Sunilraj Othena

Associate Vice President - Quality Assurance

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A professional with experience in management of pharmaceutical Quality Assurance and Quality Control of both drug product and drug substances. My core competencies include, PQS implementation & review at manufacturing sites, Quality Risk Assessment, regulatory audits & compliance, data integrity assurance, analytical process improvements, vendor management, internal quality audits, continuous improvement programs, training & development. Hosted many regulatory inspections successfully. I have created highly compliant and competent teams of quality professionals throughout my career.

SKILLS

Pharmaceutical Quality Systems | Quality Assurance | Quality Control | Internal Quality Audits | Vendor Management | Hosting Regulatory Inspections | Training | Quality Risk assessment

WORK EXPERIENCE

Associate Vice President
Syngene International Limited

05/2014 – Present *Bangalore, India*

Syngene is a contract manufacturing services organization, engaged in manufacture of early phase clinical and commercial finished Formulations, API and Biological products. Syngene, was inspected by USFDA twice, EMA and PMDA successfully.

Achievements/Tasks

- I lead a strong and competent team of about 140 QA professionals and subject matter experts as Head of Quality including Quality Assurance and Regulatory Affairs
- I hold the core responsibility to implement and maintain quality systems, ensuring the organization operates in compliance to the regulatory requirements. Responsibility includes continual improvement of systems, development of personnel and training.
- built client relationships, established governance structures between quality groups.
- Current responsibility encompasses, small molecule API, small molecule Drug Product and Large molecule manufacturing.
- Have implemented a continuous improvement team successfully
- Have harmonized and implemented phase appropriate quality systems.
- Have successfully hosted regulatory inspections from FDA and PMDA for small molecule drug products, drug substances and large molecules.
- Implemented a corporate policy on Data integrity across the organization and rolled out a auditing / monitoring mechanism.
- Standardized internal auditing program and a robust vendor evaluation process.
- Improved operational efficiency of Quality Assurance 30% over the last two years.

WORK EXPERIENCE

Vice President- Corporate Quality Assurance
Micro Labs Limited

12/2008 – 05/2014 *Bangalore*

Micro Labs is a leading pharmaceutical manufacturer having markets in US, Europe and Rest of the world apart from India. They are a leading manufacturer for sterile ophthalmic products and penicillin type dry powders.

Achievements/Tasks

- Handled the core responsibility of PQS implementation, review and compliance, across four Drug Product manufacturing sites of Micro Labs. The Drug Products included Tablets, Capsules, Dry Powders and Sterile Ophthalmic preparations.
- Hosted regulatory audits from FDA, MHRA, MCA & WHO and submitted compliance to regulatory deficiencies, successfully.
- Drove market complaint investigations, which required detailed client liaison and even visits to client sites.
- Conducted laboratory system review &compliance. Lead OOS & failure investigations, identification & implementation of CAPA and monitored CAPA effectiveness.
- Conducted vendor audits. Co-ordinated with Qualified Person (QP) for quality matters.
- Conducted corporate quality audits at sites and implemented global corrective and preventive actions.
- Coordination with R&D for execution of submission / validation batches. Conducted Review of development data and related documents of new products.
- Developed and submitted pharmacopoeial monographs for IP. Trained personnel across all sites on QMS, cGMP and DAta Integrity.
- Harmonized Quality Assurance and Control systems across all manufacturing sites.

Associate Director - Quality Control
Dr. Reddy's Laboratories

01/2005 – 12/2008 *Hyderabad*

Dr. Reddy's Laboratories is an Indian multinational pharmaceutical company based in Hyderabad, Telangana, India. It has several API and Drug Product manufacturing facilities across India. They manufacture, OSDs, Sterile injections and High Potent anti- cancer products.

Achievements/Tasks

- Maintained strict level of compliance in one of the largest laboratory. Ensured deliverable are met in a timely manner.
- Implemented lean management concepts for improving productivity. and efficiency.
- Improved analytical processes, conducted analytical method transfers.
- Have been a member of new product launch team and cost improvement team
- Spearheaded change management and investigations of OOS results.
- Recruited staff, trained and inducted them. Talent management and leadership development was part of my responsibilities.
- Faced regulatory and customer audits successfully.
- Co ordination with regulatory, R&D and Analytical R&D.

Manager Regulatory Affairs
Biocon Limited

06/2002 – 01/2005 *Bangalore*

Achievements/Tasks

- Prepared dossiers and submitted to regulatory agencies such as FDA, TPD and MHRA.
- Liaised with customers of different geographies on regulatory aspects. Communicated with different regulatory agencies on filing dossiers, filing variations and answering deficiencies.

Management Staff- Quality
Cipla Limited

06/1996 – 06/2002 *Bangalore / Goa*

Achievements/Tasks

- Day-to-day deliverable to support manufacturing. • Management of Stability studies of both API and Dosage forms. • Preparation of specifications and test procedures. • Analytical method development and methods validation. • Management of laboratory standards.
- Designed and commissioned a Quality Control Laboratory at Cipla Goa Green Field Project. Implemented QA systems in coordination with Corporate Quality and hosted successful first regulatory audit of the site from MHRA.

WORK EXPERIENCE

Executive Quality Control
Orchid Chemicals and Pharmaceuticals

11/1994 – 06/1996 *Chennai*

Achievements/Tasks

- Developing methods and optimizing them. • Analysis of materials, intermediates and Active pharmaceutical ingredients.

Officer - Quality Control
Lupin Laboratories

03/1991 – 11/1994 *Bhopal*

Achievements/Tasks

- Sampling and Analysis of materials, API and finished dosage forms.

ACHIEVEMENTS

• Implemented phase appropriate Quality System at Syngene.

• Executed a Quality System Enhancement Plan successfully at Syngene.

• Hosted multiple regulatory inspections successfully. Including USFDA, MHRA, WHO (Geneva) and PMDA inspections. Investigated reported deficiencies and CAPA were identified and implemented.

• Successful 1st USFDA inspection and subsequent inspections of Micro Labs Ltd.

• Set up a robust Quality Assurance and Laboratory systems at the green field project of Cipla, Goa.

• A faculty for Quality systems /procedures at PTI (Pharma training institute, Bangalore).

Implemented a continuous improvement process successfully.

EDUCATION

Masters in Organic Chemistry
St. Thomas College / Calicut University

06/1988 – 06/1990 *Thrissur, Kerala*

Bachelor of Science- Chemistry
St. Thomas College / Calicut University

06/1985 – 06/1988 *Thrissur, Kerala*

LANGUAGES

English | Hindi | Malayalam | Tamil | Kannada

REFERENCES

Mr. Ajit Simh- Strategic Advisor - Quality, Syngene International Ltd.

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Mr. Antony John Peter, Head Engineering - Micro Labs Limited

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