Common Job Interview Questions With Answers Asked in Quality Assurance & Quality Control Interview

Pristyn
Way to Success

By: Pristyn Research Solutions

9028839789 | 9607709586

info@pristynresearch.com

pristynresearch.com

Q 1- What are the contents of the SOP?

Ans -Objective/Purpose, Scope, Responsibility, Accountability, Procedure, List of formats/Annexure, Abbreviations, Reference, Revision History.

Q 2-What is the difference between intermediate and drug substance (API)?

Ans- Intermediate: A material produced during steps of the processing of an API that undergoes further molecular change or purifications before it become an API

API: Any substance or mixture of substances intended to be used in the manufacturing of a drug (medicinal) product and that when used in the production of a drug, becomes an API of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affectthe structure & function of the body.

Q 3-What is documentation?

Ans-All the written production procedures, instructions and records, quality control procedures and recorded test results involved in the manufacturing of a medicinal product.

Q 4-What do you mean by “Quality Assurance”?

Ans-The sum total of the organized arrangements made with the objects of ensuring that all APIs are of the quality required for their intended use and the quality systems are maintained.

Q 5-What is cGMP?

Ans-Current Good Manufacturing Practices. This means any procedure / system adopted by the manufacturer which proves to be necessary and important foridentity, strength and purity of a product.

Q 6-How are cGMP implemented?

Ans-Training, compliance to SOPs, control on operations, following procedures / systems,monitoring through compliance audits.

Q 7-What is the different types of Qualifications and write its flow?

Ans-Qualifications are as follows: Design Qualification, Installation Qualification, Operational Qualification, and Performance Qualification.

URS/DS -----FAT-----SAT-----DQ-----IQ-----OQ-----PQ

Q 8-What is OOS?

Ans-Out of Specification (OOS) results are those results, generated during testing that do not comply with the relevant specification or standards or with the defined acceptance criteria.

Q 9-How many types of raw material and packing material?

Ans- Raw materials are classified into two types. Those are as follows:

1. raw material
2. Other raw material

Packing materials are classified into two types. Those are as follows:

1. Primary Packing material
2. Secondary Packing material

Q 10-What is limit of Temperature and relative humidity in the pharma area?

Ans-Temperature: 25±2˚C & Relative Humidity: 50±5%

Q 12-What is calibration?

Ans-The demonstration that a particular instrument or device produces results within specified limits by comparison with results produced by a reference or traceable standard over an appropriate range of measurements.

Q 13-Why cGMP should be followed?

Ans-This is a regulation that each one of us is trained in cGMP and practices cGMP

- It minimizes the possibilities of any errors caused by subjectivity.
- It makes you do your job right the first time and every time.

Q 14-Why do we conduct trainings?

Ans-It brings awareness and helps us in becoming competent.

Q 15-What do you mean by Critical Quality Attributes?

Ans-A critical quality attributes is a physical, chemical, biological or microbiological property or characteristic that should be within an appropriate limit, range, or distribution to ensure the desired product quality.

Q 16-What do you mean by production?

Ans -All operations involved in the preparation of an API from receipt of material through processing and packaging of an API.

Q 17. What Is The Hplc Principle?

Ans- It is a technique used for separating the mixture of components into individual components based on adsorption, partition, ion exchange and size exclusion principles. Stationary phase and mobile phase used in it. HPLC used for identification, quantification and purification of components form a mixture.

Q 18. Explain Hplc Instrumentation?

Ans- It involves solvent system, pump, Sample injector, HPLC columns, Detectors and Recorder. Firstly, solvent(mobile phase) is degassed for eliminating the bubbles. It is passed through the pump with a uniform pressure. The liquid sample is injected into the mobile phase flow stream. It passes through the stationary phase identified by the detectors and recorded.

Q 19. In Reverse Phase Hplc, Which Type Of Stationary Phase Is Used And Give Example?

Ans- Non polar stationary phase used

Ex: Silica gel C-18

Q 20. What Are The Detectors Used In Hplc?

Ans- UV detector, IR detector, Fluorescence detector, Mass spectroscopy, LC MS etc.

Question 21. Difference Between Humidity And Relative Humidity?

Ans-

•**Humidity –** Measure of amount of water vapour present in the atmosphere.

•**Relative humidity-** Water vapour amount exists in air expressed as a percentage of the amount needed for saturation at the same temperature.

Q 22. What Is Room Temperature?

Ans- 25 degree centigrade

Q 23. What Is The Ultraviolet(uv) And Visible Spectroscopy Range?

Ans- UV spectroscopy range 200-400 nm, Visible spectroscopy range 400 nm to 800nm.

Q 24. What Is The Use Of Uv Spectroscopy?

Ans- Spectroscopy used for detecting the functional groups, impurities. Qualitative and quantitative analysis can be done.

Q 25. What Is The Difference Between Qualitative And Quantitative Analysis?

Ans- Qualitative analysis involves identification of the compound or chemical based on their chemical(absorption, emission)or physical properties(e.g Melting point, boiling point). Quantitative analysis involves estimation or determination of concentration or amount of the chemical compounds or components.

Q 26. Explain The Principle Of Ultraviolet Spectroscopy?

Ans- UV spectroscopy uses light in the UV part of electromagnetic spectrum. UV absorption spectra arises in which molecule or atoms outer electrons absorb energy, undergoes transition from lower energy level to higher energy level. For each molecule, absorbance at wavelength is specific

Q 27. Explain About Beer Lamberts Law?

Ans- It states that the intensity of monochromatic light absorbed by a substance dissolved in a fully transmitting solvent is directly proportional to the substance concentration and the path length of the light through the solution.

Q 28 . Explain the difference between QC and QA?

Ans) QA provides the confidence that a product will full fill the quality requirements. QC determines and measures the product quality level.

Q 29. What are types of climatic zones? India belongs to which climatic zone?

Ans- India belongs to Zone III(Hot dry zone) and Zone IVb(Hot/Higher humidity)

FYI

Pristyn
Way to Success

ICH Stability Zones

Zone	Type of Climate
Zone I	Temperate zone
Zone II	Mediterranean/subtropical zone
Zone III	Hot dry zone
Zone IV	Hot humid/tropical zone
Zone IVb	ASEAN testing conditions hot/higher humidity

Long Term Testing Conditions

Climatic Zone	Temperature	Humidity	Minimum Duration
Zone I	21°C ± 2°C	45% rH ± 5% rH	12 Months
Zone II	25°C ± 2°C	60% rH ± 5% rH	12 Months
Zone III	30°C ± 2°C	35% rH ± 5% rH	12 Months
Zone IV	30°C ± 2°C	65% rH ± 5% rH	12 Months
Zone IVb	30°C ± 2°C	75% rH ± 5% rH	12 Months
Refrigerated	5°C ± 3°C	No Humidity	12 Months
Frozen	-15°C ± 5°C	No Humidity	12 Months

Accelerated and Intermediate Testing Conditions

Climatic Zone	*Temperature*	*Humidity*	*Minimum Duration*
Accelerated Ambient	*40°C ± 2°C*	*75% rH ± 5% rH*	*6 Months*
Accelerated Refrigerated	*25°C ± 2°C*	*60% rH ± 5% rH*	*6 Months*
Accelerated Frozen	*5°C ± 3°C*	*No Humidity*	*6 Months*
Intermediate	*30°C ± 2°C*	*65% rH ± 5% rH*	*6 Months*

Q 30. Expand cGMP and what is the difference between GMP and cGMP?

Ans) cGMP known as Current Good Manufacturing Practices. It is a USFDA regulations to assure proper design , manufacturing and control of manufacturing processes and services.
GMP-Good Manufacturing Practices. These are the standard guidelines given by Food and Drug administration to make sure that a product is manufactured with safety and quality. c
in cGMP means current. It refers to recent and advance updates to these standard guidelines.
cGMP is up to date standard reference guidelines.

Q 31. Expand BMR and BPR?

Ans) BMR – Batch Manufacturing Record , is prepared as a written file during the manufacturing a product by writing. Step by step manufacturing process and details about batch recorded here.
BPR Batch Packaging Record, is kept for every BMR. BPR is depends on packaging operation.

Q 32. What do you know about stability studies?

Ans) These are necessary for developing the pharmaceutical products. It helps to evaluate the effect of environmental factors (e.g Light, Humidity, Temperature etc) on Active Pharmaceutical Ingredient(API) or Pharmaceutical formulation.

Q 33. Expand ICH? Tell me about ICH Guidelines?

ICH known as The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use. It brings the regulatory authorities and pharmaceutical companies together to discuss the drug registration technical aspects.

The aim of the ICH is to enhance the harmonization world wide to make sure that safe, high quality and effective drugs are developed and registered in the most efficient manner.

ICH provides guidelines on 4 aspects that is quality , safety , Efficacy and Multidisciplinary guidelines.

Q 34.. How To Calculate Retention Factor In Paper Chromatography?

Ans- Rf = Distance travelled by solute/ Distance travelled by solvent.

Q 35. What is the time period required for long term and accelerated stability studies?

Ans) Long term 12 months, Accelerated studies- 6 months

Q 36. Expand IQ OQ PQ DQ

Ans- IQ- Installation Qualification

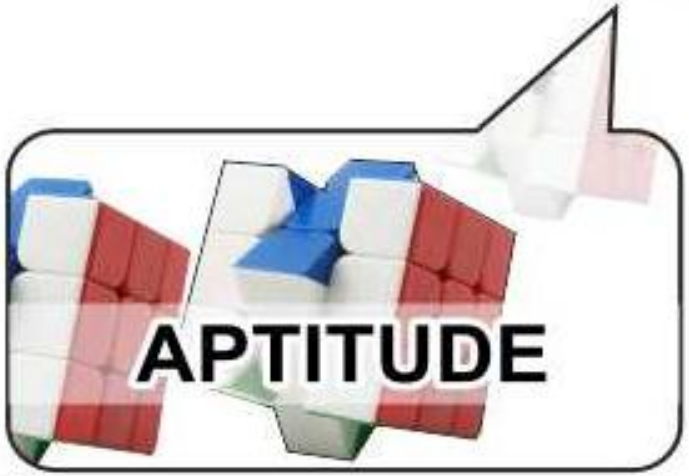
OQ-Operational Qualification

PQ-Performance Qualification

DQ-Design Qualification

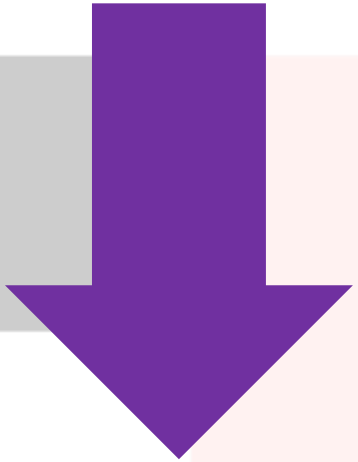
Current Standard Hiring Process of Companies

Pristyn®
Way to Success



Pristyn
Way to Success

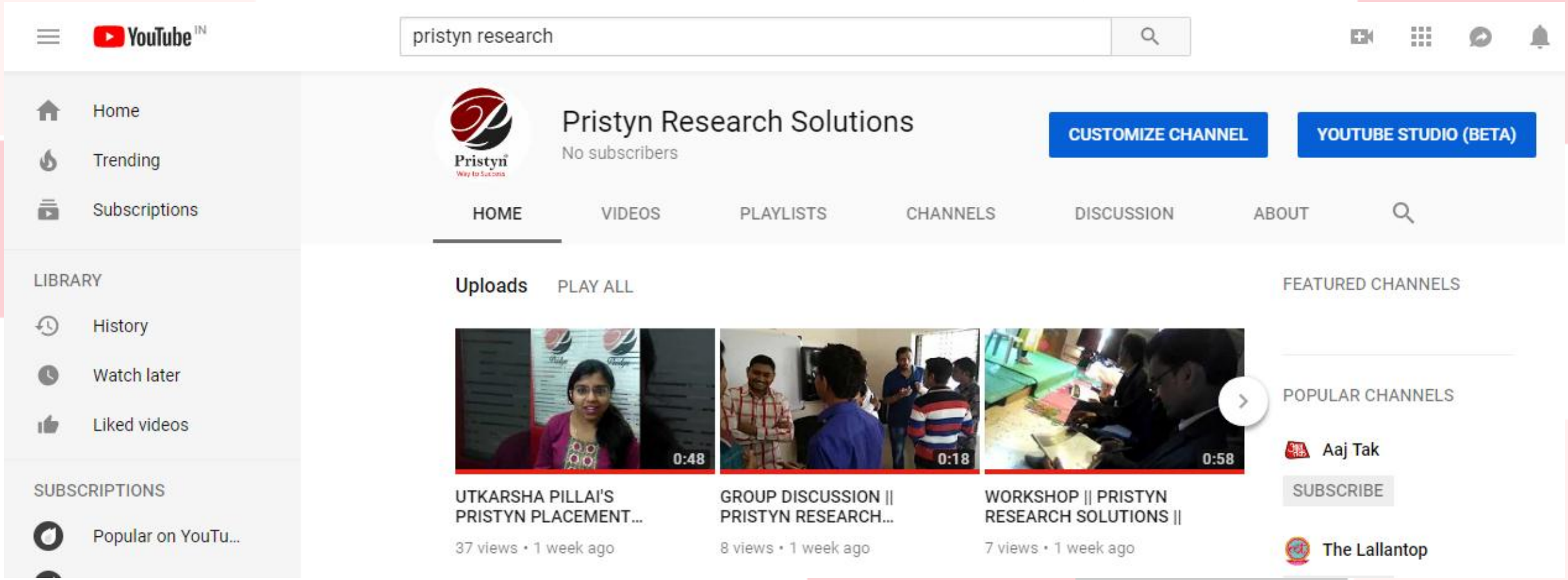
For Job Oriented Regular / Weekend /Online Certified Industrial Training | Internship & Short Term Courses with placements assistance and guarantee Kindly call us



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

Pristyn
Way to Success



OUR M.O.U PARTNERS

AMERICAN SPECIALTY PHARMACY · Xplore Tech · CT QUEST · Dignity Health · CURE MEDICINES (INDIA) PVT. LTD. · Wobble Base Bio Research · ACCENTRA SOFTWARE · Chhatrapati Shivaji College of Pharmacy · T9 TechNexa Giving wings to your success... · Sara Hospital · S.Medicare

CORPORATE SERVICES

CDMS| e –CRF| EDC| Protocol| SAS| Oracle| Hadoop | ERP| CRM| ADRs and SAE fillings
e-CRT| I.B| Medical Coding | PSUR| RMP| Systematic Review and Meta-Analysis
Medical and Clinical Data Entry Pharma and Medical Translation |
Employee Development Programs | Software Development and Frame-work services
Outsourcing for compilation of research data | Regulatory Submission | Proof Reading
Pharma | Medical Digital Marketing Research Publications
Arrangement of Placement Drives

Our Trainees/ Students are placed in:

LIFEPOINT MULTISPECIALITY HOSPITAL · NOVARTIS · WOCKHARDT · ASENTECH · SYNTEL Consider IT Done · Emcure SUCCESS THROUGH INNOVATION · accenture · Cipla · SUN PHARMA · TRANSPERFECT · Pfizer · TATA CONSULTANCY SERVICES Experience certainty · Zydus dedicated to life · INAMDAR MULTISPECIALITY HOSPITAL · EXCEL LIFE SCIENCES · Cognizant · Biocon

STUDENT SPEAK ABOUT PRISTYN TRAINING & PLACEMENT PROGRAM

"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.

Last Batch Placed Students / Trainees Trough Pristyn Training and Courses:

Regarding Job Training & Placement Contact: 9028839789
T-21/4, Opposite Expert Global, Software Technology Park of India, Aurangabad - 431001 | 9028839789

www.pristynresearch.com Instant Help 9028839789

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

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