

# RESUME

**PHANI. K**  
**[M.Sc. ORGANIC CHEMISTRY]**

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**Professional Objective:**

Seeking a Challenging Position in Quality Focused Areas where my expertise in 21 CFR Compliance, ALCOA+ & DI Policies, GDP/GLP and QMS monitoring, GAP assessment, Method development, validation, transfers, in vitro- in vivo studies related to drug/dosage and suitable analytical techniques required for all types of solid/liquid dosage forms will be contributed and to be part of the team, training, enhancing the skills both as professional 'n' personal and to deserve a highly responsible Senior position in the organization.

**Profile Summary:**

20+ Years of Versatile experience in Management role by balancing all relevant Analytical-Quality functional areas with demonstrated leadership by pivoting roles successfully in the departments of ARD-QC& AQA

**Core Competencies:**

- Passion for excellence
- Leadership and Time management
- Adept at Conflict Management & Resolution
- High level resource management
- Ability to drive and guide quality teams
- Demonstrated Operational excellence
- Wide Knowledge on solids/liquids dosage forms
- Keep Abreast of all regulatory/GXP Changes
- Result orientation with multi-tasking
- Ability to influence with Strategic thinking
- Commercially astute
- Ability in effective presentations to hierarchy
- Strict adherence to 21 CFR and cGMP policies
- Strong Verbal and written communication skills
- Ability in establishment of New Lab set-up

**Professional Experience [Current Role]:**

- Working as **General Manager-ARD/QC** in a CRO [**SLB Pharma Pvt Ltd**] from **May-2023 to till the date**
- Active participation in analytical development to technology transfer in compliance with GXP systems.
- Hands-on experience in presenting the regular updates, developments and Project progress to hierarchy.
- Sound knowledge in preparation/review of documents required for successful TT to CMO sites from R&D.
- Correlation of Analytical data received Externally from Testing labs, vendors, CMO...etc.
- Experience in developing methods for evaluation/monitoring of Nitrosamines and Genotoxic impurities.
- Responsible for Preparation and implementation of SOP's, Specifications and STP's.
- Delivering updates on Project(s) progress, Instrument status, Calibrations and all relevant key events.
- Responsible in ensuring the materials, products and processes are met all specifications and requirements before giving approval for release/dispatch.
- Responsible for Testing laboratory 5S-compliance and ready to audit state in line with inspection schedules.
- Demonstrated experience in implementation of Quality systems, cGMPs as per regulatory standards.
- Sound knowledge in developing secondary standards and impurity standards with characterization data.
- Accountable for Qualifying outsourcing commercial testing laboratories, sample flow, review of results.
- Hands-on experience in developing LC/GC methods within stipulated timelines, compatible for MS analysis.
- Experienced in establishing Material/Product shelf life by conducting Hold time/degradation study and ensuring periodical updates and quality tracking according to schedule.
- Sound knowledge in developing validated LC/GC method(s) for all API, intermediates and finished dosages to support Synthesis/Process R&D experiments/Manufacturing units.
- Experienced in ensuring the completion of Project / Product milestones as per committed timelines.
- Experienced in conducting product/material purification by using advanced Lab applications like Flash Chromatography, Preparative HPLC and Lyophilization techniques.
- Capable of Managing direct and indirect costing of the Leading department in line with allotted budget.
- Responsible for adherence of EHS policies within the department to develop safe working culture.
- Define and maintain a strong people management through recruitment, training, KPI establishment and engagement culture to ensure a high and constantly improving right first-time rate in testing.
- Experienced in handling high pressure and conflict situations and able to take quick decisions.
- Capable in effective utilization of 3M [Men, Machine and Materials].

**Biographical Data:**

D. O. B	Marital Status	Languages Known	Technical Skills	Hobbies
31/08/1982	Married	English, Hindi & Telugu	MS office, SAS & Type-English	Playing Chess, Listening Music, Book reading & Learning New things

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## Professional Experience [Organizations worked in Above Managerial role]:

<b>General Manager-ARD/QC:</b> <b>ESPI Industries, Hyderabad.</b> <b>Oct-2021 to April-2023</b>	<ul style="list-style-type: none"> <li>➤ Creation and revision of SOP's &amp; STP's (Systems, Process, Testing&amp; Instrumental)</li> <li>➤ Responsible for Equipment/instrument procurement, qualification, validations, calibrations and troubleshooting of testing facility.</li> <li>➤ Experience in development and establishment of cleaning procedures.</li> <li>➤ Responsible for timely release of all RM, PM, IP and FP Samples in time as per FIFO.</li> <li>➤ Development of Team's Technical Skills by interacting discussions and trainings.</li> <li>➤ Best in class strategic thinking and planning to reduce batch release window criteria.</li> <li>➤ Hands-on experience in handling Sachets/Bottles/injections/pellets/Capsules and tablets.</li> <li>➤ Proven track record in successful implementation of operational excellence to improve the annual turnovers.</li> <li>➤ Represented as MR (Management representative) for required audits [WHO, Customer, FDA / Internal accreditations as and when required].</li> <li>➤ Development, Validation of Analytical test procedures and transfers as per regulatory / market and customer requirements including impurity profiling and Stability studies.</li> <li>➤ Sound knowledge on handling Software like LIMS, ERP, SAP for Material procurement and Consumption tracking.</li> <li>➤ Hands-on experience in resolving QMS events like lab incidents, OOS/OOT, change controls, CAPA and deviations in timely manner and ability in forecasting such issues based on the trend-data with correlation during existing/planned analysis.</li> <li>➤ Excellent Communication and leadership skills and hands-on experience in data compilation and presentation.</li> <li>➤ Ability to handle Purchase/Out sourcing activities/Systems-Instruments service contract renewals /up gradation including customs clearance for imports/exports., not limited to...</li> </ul>
<b>Senior Manager-ARD/QC</b> <b>EvertoGen Life Sciences Pvt Ltd</b> <b>Jadcherla,</b> <b>April-2017 to October-2021</b>	<ul style="list-style-type: none"> <li>➤ Designing cost effective, robust analytical method development for all types of dosage forms with Scientific and regulatory approach.</li> <li>➤ DQ, IQ, OQ, PQ of all Lab instruments such as HPLC, GC, UV-VIS Spectroscopy...etc.</li> <li>➤ Responsible for timely releasing of all RM, PM, IP and FP batches as per scheduled production / Marketing planning.</li> <li>➤ Excellent skills in establishment of documents and data base related to methods, SOP, analytical data sheets, Specifications and investigation reports...etc.</li> <li>➤ Responsible for ARD &amp; QC functions to meet method development, validation, transfer, timely releases of Materials/In process stage Sample to final batch dispatch.</li> <li>➤ Excipient-Compatibility/Degradation and Stability studies for R&amp;D / Filing Batches.</li> <li>➤ Dissolution method development, Profile Study and Multimedia Dissolution studies to establish bio relevant media and conducting FaSSIF and FaSSGF study with RLD.</li> <li>➤ Designing of Analytical Validation Protocols &amp; Reports as per regulatory requirements.</li> <li>➤ Experienced in using data investigation tools in assessment of Non-conformance.</li> <li>➤ Hands-on experience in handling liquids / solid dosages including veterinary products.</li> <li>➤ Faced as direct department representative for regulatory audits like USFDA, MHRA, UKRAINE MOH, HEALTH CANADA, TGA, cGMP, WHO and Various Customer Audits.</li> <li>➤ Hands-on experience in compilation of data and presentation skills., not limited to...</li> </ul>

## Professional Experience [Organizations worked in Under Managerial role]:

Name of Organization	Designation	Working Period
Epione Labs Pvt Ltd-Hyderabad	Deputy Manager-ARD	Aug-2013 to Apr-2017
Disto Pharmaceutical Pvt Ltd- Hyderabad	Team Lead-Analytical	Jan-2010 to July-2013
Inventis Drug Delivery Systems Pvt Ltd- Hyderabad	Sr. Executive-ARD	May-2005 to Dec-2009

## Academic Profile:

PG/Masters	Graduation	Intermediate	S.S.C
M.Sc. Organic Chemistry	B.Sc. MPC	MPC	MPC with Languages
Acharya Nagarjuna University	Nagarjuna University-Guntur	BIE/TJ College/Tenali	BSE/ZPPH/Guntur
78.1% [2003-2005]	80.5% [1999-2002]	71.6% [1997-1999]	84.6% [1997]

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## Instrumental Exposure:

Technique	Relevant Instruments	Technique	Relevant Instruments
Chromatography	HPLC, GC, Prep /Flash-LC, ICP	In-Vitro/In-vivo- DPDM	Dissolution apparatus
Identifications	UV, IR, SOR, AAS, Melting	Wet Lab	KF, Titrator...etc.
Purification	Preparative, Flash, Lyophilizer	Packing & Testing	All Quality Control relevant

## Skill Summary:

Professional	Personal	Management
<ul style="list-style-type: none"> <li>➤ Designing Raw material and finished product specifications / Testing procedures with related instrumental SOP's</li> <li>➤ Strong in preparation and implementation of Calibration / Validation schedules to ensure cGLP compliance</li> <li>➤ Knowledge on Instrument / Quality tools &amp; software with Server Maintenance including Data backup control and Audit trails review</li> <li>➤ Collaborative with other (R&amp;D, production, supply chain, and procurement) departments to ensure quality is maintained at all stages</li> <li>➤ Strong project management skills with the ability to manage multiple initiatives parallel to support business operations</li> </ul>	<ul style="list-style-type: none"> <li>➤ Achieved University 1st Prize for the seminar "advanced technologies In Spectroscopic instrumental analysis"</li> <li>➤ Achieved University 2nd rank for the Post graduation batch 2003-05</li> <li>➤ District level participation in chess and cricket during college studies</li> <li>➤ Visited Egypt, Algeria, Dubai and many domestic states for TT &amp; Joint analysis</li> <li>➤ Proven success rate at Various customer locations in resolving analytical issues</li> <li>➤ Team player with a-can-do-attitude</li> <li>➤ Acts responsible in handling non-conformance/deviations</li> <li>➤ Highly detail-oriented and organized with advance planning strategies</li> <li>➤ Pro-active and Self-motivated</li> <li>➤ Ability to implement, adopt and drive the changes for quality culture</li> <li>➤ Quick Lerner</li> </ul>	<ul style="list-style-type: none"> <li>➤ Proactively forecasting the problems to avoid last minute surprises</li> <li>➤ Effective utilization of 3M (Men, Machine &amp; Materials) resources</li> <li>➤ Continuous monitoring the team's technical capabilities and identifying the necessary trainings</li> <li>➤ GAP analysis, Risk assessment studies for Regulatory compliance</li> <li>➤ Laboratory incidents, OOS, OOT, Change control and Deviations Management</li> <li>➤ Ability in establishment of new laboratory/Testing facilities</li> <li>➤ Excellent analytical and problem-solving skills</li> <li>➤ Strict adherence to EHS and cGMP regulations all the time</li> <li>➤ Strong in root-cause analysis and implementing CAPA to avoid occurrences</li> </ul>

## Quality tools:

Investigations related	Monitoring and control related
<ul style="list-style-type: none"> <li>➤ Investigation tools [Ex: Fishbone/Ishikawa, FMEA, Histograms, Control charts, Check list...etc....]</li> <li>➤ Risk assessment reports</li> <li>➤ CAPA and Change control management</li> <li>➤ Internal Audits &amp; GAP assessments</li> </ul>	<ul style="list-style-type: none"> <li>➤ LIMS [Document controls]</li> <li>➤ Instrument Software's/Servers for Audit trails review</li> <li>➤ SAP /ERP [Material management]</li> <li>➤ Annual Master Schedules &amp; Validation plans</li> <li>➤ Trend reports to improve productivity</li> </ul>

## Trainings and Certifications:

Trainings attended	Certifications
<ul style="list-style-type: none"> <li>➤ Various training sessions conducted by Waters, Lab India, Agilent, Thermofisher &amp; Spincotech</li> <li>➤ Code of ethics and DI policies</li> <li>➤ Good Documentation practices for WHO GMP by Trust chem- Consultancy</li> <li>➤ Importance of cGLP &amp; Accuracy in analysis by Various local Industrial authorities</li> </ul>	<ul style="list-style-type: none"> <li>➤ Certified by DNV-GL agency in QMS and ISO compliance systems</li> <li>➤ Certified in Advanced Chromatography skills by Spincotech</li> <li>➤ GC trouble shooting by Phenomenex India</li> <li>➤ Active participation in personality development and management development sessions</li> </ul>

## Self-Declaration:

I hereby declare that the above details given by me are true to the best of my knowledge.

Place: Hyderabad

**Phani. K**