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**Pallanti C V S Balaji**

Corporate Quality Assurance Professional

**CONTACT**

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 Hyderabad, India

**PERSONAL DETAILS**

**Nationality:** Indian  
**Languages:** English, Telugu, Hindi

**EXPOSURE TO AUDITS**

USFDA

Health Canada

MHRA

SFDA

MALTA

Other regulatory bodies and customer audits

**SKILLS**

Vendor/Supplier Qualification

Internal Audits / Self Inspection

GMP / cGMP Compliance

Complaints &amp; Deviations Investigation

APQR / PQR

QMS / CAPA

SAP &amp; ERP Systems Maintenance

Document Management

Support to Regulatory Affairs

**Profile**

Quality Assurance professional with 11+ years of experience in vendor qualification, GMP compliance, internal audits, and documentation management within the pharmaceutical industry. Proven track record of leading vendor audits, ensuring regulatory compliance, and managing quality systems across multiple organizations. Adept at driving continual improvement and supporting regulatory and customer audits to uphold the highest quality standards.

**Work Experience****Assistant Manager – Corporate Quality Assurance**

Evertogen Life Sciences Ltd., Hyderabad

May 2022 - Present

- Leading vendor qualification process for new and existing vendors through SAP and ERP platforms
- Evaluating vendor questionnaires, performing risk assessments, and coordinating approvals
- Conducting onsite audits and preparing vendor audit reports; maintaining Approved Vendor List (AVL)
- Ensuring supplier compliance with GMP standards; managing QMS elements (change control, deviations, complaints, CAPA)
- Planning and executing self-inspections/internal audits and tracking CAPA to closure
- Supporting regulatory and customer audits and coordinating training programs
- Support to Market Complaints and Deviation Investigation
- Maintaining quality management systems and ensuring regulatory compliance
- Preparing comprehensive audit reports and performance evaluations
- Coordinating with cross-functional teams for quality initiatives
- Implementing process improvements in quality assurance methodologies

**Senior Executive – Quality Assurance (IPQA)**

Optimus Pharma Pvt Ltd, Hyderabad

Dec 2021 - Apr 2022

- Performing IPQA activities: line clearance, sampling, and verification during manufacturing and packing
- Monitoring adherence to cGMP during batch execution; reviewing and approving batch records
- Handling deviation identification and escalation; supporting cross-functional teams during quality events
- Conducting shop-floor audits to verify regulatory and documentation standards
- Ensuring quality compliance throughout manufacturing processes
- Participating in quality improvement initiatives and process optimization

**Officer – Quality Assurance**

Sri Krishna Pharmaceuticals Ltd. (Unit-II), Hyderabad

Jun 2018 - Dec 2021

- Leading vendor qualification via SAP/ERP; maintaining AVL and coordinating approvals
- Managing document control lifecycle: issuance, retrieval, archival of GMP documents
- Ensuring GMP/SOP compliance; facilitating regulatory and customer audits
- Preparing and reviewing Annual Product Quality Reviews (APQRs); supporting Regulatory Affairs submissions
- Participating in internal audits and maintaining inspection readiness
- Coordinating with regulatory bodies for compliance verification

### Associate – Quality Assurance

Dr. Reddy's Laboratories (FTO-SEZ, PU-1), Pydibimavaram, Vizianagaram

Jun 2016 - May 2018

- Handling distribution, control, and archival of documents in line with regulatory standards
- Preparing QA SOPs and reviewing cross-functional SOPs for compliance with cGMP and corporate policies
- Performing validation and maintenance of Document Management System (DMS)
- Approving artwork/specifications; uploading ROA data into SAP; supporting inspections with accurate documentation
- Ensuring regulatory compliance across all quality processes

### Junior Officer – Quality Assurance

Hetero Labs Ltd. (Unit-V), Hyderabad

Jun 2014 - May 2016

- Prepared Quality Assurance SOPs and reviewed cross-functional SOPs for compliance
- Handled document distribution, control, and archival of batch manufacturing and packing records
- Managed conditional approval notes for timely batch disposition
- Coordinated batch release through SAP
- Provided document support to the Regulatory Affairs (RA) team for filings and submissions
- Coordinated and reviewed artwork and specifications to ensure compliance with RA and QA requirements
- Submitted documents to Regulatory Affairs and maintained traceability of controlled documents
- Coordinated Regulatory and Customer audits and ensured CAPA compliance

### Education

#### B.Pharm - Pharmacy

Jawaharlal Nehru Technological University (JNTU), Kakinada, AP  
Graduated in 2013

#### D.Pharm - Diploma in Pharmacy

State Board of Technical Education & Training, Andhra Pradesh  
Graduated in 2010

### Key Achievements

- **Pharmaceutical Quality Excellence:** 11+ years of progressive experience in pharmaceutical quality assurance with expertise in GMP compliance and regulatory standards.
- **Led comprehensive vendor qualification initiatives** across multiple pharmaceutical organizations with high compliance rates.
- **Expert in regulatory compliance validation** and audit management using SAP, ERP, and Document Management Systems.
- **Extensive experience with pharmaceutical manufacturing processes** including IPQA, batch release, and quality methodologies.
- **Implemented process improvements** in quality assurance methodologies and regulatory compliance practices.
- **Recognized multiple times as Star Employee** for contribution and performance in quality management.