

### SKILLBEE SOLUTION



#### 2 MONTHS ADVANCE COURSE



https://skillbee.co.in/



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COURSE

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## COMPANY OVERVIEW

# 01



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



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 COMPUTERIZED SYSTEM 02 VALIDATION (CSV)

### MODULES FOR COMPUTERIZED SYSTEM VALIDATION (CSV)



Module 1. Software Validation & Infrastructure Qualification

Module 2. Computer System Validation (CSV) - Overview, Regulatory requirements (GAMP & 21 CFR Part 11) and documentation

Module 3. High Level Risk Assessment (GxP Assessment, Software Categorization as per GAMP 5, ERES Assessment)

Module 4. GAMP 5 and documentation (URS, FS, DS, CS, Source Code Review Report, Validation Plan, Validation Report, Test Plan & Test Summary Report)

Module 5. Testing of Computerized System (IQ, OQ, PQ, UAT, Regression Testing, Smoke Testing, Sanity Testing)

# MODULES FOR COMPUTERIZED SYSTEM VALIDATION (CSV)

Module 6. Penetration Testing (Threat Modeling, SAST & DAST)

Module 7. Excel Sheet Validation

Module 8. Cloud Computing (SaaS, PaaS, IaaS)

Module 9. Software Development Life Cycle (SDLC):

Waterfall, V-Model, Agile Methodology, DevOps etc.

Module 10. Back-up and Restore, Archival & Retrieval of Data

Module 11. Business Continuity Management

Module 12. System Retirement & Data Migration

Module 13. Quality Management System and Quality Risk Management

Module 14. Computer Software Assurance (CSA Approach), A New way of working for CSV Projects:

- Data Acquisition System (DAS)
- Chromatography Data System (CDS)
- E-pedigree bottle or carton Serialization System

# CERTIFICATION COURSES WE OFFER

- · 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.

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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.

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#### For Google Review Click here

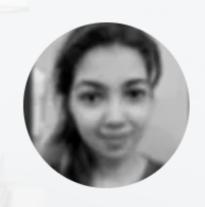
# TESTIMONIALS OF OUR STUDENTS AND THEIR PLACEMENT DETAILS





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 Banalor

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

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#### For more testomonials click here!



#### 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**

Computerized System Validation scope is very wide in the field of Pharmaceuticals, Medical Device industry and Clinical Trail Industry. CSV person demand is very high as compare to other curses, relative career growth is 50% higher than other industrial courses. After completion of this course professionals can work as Validation Lead, Assistant Manager, Manager, and goes higher based on his knowledge and skill set.

#### **Program Duration:**

The candidate is expected to complete the course in 2 months.

#### Registration

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



#### **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.



- Free Membership for one year to avail chat with our lecturer and other members of the same group
- Free access to study material worth 70,000 INR 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 30 days from day 1 of class on website to recall and create your own notes
- Resume preparation assistance



#### **Company Connect Consultancy Head Office:**

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