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AN OVERVIEW OF REGULATORY AFFAIRS IN PHARMACEUTICALINDUSTRY

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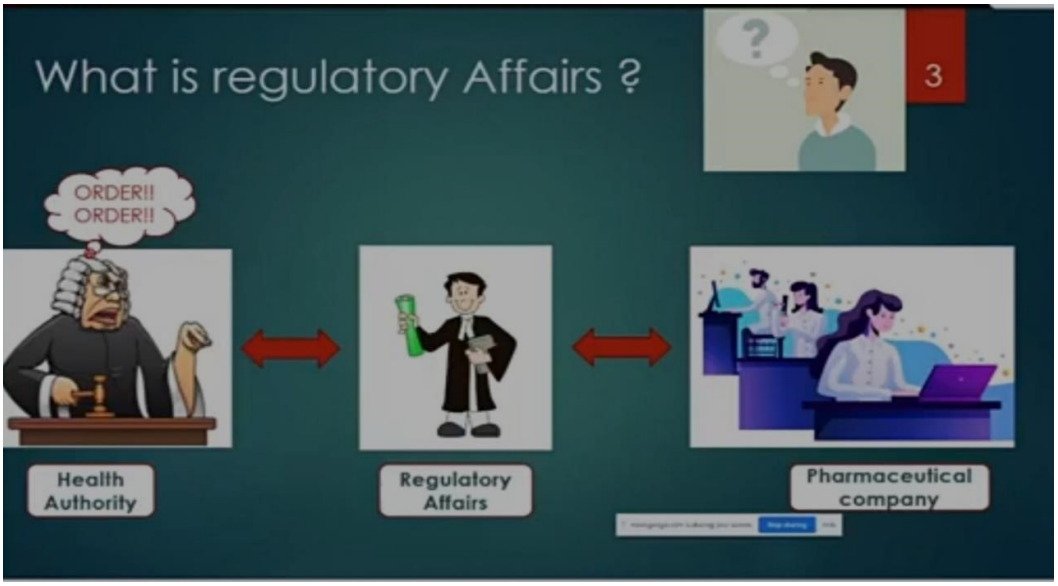
ABSTRACT:

Regulatory Affairs (RA) professionals play critical roles in pharmaceutical industry because it. Concern about the healthcare product lifecycle's, it provides strategic, tactical and operational direction and support for working within regulations to expedite the development and delivery of safe and effective healthcare product to individual around the world. It also made an interface between the pharmaceutical company and the regulatory agencies. It is also responsible for maintaining the appropriateness and accuracy of the product information and its main role to act as a liaison with the regulatory agencies, providing expertise and regulatory intelligence in translating regulatory requirement into practical workable plan, advising the company on regulatory aspect and climate.

Keyword- Regulatory Affairs, Phaemaceutical Industry, World Regulatory Body

INTRODUCTION:



Word regulate: -

The word regulate means standardize.
The word affairs mean businesses.
In general, the word regulatory affairs mean Standardize Businesses.

Why do you need to regulate the pharma industry?
The pharma industry is interlinked with the Quality, Safety & Efficacy of a product and needs to be regulated as there is a huge risk to the public health if not organized and standardize.
The need for professional advice is essential and hence to standardize the pharma business, regulatory affairs department is required in each pharma company.
Regulatory professionals are not only in the pharmaceutical industry, but they are also present in biopharmaceutical, medical device, food and nutrition

and cosmetics etc.

Regulatory Affairs Department & Scope

What is regulatory affairs?
In simple term, we can say that the regulatory affairs department is a team of professional members who act as the bond or linking bridge between the pharmaceutical company and global health authorities and ensuring that the product meets the healthy authority standard.
The member who work with regulatory affairs department are called regulatory affairs professional

Scope
Regulatory affairs discipline plays an important role in global health and because of that the job market is growing.
As long as medical product are there which needs to be regulated and regulatory affairs jobs and grow will be there .
Regulatory affairs field will continue to grow at an average rate of eight percent.

Regulatory Affairs profession

Regulatory affairs professional combines scientific, legal, and business knowledge to ensure products, which are developed, manufactured, or distributed by company ,meet the required HA criteria
Here product means

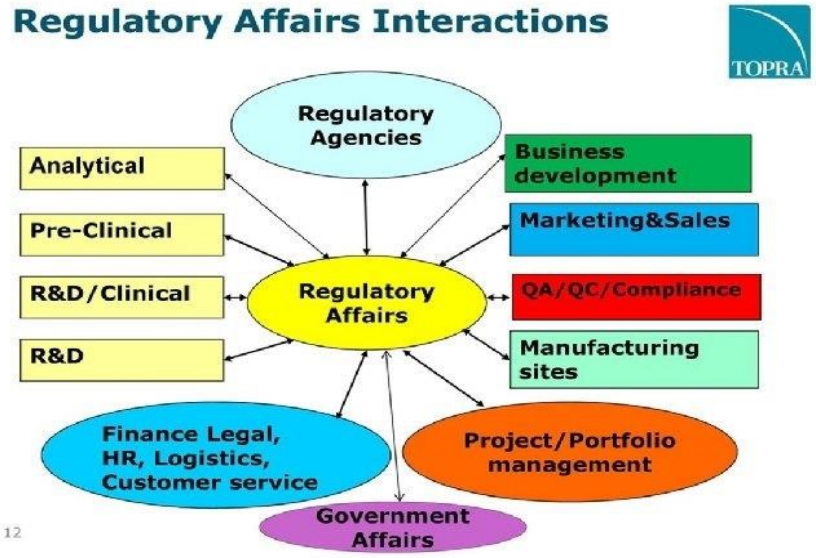
- Pharmaceutical
- Medical device
- In vitro diagnostics
- Biological and biotechnology
- Nutritional product
- Cosmetics
- Veterinary Industry

But focus is on the pharmaceutical department only, especially on drugs, biologics and medical device.

Roles and Responsibility of a regulatory affairs professionals

- Assure that a firm product complies with the regulations of the regions where it is plan for distribution.
- Monitor National and international legislation, guidelines.
- Document & maintain new product licenses and license renewals.
- Prepare, Monitor, and set timeline for different submission.
- Dossier Creation.
- Plan and Developed and interpret data
- Ensure another department follow regulatory requirement.
- Manage regulatory inspections.
- Interact with regulatory authorities and handle RA queries.

Division within Regulatory Affairs



Regulatory affairs qualification

Master or Bachelor`s degree in the field of science especially *pharmacy* are the highly desired candidates. However, professionals with essential skills in the life sciences, clinical sciences, management and writing are also chosen for these jobs.

Skills of regulatory affairs

1. key knowledge in current pharma regulation
2. Global perspective in pharma.
3. Good communication skill.
4. Excellent computer skill.
5. Project management skill.
6. Hand on experience on eCTD Tools.
7. Judgement skill and presentation skill.

Different titles used for regulatory affairs professionals

Based on the experience in years

- Regulatory affairs junior associate (0-1)
- Regulatory affairs associate (1-3)
- Regulatory affairs senior associate (3-4)
- Regulatory affairs senior executive (5-7)
- Regulatory affairs team lead (7-9)
- Regulatory affairs assistant manager (9-11)
- Regulatory affair manager (11-13)
- Regulatory affairs senior manager (14-16)
- Regulatory affairs director (14-20)

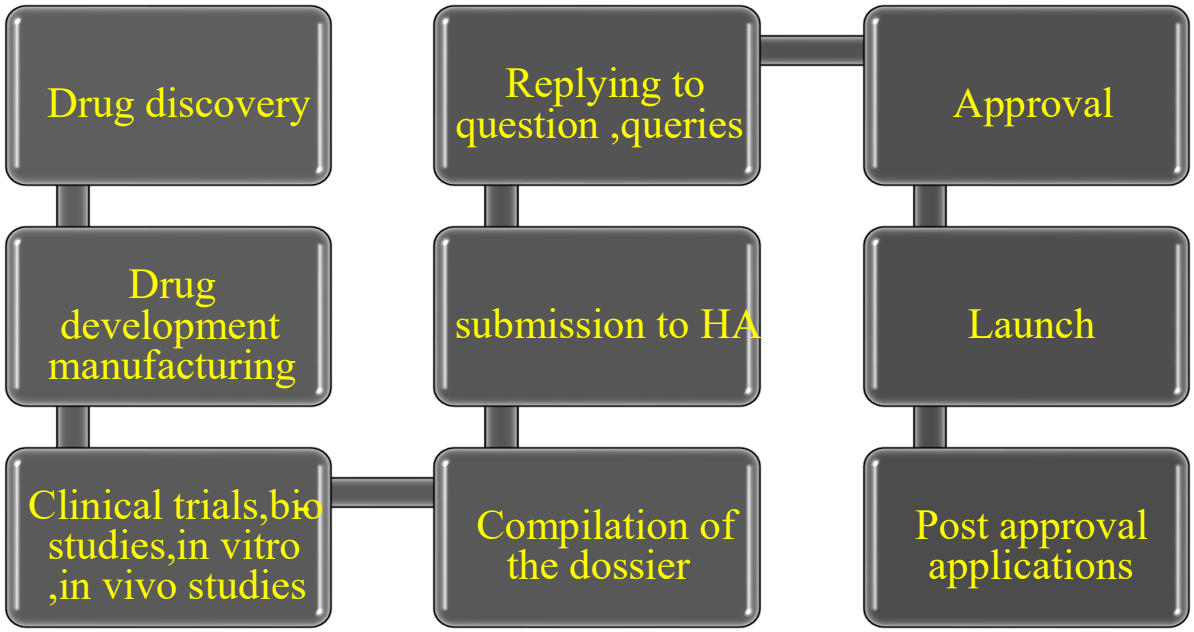
Regulatory affair job salary

Salaries vary depending on the type of company, location, your qualification and experience.

Experience average	*EU*	*INR*
0-2	*30,000 to 40,000*	*2.8L -4.0 L*
2-5	*40,000 to 50,000*	*3.6L-5.8 L*
6-8	*50,000 to 70,000*	*5.2L-9.0 L*
9-12	*50,000 to 70,000*	*8.2L-13.5 L*
12+	*1,00,000*	*14.0L-18.0*

Working hours

Basically 8 to 9 hours job in some cases it can be more…...



Invovelment of regulatory affairs in pharmaceutical industry

Common terminologies

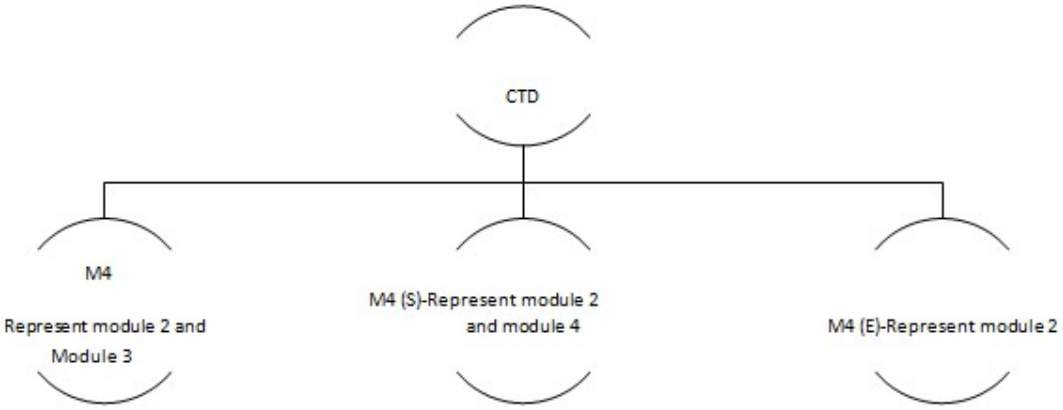
- DMF-Drug Master File
- ASMF-Active Substance Master File
- CEP-Certificate of Suitability
- ICH-International Council for Harmonization
- CTD- Common Technical Document

TYPE 4
Excipient,Colorant,flavor,Essence,or material used in their preparation

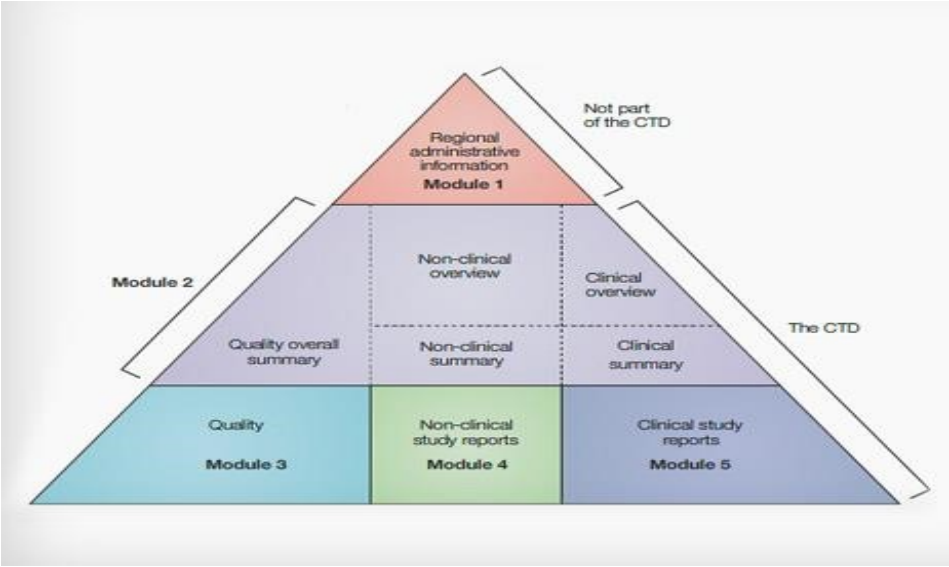
TYPE 5
FDA,Accepted reference information (FDA discourage its use)

CTD

- ICH m4 -CTD guideline.
- CTD was agreed in November 2000 in San Diego, USA.
- If provides for a harmonized structure and format for new product application
- CTD is a set of specification of medicine and designed to be used across Europe, Japan, US and many countries



CTD TRIANGLE



Module 1:

a) Application form
b) Approval Certificate {GMP, FSC, Manufacturing license etc.}
c) Labelling details
d) PIL, SPC
e) And many more …….

Note- Not a Part of CTD

Module 2:

a) 2.1 – Table of Contents
b) 2.2 – Introduction
c) 2.3 – Quality overall summery {2.3, S part and 2.3 P part}
d) 2.4 – Non -Clinical overview
e) 2.5 – Clinical overview
f) 2.6 – Non -Clinical written and Fabulized summaries
g) 2.7 – Clinical summaries

Module 3: Quality

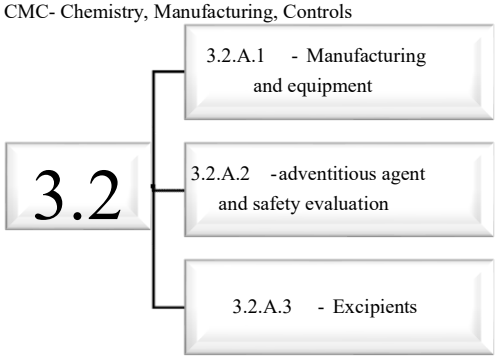
3.1 – Table of content
3.2.S – drug substance

a) 3.2.S.1 – General information
b) 3.2.S.2 – Manufacturing details
c) 3.2.S.3 – Characterization
d) 3.2.S.4 – Control of drug substance
e) 3.2.S.5 – Reference standard and Materials
f) 3.2.S.6 – Container closure system
g) 3.2.S.7 – Stability

3.2.P – Drug product

a) 3.2.P.1 – Description and Composition
b) 3.2.P.2 – Pharmaceutical Development
c) 3.2.P.3 – Manufacture
d) 3.2.P.4 – Control of Excipient
e) 3.2.P.5 – Control of Drug Product
f) 3.2.P.6 – Reference Standard and Material
g) 3.2.P.7 – Container Closure System
h) 3.2.P.8 – Stability

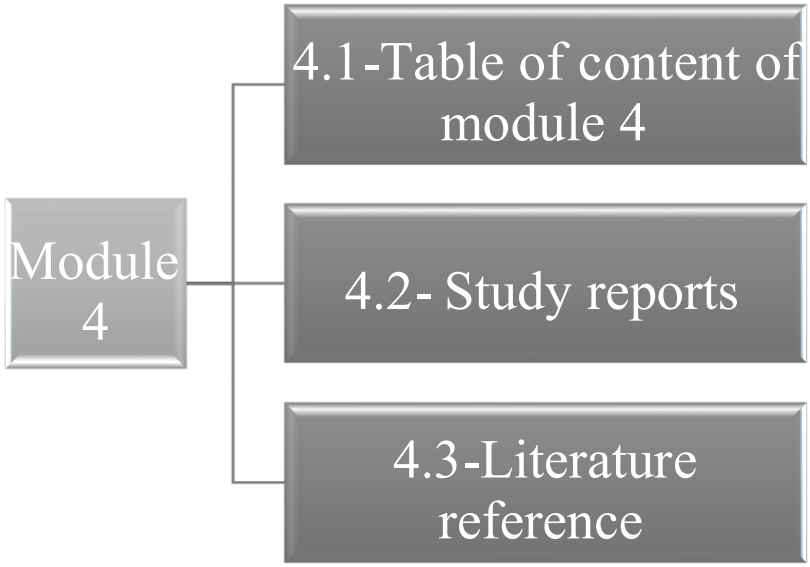
3.2.A
CMC- Chemistry, Manufacturing, Controls



3.2.R- Regional information (exhibit batches BMR / BPR, process validation scheme 3,3 – Literature reference

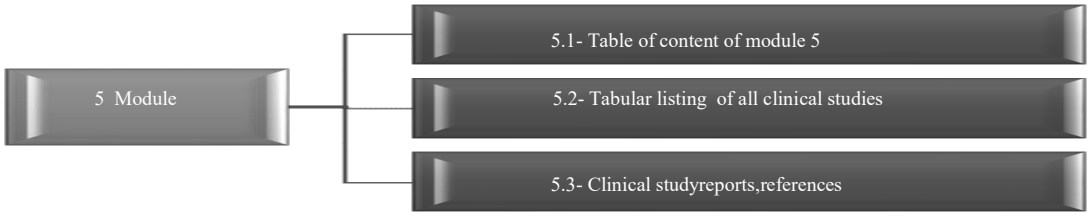
MODULE 4: Safety – M4 (S)

a) M4 describes the structure and format of the non-clinical data in module -2 of the CTD
b) If also provide the organization of module-4 i.e. The non-clinical study reports.
c) The non- clinical data, discussion of the non-clinical information on pharmacology. Pharmacokinetics and toxicology.



MODULE 5: Efficacy – M4 (E)

a) M4 describes the structure and format of the clinical data is an application, including summaries and detailed study reports.
b) If also provides the organizations of modules -5 the clinical study reports.



IMPORTANT POINTS TO REMEMBERED FROM M4 GUIDELINES

- Pagination and Segregation
- Table of Contacts
- Header and Footer

DIFFERENT PROCEDURE IN EU

- Centralized Procedure
- National Procedure
- De-centralized Procedure
- Mutual Recognition Procedure

CENTRALISED PROCEDURE (CP)

- Applying for a single marketing authorization that covers all EU countries.
- Centralized process is compulsory for:
  - 1-Medicine derived from Genetic engineering (Biotechnology)
  - 2-Medicine for HIV, Cancer, Neurogenerative disorders. 3 Orphandrugs (rare disease)
- Assessed by EMA and granted by European Commission.
- Assessment time: 210 days +time taken by EC.

NATIONAL PROCEDURE (NP)

- Used when applying for a marketing authorization is one individual EU member state.
- The national procedure can only be used if the medicinal product does not already have a marketing authorization in another EU member state.

Assessment time: 210 days.

- **DE- CENTRALISED PROCEDURES (DCP)**

The de- centralized procedure should be used if the product does not yet have a marketing authorization in any EU country and applicant wants approval in several countries at once.

In the de-centralized procedure, the applicant asks one-member state to act as the reference member state (RMS) which evaluates the application and prepare as assessment report.

The Concerned member states (CMS) can comment on the assessment report, at the end of the process, a marketing authorization will be granted in each of the involved member state after completion of the national phase.

Assessment time: 210 days +30 days

- **MUTUAL RECOGNISATION PROCEDURE (MRP)**

The MRP procedure should be used if the product does have a marketing authorization in any EU country and applicant wants approval in several countries at once.

- Evaluation remains same as DCP.
- Assessment time: 210 days +30 days (national phase)

HEALTH AUTHORITIES

1) USA- FOOD AND DRUG ADMINISTRATION
2) UK – MEDICINES AND HEALTHCARE PRODUCT REGULATORY AGENCY
3) AUSTRALIA – THERAPEUTIC GOODS ADMINISTRATIONS
4) INDIA – CENTRAL DRUG STANDARD CONTROL ORGANIZATION
5) CANADA – HEALTH CANADA
6) EUROPE – EUROPEAN MEDICINES AGENCY
7) JAPAN – MINISTRY OF HEALTH, LABOUR AND WELFARE
8) BRAZIL – BRAZIL NATIONAL HEALTH SURVEILANCE AGENCY

OPPORTUNITIES IN RA

- Regulatory associate
- Regulatory CMC expert
- Labeling expert
- Regulatory publisher
- Regulatory writer
- CMC faciliatory
- Regulatory compliance
- Pre-clinical /clinical specialist

IMPORTANT GUIDELINES

Q1A – Q1F – STABILITY
Q2 – ANALYTICAL VALIDATIONS
Q3A – Q3E – IMPURITIES
M4 – THE COMMON TECHNICAL DOCUMENT

CONCLUSION:

- Regulatory agencies and organizations around the world need to ensure the safety, quality and efficacy of medicines and medical devices, harmonization of legal procedure related to drug development of legal procedure related to drug development, monitoring and ensuring compliance with statutory obligations.
- However, the need of the labor is:

1)More centralized procedure in drug regulation
2)Harmonization of regulatory norms.
3)Strengthening the regulatory authorities.

- Regulation bodies, professional organization and union self-defense oversee, with almost all covering health care quality and safety and others encompassing issues related to reputation and trust.
- These inconsistencies have significant implications for professional mobility, patient, safety and quality care.

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