from Drug Controller General of India (DCGI) Company has to take No Objection Certificate (NOC) for form 29.^[6] Using new clinical trial strategies, gaining quick approval from regulatory authorities and avoiding drawbacks in processes can fast-track the development of new products which will reduce shortage of the drugs.¹¹

3. Production department

Production department having different responsibilities, first one is to establish standards in regard to the quality and the quantity of the products being made. Usually, these standards are placed all over the process, not just at the beginning or end. The second function of the department is to work with the purchasing department to ensure sufficient materials are on the production line and to ensure replacement of any damaged equipment. The purchasing department works with other departments to make sure purchased equipment and materials are all stocked and available.^[8] Next function is to work with the design and technical department to ensure the product is built to the correct specifications and to place any new designs or changes to the product onto the line. Finally, the production department collaborates with the works department to ensure there is a proper workforce available to check the quality of the product and make any necessary repairs to any equipment that breaks. RA officer will check in between that, proper Good Manufacturing Process guidelines (GMP) following by production department and proper production permission they have or not. Full process is done according to Standard testing procedures (SOPs) and Batch Manufacturing Record (BMR). After proper verification by RA or In-process quality assurance

(IPQA) material will transfer to next stage.¹²

4. Medical Devices department

This is most sensible department in Pharmaceutical industry, the regulation of Medical Devices is overseen by both, the central government and the state governments. For manufacture, import, distribution and sale of medical devices require licenses or permissions from State FDCA and DCGI as the case may be. There is different forms available for import, export and manufacture of medical devices. Certificate of registration of the foreign manufacturer and the medical devices to be imported (Registration Certificate) approval will obtained in Form 41.^[10] For Import of Notified Medical Devices in India license will obtained in Form 10. License to manufacture Notified Medical Devices will obtained in Form 28 from DCGI. It is the duty of the RA officer to make sure that labelling and packaging is done according to proper guidelines given by DCGI. During manufacturing, GMP guidelines are the key portion in medical devices.¹³

5. Quality Control department

Quality Control (QC) department having the duty to testing of raw materials, packaging materials and carried out in process controls. In QC highly trained and experienced personnel will done testing with modern analytical techniques. QC also undertake reference standard certification in compliance with GMP regulations. RA department role is to collect the certificate of analysis, Stability studies, Analytical method validation reports (AMV) and AMV Protocol for submit the dossier for registration of the product.¹⁴

AIM AND OBJECTIVE

AIM:

The main aim is to determine the inter relationship between RA, QA and QC for regulatory submission

OBJECTIVES:

CDSCO (Central Drug Standard Control Organization) Director General of Health Services, Ministry of Health & Family Welfare, Govt. of India is the regulatory authority for approval of new drugs, clinical trials, laying down the standards for drugs and control over the quality of imported drugs.

To know the rules of Quality Assurance department

To know the regulations of Quality Control department
To know the roles of Regulatory Affairs department and

To determine the inter relationship between RA, QA and QC department for regulatory submission

DISCUSSION:

Pharma companies are required to report safety information to regulatory authorities according to specific timelines.

Regulatory submission is the process through which pharmaceutical companies submit the information about their newly developed healthcare product to a regulatory agency for review. They can also submit their documentation seeking additional knowledge about their device.

A regulatory affair is a profession developed from the desire of governments to protect public health by controlling the safety and efficacy of products. It serves as the interface between the regulatory authority and the project team, and is the channel of communication with the regulatory authority as the project proceeds, aiming to ensure that the project plan correctly anticipates what the regulatory authority will require before approving the product. It is the responsibility of RA to keep abreast of current legislation, guidelines and other regulatory intelligence. Such rules and guidelines often allow some flexibility, and the regulatory authorities expect companies to take responsibility for deciding how they should be interpreted. It plays an important role in giving advice to the project team on how best to interpret the rules. During the development process sound working relations with authorities are essential, e.g. to discuss such issues as divergence from guidelines, the clinical study programme, and formulation development.

Regulatory affairs is an industry tasked with overseeing how certain products are developed, tested, manufactured, marketed, and distributed to ensure each process is compliant with the relevant regulatory statutes implemented by various regulatory agencies. These professionals often work in the biopharmaceutical, medical devices, and food safety industries.

Quality assurance, on the other hand, ensures a company's products meet quality standards for distribution to the market. These include both internal and industry standards, as well as safety standards set by local, state, national, and international governing bodies. Quality assurance professionals work in a variety of industries, seeing that the need for high-quality products is not industry-specific.

The line between regulatory affairs and quality assurance can sometimes be difficult to distinguish, but there are fundamental differences that set the two disciplines apart

Regulatory affairs professionals are concerned with ensuring that products comply with government regulations, while quality assurance professionals are focused on delivering high-quality products to consumers. Professionals in both industries assess products against certain standards that must be met,

but the difference lies in the types of standards and the stakeholders involved.

The Quality Control Department is responsible of monitoring and ensuring that each stage of production is followed by all the necessary procedures for safe use of machinery and that each product coming out of the production process, complies with all standards and specifications that have been defined so to ensure a smooth and trouble free operation.

Quality control department aims at investigating manufactured drug products according to compendial specifications and standards to monitor that they are of the required quality. QC is concerned with setting up specifications, drawing samples, testing them, and generating documentation related to the tests and their reports. QC also evaluates the analysis reports and ensures that no material is released for use or supply or sale until it meets the necessary quality requirements and pre-determined specifications. The scope of QC is not limited to mere laboratory work; this department is involved in all situations that involve the quality of the product.

RECENT DEVELOPMENTS

Starting in 1980 the European Union started to harmonize the regulation of healthcare products in the member states. The concept of regulating medicines was well established in most member countries along similar lines to the US model, but many countries did not have any significant medical device regulation. Concurrently the EU had been developing the concept of New Approach Directives where only broad concepts were written into the law and the bulk of the technological detail delegated to compliance with recognized standards (which are more readily update-able). The Europeans took the radical approach of applying the New Approach Directive to Medical Devices and by doing so made the first significant conceptual advance in healthcare regulation for nearly 100 years. The European Model for medical device has largely been adopted by the Global Harmonization Task Force as the international template.

FUTURE DEVELOPMENTS

Many in the regulatory affairs profession believe the new approach to regulation will eventually be adopted for all healthcare products as it represents the best model for delivering new healthcare advances to market in a reasonable time with acceptable safety. Regulatory affairs departments are growing within companies. Due to the changing resources necessary to fulfill the regulatory requirements, some companies also choose to outsource or outtask regulatory affairs to external service providers. Regulatory affairs department is constantly evolving and growing and is the one

which is least impacted during the acquisition and merger, and also during recession. Global harmonization in standards has led to consistent approach in regulatory submissions and hence its review.

CONCLUSION:

From this review we concluded that there is correlation between Regulatory affairs Quality control and Quality assurance departments of pharmaceutical industry. For register a new drug in market RA department is the main key. It is the duty of all departments that they should follow updated regulations in their departments provided by regulatory authorities for faster growth and availability of medicines in the market.

ACKNOWLEDGEMENT

The Authors are thankful to the Management and Principal, Holy Mary Institute of Technology and Science (College of Pharmacy), Keesara - Bogaram - Ghatkesar, Telangana, Telangana, for extending support to carry out the research work. Finally, the authors express their gratitude to the Sura Pharma Labs, Dilsukhnagar, Hyderabad, for providing research equipment and facilities

REFERENCES:

1. Babiarz, J.C. (2008). Chapter 3. The new drug application. In D.J. Pisano & D.S. Mantus (Eds.) FDA Regulatory affairs. A guide for prescription drugs, medical devices, and biologics (2nd ed). New York: Informa Healthcare.
2. Kumar, S. & Hall, Y. (2008). Chapter 10. Electronic submissions – A guide for electronic regulatory submissions to the FDA. In D.J. Pisano & D.S. Mantus (Eds.) FDA Regulatory affairs. A guide for prescription drugs, medical devices, and biologics (2nd ed). New York: Informa Healthcare.
3. 1978 Preamble to the Good Manufacturing Practice Final Regulations – Federal Register Docket No. 73N-0339] CPGM 7356.002 Compliance Program – Drug Manufacturing Inspections.
4. Quality Planning and Analysis, 3rd Ed. by J.M. Juran, F.M. Gryna (McGraw-Hill, New York, N.Y. 1993)
5. Agalloco J. Validation: an unconventional review and reinvention. PDA J. Pharm. Sci. Tech. 49:175–179 (1995). Aleem H, Zhao Y, Lord S, McCarthy T and Sharratt P. Pharmaceutical process validation: an overview. J. Proc. Mech. Eng. 217: 141-151 (2003). Chitlange S. S, Pawar A. S, Pawar H. I, Bhujbal S. S. and Kulkarni A. A. Validation.

- pharmainfo.net/reviews/validation . 4: 318-320 (2006).
6. Dashora K, Singh D and Saraf S. Validation - the Essential Quality Assurance Tool for Pharma Industries. pharminfo.net. 3: 45-47 (2005).
 7. Drug Regulations : History, Present and Future by Lembit Rago, Budiono Santoso A Brief History of the GMPs for Pharmaceuticals, Barbar K. Immel, Pharmaceutical Technology, July 2001, PP 44 - 52