RAVI G. CHINCHALKAR

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EXECUTIVE PROFILE

- 18 years of diverse experience in the field of API Quality Assurance, Process Validations, failure Investigations.
- Worked with major Indian Pharma. Companies: Lupin, Orchid and Dr Reddy's Ltd.
- Over 50 API New Products validation after scale up from R & D scale (development life cycle).
- Hosting for various customer audits, review of proposed remedial CAPAs for compliance.
- Remarkable work in investigations and compliance of the WL sites.
- Managing 60 cr/ annum business of the CMO / Outsourcing sites.

AREAS OF EXPERTISE

- Complete Process validation.
- IPQA activities.
- 21CFR Part 11 Compliance.
- SuCCEED: A quality culture initiative.
- Investigation and compliance.
- Manufacturing assurance.
- Clinical trial support.
- Computer System Validation (CSV).
- Deviation management.
- QMS Systems establishing.
- Technical writing.

CORE ACCOMPLISHMENTS

- Enhanced process compliance by reducing 60% investigation TAT per annum at site.
- Remarkably improved the quality of investigation reports for OOS/OOT and deviations.
- Successfully managed failure investigation at sites with FDA warning letters.
- Responsible for overseeing life cycle management (process validation) for over 50 APIs.
- Received special recognition for internal audit readiness check and authoring high quality investig. Reports.
- Successfully managed three external manufacturing sites in QA perspective.

PROFESSIONAL EXPERIENCE

Dr. Reddys, Hyderabad (T.G.)

Team Lead (Manager) - Quality Assurance (Site investigation team) **April 2016 to Aug.2020**

- SME in Manufacturing, Process Validations, Compliances.
- Lead Investigations for deviations, OOS, OOT and market complaints.
- Identification of the root cause and propose CAPA.
- Cross functional team liasoning for the investigation and CAPA finalisation.
- Evaluation of CAPA effectiveness check as per timelines of deviations, OOS, OOT.
- Perform analysis on audit observations and to share summary to the quality head.
- Providing support to site for regulatory audits and remediation actions.
- Establishment of various tools like Rubrics, SOP, and investigation formats for investigations (new dept.).

- Oversee plant readiness for regulatory Audits.
- Plant personnel Trainings for Audit readiness.
- APQR review for the ongoing manufacturing products.
- To overview the remediation action for the proposed CAPA.

PharmaZell India Pvt. Ltd., Vizag [A.P.]

(A group company of PharmaZell Gmbh. Germany - Green field project).

Asst. Manager – Quality Assurance (New products validation) February - 2010 to March - 2016

- Review and approval of BPR, validation protocols, validation reports, change controls, STPs.
- Review of various technical documents, SOP, work instructions, IQ, OQ, PQ.
- Facility readiness check before the validation campaign execution.
- Investigation reports review for deviations, OOS, OOT and market complaints.
- Sharing of FDA and other audits findings with remedial actions with management.
- Cross functional Supporting for the submission of new products to various agencies.
- Coordination with the overseas sites (Germany, Denmark, and Switzerland) for the product validation.
- Conducting GMP audits in plant for correcting the SOP Vs practices.
- Quality agreement finalization with the cross functional team coordination.
- Establishment of QMS system and ensuring adequate oversights at the CMOs sites.
- Review and approval of the documents Such as BPR, Validation documents, Specs. and MoA.
- Performing daily IPQA rounds for online compliance of the CMOs sites.
- Supervise the team of QA associates and CFT at CMO sites for routine cGMP activities.
- Coordinating customer audits and regulatory inspections at the CMOs sites.
- To perform self –inspections prior to various regulatory audits.
- Product release decision at the CMO sites.
- Single point of contact for all quality related activities for the CMO sites.

Orchid Pharmaceuticals Ltd. Aurangabad [M.S.] / Chennai [TN].

Executive - Quality Assurance (Site transfer Activities) July 2006 to January 2010

- Review and approval of BPR, validation protocols, validation reports, change controls.
- Review of various technical documents, technical Reports, SOP, work instructions.
- Facility readiness check before the validation campaign execution.
- Investigation reports review for deviations, OOS, OOT and market complaints.
- Cross functional Supporting for the submission of new products to various agencies.

Lupin Ltd. Mandideep, Bhopal [M.P.].

Shift officer, API: Manufacturing. **December 2002 to July 2006**

- Batch operation for API manufacturing in shifts.
- Execute all tasks and activities as per the applicable SOP's.
- Preparation of Process write-up / Batch production record, protocol and report etc.
- Technology transfer documents preparation for the process validation.
- IPQA rounds in shift for the manufacturing assurance.

EDUCATION/ACCOMPLISHMENTS

- B.Sc. - Chemistry [special] - 1996 / Nagpur (M.S.) - 79.0%.
- M.Sc. - Organic Chemistry - 1999 / Amravati (M.S.) - 62.0 %.
- Visited Denmark, Sweden and Germany to provide quality oversight for process transfer to CMO sites.
- Microsoft Project Planning certificate by Datapro Institute Poona.
- Green belt certificate, Title: Reduction of human errors in API manufacturing.
- Certificate Program on GAMP5, 21CFR Part 11, Annex. 11 CSV ICS Academy, Baroda.
- SuCCEED implementation: Quality culture transformation initiative to achieve all time audit readiness.

PERSONAL PARTICULARS

- Languages Known : Marathi, Hindi, English and Telugu.
- Hobbies : Cricket commentary in English, face reading.

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