

1.What is Regulatory Affairs?

Ans-Regulatory Affairs in a Pharmaceutical industry, is a profession which acts as the interface between the pharmaceutical industry and Drug Regulatory authorities across the world. It is mainly involved in the registration of the drug products in respective countries prior to their marketing.

2.What are the goals of Regulatory Affairs Professionals?

Ans- Protection of human health

- 1) Ensuring safety, efficacy and quality of drugs
- 2) Ensuring appropriateness and accuracy of product information

3.What are the Roles of Regulatory Affairs professionals?

Ans- Act as a liaison with regulatory agencies

- Preparation of organized and scientifically valid NDA, ANDA,INDA ,MAA,DMF submissions
- Ensure adherence and compliance with all the applicable cGMP, ICH, GCP, GLP guidelines, regulations and laws
- Providing expertise and regulatory intelligence in translating regulatory requirements into practical workable plans
- Advising the companies on regulatory aspects and climate that would affect their proposed activities
- Apart from the above main roles, there are various other roles which Regulatory Affairs professionals play.

4.What is an Investigational New Drug (IND) application?

Ans- It is an application which is filed with FDA to get approval for legally testing an experimental drug on human subjects in the USA

5.What is a New Drug Application?

Ans- the NDA is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S. The data gathered during the animal studies and human clinical trials of an Investigational new drug become part of the NDA.In simple words, "It is an application which is filed with FDA to market a new Pharmaceutical for sale in USA"

6. What is an Abbreviated New Drug Application (ANDA)?

Ans- It is an application filed with FDA, for a U.S. generic drug approval for an existing licensed medication or approved drug.

In simple words, "It is an application for the approval of Generic Drugs "

7. What is a Generic Drug Product?

Ans- A generic drug product is the one that is comparable to an innovator drug product in dosage form, strength, route of administration, quality, performance characteristics and intended use.

8. What is a DMF?

Ans- a Drug Master File (DMF) is a submission to the Food and Drug Administration (FDA) that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs.

Important facts regarding DMFs

- It is submitted to FDA to provide confidential information
- Its submission is not required by law or regulations
- It is neither approved nor disapproved
- It is filed with FDA to support NDA, IND, ANDA another DMF or amendments and supplements to any of these
- It is provided for in the 21 CFR (Code of Federal Regulations) 314. 420
- It is not required when applicant references its own information

9. What are the types of DMF's?

Ans-

Type I: Manufacturing Site, Facilities, Operating Procedures, and Personnel (No longer accepted by FDA)

Type II: Drug Substance, Drug Substance Intermediate, and Material Used in Their Preparation, or Drug Product

Type III: Packaging Material

Type IV: Excipient, Colorant, Flavor, Essence, or Material Used in Their Preparation

Type V: FDA Accepted Reference Information (FDA discourages its use)

10. What is a 505 (b)(2) application ?

Ans- 505 (b)(2) application is a type of NDA for which one or more investigations relied on by applicant for approval were not conducted by/for applicant and for which applicant has not obtained a right of reference.

11. What kind of application can be submitted as a 505(b)(2) application?

Ans-

- New chemical entity (NCE)/new molecular entity (NME)
- Changes to previously approved drugs

12. What are the examples of changes to approved drug products for which 505(b)(2) application should be submitted ?

Ans-

- Change in dosage form.
- Change in strength
- Change in route of administration
- Substitution of an active ingredient in a formulation product
- Change in formulation
- Change in dosing regimen
- Change in active ingredient
- New combination Product
- New indication
- Change from prescription indication to OTC indication
- Naturally derived or recombinant active ingredient
- Bio-inequivalence



13. What are the chemical classification codes for NDA?

Ans- Number Meaning

- 1 New molecular entity (NME)
- 2 New ester, new salt or other noncovalent derivative
- 3 New formulations
- 4 New combinations
- 5 New manufacturer
- 6 New indication
- 7 Drug already marketed, but without an approved NDA
- 8 OTC (over-the-counter) switch

14. What are the differences between NDA and 505 (b)(2) application ?

Ans-

S.No. New Drug Application (NDA) 505 (b)(2) Application

1. All investigations relied on by applicant for approval were conducted by/for applicant and for which applicant has right of reference

One or more investigation relied on by applicant for approval were not conducted by/for applicant and for which applicant has not obtained a right of reference

2. Generally, filed for newly invented pharmaceuticals.

Generally, filed for new dosage form, new route of administration, new indication etc for all already approved pharmaceutical.

Note: 505 (b)(2) application is a type of NDA.

15. What is a Marketing Authorization Application?

Ans- It is an application filed with the relevant authority in the Europe (typically, the UK's MHRA or the EMA's Committee for Medicinal Products for Human Use (CHMP)) to market a drug or medicine.

As per UK's MHRA-

Applications for new active substances are described as 'full applications'.

Applications for medicines containing existing active substances are described as 'abbreviated' or 'abridged applications'.

16. What is an ASMF?

Ans-Active substance master file is a submission which is made to EMA, MHRA or any other Drug Regulatory Authority in Europe to provide confidential intellectual property or 'know-how' of the manufacturer of the active substance.

In simple words, "It is a submission made to European Drug regulatory agencies on the confidential information of Active Substance or Active pharmaceutical Ingredient (API)".

17. What are the types of active substances for which ASMFs are submitted?

Ans- · New active substances

- Existing active substances not included in the European Pharmacopoeia (Ph. Eur.) or the pharmacopoeia of an EU Member State
- Pharmacopoeial active substances included in the Ph. Eur. or in the pharmacopoeia of an EU Member State

18. What is the difference between DMF and ASMF (with respect to submission)?

Ans-ASMF is submitted as Applicant's Part (Open Part) and Restricted Part (Closed Part)

There isn't any differentiation of DMF's into parts

19. What is ICH?

Ans-International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH): is a project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of pharmaceutical product registration.

20. What is CTD?

Ans-The Common Technical Document (CTD) is a set of specification for application dossier, for the registration of Medicines and designed to be used across Europe, Japan and the United States. Quality, Safety and Efficacy information is assembled in a common format through CTD. The CTD is maintained by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

CTD format for submission of drug registration applications/dossiers is widely accepted by regulatory authorities of other countries too like Canada, Australia etc.

21. What are the ICH guidelines to be referred for preparation of registration dossiers/applications of medicines (With respect to format and contents in each module)?

Ans-

M4 Guideline

M4Q Guideline

M4S Guideline

M4E Guideline

22. What are the modules in CTD?

Ans- The Common Technical Document is divided into five modules:

Module 1. Administrative information and prescribing information

Module 2. Common Technical Document summaries (Overview and summary of modules 3 to 5)

Module 3. Quality

Module 4. Nonclinical Study Reports (toxicology studies)

Module 5. Clinical Study Reports (clinical studies)

22. What is Orange Book?

Ans- It is the commonly used name for the book "Approved Drug Products with Therapeutic Equivalence Evaluations", which is published by USFDA.

· It contains the list of drug products, approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act.

23. What is Hatch-Waxman act?

Ans- It is the popular name for Drug Price Competition and Patent Term Restoration Act, 1984. It is considered as the landmark legislation which established the modern system of generic drugs in USA. Hatch-Waxman amendment of the federal food, drug and cosmetics act established the process by which, would be marketers of generic drugs can file Abbreviated New Drug Application (ANDA) to seek

FDA approval of generic drugs. Paragraph IV of the act, allows 180 day exclusivity to companies that are the "first-to-file" an ANDA against holders of patents for branded counterparts.

In simple words "Hatch-Waxman act is the amendment to Federal, Food, Drug and Cosmetics act which established the modern system of approval of generics "

24.What are the patent certifications under Hatch-Waxman act?

Ans-As per the Hatch and Waxman act, generic drug and 505 (b) (2) applicants should include certifications in their applications for each patent listed in the "Orange Book" for the innovator drug. This certification must state one of the following:

(I) that the required patent information relating to such patent has not been filed (Para I certification);

(II) that such patent has expired (Para II certification);

(III) that the patent will expire on a particular date (Para III certification); or

(IV) that such patent is invalid or will not be infringed by the drug, for which approval is being sought(Para IV certification).

A certification under paragraph I or II permits the ANDA to be approved immediately, if it is otherwise eligible. A certification under paragraph III indicates that the ANDA may be approved when the patent expires.

25.What is meant by 180 day exclusivity?

Ans-The Hatch-Waxman Amendments provide an incentive of 180 days of market exclusivity to the "first" generic applicant who challenges a listed patent by filing a paragraph IV certification and thereby runs the risk of having to defend a patent infringement suit.

180 Day Exclusivity could be granted to more than one applicant. The recent example is- 180 day exclusivity was granted to Ranbaxy and Watson Laboratories for marketing generic version of Lipitor (Atorvastatin calcium).

26.What are the procedures for Approval of Drug in EU?

Centralised Procedure (CP)

Decentralised Procedure (DCP)

Mutual Recognition Procedure (MRP)

National Procedure (NP)

27. What is the Full form of abbreviation, CEP?

Certificate of Suitability to the monographs of the European Pharmacopoeia (or) Certificate of suitability of monographs of the European Pharmacopoeia (or) Certification of suitability of European Pharmacopoeia monographs

It is also informally referred to as Certificate of Suitability (COS)

28. What is a CEP?

It is the certificate which is issued by Certification of Substances Division of European Directorate for the Quality of Medicines (EDQM), when the manufacturer of a substance provides proof that the quality of the substance is suitably controlled by the relevant monographs of the European Pharmacopoeia.

29. What are the recently approved new Drugs by FDA (Under NDA Chemical Type 1)? (As on 14th March, 2012)

Ans-

S.NO.	NDA #	NAME OF DRUG	NAME OF ACTIVE INGREDIENT	COMPANY
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1	203188	KALYDECO	IVACAFTOR	VERTEX PHARMS
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2	203388	ERIVEDGE	VISMODEGIB	GENENTECH
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3	202324	INLYTA	AXITINIB	PFIZER
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4				
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	202833			
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		PICATO		
--	--	--------	--	--

		INGENOL	MEBUTATE	
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		LEO PHARMA	AS	
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5				
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	202514			
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		ZIOPTAN		
--	--	---------	--	--

		TAFLUPROST		
--	--	------------	--	--

		MERCK SHARP	DOHME	
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30.Full forms of some of the Abbreviations related to Regulatory Affairs-

S.No.

Abbreviation

Full Form

1

NDA

New Drug Application

2

ANDA

Abbreviated New Drug application

3

IND

Investigational New Drug Application

4

DMF

Drug Master file

5

ASMF



Active Substance Master File

6

MAA

Marketing Authorisation Application

7

CEP

Certificate of Suitability to the monographs of the European Pharmacopoeia

8

ICH

The International Conference on Harmonisation of technical requirements for registration of Pharmaceuticals for human use.

9

CTD

Common technical document for the registration of pharmaceuticals for human use.

10

AP

Applicant's Part

11

RP

Restricted Part

12

OP

Open Part

13

CP

Closed Part



14

NME

New Molecular Entity

15

NCE

New Chemical Entity

16

SmPC

Summary of Product Characteristics

17

PL

Packaging Leaflet

18

RMS

Reference Member State

19

CMS

Concerned Member State

20

CHMP

The Committee for Medicinal Products for Human Use

21

CPMP

Committee for Proprietary Medicinal Products

22



CVMP

Committee For Medicinal Products For Veterinary Use

23

SUPAC

Scale-up and post approval changes

24

BACPAC

Bulk Active Chemicals Post approval Changes

25

cGMP

Current good Manufacturing Practice

26

GCP

Good clinical Practice

27

GLP

Good Laboratory Practice



31. Well known Drug Regulatory Agencies across the world-

S.No.

Country /Region

Regulatory Agency

1

United States of America

United States Food and Drug Administration (USFDA)

2

United Kingdom

Medicines and Healthcare products Regulatory Agency (MHRA)

3

European Union

European Medicines Agency (EMA)

4

European Union

European Directorate for the Quality of Medicines (EDQM)

5

Australia

Therapeutic Goods Administration (TGA)

6

Canada

Therapeutic Products Directorate (TPD) in Health Product and food branch (HPFB) of Health Canada (HC)

7

Japan

Pharmaceutical and Medical Devices Agency (PMDA)

8

France

Agence Francaise de Securite Sanitaire des Produits de Sante (AFSSAPS)

Translated into English as- French Agency for the Safety of Health Products

9

Germany

Bundesinstitut für Arzneimittel und Medizinprodukte, (BfArM)



Translated into English as- Federal Institute for Drugs and Medical Devices

10

Brazil

Agência Nacional de Vigilância Sanitária (ANVISA)

Translated into English as- The National Health Surveillance Agency

11

India

Drugs Controller General of India (DCGI) who heads Central Drugs Standard Control Organisation (CDSCO)

12

Switzerland

Swiss Agency for Therapeutic Products (SWISSMEDIC)

14

Singapore

Health Sciences Authority (HSA)

15

New Zealand

New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE)

- See more at: <http://blog.cliniindia.com/p/pharma-regulatory-affairs.html#.U5ftnfmSwSM>

