RESUME

K. Kousalya
H. No.32B, 1st Floor,
Alwarthirunagar Annexe,
Alwarthirunagar, Chennai-600087

Email id: kousalyasmailbox@gmail.com
Mobile No: +91-9677209941

WORK SUMMARY:

- 16 years of experience within Analytical R&D and Quality Control, including pharmaceutical technology transfers, API Stability, Quality and Technical Documentation Remediation and readiness.
- Handling of Change control Management, deviations and OOS.
- These experiences are with multiple products and delivery platforms (primarily Small Molecule Sterile Injectables and Bulk drug) across domestic and Global Pfizer & Mylan manufacturing sites and supply nodes.
- Collaborated effectively with internal and external colleagues globally.
- Accustomed to working in fast-paced, challenging environments while performing assigned tasks within standard times and under minimum guidance.
- Possessing knowledge of cGMP, GLP, FDA and ICH guidelines.
- Possessing a good understanding and essentials of safety and quality.

AREAS OF EXPERTISE

- Yellow belt - Certified
- Computer Skills : MS outlook and MS-office (Word, Excel and PowerPoint)
- Change control management
- Continuous improvement
- Technical Documentation
- Written and Oral Communication
- Handled Regulatory audits (USFDA, EDQM, TGA, Hungarian Regulatory audit) and other customer audits

- Product testing (Wet Analysis and Laboratory Instrumentation techniques (HPLC, Preparative HPLC, FTIR, Auto titrator, KF titrator, UV spectrophotometer and Polarimeter))

WORK EXPERIENCE :

<u>May 2011 – May 2019 (Assistant Manager) – Pfizer Healthcare Private Ltd</u>

<u>(Sterile Injectables)-Chennai</u>

Technical Documentation Remediation Activities in Analytical Research &Development:

- Responsible for Gap assessment of documents for method transfer activities with Current USP monograph and General Chapters and ICH guidelines.
- Responsible for review and updation of Technology Transfer Protocol and Scientific reports for Sterile Injectables (Product-wise).
- Responsible for preparation of SOP's, Specifications and Standard Test Procedures of Parenteral formulation projects (API, Excipients, In-Process, Release and Stability) based on Analytical Method Validation Report and current USP monograph and General Chapters.
- Responsible for Assessment of Compendial Changes (USP) for the site and updation of related documents as applicable.
- Responsible for Assessment of Supplier change notification for the site and updation of related documents as applicable.

Technical Activities in Analytical Research &Development:

- Performed Impurities isolation and Purification for Sterile Injectables Projects.
- Performed Method Feasibility studies for Sterile Injectables in Analytical R&D.

Packaging:

- Responsible for preparation of STPs for Primary and Secondary Packaging Commodities like Glass Ampuls, Glass Vials, Plastic Vials, Rubber Stoppers, Trays, Enclosures etc.

<u>April 2003 to April 2011 - Executive –API -Mylan Laboratories Limited, Hyderabad</u>

<u>(8 Years):</u>

Stability studies (Quality Control):

- Responsible for Loading of Holding time samples (In-Process) and Stability study samples (API) and performed the analysis for the same and compilation of data.
- Responsible for review of all online stability documents.
- Responsible for preparation of Stability study trend chart by product wise.
- Responsible for preparation of Monthly plan, stability Study protocol and SOPs.

EDUCATIONAL QUALIFICATION

2007-2010: M.Sc (Tech) Pharmaceutical Chemistry. From Birla Institute of Technology and Science, Pilani (Distance learning education sponsored by Mylan Laboratories Limited) CGPA : 7.80

1999-2002: B.Sc Microbiology from Osmania University with 73% of marks.
School and Intermediate studies were from Andhra Pradesh State board.

AREAS OF STRENGTH:

- Ability to manage multiple-tasks. Ability to lead a team
- Excellent written/verbal communication skills
- Strong sense of responsibility and desire to get things done properly
- Self-motivated. Strong decision-making skills

PERSONAL SKILLS:

- Good interpersonal and communication skills
- Creative and Highly Motivate

K.KOUSALYA