



SKILLBEE

SOLUTION

**PHARMA &
LIFE SCIENCES
CONSULTING
SERVICES**



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



CONTENT

- 01 COMPANY OVERVIEW
- 02 SERVICES PROVIDED BY US
- 03 INDUSTRIES WE SERVE
- 04 WHY CHOOSE US
- 05 CONTACT INFORMATION

COMPANY OVERVIEW

01



VISION



To be a trusted global partner in delivering end-to-end compliance, validation, and consulting services for the life sciences industry. We aim to empower pharmaceutical, biotechnology, and medical device organizations with innovative, reliable, and regulatory-compliant solutions that ensure patient safety, product quality, and data integrity.

By combining deep domain expertise, robust methodologies, and a customer-centric approach, we strive to simplify complex compliance requirements and help our clients remain audit-ready, future-ready, and globally competitive.

Our vision is not just to validate systems, but to build confidence in technology, enable operational excellence, and foster sustainable growth for every client we serve.

COMPANY OVERVIEW



ABOUT US



Skillbee Solutions, ISO 9001: 2015 certified company (certificate number: IMC-CTCY-22-0513477), registered under the Registration Act, 1958 with Government of India Registration Number C/1765843 and affiliated with Life Sciences Sector Skills Council (SSC) - presents unique, friendly and interactive platform to get rid of all your GMP related glitches.

SERVICES

02

SERVICES PROVIDED BY US



1. Audit Management

Audit Exposures -

✓ US-FDA Approvals

- Team Leader at Vovantis Laboratories Pvt. Ltd. (Formulation).
- 2nd line QMS leader at Ipca Laboratories Ltd. (API).

✓ TGA & MHRA

- At J.B. Chemicals & Pharmaceuticals (JBCPL) – interacted directly and as 2nd line for QMS.

✓ WHO Geneva

- Represented Ipca and JBCPL for API & Pharma audits. Led some audits and acted as 2nd line in others.

✓ African & Asian MOH Audits

- Interactions with health authorities of Kenya, Ivory Coast, Congo, Sierra Leone, Uganda, Ghana, Yemen, Cameroon, Philippines, Ethiopia.

✓ WHO India

- At Ipca, JBCPL, and Vovantis—attended 5 audits as leader, 2 as 2nd line.

✓ Overseas Customer Audits (Intertek, UL, NSF GMP)

- Maintained certifications for CVS, Walmart, Walgreens, Target—over 4 years.

Social Audits –

✓ Conducted successfully for CVS, Walmart, Walgreens, Target.

✓ Managed by Intertek and UL Labs—maintained compliance for over 4 years.

GMP Audits (Neutral Auditor Role) -

✓ Worked as a neutral auditor for overseas customers assessing Indian and global suppliers of APIs and drug products.

✓ Completed 60+ audits in India and 15 abroad.



SERVICE PROVIDE BY US

cGMP Documentation & Training (Quality System Implementation) -

- ✓ Handled 15+ projects (completed/ongoing) covering:
- ✓ Train-the-trainer programs.
- ✓ Quality Management System (QMS) & Risk Management.
- ✓ Investigation skills, stability management, technology transfer.
- ✓ Trending & data analysis, CAPA management.
- ✓ Harmonization & simplification of GxP systems.
- ✓ Facility audits, gap analysis, qualification activities.
- ✓ Project progress reviews & waste elimination initiatives.
- ✓ On-the-job training for both workmen and management staff with evaluation and QMS system reviews.

DMF (Drug Master File) Preparation & Filing -

- ✓ Supported technical teams in documentation and submission to regulatory authorities.
- ✓ Assisted in preparing and sourcing documents for smooth DMF filing.

Consultant Role in Regulatory Audits –

- ✓ Acted as observer during critical audits: USFDA, PIC, EU QP, Yemen MOH, NAFDAC, WHO-India.
- ✓ Assisted in customer audits and compliance preparation.
- ✓ Led gap analysis for plant design and creation of new manufacturing sections.

Project Consultancy -

- ✓ Supporting EU GMP (API projects) and USFDA (formulation projects).
- ✓ Involved from project commissioning stage—covering QMS, training activities, facility design review.
- ✓ Worked on new molecule development for both APIs and drug product facilities.

SERVICES PROVIDED BY US



Auditor's Detail -

- ✓ B. Makwana is a freelance consultant with 43+ years of progressive experience in pharmaceutical manufacturing and quality assurance.
- ✓ He has worked across diverse dosage forms—solid orals (general tablets, effervescent tablets, sachets, lozenges), liquids, parenterals, intermediates, and APIs.
- ✓ Recognized as a champion of Total Quality Management (TQM) with nearly two decades in leadership positions at top pharma companies.
- ✓ Proven track record in Quality Assurance, Good Laboratory Practices (GLP), and strong focus on global regulatory compliance.
- ✓ Adept at handling regulatory and social audits (e.g., Walmart, CVS) and liaising with international regulatory bodies.
- ✓ Known for implementing best practices that harmonize global operations, ensuring growth and compliance.
- ✓ A strategic thinker and pragmatic problem solver with deep understanding of US, EU, and cGMP requirements.
- ✓ Skilled in working within multicultural and multinational environments with excellent communication abilities across all organizational levels.

2. Computerized System Validation (CSV) Services

- ✓ Project Management (Tollgate/Quality gate Concept) handling using JIRA Software
- ✓ Validation using various Software Development Life Cycle (SDLC) Methodologies like V-Model, Waterfall Model and Agile Model Approach.
- ✓ Validation Deliverables approach decision based on Category of software (cat- 3, 4 & 5)
- ✓ Medical Devices & Software as Medical Devices (FDA & EU) validation
- ✓ ERES 21 CFR Part 11 / EU Annex 11 Check List Assessment
- ✓ Software categorization as per GAMP-5 Guideline
- ✓ Risk Management by following FMEA, or FMECA methodology
- ✓ Validation Plan Preparation and Validation strategy decision
- ✓ Preparation or review of URS / FRS / PRS / SRS
- ✓ Source Code Review Report (Live Understanding)
- ✓ Software Testing Lifecycle (STLC)
- ✓ Testing of Software using Test Management Tools like HPALM, codeBeamer, JIRA (X-ray, Zephyre scale) etc.
- ✓ Defect Management Tools handling

SERVICES PROVIDED BY US



- ✓ Test Summary Report and Validation Summary Report
- ✓ Operation / Maintenance of Software
- ✓ Periodic Review of Software
- ✓ Decommissioning of Software
- ✓ Data Migration from one system to another
- ✓ PLC Validation
- ✓ Disaster Recovery and Business Continuity & IT Resilience Plan preparation or review
- ✓ Cloud Computing (IaaS, PaaS, SaaS) Validation approach
- ✓ Expert in validating software using Computer Software Assurance (CSA) approach.

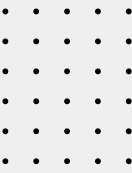
Expert in Validating System -

- ✓ High Performance Liquid Chromatography
- ✓ Total Organic Carbon
- ✓ Gas Chromatography
- ✓ Stability management
- ✓ Laboratory Information Management System
- ✓ Systems, Applications, and Products in Data Processing
- ✓ Manufacturing Execution System
- ✓ Data Acquisition System
- ✓ US and EU packing Serialization

3. IT Infrastructure qualification

- ✓ Infrastructure Qualification (Physical & Cloud) Plan Preparation
- ✓ Preparation or review of URS /Infrastructure platform Requirement specification/ Infrastructure Requirement specification.
- ✓ Preparation or review of Functional Specification
- ✓ Testing of Software using Test Management Tools like HPALM, codeBeamer, JIRA (X-ray, Zephyre scale) etc.
- ✓ Defect Management Tools handling
- ✓ Test Summary Report and/or Qualification Summary Report
- ✓ Operation / Maintenance of Software
- ✓ Periodic Review of Software
- ✓ Decommissioning of Infrastructure
- ✓ Data Migration from on-premise to on-premise or to cloud.

SERVICES PROVIDED BY US



- ✓ PLC Validation
- ✓ Disaster Recovery and Business Continuity & IT Resilience Plan preparation or review
- ✓ Cloud Computing (IaaS, PaaS, SaaS) validation approach

4. Excel sheet validation

- ✓ Validation using various Software Development Life Cycle (SDLC) Methodologies like V-Model,
- ✓ Validation Deliverables approach decision based on Category of excel sheet (cat- 3, 4 & 5)
- ✓ ERES 21 CFR Part 11 / EU Annex 11 Check List Assessment.
- ✓ Spreadsheet (Excel sheet) categorization as per GAMP-5 Guideline
- ✓ Risk Management by following FMEA, or FMECA methodology
- ✓ Validation Plan Preparation and Validation strategy decision
- ✓ Preparation or review of URS / FRS
- ✓ Software Testing Lifecycle (STLC)
- ✓ Testing of Software using Test Management Tools like HPALM, codeBeamer, JIRA (X-ray, Zephyre scale) etc.
- ✓ Defect Management Tools handling
- ✓ Test Summary Report and Validation Summary Report

5. Regulatory Compliance

- ✓ Quality management System Document control (Change Control, Deviation, Incident, Risk management)
- ✓ Auditing of Pharma process
- ✓ Vendor Management Lifecycle (Vendor/Supplier Assessment)
- ✓ Data Integrity

6. Pharmaceutical validation

- ✓ Process validation
- ✓ Analytical method Validation

SERVICES PROVIDED BY US

- ✓ Cleaning validation
- ✓ Computerized System Validation
- ✓ HVAC Validation
- ✓ Compressed Air Validation
- ✓ Water System validation

7. LIMS Consulting Services

- ✓ Implementation and configuration of Laboratory Information Management Systems.
- ✓ Integration of LIMS with instruments, ERP (e.g., SAP), and MES systems.
- ✓ Custom workflow design to align with laboratory processes.
- ✓ Data migration from legacy systems to new LIMS platforms.
- ✓ Validation support (CSV) in compliance with FDA 21 CFR Part 11 and GAMP guidelines.
- ✓ User training and documentation for LIMS operation and maintenance.
- ✓ Support for multi-site LIMS deployment and harmonization.
- ✓ LIMS system audit, optimization, and performance tuning.
- ✓ Vendor selection and RFP support for LIMS projects.
- ✓ Ongoing system support, upgrades, and change management.

8. DRA (Drug Regulatory Affairs) Consulting Services

- ✓ Regulatory strategy development for global market entry (US, EU, ROW).
- ✓ Preparation and submission of IND, NDA, ANDA, and MAAs.
- ✓ Lifecycle management and regulatory compliance monitoring.
- ✓ Dossier preparation in CTD/eCTD formats for various regions.
- ✓ Labelling and artwork review for regulatory compliance.
- ✓ Support for product registration, renewals, and variations.
- ✓ Gap analysis and remediation of existing regulatory documents.
- ✓ Liaison with health authorities (e.g., FDA, EMA, MHRA).
- ✓ Regulatory intelligence and impact assessments.
- ✓ Support for clinical trial applications and amendments.

SERVICES PROVIDED BY US



9. Website Design & Development Services

- ✓ Custom Website Design – Creative, responsive, and brand-focused layouts.
- ✓ Front-End & Back-End Development – Seamless functionality with modern technologies.
- ✓ E-Commerce Solutions – Online store setup, payment gateway, and order management.
- ✓ CMS Development – WordPress, Shopify, or custom CMS tailored to your needs.
- ✓ UI/UX Design Optimization – User-friendly interfaces to enhance visitor engagement.
- ✓ SEO & Performance Optimization – Fast-loading, search-engine-optimized websites.
- ✓ Website Maintenance & Support – Regular updates, security checks, and backups.
- ✓ Branding & Graphic Design – Logo, visuals, and brand identity creation.
- ✓ Integration & Automation – CRM, chatbots, and third-party tools integration.
- ✓ Custom Web Applications – Tailored solutions like portals, dashboards, or booking systems.

10. SEO (Search Engine Optimization) Services

- ✓ Website Audit & SEO Strategy – In-depth analysis to identify growth opportunities.
- ✓ Keyword Research & Planning – Targeted keywords to improve visibility and reach.
- ✓ On-Page Optimization – Meta tags, headings, URLs, and content structure refinement.
- ✓ Technical SEO – Website speed, mobile optimization, indexing, and crawlability.
- ✓ Content Optimization – SEO-friendly content writing and blog strategy.
- ✓ Link Building & Off-Page SEO – High-quality backlinks to boost domain authority.
- ✓ Local SEO – Google My Business setup and location-based optimization.
- ✓ Analytics & Performance Tracking – Regular reports using Google Analytics & Search Console.
- ✓ Competitor Analysis – Benchmarking against industry leaders for continuous improvement.
- ✓ Continuous SEO Maintenance – Ongoing updates and ranking improvement strategies.

INDUSTRIES WE SERVE 03

We bring tailored solutions to a wide range of regulated industries:



Pharmaceutical

Compliance-driven services to ensure product quality, system validation, and regulatory approvals.



Biotechnology

Support for emerging biotech firms with scalable, cost-effective validation and regulatory strategies.



Healthcare

Implementation of validated IT systems and compliance frameworks for hospitals, diagnostics, and labs.



Life Sciences

Customized validation and audit services for laboratories, R&D centres, and scientific institutions.



Contract Manufacturing Organizations (CMOs)

Validation, documentation, and audit-readiness solutions that meet client and regulatory expectations.

WHY CHOOSE US



05

✓ Domain Expertise

A team of seasoned professionals with 10+ years of experience in regulated industries.

✓ Flexible Engagement Models

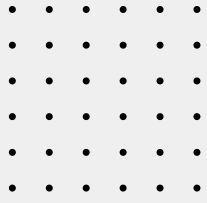
Onsite, remote, hybrid — we adapt to your needs and project scale.

✓ Global Regulatory Knowledge

In-depth understanding of FDA, EMA, WHO, MHRA, TGA, and other health authorities.

✓ Strong Compliance Track Record

Proven success in managing audits, preparing regulatory submissions, and validating complex systems with full documentation support.



CONTACT INFORMATION



Skillbee Solutions Head Office:

17 A Suryadev Nagar, Gopal market, Gopur Square, Indore

PH: +91-9691633901, +91- 889538846

Landline Number: 0731-3520480

Mail: info@skillbee.co.in

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

