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Research Article

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A comprehensive synopsis on cognizance of Regulatory Affairs in different sectors of Pharmacy

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Abstract

A pharmaceutical drug regulatory Affairs is mainly involved in registration process parameters of different pharmaceutical products and new drug application. Regulatory affairs (RA) professionals play vital roles in a pharmaceutical field as, it is related to healthcare products. It provides strategic, operational direction and support for working within regulations to expedite the development of pharmaceutical, biological and medical devices. Also, it is principally concern with safety and efficacy, low risk/high benefit and quality assessment of healthcare drug products throughout the world. Regulatory system of each and every country has different regulatory agencies which govern certification and good manufacturing practices. Regulatory Affairs also has a very specific importance within the formulation and marketing of drug product in pharmaceutical industries. Current abstract reports for the first time and emphasizes on studies concerning awareness and knowledge testing in regulatory affair field by the various pharma professionals. This is completely certified online survey of quiz questionnaire based on important concepts in RA and circulated via google form to different social medias to more than 1000 pharma professionals (Academics, Students, Industrials area). The systematic analysis of received responses reveals awareness and knowledge of the participants about RA in selected pharma professionals. It shows that, participants form industrial area having more knowledge than academics and students. This survey comes out with conclusion that, there is more need to raise RA information sources by the inclusion of this subject in syllabus for academics via various courses to fulfill more RA professional demands in future.

Keywords: Survey, Cognizance of regulatory affairs, Regulatory Affairs professionals, Regulatory agencies, safety and efficacy.

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1. Introduction

Regulatory Affair plays vital role to protect public health worldwide. Government of various countries have developed the regulation for pharmaceutical product, cosmetic product, pesticides, medical device, veterinary medicines, agrochemical and complementary medicines by controlling the safety and efficacy of product. (1) The pharmaceutical companies have imperative involvement in community health by providing the product that are safe, effective with standard quality. To fulfill these requirements the companies, undergo detection, evaluation, formulation and marketing of the product.

Regulatory Affairs (RA) also called as Government Affairs. It is a profession within regulated industries, such as pharmaceuticals, medical devices, energy and banking. RA profession at its core is all about collecting, analyzing and communicating the safety, efficacy, Risks and Benefits of health care products. It also has a very specific meaning within the healthcare industries (pharmaceuticals, medical devices, Biologics, nutraceuticals, cosmeceuticals and functional foods) and most companies (whether they are major multinational pharmaceutical corporations or small, innovative biotechnology companies) consist of individual departments of regulatory affairs professionals. (2) The main strategies of regulatory affairs rely on interpretation, application and

communication within or outside the industries. RA is discipline of developing new methodologies and standards to evaluates the safety, efficacy, quality and performance of regulated pharmaceutical products and medical devices. (3)

2. History of Regulatory Affairs (4,5)

Now a days, RA scrutinizes production, quality assessment and distribution of novel medicines which becoming more and more globalized. As a consequence, the manufacturing processes and supply chains of pharmaceutical products, including generics, are increasingly complex. Because, same medicinal product is often distributed in several regions of various countries or used by patients all over the world. Also, it is more usual that, different manufacturing phases for the same product take place in different countries, which are often distant from each other. Likewise, at the same time, more and more common elements are present in the dossiers submitted in different jurisdictions. Hereafter, some disasters like vaccine, sulfanilamide elixir and thalidomide disaster revealed urge of regulatory affairs with considerable increase of rules and regulations for safety, efficacy and quality of pharmaceutical products. Hence Marketing Authorization (MA) and Good Manufacturing Practices (GMPs) also resulted into firmer rules. The historical development of RA is summarized in table 1.

Regulatory division is bridging link between company, product and regulations. RA strictly regulates pharmaceutical product development to marketing authorization and commercialization. These regulation standards are established by regulatory authorities of the particular countries such as FDA in United States, EMA in Europe, TGA in Australia and DCGI in India etc. The authorization of any drug before entering in the market must undergo thorough analysis, preclinical and clinical trials to confirm its safety, efficacy and quality. Regulation marks all facets of the pharmaceutical company and marketing, from autonomous trendsetters and pharmaceutical industries to regulatory authorities and patients also. History of RA is compiled in table 1.

Table 1. Historical Development of RA

Sr. No	Development Year	Description
1.	1970	RA was began to develop in US as health care profession due to drug disasters.
2.	1980	RA profession is emerging, recognized internationally and professional demand increased.
3.	1991	Regulatory affairs Certification (RAC) was established
4.	2000	RA profession was well established various rules and regulation, certification was started.
5.	2005	RA professional demand was emerged highly
6.	2010	RA become indespensible, important and critical without which no pharmaceutical company can sustain manufacturing, purchase and sales, imports and exports, research and development
7.	2011	DMF, CTD, ACTD become important for marketing authorization of pharmaceutical product and medical devices.
8.	2012 onwards	RA coupled with suspension or withdrawal or cancellation of license.
9.	Present	Regulatory department holds an important bridge between Pharmaceutical products, pharmaceutical companies and regulatory authorities or professionals in deciding the chances of drug discovery and the product to run in the market. Currently regulation has a wide valuation of a new drug for the protection of marketing authorization, pharmacovigilance, import, export, public health, drug registration and distribution of the marketed product.

3. Major Regulatory Authorities

Regulatory bodies are responsible for approving whether a drug can proceed to clinical trials and whether it should be allowed on the market. The regulatory body has to evaluate the scientific and clinical data to ensure about drug manufacturing with consistently high purity, about its clinical effect claimed, and unaccepted side effects. It must also approve the labeling of the drug and the directions for its use. Over-all, the regulatory body is interested in all aspects of a drug, once it has been identified potent medicine for society.

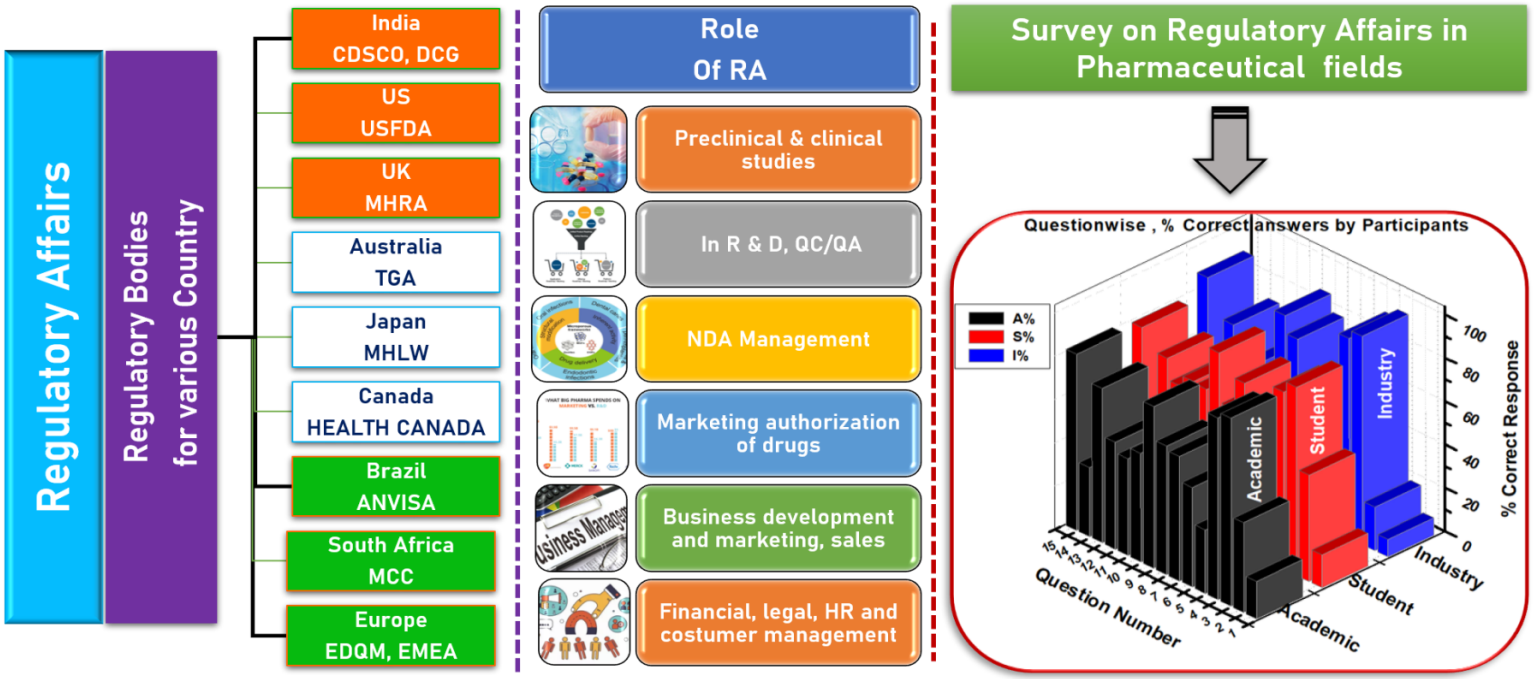

Figure 1. Regulatory Bodies and roles of RA

Table 2. Regulatory agencies in different Countries

Sr. No.	Country	Regulatory Authority	Description
1	India	Drug controller general of India (DCGI) Central Drugs Standard Control Organization (CDSCO)	The Drug and Cosmetic Act 1940 and Rules 1945 were proclaimed by the India's parliament to regulate the import, manufacture, distribution and sale of drugs and cosmetics. The Central Drugs Standard Control Organization (CDSCO) and the office of its leader, the Drugs Controller General (DCGI) was established. In 1988, the Indian government added Schedule Y to the Drug and Cosmetics Rules 1945. Schedule Y provides the guidelines and requirements for clinical trials, which was further revised in 2005 to bring it at par with internationally accepted procedure. When a company in India wants to manufacture or import a new drug it has to apply to seek permission from the licensing authority (DCGI) by filing in Form 44 also submitting the data as given in Schedule Y of Drugs and Cosmetics Act 1940 and Rules 1945. (6)
2	United States	Food and Drug Administration (US FDA)	Currently such applications are accepted for review in eCTD format. The major concern about NDA is that the product shall be safety and effective. FDA approval process begins only after submission of investigational new drug (IND) application. (7)

3	United Kingdom	Medicines and Health care products regulatory Agency (MHRA)	The rolling review is a new route for marketing authorization applications (MAA), where an applicant for a marketing authorization submits modules of the eCTD dossier incrementally for pre-assessment by the MHRA rather than as part of a consolidated full dossier submission. (8)
4	Australia	Therapeutic Goods Administration (TGA)	The submission process consists of 8 phases and eight milestones,for effective planning and tackling by TGA and sponsor. During presubmission phase, sponsor completes and camps a Pre-submission. Pre-submission Planning Form (PPF) provides information of quty, preclinical and clinical information. The PPF should be submitted at least two and half months prior to authentic submission. Sponsor submit well strategic, high quality complete submission dossier. Submission must ensure to meet the TGA requirements for format and content. TGA may ask to sponsor for data at any stage during the appraisal process through multiple request. (9)
5	Japan	Japanese Ministry of health, Labour and Welfare (MHLW)	Ministry of Health, Labour, and Welfare (MHLW), Pharmaceuticals and Medical Devices Agency (PMDA) is in authority for amendable pharmaceutical product and medical device in Japan. Only a local entity qualified as a **Marketing Authorization Holder (MAH)** or a **Designated Marketing Authorization Holder (DMAH)** may import, register and retail medical products in the Japanese market. For new drug formulation and marketing, collected data should be given with approval submissions in order to conduct clinical studies. Good Clinical Practice, along with its proposed protocol required by MHLW earlier. (10)
6	Canada	Health Canada	A draft standard was issued in 2012 (6) which details how information submitted by applicants on reviews carried out by Health Canada through foreign reviews during the evaluation of applications. The guideline distinguishes that the Canadian law does not foil Health Canada from using, where suitable, foreign reviews to perform part of the assessment or to inform Health Canada's administrative. Health Canada however cannot endowment (or refuse to grant) marketing authorization based only on the existence of a foreign review and its equivalent regulatory decision. (11)
7	Europe	European Directorate for Quality of Medicines (EDQM) European Medicines Evaluation agencies (EMEA)	EMA enables one assessment, one market authorization, one application for the whole of the EU. The centralised procedure consents the marketing of a medicine on the basis of a single EU-wide assessment and marketing authorization. The decentralised procedure where companies can apply for the simultaneous authorisation of a medicine in more than one EU Member State if it has not yet authorised in any EU country and does not descent within the scope of the centralised procedure The mutual-recognition procedure where companies that have a medicine authorised in one EU Member States can apply for this authorisation to be recognised in other EU countries. (12)
8	Singapore	Therapeutic Products Branch (TPB)	The reference agencies accepted by the Singapore Health Sciences Authority (HSA) are EMA, U.S. FDA, Health Canada, TGA and MHRA. Legislation in Singapore consents for borrowing of foreign reports to issue marketing authorizations. For applications that prior approval from these reference agencies, HSA has a system that enables leveraging of evaluations made by these agencies, referred as the Verification Route (VR). The VR takes to the 180 days for products authorized by at least one drug regulatory authority (Abridged Route) or 60 days as opposed to the 270 days necessary for products not previously authorized by any other authority (Full Route). (13)

4. Responsibilities of Regulatory Affairs Department

The Regulatory Affairs profession is to keep track of the advanced legislation in all the regions in which the company demands to distribute its products. They also counsel on the legal and technical requirements and evaluate the scientific data for the research and development. They are responsible for the presentation of process documents to regulatory agencies, and carry out all the successive negotiations required to maintain marketing authorization for the product. (14)

They give strategic advice at the highest level in their companies, right from the start of the development of a product, making a vital contribution both commercially and scientifically to the accomplishment of a development program and the company as a whole. It may take up to 15 years to formulate and promote a new pharmaceutical drug product/ medical device thus various difficulties may arise in the process of scientific development and because of a changing regulatory milieu. So RA professionals aid the company to avoid problems caused due to badly saved records, inappropriate scientific data or poor interpretation of data. (15) The responsibilities of RA in various level of drug development are briefly shown in figure 2.

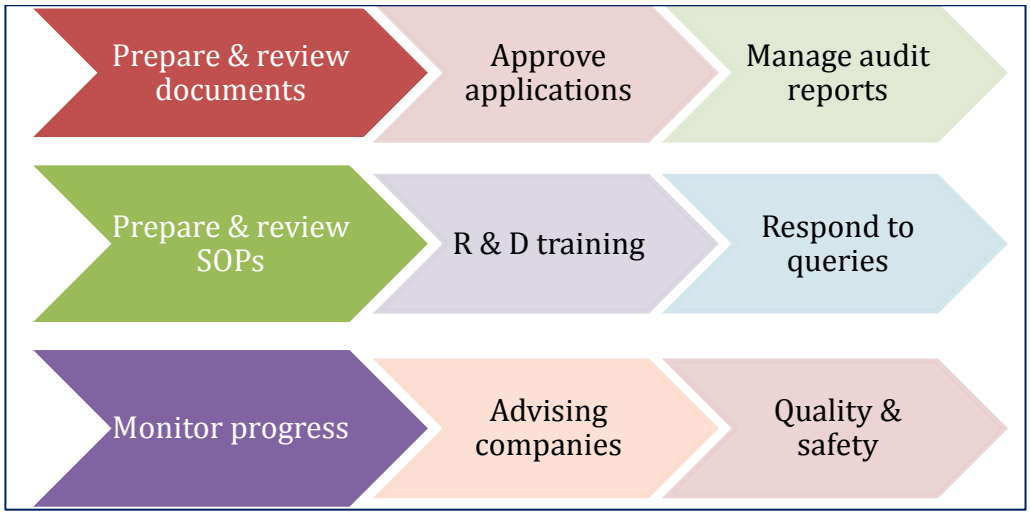

Figure 2. Responsibilities of Regulatory Affairs

- Keep up to the date with an organization's item range
- Ensure that an organization's items conform to the current guidelines.
- The Regulatory Affairs expert's responsibility is to monitor the steadily changing enactment in every one of the locations where the organization wishes to disperse its items. They additionally prompt on the lawful and logical limitations and prerequisites, and gather, order, and assess the logical information that their innovative work partners are producing.
- Formulate administrative methodology for all fitting administrative entries for homegrown, global or potentially contract projects.
- Coordinate, get ready and audit all suitable archives for instance dossier and submit them to administrative specialists inside a predetermined time span in formation with the association.
- Prepare and audit of standard operating procedure identified with RA. Audit of BMR, MFR, change control and other pertinent archives
- Monitor the advancement of all enlistment accommodation.
- Maintain supported applications and the record of enlistment expenses paid against accommodation of DMF's and different archives.
- Respond to questions as they emerge, and guarantee that enrolment /endorsement are conceded right away.
- Colleagues on current administrative prerequisites.
- Advising their organizations on the administrative viewpoints and environment that would influence proposed exercises. for example depicting the "administrative environment" around issues like the advancement of physician recommended medications and Sarbanes-Oxley consistence.
- Manage survey review reports and consistence, administrative and client investigations.
- Regulatory Affairs experts assist the organization with staying away from issues brought about by gravely kept records, improper logical reasoning or helpless show of information. In most item regions where administrative prerequisites are forced, limitations are likewise positioned upon the cases which can be made for the item on marking or in promoting.
- Have an obligation to furnish doctors and other medical services experts with precise and complete data about the quality, wellbeing and viability of the item. (16, 17)

5. Need of regulatory affairs in the pharmacy course

India is diversified country and emerging very rapidly in pharmaceutical field. Thus, there is a necessity of RA professionals to fulfil the current needs of pharma industries for the global race. Regulatory affairs authorities and professionals are the linkage between worldwide regulatory agencies and pharmaceutical industries. There is demand of RA individuals with well knowledge about the laws, regulations and guidelines of

the regulatory agencies. There is a promising need to incorporate the present requirements of pharmaceutical trades in the standard curriculum of pharmacy institutes. So that, it will benefit to prepare the students with the latest developments to serve the industries. (18)

Currently, the Govt. of India has constituted a few autonomous regulatory bodies like National Board of Accreditation (NBA) under the guidance of All India Council for Technical Education (AICTE) and National Assessment and Accreditation Council (NAAC) by the University Grants Commission to analyze the standards of profession of pharmaceutical field & grade the institutes consequently so that the students, parents, employers and funding agencies have a valid & reliable rating of the various pharmaceutical institutes in the country. (19)

In this competitive environment the reduction of the time taken to enter the pharmaceutical product in the market is imperative and hence the company's feat. The proper conduct of Regulatory Affairs activities is therefore of considerable financial significance for the company. A virtuous RA professional will have a quick approach and will play a very significant part in coordinating scientific endeavor with regulatory demands. RA professionals respond much better to a company whose representatives are methodically precise and knowledgeable. (20,21)

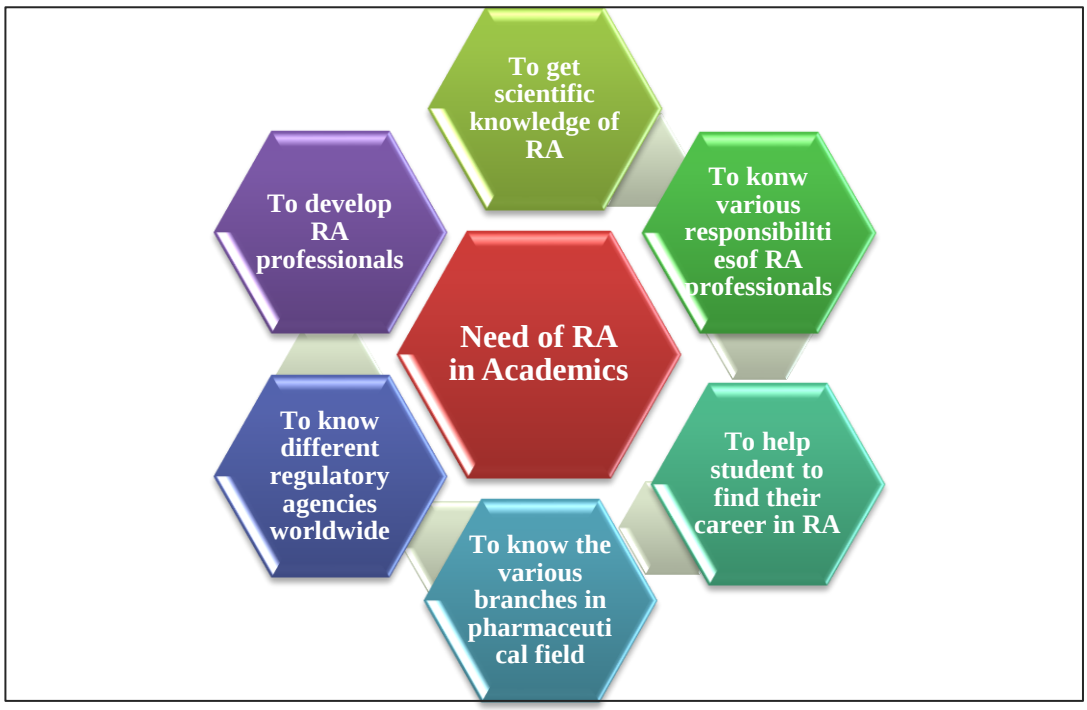

Figure 3. Need of regulatory affairs in acedicmic area

6. Methodology (22)

6.1. Statement of the study

The cognizance of current study as a survey on regulatory affairs in pharma field conducted for testing knowledge of students, academician and industrial area for their concept of RA.

6.2. Objectives

1. To analyze the information about RA to various level in pharmacy

2. To analyze awareness of RA in academics, student and industrial area

3. To check people's interest in this field

6.3. Research methodology

The research design is descriptive and empirical. The researcher intends to use this type of survey in order to test RA perception and knowledge to different area in pharmaceutical field. Necessary data required for analysis is collected through online quiz questionnaire.

6.4. Methods study design and sample

This was a cross-sectional study of 1000 randomly selected participants from different areas in pharmaceutical field. The samples were selected from academics (principals, professors, associate professors, assistant professors), pharmacy students (UG, PG) and industrial area. A google form containing 15 quiz questions related to regulatory affair was provided to participants for conducting this survey. (23)

6.5. Data collection tool (24)

Data were collected using an online quiz question. After discussing required information, the questionnaire was framed in google form and circulated by e-mail and different social media viz whatsapp, facebook, telegram etc. This form was circulated to more than 1000 participants out of them tentative number is decided of 1000 participants. As per considering feasibility of participants the questionnaire was developed in multiple choice question manner so that they should not be confuse with question and appropriate data will collected. The participant feedback is included with

same questionnaire to know how they were satisfied with the survey regarding knowledge.

6.6. Ethical issues

The study protocol was approved by the Shardabai Pawar Institute of Pharmaceutical Sciences and Research, Shardanagar, Baramati. Participants were assured of the confidentiality of personal data, voluntary participation, and the absence of conflicts of interest. Participants from pharmaceutical industry are kept optional for their information of industry name because such surveys are not allowed by many of industries.

6.7. Sources of information

The main source of information for this study was primary data. Primary data was collected though the online survey of quiz questionnaire with rating scale and close–ended questions that are logically framed and basically aims at achieving the objectives of the study. By considering the importance and responsibility of regulatory affairs it comes to know that this is very valuable profession. In this research paper we conducted survey titled with "A COMPREHENSIVE SYNOPSIS ON COGNIZANCE OF REGULATORY AFFAIRS IN DIFFERENT SECTORS OF PHARMACY". The questionnaire was prepared is mentioned below https://forms.gle/t4dAteCpp5EYr8r29

6.8. Statistical analysis

Tools used for the Analysis of data is carried out by tabulating the collected data in a suitable manner by which the interpretation can be done. (25, 26)

7. Results

7.1 Response count particulars

The 1000 participants were selected for this study randomly. After 1 month survey, we received total 650 interested participants answers. Remaining 350 participants were found uninterested for this survey. So out 1000 participant we compiled all data from participants n=650 that belongs to different sectors in pharmacy. This data was divided into two groups viz number of correct and incorrect responses received for each question. This information is adequate to check question wise knowledge of participants. The knowledgeable participants decided according to correct responses received as per each question. This showed more than 50% participants are well knowledgeable with regulatory affairs field. The incorrect responses received from participants revealed that participant have no or less knowledge for that particular question. This indicated that more than about 40% participants differ their knowledge of regulatory affairs. This information is summarized in table No.4.

7.2. Knowledge analysis as per expertise area

This method is implemented to check question-wise correct responses by different expertise area in pharmacy. Here, all correct responses received were divided according to expertise viz; academics, pharmacy student, industrial. Academic responses were sorted from master data, total 149 participants from academic area were responded in this survey. For their knowledge analysis, we analyzed all 15 questions for their correct responses. This showed above ranging from 54% participants have responded correct answers, which concludes that many of them have good knowledge regarding RA and few were unmindful about RA. Further this data sorted for student responses. It was found that about 61% student were soundly aware about some information about RA. The data received from 26 industrial people is much considerable and found to be 57% of knowledgeable for RA field. This is collectively represented in figure 3. According to this survey it concludes that, expertise area from industry is much more reliable and knowledgeable as compare to student and academics. All this data summarized in table 5.

Table 4. Response count particulars(n= 650)

Question No.	No. of correct responses	No of incorrect responses	No. of non-respondent	% of correct responses for knowledge analysis	% of incorrect responses for knowledge analysis
1	449	201	350	69.07	30.92
2	291	359	350	44.76	55.23
3	567	83	350	87.23	12.76
4	538	122	350	82.76	18.76
5	244	406	350	37.53	62.46
6	347	303	350	53.38	46.61
7	456	185	350	71.53	28.46
8	405	245	350	62.30	37.69
9	538	112	350	82.76	17.23
10	396	254	350	60.92	39.07
11	396	254	350	60.92	39.07
12	375	275	350	57.69	42.30
13	462	188	350	71.07	28.92
14	210	440	350	32.30	67.69
15	521	129	350	80.15	19.84

Table 3. Questionnaire of Survey

Que. No.	Question	Options	Correct Answer
1	What is the responsibility of RA personnel?	a. To analyze the content of the active ingredient in the formulation b. Work with federal, state and local governing agencies to get the approval for drug c. To undertake stability studies of the drug products d. To supervise the production of the formulation	b. Work with federal, state and local governing agencies to get the approval
2	Which of the following is responsibility of state authority of CDSCO?	a. Regulatory control over the import of drugs b. Approval of new drugs and clinical trials c. Meetings of Drugs Consultative Committee and Drugs Technical Advisory Board d. Regulation of manufacture, sale and distribution of Drugs	b. Approval of new drugs and clinical trials
3	Identify activity related to Pharmacovigilance	a. Deals with animal studies for pharmaceutical product. b. Deals with export of drug product. c. Deals with detection, monitoring and prevention of adverse effect with pharmaceutical product. d. Deals with manufacturing and packaging of pharmaceutical product.	c. Deals with detection, monitoring and prevention of adverse effect with pharmaceutical product.
4	List of approved drugs and their associated IPR is available in------	a. Pink book b. Orange book c. Red book d. Black book	b. Orange book
5	------- are the committees related to EU Regulations	a. TGA b. CDER c. CBER d. COMP	d. COMP
6	The initiation of ICH took place with representatives of regulatory agencies of --------- to discuss the wider implications and terms of reference.	a. Japan, Australia, US b. US, Europe, India c. US, Europe, Japan d. Europe, Australia, US	c. US, Europe, Japan
7	Common Technical Document (CTD) is divided into ---------- modules	a. 3 b. 4 c. 5 d. 6	c. 5

8	Which of the following is regulatory authority of Australia ?	a. Pharmaceutical and Medical Devices Agency b. Therapeutic Goods Administration c. Medicines and Healthcare Products Regulatory Agency d. Central Drug Standard Control Organization	b. Therapeutic Goods Administration
9	CFR stands for --------	a. Code of Federal Regulations b. Centre of Federal Regulations c. Code of Federal Register d. Centre of Federal Regulator	a. Code of Federal Regulations
10	Marketing Authorization Application (MAA) is an application to the relevant authority to market a drug or medicine in	a. US market b. Europe market c. Canadian market d. All countries	b. Europe market
11	CTD module 2 is related with --------	a. Administrative information and prescribing information b. All CTD summaries c. Quality of pharmaceutical product d. Non clinical Study	b. All CTD summaries
12	In India the Certificate of Pharmaceutical Product (CoPP) is issued by which agency	a. DCGI b. CDA c. CDSCO d. DTAB	a. DCGI
13	Asean Common Technical Document (ACTD) is documentation structure followed by which countries	a. Indonesia b. Thailand c. India d. All of above	d. All of above
14	After NDA submission periodic safety update report is submitted within_____ days	a. 90 b.60 c.120 d.180	c.120
15	The core principle of regulatory system is	a. Safety & efficacy b. Low risk/ high benefit c. Quality d. All of above	d. All of above

Table 5. Question wise analysis as per expertise area

Question No.	Academic (n=149) (Total correct response)		Student (n=475) (Total correct response)		Industrial (n=26) (Total correct response)	
	Count	% Count	Count	% Count	Count	% Count
1	26	17.33	72	15.16	2	8.00
2	62	41.33	233	49.05	5	20.00
3	130	86.67	412	86.74	24	96.00
4	126	84.00	388	81.68	23	92.00
5	44	29.33	192	40.42	8	32.00
6	69	46.00	264	55.58	14	56.00
7	86	57.33	365	76.84	14	56.00
8	89	59.33	296	62.32	20	80.00
9	112	74.67	404	85.05	22	88.00
10	75	50.00	311	65.47	10	40.00
11	67	44.67	314	66.11	15	60.00
12	74	49.33	290	61.05	11	44.00
13	107	71.33	337	70.95	18	72.00
14	48	32.00	154	32.42	8	32.00
15	122	81.33	377	79.37	22	88.00
% Count Average		**54.98**		**61.68**		**57.60**

7.3. Knowledge analysis as per score

Another tool used for analysis of RA knowledge in different sectors was their score in survey. This seems important parameter to test their knowledge in field of RA. This data was sorted based on their score for respective question viz academics, student and industrial area. In academic area it is observed that out of 149 participants, 20 participants scored highest mark i.e., 12 out of 15 (80%). However, for student group, highest marks scored by 79 participants i.e., 11 out of 15 (~73%) directs good remark. Similarly for industrial area, 6 participants out of 25 scored max 10 marks (i.e., ~66%). This is given in table 6.

Table 6. Knowledge analysis as per score

Score	No. of Academics score out of 15 marks	No. of Students score out of 15 marks	No. of Industrial area score out of 15 marks
1	-	1	-
2	2	5	-
3	5	5	-
4	4	25	1
5	13	14	-
6	12	28	4
7	12	29	-
8	17	34	4
9	14	40	5
10	18	63	**6**
11	17	**79**	2
12	**20**	66	3
13	13	55	1
14	2	24	-
15	-	7	-

The table no. 7 emphasizes about score range and grade wise sorting of academic, student and industrial area participants for knowledge evaluation. The score range referred as 1-5: poor, 6-10: good and 11-15: excellent for qualitative analysis. In Academics, average "good" grade is highly gained by ~49% participants. Also, students obtained about 41% "good" and ~48% "excellent" grade. However, 73% participants from industrial area significantly obtained "good" grade and 23% counted with "excellent" grade**.** This is represented in figure 4.

Table 7. % of score and Range for Remark

Score Range	No. of Academics count	% Count	No of student count	% Count	No. of Industrial count	% Count
1-5	24	16.11	50	10.50	1	3.85
6-10	73	48.99	194	40.76	19	73.08
11-15	52	34.90	231	48.53	6	23.08

1-5: poor, 6-10: good, 11-15: excellent

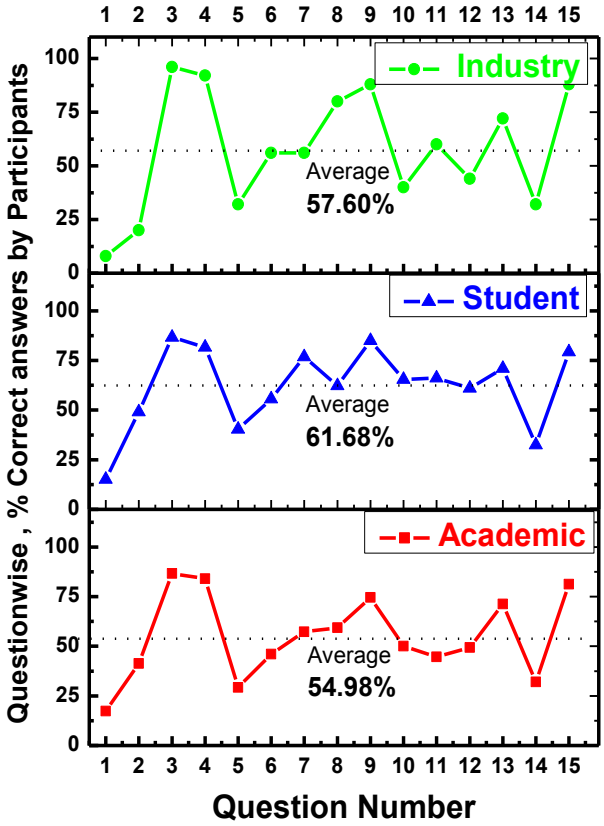

Figure 4. Knowledge analysis as per expertise area depend on correct responses for question

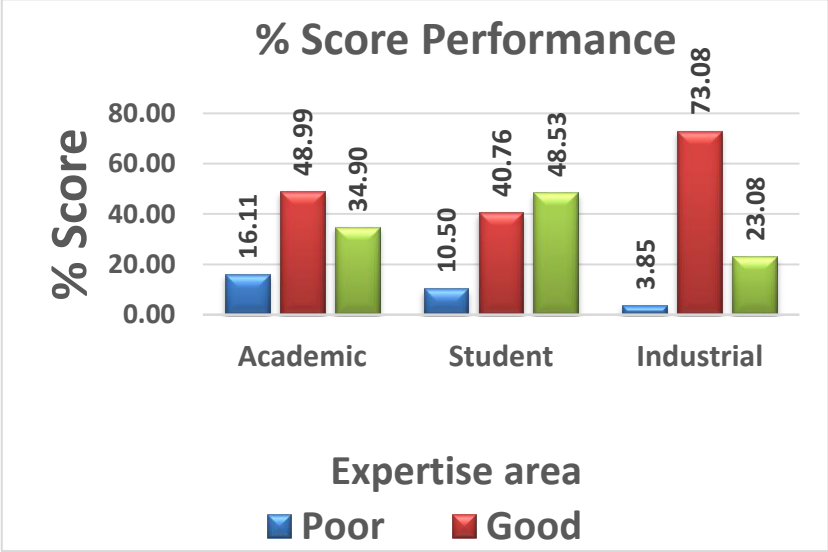

Figure 5. Knowledge analysis as per % score

8. Discussion

Regulatory Affairs (RA), also called Administration Affairs, is an occupation within different regulated industries, such as energy, banking, pharmaceuticals and medical devices. Regulatory Affairs has a very important role within the medical industries (pharmaceuticals, medical devices, Biologics). (1) The existing Pharmaceutical Industry is well planned and methodical to universal regulatory standards for manufacturing of pharmaceutical products. Respective regulatory system had faced certain situations which led to up-to-date well-defined controlled regulatory agenda. (8) This bring about into well organized production and marketing of safe, efficacious and qualitative drugs, biological preparations and medical devices. As it is basic of all about collecting, evaluating and communicating the risks and benefit of medicines concerning public health. With the development of industry, the regulations from each region have become more and more complicated and need was increased for regulatory professionals. (5)

There are different regulatory authorities in each country like USA- Food and Drug Administration (FDA), UK- Medicines and Healthcare Products Regulatory Agency (MHRA), New Zealand- Medsafe - Medicines and Medical Devices Safety Authority Netherlands Medicines Evaluation Board, Denmark- Danish Medicines Agency Sweden Medical Products Agency (MPA), Ireland- Irish Medicines Board Italy Italian Pharmaceutical Agency, Ukraine- Ministry of Health, Nigeria- National Agency for Food and Drug Administration and Control (NAFDAC), Singapore- Centre for Pharmaceutical Administration Health Sciences Authority, Hong Kong- Department of Health: Pharmaceutical Services, Sweden -Medical Products Agency (MPA), Paraguay -Ministry of Health, China - State Food and Drug Administration, Thailand- Ministry of Public Health Germany Federal Institute for Drugs and Medical Devices, Malaysia- National Pharmaceutical Control Bureau, Pakistan- Drugs Control Organization Ministry of Health, South Africa- Medicines Control Council, Sri Lanka- SPC, Ministry of Health, Switzerland-Swissmedic , Swiss Agency for Therapeutic Products, India- Central Drug Standard Control Organization (CDSCO), Australia -Therapeutic Goods Administration (TGA), Europe -European Medicines Agency (EMEA), Canada- Health Canada, Costa Rica -Ministry of Health, Japan- Ministry of Health, Labour & Welfare(MHLW), Brazil -Agencia Nacional de Vigiloncia Sanitaria (ANVISA), Uganda- Uganda National Council for Science and Technology (UNCST). (7)

Regulatory affairs play important role in industrial area and for this consideration the knowledge regarding RA needs to spread in each emerging regulatory professional. The main purpose of this survey is to check awareness of knowledge about RA in different profession. This research work framed to be beneficial to spread and check how many populations differ their information in RA. So after all analysis it seems we need to increase more sources to inform about RA in each level of professionals. In our study academic peoples finds less knowledgeable as compare to student and industrial area. There are two possibilities as either they have very less information or they had not any sources to study regarding RA. In case of student group it seems they are better knowledgeable. Here if we check for the same group it find more possibilities for their knowledge that means as they are youth due to social networking they were aware of regulatory field or via any browser they had searched for correct answers and then responded. But this survey found them important as after responding they must be cautious for information in RA. This will be helpful for them to be RA professional in their career. In case of industrial area whatever responses we had received it reflects they are much more knowledgeable in basic RA concepts and also need to improve in advanced RA information.

We have framed the 15 questions for 1 mark based on responsibilities of RA, CTD modules, regulatory agencies in different countries, abbreviations used in RA, pharmacovigilance, principles of RA and other important concepts in RA. Each question consists of four options from which respondents have to choose correct option for each question. This survey analyzed from their score received after submitting survey.

In this research paper along with quiz questionnaire, we collected feedback for this survey from all participants through suggestions and points for survey out of 10. We had received all positive and negative feedback responses. Most of student responded for no any suggestion in this survey. All positive feedback received that responded us for our nice initiative work, to arrange more knowledgeable surveys, good survey, very informative survey and so on. Few negative feedback responses received that suggested us as they find this more difficult, some of them find irrelevant question etc. If we analyses this feedback all positive feedback showed this survey found to be more knowledgeable and were inspired to increase their knowledge regarding RA.

9. Conclusion

Regulatory Affairs profession sets profoundly the innovative approach to regulation for all healthcare products that denotes the best model for delivering new healthcare product to market in a correct time with satisfactory safety and efficacy. The appropriate regulations by Regulatory Affairs activities are considerable to commercial importance for the company for marketing their product. This survey is conducted to check awareness regarding RA in different field in pharmacy. The results obtained from this survey are quite satisfactory which demand more development of sources. This can be fulfilled by incorporating RA subject in academics, via development of RA diploma or post graduate diploma courses, and RA practice trainings in industries. The respondent from academic and student area should understand the basic concept regarding RA. This result better to spreading information and widening RA field. This leads to attract and motivate more youth brains as a career opportunity than conventional options.

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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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