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PERSONAL SUMMARY

- Having 28 years hands on experience in Regulatory, Quality Assurance, Quality Control and Project Management of pharmaceutical Formulation and Medical Device.

- Qualification :
  - Master's degree in chemistry

- Technical :
  - Diploma in System Management.
  - Certified Lead Auditor for Auditor for ISO 13485:2003
  - Certified Internal Auditor for ISO 13485:2016
  - Certified Lead Auditor for ISO 9001:2015
  - Certified Internal Auditor for ISO 14001:2015
  - Implementation of MDSAP requirements
  - Implementation of 21 CFR Part 820 requirements
  - Certified Medical Device Regulation induction course (CE Mark)
  - Awareness of Product Standards ISO 4074:2015 and ISO 23409:2011.
  - Awareness of Biological evaluation of Medical Device (ISO 10993-1, 10993-5, 10993-10 & 10993-11)
  - Trained on Device Calibration and importance of Calibration.
  - Trained on Accident Reduction Techniques
  - Trained on Factory Management Team Health and safety.
- Product Registration activity in CDSCO portal.
- Approved as Analytical chemist by Andhra Pradesh Drugs Control Administration, Hyderabad, Telangana, India.
- Approved as Technical Assistant by Puducherry Drugs Control Administration, Puducherry.

TECHNICAL SKILLS

- Experience in Design, QA and Regulatory activities of manufacturing of Condoms (Natural Rubber and Synthetic Polyisoprene).
- Experience in Condoms Manufacturing process of Natural Rubber and Synthetic Polyisoprene
- Experience in Design Transfer, Risk Assessment etc.
- Experience and Knowledge on Manufacturing Process, Testing and Inspection of
  - Tablets (uncoated and coated tablets)
  - Capsules
  - Liquid Orals
  - Pellets
  - Soft Gelatin Capsules
  - Natural Rubber Latex Male Condoms
  - Synthetic Polyisoprene Male Condoms
  - Filed Latex process
- Design Control for
  - Tablets, Liquid Orals, Pellets etc. (Lab scale, Pilot scale and commercial)
  - Natural Rubber Latex Male Condoms
  - Synthetic Polyisoprene Male Condoms
- Review and approval of Documentation
  - Technical Documentation for Tablets, Capsules, Liquid Orals, Pellets etc.
  - Technology Transfer
  - Device Master Records
  - Process Validation
  - Equipment Qualification
  - Process and Product Risk Assessment
- Product Registrations at various countries like
  - US, UK, Canada, Brazil, China etc.
- Handled Audits
  - USFDA Inspection (twice) and the outcomes was No Warning and ZERO 483s.
  - MHRA
  - TGA
  - ANVISA

- Product Mark (CE mark and Kite mark),
- ISO
- Customer Audits etc.

- Review the External Lab results like Protein, Biocompatibility, Microbial etc.
- Developed Analytical Methods through UV-VIS Spectrophotometer.
- Developed around 15 Products dissolution methods (non-pharmacopeia drugs)
- Conducted Supplier audits.

EMPLOYMENT HISTORY

- **November 2014 to Till date: M/s. Suretex Prophylactics (India) Private Limited, Bangalore**
  Designation : Sr. Manager – Quality Assurance & RA
  Reporting to : Director – QA & Sr. Director - RA

JOB RESPONSIBILITIES:

- Handling of following Medical Devices manufacturing process related to Quality.
  - Natural Rubber Latex Male Condom (Parallel, Textured, Thin, Ribbed, Ultrathin, Contoured, CDR, Flared, Large etc.)
  - Synthetic Polyisoprene Male Condoms (Parallel, Thin, Dotted).
- Involving Design Activities from Input to output and Design Transfer to Suretex.
- Review the Design Validation and Verification activities in the Plant.
- Review the Design transfer document
- Review and approval of DURA and PRA.
- Biocompatibility Tests results and Clinical Evaluation.
- Antigenic Protein results review.
- Handling of External Audits like USFDA, ISO and Various Customer Audits
- Audit observation response and co-ordination for the compliance of Non-conformances.
- Review and approval Validation Protocol & Reports and Equipment qualification protocols & reports.
- Review Design Validation Protocols and reports.
- Conducting Supplier Audits and review their Evaluations.
- Review and approve of DMF.
- Approve and follow-up for closure of Change controls and Deviations.
- Review and ensure to completion of process CAPAs
- Review and approval of Equipment Equivalence Study.

- To ensure effective handling of Customer Complaints, investigation, CAPA and responses.
- Review and approve the Quality Trends.
- Review the Stability Data.
- To identify the training needs of quality team in their functions and ensure that the personnel are trained and verifying the effectiveness.
- Conducting the Trainings to the subordinates against the Standards, Testing methods etc.
- Submission of 510K registrations.
- Handling of Product Approvals / Registration in India time to time to achieve Market demands.
- Product Registrations in various countries. (Australia, Brazil, Germany, China, USA etc.)
- Implementation of robust QMS in Site
- Conducting Quality Meets on regular basis.
- Reviewing the Third-Party Product Inspection reports.
- Involving the Quality Projects review and ensuring the closure.
- Reviewing the process and parameters results and narrow down the specification for getting the constant results.
- Review of Condoms Chemical Residue tests results
- Review of Condoms Nitrosamine Testing results.
- Review and approval of Transportation Study Reports.

ACHIEVEMENTS:

- Developed Raw and Packing Materials test protocols as per the specifications.
- Software validation for SPC.
- QMS documentation upgradation.
- Harmonized the Validation protocols.
- Equipment re-qualification.
- Incoming Materials inspection Reports generating from Microsoft.

♦ **January 2011 to October 2014:** **M/s. TTK PDL, Puducherry**
Designation : Manager – Quality Assurance
Reporting to : Head – Quality Assurance & RA

JOB RESPONSIBILITIES:

- Handling of following Medical Devices manufacturing process related to Quality.

- Natural Rubber Latex Condom (Parallel, Textured, Colored, Ribbed)

- Approval and closing review of Change controls, Non-conformance and Concessions.
- Implementation of QMS in Site.
- Review and approval Validation Protocol & Reports and Equipment qualification protocols & reports.
- Monitor and Conducting the Internal Quality Audits. (Includes interplant audits)
- Co-ordinating for the External audits. (USFDA, ISO audits etc.)
- Prepare the Audit observations response and co-ordination for the compliance of observations.
- To ensure effective handling of Customer Complaints, investigation, CAPA and responses.
- To review of Analysis of Data and Stability Data.
- Monitoring the Quality KPIs with Gap analysis.
- Reviewing the Corrective and Preventive Actions for the Quality Projects.
- To identify the training needs of quality team in their functions and ensure that the personnel are trained and verifying the effectiveness.
- Trained the people against the Standard requirements, and internal procedure requirements.
- To ensure supplier evaluation / audits of Raw and Packing Materials.
- To ensure product quality reviews are performed are investigated.
- To report to management on defined periodicity or as required.
- Reduce the Third-party testing charges by developing the inhouse test methods.

ACHIEVEMENTS:

- Developed analytical method for Benzocaine by UV method.
- Developed Raw and Packing Materials test protocols as per the specifications.

♦ **June 2009 to December 2010:** **M/s. Geltec Pvt. Ltd., Bangalore**
Designation : Manager – Quality Assurance
Reporting to : Vice President – Quality & Regulatory

JOB RESPONSIBILITIES:

- Handling of following Solid Dosage Products manufacturing process to Quality
  - Soft Gelatin Capsules
- To review the Process validation protocols and reports.
- To review preventive maintenance and calibration records.
- To review of qualification documents related to equipments used for manufacturing and testing.

- To prepare and review of Cleaning validation Protocols and reports (Matrix).
- To review of APQRs.
- To review the Stability studies data.
- To help in drafting, reviewing and approval of SOPs.
- Prepare the response for the Audit observations and co-ordination for the compliance of observations.
- Co-ordination and sending the required documents to Regulatory department.

♦ **April 2007 to May 2009: M/s. Medreich Ltd., Bangalore**
Designation : Assistant Manager – Quality Assurance
Reporting to : Sr. Manager – Quality Assurance

JOB RESPONSIBILITIES:

- Handling of following Solid Dosage Products manufacturing process to Quality
  - Tablets, Capsules & Liquid orals,
  - Delayed Released Tablets
- Closing review of Change controls and Deviations.
- To ensure the compliance of Raw material Finished product and packaging material with respect to established specification.
- To review and approval of STPs and Specifications.
- To review the Process validation documents.
- Handling of Process Validation activity.
- To Prepare and review the Retrospective Validation reports.
- To review preventive maintenance and calibration records.
- To review of qualification documents related to equipments used for manufacturing and testing.
- To review the hold time study protocol and reports.
- To prepare and review of Cleaning validation Protocols and reports (Matrix).
- To review and approval of Batch processing records and Batch manufacturing records for New Products. (received from F & D and TT with Customer License copy and PIF)
- To review Nonconformance Trends
- Prepare and review of Customer Complaints Trends.
- To review of APQRs.
- To review the Stability studies data.
- To review the OOSs and OOTs reports.
- Prepare the response for the Audit observations and co-ordination for the compliance of observations.
- To review the analytical and manufacturing documents intended for regulatory submission and dispatches.
- Prepare the Training schedules and coordinating training programs.

- To help in drafting, reviewing and approval of SOPs.
- Co-ordination and sending the required documents to Regulatory department.
- Releasing / updating the documents through SAP system
  - Batch numbering allocation.
  - Batch releasing.

♦ **May 2006 to March 2007:** **M/s. Kopran Limited, Khopoli, Maharashtra.**
Designation : Assistant Manager – Quality Assurance
Reporting to : General Manager – Quality Assurance

JOB RESPONSIBILITIES :

- Review of Process Validation Protocols and Reports.
- Submitting the required documents to RA for Product registration.
- Preparation of Cleaning Validation matrix
- Review, approval and maintenance of standard operating procedure.
- Coordinating of Training sessions.
- Review of Process data sheets.
- Preparation of new products Master Batch documents (BMR, BPR & MFR).
- Supporting to Plant QA for External Audits.

♦ **Feb. 1999 to April 2006:** **M/s. Cipro Pharmaceuticals (100% EOU), Hyderabad**
Designation : Sr. Executive – QA & QC
Reporting to : Manager – Quality Assurance

JOB RESPONSIBILITIES :

- Handling of following Solid Dosage Products manufacturing process to Quality
  - Tablets, Capsules, Pellets,
  - Extended release Tablets
  - Control Delivery Pellets
- Preparation and maintenance of SOPs and MFRs.
- Preparation and review of Equipment Qualification documents.
- Preparation of Process & Analytical Method validation documentation.
- Document preparation for Export Registration purpose (Providing technical details regarding Dossier preparation for export purpose).
- RM / PM / FP analysis in combined dosage form of Tablets, Capsules and Pellets.

- Experience in handling instruments like HPLC, UV, FTIR, Auto Titrator, Dissolution Tester, Tap Density tester, Friabilator, etc.

ADDITIONAL RESPONSIBILITY:

- Coordination with Project Manager and Production Manager of Unit II to complete the documentation. (New facility)

ACHIEVEMENTS:

- Joined as QC Chemist and Promoted as a Sr. Executive QA and QC
- Successful implementation of documents as per cGMP requirements like Equipment Qualifications, Process Validation, Equipment Calibration, log sheet, Analytical Method Validations, analytical templates and batch manufacturing records.

♦ **Aug. 1995 to Feb. 1999:** **M/s. Trans Medicare Limited, Hyderabad**
Designation : Chemist – QC
Reporting to : Asst. General Manager – QC

JOB RESPONSIBILITIES :

- Preparation and maintenance of SOPs.
- Preparation of Volumetric Solutions & Standard solutions.
- RM / PM / FP analysis in combined dosage form of Tablets, Capsules, Syrups and Pellets.
- Experience in handling instruments like UV, Dissolution Tester, Tap Density tester, Friabilator, etc.

ACHIEVEMENTS:

- Prepared RM / PM / FP test protocols
- Developed additional test methods for Paracetamol, Chlorpheniramine Maleate, Metoprolol and etc.

PERSONAL DETAILS

- DATE OF BIRTH : 10 – 08 – 1970
- LANGUAGES KNOWN : English, Hindi, Tamil, Kannada and Telugu.
- MARITAL STATUS : Married

(N.V.S.V. Prasada Rao)