

# GADDAM BHASKARA RAO

## Business Consultant – IT GxP Compliance | Pharma Domain

**Dear Hiring Team,**

I am writing to express my strong interest in a position within your organization. With over 13+ years of experience in Computer System Validation (CSV), LIMS & CDS Administration, Track & Trace (Serialization), Digital Transformation, and IT Infrastructure Management within leading pharmaceutical organizations, I am confident in my ability to contribute effectively to your company's compliance and operational excellence initiatives.

Throughout my career, I have successfully implemented and validated a wide range of GxP systems, including Caliber eLIMS, LabWare LIMS, ELN, Empower CDS, Chromeleon CDS, Track & Trace CRM, SCADA, QMS, and other regulated applications. My focus has consistently been on ensuring compliance with 21 CFR Part 11, EU Annex 11, GAMP 5, and Data Integrity requirements while improving business productivity and system reliability.

In my recent roles, I have:

- Led multiple CSV and system implementation projects, achieving zero critical audit findings.
- Executed Data Integrity remediation programs and provided regulatory audit support for USFDA, MHRA, and WHO inspections.
- Enabled end-to-end serialization compliance for packaging lines, including EPCIS, SSCC, GTIN, and aggregation processes.
- Strengthened infrastructure reliability through secure server deployments and network optimization.
- Supported cross-functional digital transformation initiatives that significantly reduced manual processes and improved operational efficiency.

What excites me most about your organization is the opportunity to contribute to a forward-thinking company that prioritizes compliance, innovation, and patient safety. I am confident that my technical expertise, regulatory knowledge, and collaborative problem-solving approach will allow me to deliver meaningful and measurable results.

I would welcome the opportunity to further discuss how my experience aligns with your current and future objectives. Thank you for considering my application. I look forward to the opportunity to contribute to your team.

**Sincerely,**  
Gaddam Bhaskara Rao

# GADDAM BHASKARA RAO

## Business Consultant – IT GxP Compliance | Pharma Domain

### Professional Summary:

Dynamic and results-driven IT GxP professional with 13+ years of experience in Computer System Validation (CSV), LIMS/ELN administration, Serialization & Track & Trace, Data Integrity, and Digital Transformation across API, OSD, CDMO, and Life Sciences environments.

Proven expertise in implementing and validating regulated systems aligned with 21 CFR Part 11, Annex 11, GAMP 5, and Data Integrity principles. Strong background in cross-functional collaboration, regulatory audit support, risk-based validation, and enterprise IT infrastructure management.

### Core Competencies

- Computer System Validation (CSV)
- Risk-Based Validation & Audit Support
- Data Integrity Assessments & Remediation
- Track & Trace / Serialization (DSCSA)
- SAP, LIMS, ELN, LMS & QMS Implementation & Validation
- Empower & Chromeleon CDS Implementation & Administration
- SCADA / MES / Packaging Line Integration
- IT Infrastructure & Networking Support
- Vendor Coordination & Project Leadership
- Digital Transformation in GxP Environments

### Professional Experience

#### Business Consultant – IT GxP (CSV & Application Implementation)

**VRR Life Science Services LLP** (Client: Ritsa Pharma Pvt. Ltd., Hyderabad) | Jul 2023 – Present

- Leading Computer System Validation (CSV) and implementation of manufacturing and laboratory systems, including Empower 3.8.1, LabSolutions UV-Vis, Tiamo, Track & Trace CRM, and backup solutions.
- Ensuring validated and compliant data flow between manufacturing equipment (V-Blender, RMG, FBD, Compression, Coating, Counting machines) and SCADA systems.
- Executing full system qualification lifecycle activities (URS to PQ and Go-Live) while maintaining audit-ready documentation.
- Developing SOPs, managing change controls and periodic reviews, and conducting user training to ensure compliant system usage.
- Managing user access control, email creation, software license allocation, and overall system administration.
- Providing end-to-end IT infrastructure and networking support, including desktop policy management, backup, restoration, and archival activities.

# GADDAM BHASKARA RAO

## Business Consultant – IT GxP Compliance | Pharma Domain

<ul style="list-style-type: none"><li>Delivering Track &amp; Trace support, including master data registration, batch planning, commissioning, aggregation, and EPCIS reporting (NS2, NS3, SBDH), with L1–L4 technical support.</li></ul>
<p><b>Business Consultant – IT Risk, Compliance &amp; Data Integrity   EY LLP, Hyderabad   May 2022 – Apr 2023</b></p> <ul style="list-style-type: none"><li>Performed GxP gap assessments and risk evaluations for critical laboratory and business systems.</li><li>Provided audit support for Aurobindo Pharma (Units 1, 5 &amp; 7) and Neuland Pharma (Units 1 &amp; 2).</li><li>Supported LMS assessments and Data Integrity compliance programs aligned with global regulatory expectations.</li><li>Delivered Data Integrity compliance programs aligned with global regulatory expectations.</li></ul>
<p><b>Assistant Manager – CSV GxP   Lab Iconics Technologies LLP, Hyderabad   Nov 2021 – May 2022</b></p> <ul style="list-style-type: none"><li>Implemented CSV strategy across SCADA (Automatic Loading and Unloading System with lyophilizer), LIMS &amp; supporting applications in pharma client environments.</li><li>Conducted end-to-end validation and testing of Lab Iconics LIMS &amp; ELN systems.</li></ul>
<p><b>Quality Assurance Specialist (CSV GxP)   Synthesis Solutions LLP, Bangalore   Sep 2020 – Oct 2021</b></p> <ul style="list-style-type: none"><li>Oversaw ITQA activities, deviation handling &amp; CAPA execution for lab systems. In-SOP Preparation, etc</li><li>Handled clients (i.e., Biocon, Accord Pharma, Lupin, Granules India, Sun Pharma) on LabWare LIMS, Caliber eLIMS, Sample Manager LIMS (In-house developed by Synthesis), etc</li></ul>
<p><b>Sr. Validation Engineer – CSV   Artech Infosystems (Lupin Limited), Goa   Dec 2019 – Aug 2020</b></p> <ul style="list-style-type: none"><li>Performed system validation for GxP applications, ensuring compliance with 21 CFR Part 11.</li><li>Served as a Senior Validation Engineer for pharmaceutical and biotech plant operations.</li><li>Handled Packing, Manufacturing Equipments &amp; Quality Systems eLog, SABA LMS, LIMS, etc</li></ul>
<p><b>Quality Officer – GxP (IT)   Natco Pharma Ltd.   Hyderabad   Apr 2018 – Dec 2019</b></p> <ul style="list-style-type: none"><li>Managed Caliber eLIMS as SME and System Administrator.</li><li>Conducted master data configuration, user management, training, and audit readiness activities with training on LIMS.</li><li>Administered Empower CDS, system backups, and QC IT applications.</li></ul>
<p><b>Sr. Assistant – QC (IT)   Aurobindo Pharma Ltd.   Hyderabad   Sep 2016 – May 2018</b></p> <ul style="list-style-type: none"><li>Supported ERP and eLIMS deployment, ensuring data accuracy, integrity, and compliance with quality standards.</li><li>Prepared Certificates of Analysis (CoA) in the ERP system and coordinated with QA for review</li></ul>

# GADDAM BHASKARA RAO

## Business Consultant – IT GxP Compliance | Pharma Domain

and approval.

- Led the raw material sampling team, managing allocations and overseeing sample distribution and tracking.
- Handled Empower administration, license management, and related QC IT activities.

### **Quality Analyst (IT GxP) – eLIMS & Empower | Divis Laboratories Ltd., Hyderabad | May 2012 – Sep 2016**

- Performed Empower administration, system qualification, and documentation control activities in compliance with GxP requirements.
- Supported implementation and proof of concept (POC) activities for Caliber eLIMS, QAMS, DMS, LMS, COA release systems, Tiamo, and Malvern applications.
- Contributed to API product release processes through implementation of EasyLabel software and label design configuration.

### **Career Progression Snapshot**

- 13+ Years of Progressive Growth: Quality Analyst → Sr. Assistant → Quality Officer → Sr. Validation Engineer → QA Specialist → Assistant Manager → Business Consultant → IT Risk & Compliance Consultant (Manager – IT).

### **System Expertise**

- **Laboratory Systems:** Caliber eLIMS, LabWare LIMS, Sun LIMS, Sample Manager LIMS, Lab Iconics LIMS, Caliber eLog, etc.,
- **CDS:** Empower CDS, Chromeleon CDS
- **Serialization & Packaging:** Track & Trace CRM, EPCIS 1.2, GLN, SGLN, GTIN, SSCC, Commissioning & Aggregation, Vocabulary Events, etc
- **Manufacturing:** SCADA, PLC Integrated & IPC Controlled Systems.
- **Other Systems:** DMS, QMS, HRMS, Biometric, Water System SCADA, Door Access Management, Backup, Archival & Restoration Applications

### **Key Achievements**

- Delivered multiple validated implementations with zero critical audit observations.
- Supported USFDA, WHO, MHRA, and customer audits.
- Executed Data Integrity assessments and remediation programs.
- Reduced manual operations by 40% through digital transformation initiatives.
- Implemented secure, validated server infrastructure for GxP systems.
- Ensured seamless equipment-to-system integrations across regulated environments.

### **IT Infrastructure & Networking Expertise**

- **Server Administration:** Windows Server (2014/ 2016/ 2019/ 2022), Active Directory (AD) Management.
- **Laptop/ Desktop Management:** Handling systems of Windows 10/11, Computer Management, etc.,

# GADDAM BHASKARA RAO

## Business Consultant – IT GxP Compliance | Pharma Domain

- **Database Systems:** Oracle, SQL Server 2014 & 2019 Installation, User Roles & Backup/Restore.
- **Virtualization:** VMware & Hyper-V environments setup and resource configuration.
- **Networking Skills:** LAN/ WAN, VPN, CCTV network, VLANs, DHCP, DNS, Switch & Firewall Coordination.
- **Cloud Technologies:** OneDrive, Azure AD integration for hybrid identity management.
- **Backup & DR Management:** On-prem and cloud integrated backup systems.
- **Connectivity & Device Integrations:** L2/ L3 Switches configuration support, RS232/ ETH integration for laboratory & manufacturing equipment.
- **IT Security Practices:** Role-based access controls (RBAC), Data Encryption, Antivirus/ EDR compliance tracking.

### Education

- **Master of Science (Chemistry):** CDE, Acharya Nagarjuna University, 2015, Guntur, Andhra Pradesh, India.
- **Bachelor of Science (MPC): Jagarlamudi Kuppuswamy Choudary College** (Affiliated by Acharya Nagarjuna University), 2009, Guntur, Andhra Pradesh, India.
- **Intermediate:** Sai Sadana MMP Jr. College, 2006, Guntur, Andhra Pradesh, India.
- **SSC:** Naveena Vidhyanikethan High School, 2003, Guntur, Andhra Pradesh, India.

### Personal Details

- **Nationality:** Indian
- **Languages:** English, Hindi, Telugu
- **Location:** Hyderabad, India
- **Email:** [gaddambhaskar.csv@gmail.com](mailto:gaddambhaskar.csv@gmail.com)
- **Phone:** +91-9652021788

**Declaration:** I hereby declare that the information provided is true and accurate to the best of my knowledge.

### Signature:

**Name:** Gaddam Bhaskara Rao

**Place:** Hyderabad