AJAY KUMAR MISHRA

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MANUFACTURING PROFESSIONAL (API and Formulation)

Pharma Manufacturing Professional ~ Gap Analysis~ Non-Conformance Management ~ Compliance ~ Remediation & Monitoring Plan ~ Cost Reduction by Process Optimization for unit operation and Validation for *Sterile API and Powder Injectable formulation & API Bulk and Intermediates* Plants…..

Pharma Manufacturing Professional, an astute, result-oriented leader with proven success of over 2 decades with top pharmaceutical companies in manufacturing of **STERILE API and Non-Sterile API Bulk including Intermediates and Powder Injectable Formulation** with Quality.

Technical and Strategic Leader with Critical and Problem-Solving Skills in Sterile API Bulk Drug manufacturing, Expert Bulk Manufacturing (for Sterile & Non-Sterile Product) and Controls for different Unit Operation in **Active Pharmaceutical products (API)** & intermediates.

Hands on experience in **Sterile** and **Non-Sterile** API Bulk & Expertise of **API Unit Operations (i.e., Filtration, Crystallization, Drying & critical chemical reaction i.e. Hydrogenation, Grignard reaction etc.)** and worked for leading pharma manufacturer i.e., **Ranbaxy Lab**, **Aurobindo Pharma**, **Wockhardt Limited Abbot Lab, Unimark Remedies** and others.
Hands on Experience on Qualification and Validation of **Sterile API and Formulation lines**.
Hands on Experience on **Media fill for Sterile API and Powder Injectables Line**. More than **50nos Successful Media fill validation** done for API and Formulation line throughout the Industrial Journey.

Global Exposure: U.S, U.K, E.U, Australia, JAPAN and India.

SUMMARY OF QUALIFICATION

- **Contributed in** providing leadership and strategic direction on production optimization, control on Unit Operations to repeat the Quality, establishing monitoring plans for Unit Operations and Quality of API plant , Powder Injectable plant & Intermediates, team building and integration projects
- System which indicates the effect in process controls/remediation/increasing productivity, cost reduction &, increasing efficiency.
- Consultation review for project related & statutory documents given to agency & stakeholder in time.
- Project task review within team and provide technical guidance regularly.
- **Affianced** on to Green Field project of *API & Intermediate* costing around 50Cr (INR). Strategic coordination on functional perspective and conduct periodic review and completed within the defined time line.
- **Expertise** in setting-up different unit operation/Plant of intermediates and Sterile & Non-sterile API Bulk pharmaceuticals, lead optimization, form selection, right equipments, process scale-up, commercial support. Problem solving skills to overcome Crystallization & Drying problems.
- **Hands on Experience on** Qualification and Validation of Sterile API and Powder Injectable Line, which include Successful **Medial Study** for Both the Lines**.**

- **Implementing** (Automation for unit operation for better control of Quality & time management for intermediate & API, Aseptic practices / Behavior into classified areas).

FUNCTIONAL COMPETENCIES

- **Operational Excellence** (Majority of Hand on Experience in **Sterile** API Bulk and Powder Injectable formulation, Non-sterile API & Intermediates Production management, Implementing Best Practices at shop floor with respect to Unit Operation in chemical and clean area to meet Regulatory Expectations.)
- **Managing quality operations** [Crystallization, Lyophilization (for Sterile API), Drying, Filtration of Sterile Solution, Aseptic behavior & Manipulation during Aseptic operation and non-Sterile unit operations].
- **Managing regulatory remediation** (WL, 483s & Customer) and Integration activities and remediation plan.
- **Change management** (building quality culture within the cross functional teams)
- **Managing third-party** (Investigators / SMEs / Auditors / Customers / Trainers)
- **Represented the firm & participated in** multiple regulatory audits (USFDA, MHRA, KFDA etc) and provided CAPA & compliance.
- **Continuous Improvement Plan –** Team Lead on conducting internal audits for Utility/Engineering/ Manufacturing [Sterile & non-Sterile API products / Intermediates of API].
- **QMS –** Handling of Quality documents like CCM / Deviation / Market Complaint / OOS / Incidents/ CAPA**.**
- **Qualification & Validations** – Have been part of review team for Equipment Qualification & Validation i.e. Process, Cleaning & Thermal validation.
- **Process Simulation Trial's (Media Fill Trial)** – Involved in execution and review of process simulation trial runs and Smoke Study (Air Flow Visualization).
- **Batch release –** Engaged and accomplished 3rd party Batch Review & Certification project for both API and Formulations manufacturing unit.

PROFESSIONAL EXPERIENCE

Worked as a Quality Consultant for **Business Excellence Consulting Inc. USA**, Since April'2020 to date as a SME for Production System, Material System and Facility & Equipment System. And have successfully completed assessment, certification and remediation projects with Multinational firms**.**

* **Project-1:** Batch Certification Project for OSD Facility / * **Project-2:** Batch Certification Project for API Facility

* **Project-3:** System Certification Project of API Facility / * **Project-4:** System Certification Project of OSD Facility

* **Project-5:** MOCK Audit of API Facility Thru Infill Life Sciences, India

OTHER ORGANIZATIONAL EXPERIENCE

Have overall 26+ years of experience in field of Pharmaceutical Manufacturing which Include Sterile API , Powder Injectable , API Bulk and Intermediate

Have worked with India's Leading Pharmaceutical Companies like:

- **Unmark Remedies Ltd. (**Last**)→**
- **Ranbaxy Labs Ltd. →**
- **Nectar Life Sciences Limited→**
- **Aurobindo Pharma Limited→**
- **Wockhardt Limited→**
- **Kopran Limited →**
- **Dee Pharma Limited→**
- **Armour Chemical Ltd→**
- **Abbott Laboratories (I) Ltd. (**First**)**

EXPOSURE OF REGULATURY INSPECTION

***USFDA** (05) * **MHRA** (06) * **WHO - Geneva** (02) ***TGA** (03) ***Health Canada** (03) ***PMDA** (02)*
**VARIOUS INERNATIONAL AND NATIONAL CUSTOMERS INCLUDING AUDIT BY QP (EUROPE)*

PROFESSIONAL DEVELOPMENT - TRAINING / CERTIFICATIONS:

- Underwent training programs on presentation skills, Time Management, Total Quality Management.
- Technical Training: Aseptic Behaviour / Practices and Implementation of CAPA.
- Training on **"Effective Compliance Writing for personnel Involved in Investigation"** By Mr. Manuel E. Pena, BEC-Global Puerto Rico -USA
- Training on **"Investigation/ CAPA System and Human Errors Reduction Certification"** By Mr. Manuel E. Pena, BEC-Global Puerto Rico -USA
- Training on "**Principles of effective Human Error investigation**" By **Dr. Pepe Rodríguez-Pérez** PhD, President BEC-Global Puerto Rico -USA.
- Training On "**Measuring Training System Effectiveness**" By **Dr. Pepe Rodríguez-Pérez** PhD, President BEC-Global Puerto Rico -USA.

EDUCATION & PERSONAL PROFILE

- **1988 Bachelor of Science (**Chemistry, Physics & Maths**)** Agra University, Agra
- **1990 Master of Science (**Organic Chemistry**)** Agra University, Agra
- **1994 Post Graduate in Business Administration (**PGDBA**)** MPSI, New Delhi
- **Gender** : **Male**
- **Date of Birth** : **12-Sep -1970**
- **Nationality/Citizenship** : **Indian**
- **Passport Nos.** : **M3161678**

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