

# SKILLBEE SOLUTION



**CLINICAL RESEARCH  
AND  
CLINICAL DATA  
MANAGEMENT  
SYSTEMS  
PROFESSIONAL  
CERTIFICATION COURSE**

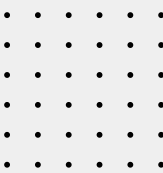


**NOW WITH HANDS ON EXPERIENCE IN  
ORACLE CLINICAL EDC DATABASE**

**1.5 MONTHS ADVANCE COURSE**



<https://skillbee.co.in/>



# CONTENT

- 01** COMPANY OVERVIEW
- 02** MODULES FOR CLINICAL RESEARCH AND CDMS
- 03** CERTIFICATION COURSES WE OFFER
- 04** ADVISORY FACULTY FROM INDUSTRY
- 05** TESTIMONIALS OF OUR STUDENTS AND THEIR PLACEMENT DETAILS
- 06** OTHER DETAILS REGARDING THE COURSE
- 07** BENEFITS OF JOINING CERTIFICATION COURSE
- 08** CONTACT INFORMATION

# 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 Trial 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



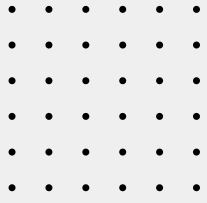
# CERTIFICATION COURSES WE OFFER

# 03

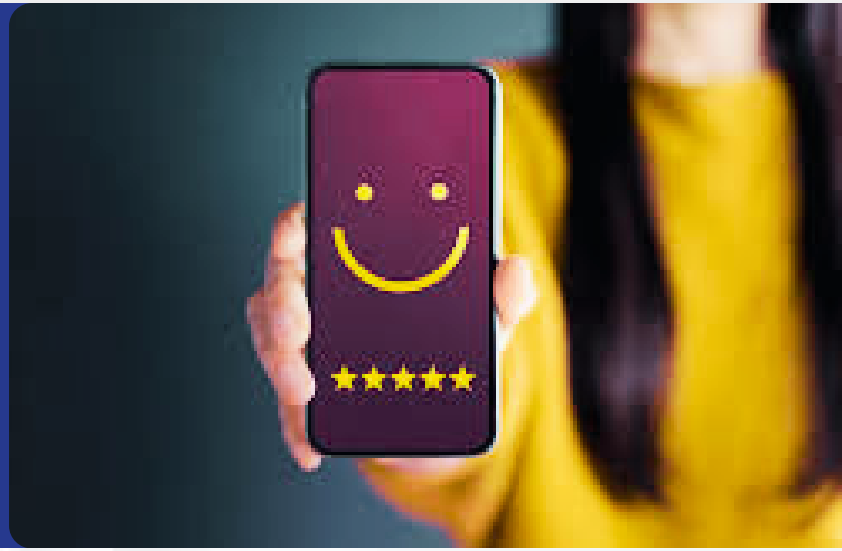
- Computerized System Validation
- Basic Laboratory Information Management Systems (LIMS)
- Advance Administrative Laboratory Information Management Systems (LIMS)
- Integrated Industrial training and certification in Pharmacovigilance, Clinical research, Clinical data management systems and Medical 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)

# 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.



## 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 Computerized System Validation. Everyone is ready to help anytime.



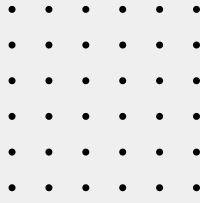
Saurabh Mashalkar

Selected in Cognizant, Hyderabad

Great learning Experience. Very helpful and informative.



**[For Google Review Click here](#)**

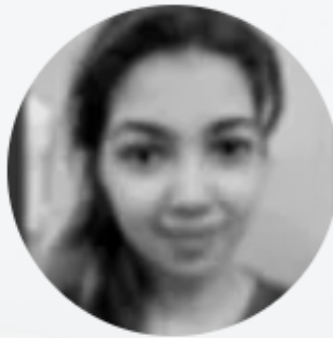


# TESTIMONIALS OF OUR STUDENTS AND THEIR PLACEMENT DETAILS



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.

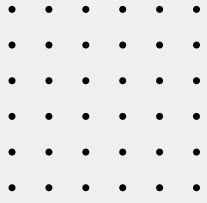


S.R.V. Vivekananda Rao  
Selected in Navitas Lifesciences Bangalore

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



**[For more testimonials click here!](#)**



# 06

## 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 & CDMS 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.

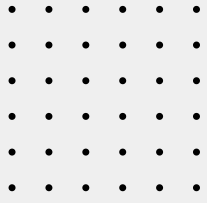
### **Program Duration:**

The candidate is expected to complete the course in 1.5 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](mailto:info@skillbee.co.in) for details of fees structure.

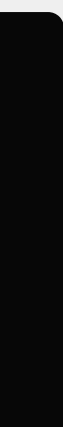
### **Assessment & Certification**

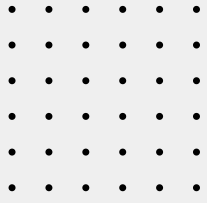
All the participants are expected to appear for online assessment. After successfully qualifying the examination, the participants will be certified as GCP Professional by SkillBee Solution.

### **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.





## 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



**Company Connect Consultancy Head Office:**  
17 A Suryadev Nagar, Indore, 452009

**Branch:** 5-46/1 Chanda Nagar Hyderabad, 500050

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**Landline number:** 0731- 3520480

**Mail:** [info@skillbee.co.in](mailto:info@skillbee.co.in)

**Website:** <https://skillbee.co.in/>

