

ILAVARAPU DEEVARARAO

SUMMARY:

Resourceful and adaptable Manager with over 14.0 years of experience in pharmaceutical field. Meticulous team builder with expertise in Analytical documentation Regulatory affairs and Research and development. Brings focus on growth, confidence in decision-making and expertise in leading organizations through periods of change and development.

Asst. MANAGER; AR&D-Method development and validation, 06/2013 - Current COVALENT LABORATORIES PRIVATE LIMITED, HYDERABAD, INDIA:

- Executive pharmaceutical fast analytical CHEMISTRY/RESEARCH and development validation experience with strong leadership managerial, technical and team building skills in knowledge of cGMP, cGLP, ICH, and FDA.
- Analytical method development/Validation for Cephalosporins products.
- Analytical Method validation, protocol Preparation and review.
- Supporting to Regulatory affairs department with respect to DMFs & comments received from regulatory agencies
- Review & Approval of Master documents (BPR/Master formula/Process flow/SOP/Spec & MOAs etc.) of products.
- Participate in handling of Out of Specification, Out of Trends, Deviation, Batch failure, Rejections, investigations and CAPA implementation at site
- QMS related activities (deviation, Incidents and Change Control related activities through track-wise) for their compliance with respect to the regulatory submissions or requirements.
- Participation in technology transfer during method transfer and coordinating with CFT Team members (AD, QC, QA).
- To review and approve Method Development/Method validation/Method verification/Method Equivalency/Method Transfer data for its adequacy, Accuracy and Completeness as regulatory and business requirement.



CONTACT

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SKILLS

ANALYTICAL DOCUMENTATION:

- Internal -Audits
- External- Audits
- QMS activities (Change control, Deviations and CAPA related activities)
- GMP-GDP Training activities
- Vendor qualifications
- Equipment qualifications
- Control Strategy
- ICH Guidelines

REGULATORY AFFAIRS:

- Support to DMF filings (US, EU, JP, INDIA)
- regulatory queries review and provide justification

- Vendor Qualification of outsource API-vendors by reviewing the DMF and TDP for Key starting materials, intermediates, Excipients, Packaging materials etc. which are related to R&D prospect.
- Extremely Knowledgeable in overall laboratory function, maintenance and project activities in relation to availabilities of resource and time line.
- Strong leadership capable of managing technical personal and training mentoring for achievement.
- Preparation of **SOP**, Periodical revision as per schedule.
- Conducted research experiments to develop solid dosage forms from early development to launch phase.
- Expert problem solver Trouble shooting
- Investigation and Corrective Action Execution.
- Product related troubleshooting, Analytical Method related troubleshooting, Design of analytical experiment.
- Maintaining and review documentation such as laboratory notebooks analytical work sheets, instrumentation log books & **calibration** Reports.

SENIOR CHEMIST WOHLER LABORATORY PVT LTD (14.08 2012 TO 03 06.2013):

- Calibration of HPLC UPLC, KF titrates, pH Meter, Melting point instrument & TLC Cabinet.
- Analysis of Finished product and inter mediate RS and Assay by HPLC.
- Reaction monitoring by HPLC & TLC.
- Ensure R&D compliance with regulatory standards and guidelines, such as FDA, ICH and cGMP throughout the drug substance development process.
- Review and ensure the vendor compliance, audited by third party before sharing to customers.
- Responsible for conducting an internal audit (cGMP/Quality) API sites and ensuring compliance to cGMP, GLP and Global Quality Standards / regulatory standards etc.

CHEMIST AS USHA VITAL CARE PVT LTD (2009 TO 2012):

- Reaction monitoring by HPLC & TLC
- Calibration & Maintain Records of KF titrate, pH meter, Polari meter, MP Meter

TECHNOLOGY TRANSFER:

- review and approval of OOS and OOT.
- Method transfer from development site to activity site.
- Product development related activities

Hostplatform : TECHNICAL SKILLS:

Programming: MS Office
WidowsXP7

LANGUAGES:

- English
- Hindi
- Telugu

- Analysis of in process samples as per approved testing procedure
- Analyzed the moisture content by Karl-fisher operator
- Analysis of in process samples as per approved testing procedure
- Analyzed the moisture content by Karl-fisher operator
- Analysis of in process samples as per approved testing procedure
- Claibration of KF titrate and pH meter and Analytical Balance

EDUCATION :

- MSc Chemistry from MP BHOJ UNIVERSITY.2006
- BSc (CBZ) From ACHARYA NAGARJUNA UNIVERSITY.SS&N Degree college Narsarapeta, Guntur (dist).

PERSONAL PROFILE:

- Name : Ilavarapu Deever rao
- Date of birth : 04-05-1978
- Gender : Male.
- Marital Status : Married
- Hobbies and interest : Browsing internet, Listening Music, reading Books.
- Address : H.No:1-120, Vallapalli (p.o), Ballikurava (mdl) Prakasam (dist), 523260 (Andhra pradesh).

DECLARATION:

I here declare that all furnish statement are true complete and correct to the best of my knowledge and belief.

I have every hope that you will give me a chance to work under control and terms opportunity to prove my claims for which act of majesty and mercy is shall be ever grateful to you sir,

Yours sincerely

(I.Deever Rao)