SKILLBEE SOLUTION

NOW WITH HANDS ON EXPERIENCE IN ORACLE CLINICAL EDC DATABASE

3 MONTHS ADVANCE COURSE

https://skillbee.co.in/

CONTENT

COMPANY OVERVIEW

01

VISION

SkillBee Solution, our vision is to empower individuals and organizations through high-quality training and certification programs, enabling them to acquire the knowledge, skills, and credentials necessary for personal and professional success in the rapidly evolving world. We strive to be a leading institute that fosters lifelong learning, innovation, and excellence, shaping the future workforce and contributing to societal progress.

COMPANY OVERVIEW

ABOUT US

SkillBee Solution, ISO 9001: 2015 certified company (certificate number: IMC-CTCY-22-0513477), registered under the Registration Act, 1958 with Government of India Registration Number C/1788348 and affiliated with Life Sciences Sector Skills Council (SSC) - presents unique, friendly and interactive platform to get rid of all your GMP related glitches.

MODULES FOR CLINICAL RESEARCH AND CLINICAL DATA MANAGEMENT SYSTEMS (CDMS)

02

SECTION A: CLINICAL RESEARCH

Module 1. Introduction, History & Overview to Pharmacology, Clinical Trials and Pharmacovigilance

1. **Drug discovery process**
- Position of Clinical research in the process
- Def: clinical research
- Different phases, study designs in clinical research, glossary
- Different parties involved in Clinical Research

2. **Regulatory authorities**
- IRB/IEC
- Sponsor
- CRO
- SMO
- Investigator
- Patients

3. **Clinical Research History**
- Food drug & cosmetic act
- Nuremberg code
- Declaration of Helsinki
- ICH
- Kefauver-Harris Amendments
- Belmont report
- National Research Act
- Sulfanilamide disaster
- Thalidomide disaster

MODULES FOR CLINICAL RESEARCH AND CLINICAL DATA MANAGEMENT SYSTEMS (CDMS)

Module 2. Introduction and responsibilities of Different Regulatory Bodies – an overview

- USFDA
- DCGI (CDSCO)
- MHRA (EMA)
- MHLW
- TGA
- IRB/IEC

Module 3. IND & NDA Application: Regulatory requirements & forms

Module 4. Audits & Inspections in Clinical Trial

Module 5. Types of audits/inspection & Reporting of findings.

MODULES FOR CLINICAL RESEARCH AND CLINICAL DATA MANAGEMENT SYSTEMS (CDMS)

SECTION B: CLINICAL DATA MANAGEMENT SYSTEMS (CDMS)

Module 1. Clinical Trail Process and Design

Module 2. ICH-GCP and GCDMP

Module 3. Clinical Data Management Systems

- CRF Design
- Data Entry & Data Collection
- Data Load/Transfer
- Data Storage
- Data Validation
- Data Export (SDTM)
- Query Management
- Data Archiving
- Quality Systems,SOPs and Audits
- Safety Management and Pharmacovigilance
- Data Management Systems and Tools
- Medical Codings and Medical Dictionaries
- CDMS, AERS,EDC,OCTMS
- Documentation and Document Management System

MODULES FOR CLINICAL RESEARCH AND CLINICAL DATA MANAGEMENT SYSTEMS (CDMS)

Module 4. Statistical Analysis (analytical Tools) and Reporting

Module 5. Project Management

Module 6. Security Systems

Module 7. Efficient Case Processing

- Case processing
- MeDRA coding & WHO DD coding
- Duplicate Check and case initiation
- SAE Narrative writing

Module 8. Hands on Experience in Oracle Clinical EDC database

MODULES FOR PHARMACOVIGILANCE

03

PHARMACOVIGILANCE

Module 1. Introduction to Pharmacovigilance

Module 2. Pharmacovigilance in India

- National Pharmacovigilance program
- National Pharmacovigilance centers

Module 3. Clinical Drug Development process & Different phases of clinical Trials

Module 4. History and objective of Pharmacovigilance

Module 5. In depth knowledge of:

- Introduction to Adverse events
- Adverse Drug Reactions
- Adverse Events &
- Serious adverse event
- Expected and unexpected adverse events

MODULES FOR PHARMACOVIGILANCE

Module 6. Different sources of Adverse events reporting & Different types of AE reporting forms

- Sources of reports
- Reporting forms
- Criteria of reporting

Module 7. Expedited reporting for clinical trials drugs and for post marketed drugs and its timelines

Module 8. Different Department and Methodologies in Pharmacovigilance (Types of AE reporting Forms)

Module 9. Regulatory guidelines and laws governing Pharmacovigilance

- ICH guidelines
- USFDA guidelines
- European union Guidelines

Module 10. Drug Safety in clinical trials and post marketed drugs

MODULES FOR PHARMACOVIGILANCE

Module 11. Reporting

- Individual Case safety Report Processing
- Case triage
- Recording of ICSR information
- Follow up of adverse events

Module 12. Specific events scenarios

- Drug overdose, abuse and misuse
- Drug exposure during pregnancy

Module 13. Introduction to safety databases and different types

Module 14. Data Management Systems and Drug Dictionaries in Pharmacovigilance (Argus, ArisG, MedWatch, MedRA, WHODD etc.)

Module 15. Periodic safety updates reporting

Module 16. Aggregate Safety Reports

MODULES FOR PHARMACOVIGILANCE

Module 17. Pharmacovigilance Regulations in Various Countries

Module 18. Pharmacovigilance Program in India (PVPI)

Module 19. Signal Detection and Data Mining

Module 20. Roles and responsibilities of case receipt unit & Triage unit

Module 21. Four factors for the reportable case

Module 22. Seriousness criteria of adverse event

Module 23. Expectedness or Listedness of adverse event

Module 24. Causality assessment of the adverse event

MODULES FOR PHARMACOVIGILANCE

Module 25. Pharmacovigilance of Herbal Drugs & Medical Devices

Module 26. Pharmacovigilance Compliance and Inspections

Module 27. Hands-on training on Argus, ArisGlobal, ABcube etc software platforms.

Module 28. Case Study

- Assessment of case report as reportable or not
- Assessment of seriousness of adverse event
- Assessment based on expectedness of adverse event
- Assessment of causality of adverse event

Module 29. Other Topics

- Narrative writing
- Case quality check, medical review and its submission.
- The Qualified Person for Pharmacovigilance (QPPV) in the European Economic Area
- PSUR and its submission timelines, ICH GCP Guideline
- E2A- E2D Guideline, GVP Module VI, VII & IX
- Schedule Y, 21 CFR Part 11, 21 CFR part 314.80, 21 CFR part 314.98

MODULES FOR MEDICAL WRITING

04

MEDICAL WRITING

Module 1. Security Systems

Module 2. What is Medical Writing

Module 3. Scope of Medical Writing

Module 4. Medical Writing in Clinical Trial

Module 5. Medical Writing & Scientific Writing

Module 6. Fundamentals of Medical Writing

Module 7. Marketing Medical Writing

Module 8. Regulatory Medical Writing

Module 9. The Writing Process

MODULES FOR MEDICAL WRITING

Module 10. Good Writing Skills

- Introduction to basic rules
- Elements of style
- Grammar and good writing

Module 11. Good Clinical Practice Guidelines

Module 12. The Clinical Study Report

Module 13. Introduction to Publication Writing

Module 14. Regulations and Industry Standards

Module 15. Writing Effective Documents

- Writing Standard Operating Procedures Policies, Procedures, Instructions, and Methods
- Writing Quality Manuals and Plans

CERTIFICATION COURSES WE OFFER

05

- Computerized System Validation
- Basic Laboratory Information Management Systems (LIMS)
- Advance Administrative Laboratory Information Management Systems (LIMS)
- Integrated Industrial training and certification in Pharmacovigilance, Clinical research, Clinical data management systems and Medical Writing
- Pharmacovigilance + Clinical Research Professional Certification
- Clinical data management + Clinical Research Professional Certification
- Medical Writing + Clinical Research Professionals Certification
- Pharmaceutical Regulatory Affairs Certification
- Pharmaceutical Quality Assurance professional training certification
- Pharmaceutical Validation Professional training
- Pharmaceuticals GMP Professionals Certification
- Pharmaceutical Engineering Professionals Certification
- Project Management Programme (PMP)

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ADVISORY FACULTY FROM INDUSTRY

Apart from regular faculty members, eminent and dynamic industrial professionals having rich industrial experience of up to 20-25 years have got associated with SkillBee Solution in regular, part-time, distance cum e-learning and Continuing Education Program (CEP).The industrial professionals who have joined SkillBee Solution in this initiative have worked in reputed pharmaceutical companies like Ranbaxy Laboratories Ltd, Cadila Pharma Ltd, Dr.Reddy's Laboratories, Quintiles, IPCA, Cipla etc. in the areas of GMP,GLP, Clinical Research, QA/QC, IPR, Regulatory Affairs, Drug Discovery, Public Health, Medical Coding etc. The continuing education training program has been launched with an initiative to provide training to work force in the industry on specific topics in short time period and to quick fix the issues with possible solutions by having an interface with senior industrial professionals.

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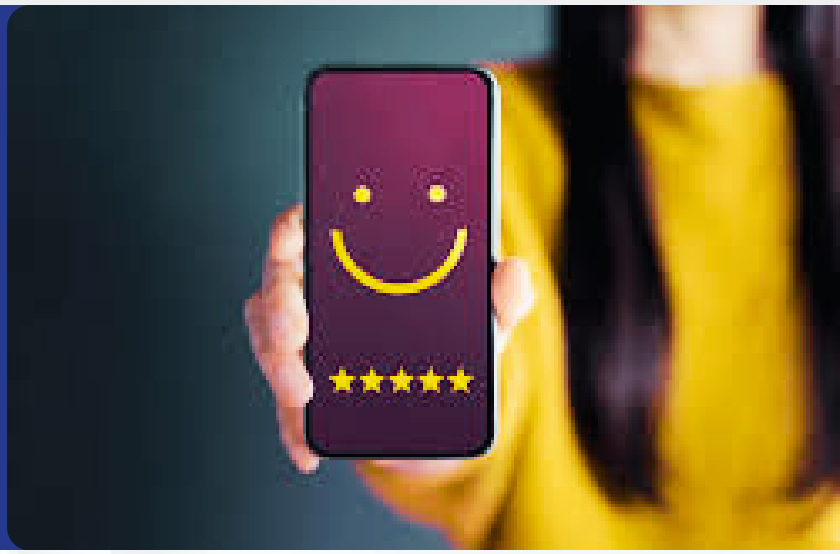
TESTIMONIALS OF OUR STUDENTS AND THEIR PLACEMENT DETAILS



Narendrapal Singh

Selected in Infosys

It's good platform to achieve the goal under the guidance of experience tutor facility.

Bhumika Barve

Selected in Mindtree

Good staff for Comuterized System Validation. Everyone is ready to help anytime.

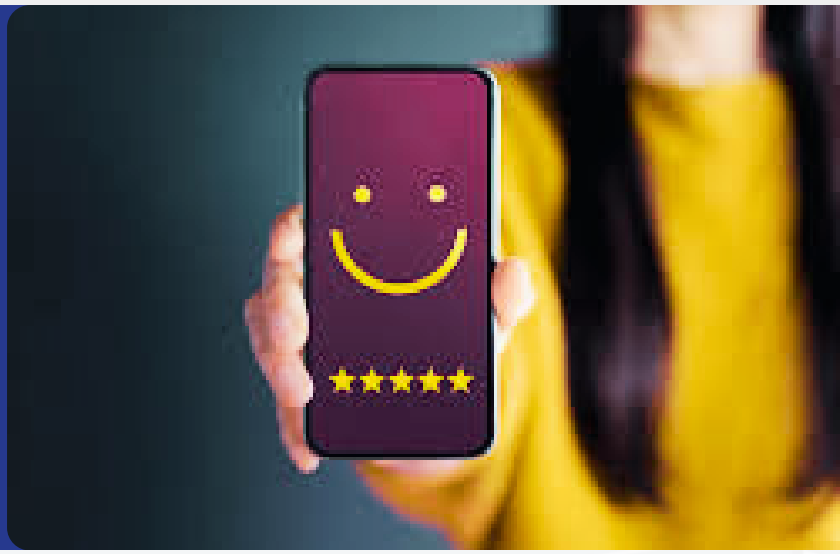
Saurabh Mashalkar

Selected in Cognizant, Hyderabad

Great learning Experience.Very helpful and informative.

For Google Review Click here

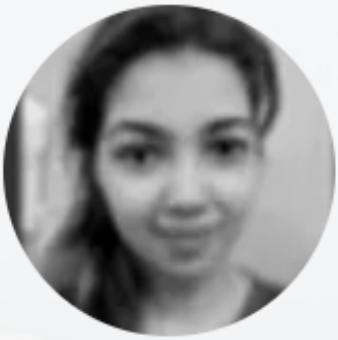
TESTIMONIALS OF OUR STUDENTS AND THEIR PLACEMENT DETAILS



Ratna Rekha

Selected in Infosys

Avneesh is really good in delivering the concepts with good examples. It is a good platform for the people who wanted to know about CSV.



Neha Mehta

Selected in Ernst & Young (EY), India

The class is good and well understandable, hoping for the best in perspective of career also. Service is very good.

S.R.V. Vivekananda Rao

Selected in Navitas Lifesciences Banglore

It was great experience. Company connect consultancy doing great job on trainings following current pharmaceutical industry requirements. Thank you Brajesh sir.

For more testomonials click here!

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OTHER DETAILS REGARDING THE COURSE

The Course we offer in is available on the below link

https://skillbee.co.in/

Eligibility

Graduation/ B. tech/ B.Sc./ Pharma/ MBBS/ BDS/ BHS/ BUMS/ BAMS or any other discipline. Diploma holders are eligible for our Executive Diploma, Industry Certificate, and Certificate Programs.

Future Career Prospects of the Program

Clinical Research and Pharmacovigilance program will boost your carrier growth in Clinical Research industry, Clinical Trials demand are increasing day by day in India and outside of India as new drug development scope is continuously increasing.

Program Duration:

The candidate is expected to complete the course in 3 months.

Registration

The registration will be carried out by contacting on SkillBee Solution.
How to Apply

OTHER DETAILS REGARDING THE COURSE

Certification and Membership Fees

Contact on +91-9691633901, +91-8839538846
Landline number: 0731- 3520480
or info@skillbee.co.in for details of fees structure.

Assessment & Certification

All the participants are expected to appear for online assessment. After successfully qualifying the examination, the participants will be certified as GCP Professional by SkillBee Solution.

Placement Assistance & Corporate Relations

The Institute has partnered with many organizations for providing with placement assistance to in its participants. Besides, it has a robust placement cell comprised of senior level Human Resources professionals and Talent Acquisition experts which maintains close links with business and industry.

In recent months the Institute has witnessed more and more participation from professionals working with global pharmaceutical, healthcare and food giants like IQVIA, Dr. Reddy's Laboratories, Aurobindo Pharma, Glenmark Generics, Cipla, Mindtree, Cognizant, Lupin, IVY works, Deloitte, EY, Global software resources, Novartis, Vaisesika, Phillips, Wipro, Wockhardt, Pfizer, Abbott, Medtronic, Foster Corporation, IPCA Laboratories, Calyx, Mother Dairy, Bliss GVS Pharma, Al Rawabi, Almarai, Green Pastures, SeQuent, PepsiCo India, Mankind, Beryl Drugs, Allergy Therapeutics, CFTRI, Ciron, Sun Pharmaceutical, GlaxoSmithKline, Ranbaxy , Biocon etc.

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BENEFITS OF JOINING THE CERTIFICATION COURSE

- Free Membership for one year to avail chat with our lecturer and other members of the same group
- Free access to costly study material at any time with membership for one year.
- Free access to Interview based question and answer.
- Mock interview class
- 100 % Placement Assistance (not guaranteed)
- Two consecutive batches can be Joined with same fees
- Recordings of class will be available for 60 days from day 1 of class on website to recall and create your own notes
- Resume preparation assistance

CONTACT INFORMATION

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CERTIFIED ISO 9001:2015 CERTIFIED