COMPANY CONNECT
CONSULTANCY

Pharma & Life Sciences Consulting Services

https://www.companysconnects.com/

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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

Company Connect Consultancy 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 Science Sector Skill 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**.

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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.

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
- 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.
- 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 excelsheet (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
- 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.

INDUSTRIES WE SERVE

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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

04

✅ **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.

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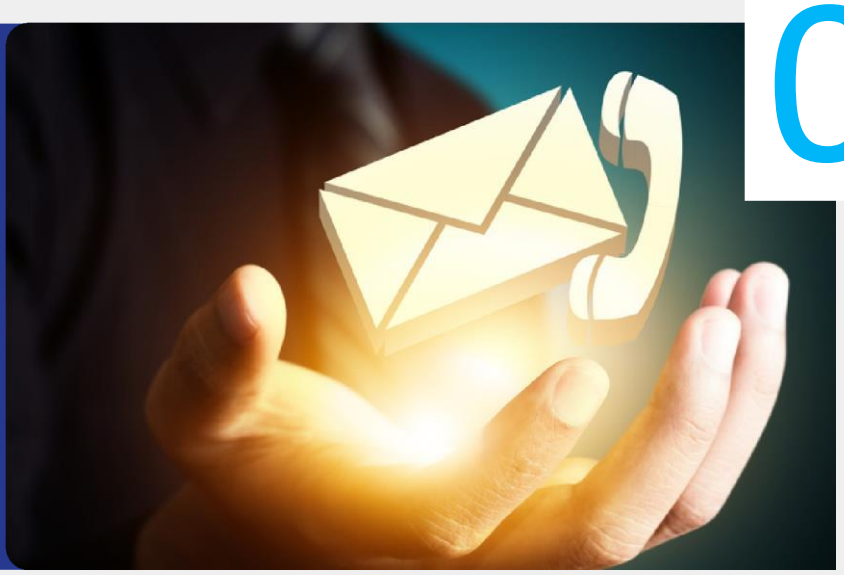
CONTACT INFORMATION



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