PHARMACY INDIA

# COMMON INTERVIEW QUESTIONS & ANSWERS

## FOR REGULATORY AFFAIRS

## PHARMA GRADUATES & POST-GRADUATES

# REGULATORY AFFAIRS INTERVIEW QUESTION AND ANSWERS

**1. What is Regulatory Affairs?**

**Answer -** 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?**

**Answer -** Protection of human health; Ensuring safety, efficacy and quality of drugs; and Ensuring appropriateness and accuracy of product information

**3. What are the Roles of Regulatory Affairs professionals?**

**Answer**

i) Act as a liaison with regulatory agencies.

ii) Preparation of organized and scientifically valid NDA, ANDA, INDA, MAA, DMF submissions.

iii) Ensure adherence and compliance with all the applicable cGMP, ICH, GCP, GLP guidelines, regulations and laws.

iv) Providing expertise and regulatory intelligence in translating regulatory requirements into practical workable plans.

v) Advising the companies on regulatory aspects and climate that would affect their proposed activities.

vi) 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?**

**Answer -** 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?**

**Answer -** 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)?**

**Answer -** 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?**

**Answer -** 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?**

**Answer -** 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:

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

**9. What are the types of DMF's?**

**Answer**

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 ?**

**Answer**

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?**

**Answer**

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 ?**

**Answer**

- 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?**

**Answer**

- New molecular entity (NME)
- New ester, new salt, or another noncovalent derivative
- New formulation
- New combination
- New manufacturer
- New indication
- Drug already marketed, but without an approved NDA
- OTC (over the counter) switch

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

**Answer**

**New Drug Application (NDA)**

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

ii) 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

**505 (b)(2) Application**

i) Generally, filed for newly invented pharmaceuticals.

ii) 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?**

**Answer**

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-

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

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

**16. What is an ASMF?**

**Answer**

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?**

**Answer**

i) New active substances

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

iii) Pharmacopeial 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)?**

**Answer**

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

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

**19. What is ICH?**

**Answer**

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?**

**Answer**

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)?**

**Answer**

- M4 Guideline
- M4Q Guideline
- M4S Guideline
- M4E Guideline

**22. What are the modules in CTD?**

**Answer**

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?**

**Answer**

It is the commonly used name for the book "Approved Drug Products 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?**

**Answer**

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?**

**Answer**

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)
(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?**
**Answer**
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?**
**Answer**

- Centralised Procedure (CP)
- Decentralised Procedure (DCP)
- Mutual Recognition Procedure (MRP)
- National Procedure (NP)

**27. What is the Full form of abbreviation, CEP?**
**Answer**
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?**
**Answer**
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 regulatory standards?**

**Answer**

Regulatory standards means all laws, rules, regulation and Regulatory authority advisory opinions or orders applicable to the manufacturing, marketing, sale, reimbursement and/or pricing of any products.

**30. What is the difference between CTD and ACTD?**

**Answer**

The ACTD consists of Parts I to IV which have subsections A to F whereas ICH-CTD has 5 Modules with subsections that are numbered. The administrative data of Part I is part of ACTD whereas Module 1 of ICH-CTD is purely country specific.

**31. What is dossier preparation?**

**Answer**

Dossier is a collection of documents on the particular subjects. Any preparation of pharmaceutical product for human use go through the process of reviewing and assessing the dossier of pharmaceutical product which contains details information about administrative, quality, non-clinical and clinical data.

Though there is no specifically recognized format, the teaching dossier typically consists of two basic components: a teaching narrative statement or philosophy, which is a short reflective narrative (two to three pages), and an appendix, which consists of supporting documentation.

**32. What is CMC in regulatory affairs?**

**Answer**

Chemistry, Manufacturing, and Controls (CMC) Regulatory Affairs (RA) is a specific area within RA that has the ultimate responsibility for providing CMC regulatory leadership and strategy required to achieve regulatory approvals.

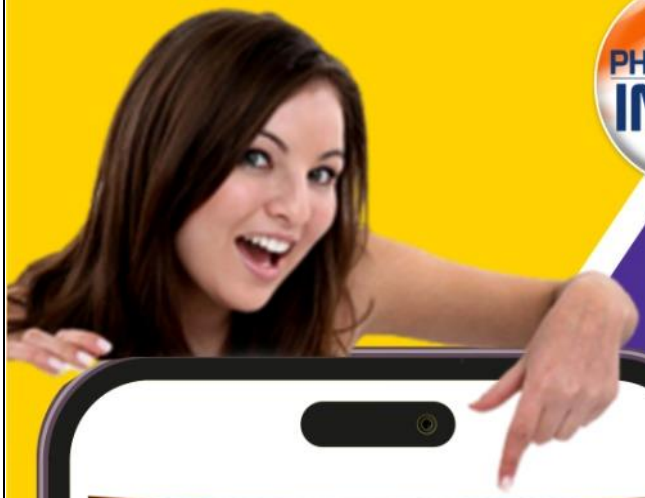
**FULL FORMS OF SOME ABBREVIATIONS**

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 Authorization 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

**REGULATORY AGENCIES**

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)Tanslated into English as- Federal Institute for Drugs and Medical Devices
10. **Brazil -** Agência Nacional de Vigilância Sanitária (ANVISA)Tanslated into English as- The National Health Surveillance Agency
11. **India -** Drugs Controller General of India (DCGI) who heads Central Drugs Standard Control Organization (CDSCO)
12. **Switzerland -** Swiss Agency for Therapeutic Products (SWISSMEDIC)
13. **Singapore -** Health Sciences Authority (HSA)



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