Common Job Interview Questions With Answers Asked in Drug Regulatory Affairs Interview

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By: Pristyn Research Solutions

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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.

What are the goals of Regulatory Affairs Professionals?

Ans-

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

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

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.

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”

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 “

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.

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’.

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

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.

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)

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

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
- Bioinequivalence

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 formulation
4	New combination
5	New manufacturer
6	New indication
7	Drug already marketed, but without an approved NDA
8	OTC (over-the-counter) switch

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.

What is a Marketing Authorization Application?

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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'.

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)".

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
•Pharmacopeial active substances included in the Ph. Eur. or in the pharmacopoeia of an EU Member State

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

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.

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.

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

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)

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.

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 ”

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.

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).

What are the procedures for Approval of Drug in EU?

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

What is the Full form of abbreviation, CEP?

Ans- 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)

What is a CEP?

Ans- 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.

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
1	203188	KALYDECO	IVACAFTOR	VERTEX PHARMS
2	203388	ERIVEDGE	VISMODEGIB	GENENTECH
3	202324	INLYTA	AXITINIB	PFIZER
4	202833	PICATO	INGENOL MEBUTATE	LEO PHARMA AS
5	202514	ZIOPTAN	TAFLUPROST	MERCK SHARP DOHME
6	021746	SURFAXIN	LUCINACTANT	DISCOVERY LABORATORIES INC

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

Full forms of some of the Abbreviations related to Regulatory Affairs-

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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

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**) 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 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)**

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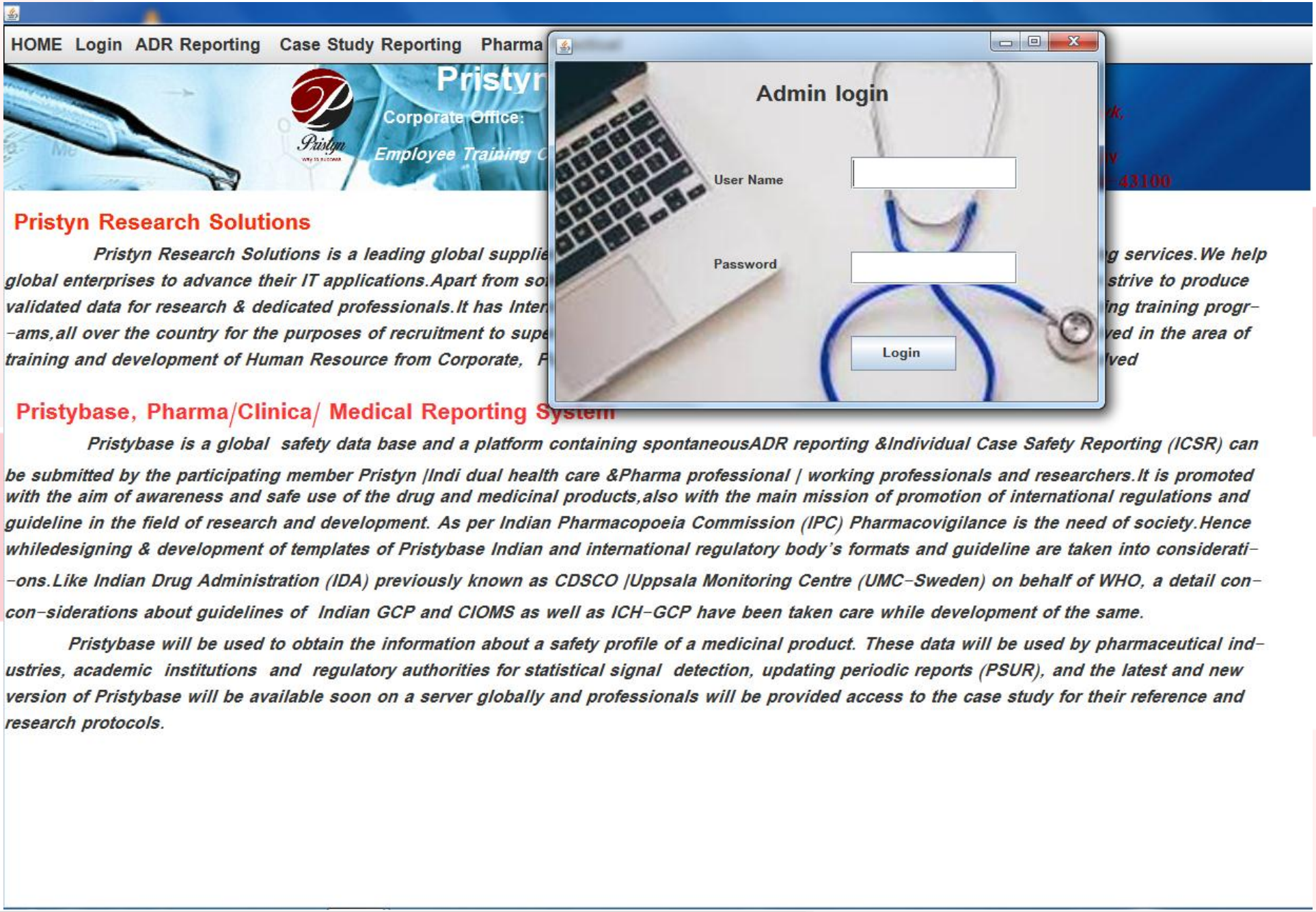

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Pristyn Research Solutions is a leading global supplie ...g services.We help global enterprises to advance their IT applications.Apart from so... strive to produce validated data for research & dedicated professionals.It has Inter... ...ing training progr--ams,all over the country for the purposes of recruitment to supe... ...ved in the area of training and development of Human Resource from Corporate, P... ...lved

Pristybase, Pharma/Clinica/ Medical Reporting System

Pristybase is a global safety data base and a platform containing spontaneousADR reporting &Individual Case Safety Reporting (ICSR) can be submitted by the participating member Pristyn |Indi dual health care &Pharma professional | working professionals and researchers.It is promoted with the aim of awareness and safe use of the drug and medicinal products,also with the main mission of promotion of international regulations and guideline in the field of research and development. As per Indian Pharmacopoeia Commission (IPC) Pharmacovigilance is the need of society.Hence whiledesigning & development of templates of Pristybase Indian and international regulatory body's formats and guideline are taken into considerati--ons.Like Indian Drug Administration (IDA) previously known as CDSCO |Uppsala Monitoring Centre (UMC-Sweden) on behalf of WHO, a detail con-con-siderations about guidelines of Indian GCP and CIOMS as well as ICH-GCP have been taken care while development of the same.

Pristybase will be used to obtain the information about a safety profile of a medicinal product. These data will be used by pharmaceutical ind--ustries, academic institutions and regulatory authorities for statistical signal detection, updating periodic reports (PSUR), and the latest and new version of Pristybase will be available soon on a server globally and professionals will be provided access to the case study for their reference and research protocols.

C. SUSPECTED MEDICATION(S)

Report Number
Sr.No
8. Name (Brand/Generic)
Manufacturer (if known)
Batch No. / Lot No.
Exp. Date
Dose used
Route used
Frequency (OD, BD etc.)
Therapy dates strated
Therapy dates stopped
Indication
Causality Assessment
Add

Report Number	S.No	8. Name (Bran...	Manufacturer (...	Batch No. / Lot...	Exp. Date (if k...	Dose used	Route used	Frequency (O...	Therapy dates...	Therapy dates...	Indication	Causality Ass...

9. Action Taken(in Yes or No)

Report Number
S.No as per C: 1
Drug withdrawn: YES
Dose increased: YES
Dose reduced: YES
Dose not changed: YES
Not applicable: YES
Unknown: YES

10. Reaction reappeared after reintroduction (please tick): YES

Effect unknown: YES
Dose (if reintroduced)
Add

Report Number	S.No as per C	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Reaction reappe...	Effect unknown	Dose (if reintrodu...

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

Report Number
Sr.No
Name (Brand/Generic)
Route Used
Frequency (OD, BD, etc.)
Therapy dates started
Therapy dates stopped
Indication
Add

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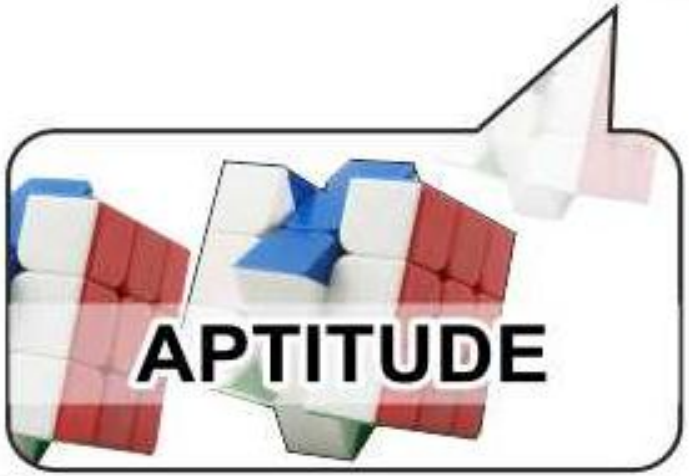

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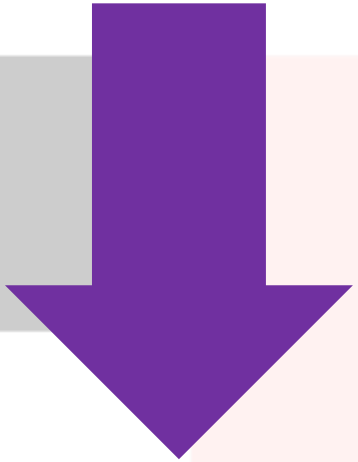

Check

Pharmacovigilance | Clinical Research | Clinical Data Management
Drug Regulatory Affairs | Pharma Q.A / Q.C | Pharma Production
Pharma Digital Marketing | R & D | Medical Coding
Medical Transcription | Medical Writing | Research Publications

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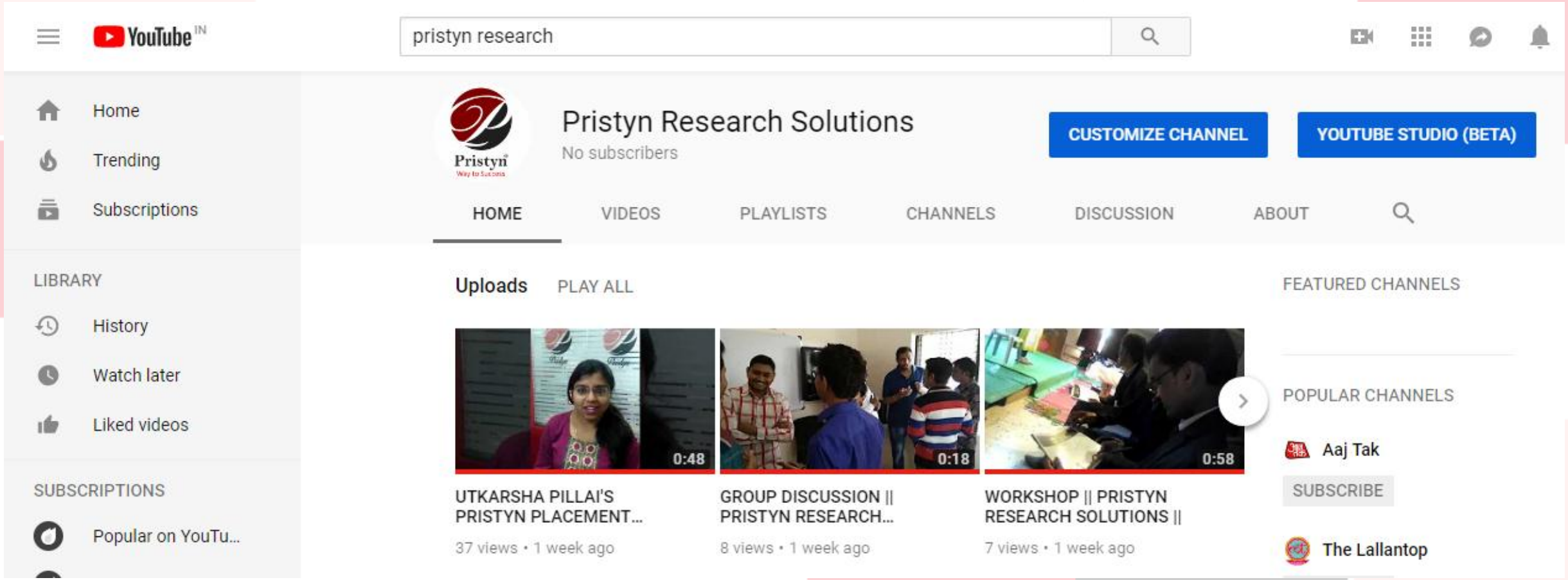

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"If you have joined Pristyn, your career and you, both are in good hands! Pristyn had a solution for every problem of mine. Joining here was the best decision. After coming here, I came to know what it takes being the best and stand out from the rest. Pristyn helped me to challenge any interview with my training and technical knowledge."
Komal.Choukhande, SGRS College of Pharmacy Saswad , Pune.

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LAST

Malviya proposed a vote of thanks.

Shivaji College of Pharmacy, Deori

Guests present at the workshop.

A DAYLONG workshop on "Students Industrial Pre-Placement Programme" was organised by Chhatrapati Shivaji College of Pharmacy, Deori in association with MSBTE, Mumbai and Pristyn Research Solution ,Pune. The main objectivebehind organising the workshop is to create awareness among the student about the industrial demand for skilled manpower to have employability. Pristyn Director Pathan Azhar Khan guided on Drug Discovery to Approval process with latest requirements and international regulations. The delegates were acquainted with role and responsibilities, interview techniques and job requirement . Pristyn Counselor Pavitra Shibad and Vinod Nair explains about the importance of having pleasant personality, soft skills and communication skills. In this workshop, Zhamsing B. Yerne, President Krushna Sahypgi Tantra Shikshan Sanstha (Deori) Presided over while Dr. Milind Umekar ,Principal SKB College of Pharmacy, Kamptee and Dr. Dinesh Biyani Associate Prof. were chiefly present alongwith Anil Z. Yerne ,Secretary and Jayshree Yerne. Dr Milind Umekar also spoke on the occasion.Earlier, Upadesh Bhimrao Lade, Principal of Chhatrapati Shivaji College of Pharmacy, Deori delivered inaugural speech. Meenakshi Mhaske conducted the proceedings while Co-ordinator Sandipkumar Agrawal proposed vote of thanks.

Shri Shivaji College, Akola

About Pristyn Research Solutions:

Pristyn Research Solutions is a leading global supplier of I.T, Clinical, Pharmaceutical services and Knowledge processing services. We help global enterprises to advance their IT applications. Apart from software developments and frame-work global services Pristyn provide corporate training in profession and skills development. We strive to produce validated data for research & dedicated professionals. It has International affiliations and regional government approvals for organizing training programs, all over the country - for the purposes of recruitment to superior posts. It has huge associations of individuals and group involved in the area of training and development of Human Resource from Corporate, Public, Private Sector Organization & other Professional Bodies.

For us every candidate is important & every company is unique. This is a place where a candidate identifies his/he career loopholes, overcome those & match the principle of RIGHT CANDIDATE FOR RIGHT JOB.

Short-Term Industrial & Corporate Training on: (Life-Science)

(A) Domain	(B) Domain	(C) Domain
1. Clinical Research	1. Pharma Q.A/Q.C	1) Medical Coding
2. Pharmacovigilance	2. Pharma Production	2) Medical Writing |MS
3. Clinical data Management	3. DRA | Ph-Digital Marketing	3) P.V| Research Publications
4. Drug Regulatory Affairs	4. R & D	4) DRA
Duration= 3 Months	Duration= 3 Months	Duration= 3 Months

28 Days Job Training

- Technical Terminologies used in Interviews and Job Workplace.
- H.R and Company Communication Skills
- Mock Interviews and Professionalism
- Aptitude Training and Brain Boosting
- Group Discussion and Teamwork
- Job Search/Job Applying Tools and Tricks
- Computer & Online literacy required for Job
- Job and companies Applications /Email Writing
- Resume/C.V and Profile Building
- Motivational Lectures by industry Persons
- Career Guidance/ Self-Confidence Boosting
- Brush up-on English language.
- Soft Skills and communication
- Personality Development & Presentation Skills
- Placement Tools and Assistance
- Other Customize and personal Support

Advanced PGD & Professional Internship Program (Life-Science)

(Drug Discovery to Approval)

All Domains

Duration= 4+ 2 Months

2 Months Project & Placement

Short-Term Industrial & Corporate Training on: (I.T)

Domain	Domain	Duration=3 M
1. JAVA	1. .NET	Live Client Project and
2. PHP	2. PYTHON	Development Work for 1 Month

Advanced PGD & Professional Internship Programed (I.T)

Domain	Domain	Duration= 6 Months
1. JAVA	1. .NET	Live Client Project and
2. PHP	2. PYTHON	Development Work for 2 Month

pristyn® to Success