Rama Vutukuri

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Strengths

- 10 years of Hands on experience in GXP (GCP,GLP & c GMP) environment in Pharmaceutical, Biotech, Biologics, Radio pharmaceuticals, Diagnostic agents and Medical device companies
- Experience with CMC, Overseeing CMO and CROs Quality operations
- Extensive Experience in Batch record review (Drug substance, Drug product, Finished goods and cell banks), Analytical data review , labeling and Packaging records review, CAPA, Deviation, Change control, OOT, OOS, Root cause analysis, Investigations and resolution, NDA documentation review
- Experience in implementing Quality systems, Vendor audits and vendor qualification
- Developing and negotiating CMO,CRO Quality agreements
- Extensive QA/QC experience in writing, reviewing and approving Standard Operating procedures, Validation protocols and Reports
- Experience of ISO9001, 13485, FDA and EU regulations, cGMP Requirements, API, IND, BLA and quality tools
- Developing training requirements for various departments personal
- Experience with PAI and regular cGMP inspections (participation in various levels and hosting client, FDA and EMA audits)
- Excellent project management and computer skills in validations and implementation of electronic systems including Microsoft Office tools, Trackwise, Documentum, Visio, SAP, Share point, Lotus Notes, LIMS and QUMAS, Cats Web
- Expert in brining lab staff from academia to cGMP level
- Exceptional team player who can take initiative in making significant contributions outside defined job functions to facilitate meeting departmental and team objectives

Experience

QA Consultant, Immuno Gen, INC., Waltham, MA **04/2013- Present**

- Clinical study reports review and approval for FDA submissions
- Clinical sites monitoring for audits and compliance
- Overseeing GCP and GLP Quality systems of internal and external partners
- SOP generation and approval
- Clinical sites deviations and investigations approval
- QUMASS support for compliance and implementation
- Testing Methods validations, protocols and reports review and approval
- Equipment qualifications guidance, protocol review and approval
- Gap assessments for methods , QA , clinical sites, internal and external for FDA,EU and Canadians regulations
- Training internal and external partners on GLP and GCP regulations

QA Consultant, AVEO Oncology Cambridge, MA 06/2012- 03/2013

- Overseen CMO Quality operations for manufacturing, Quality control, Method validation and process validation activities for domestic and international partners
- Batch Record review and Batch disposition including Analytical data review for in process, release and stability, Clinical packaging and labeling material disposition for clinical trials (early to late phase trials)
- Temperature excursions review and approving memos for use of clinical studies, labeling text review and approval for blinded and non blinded studies
- Manufacturing and QC (Drug Substance, Drug product, API, Reference standard, Cell bank), Deviations, OOS , Non conformances Investigations review and approval, OOTs, Change Control and CAPA review and approval
- Review and approval of Method transfer and method validation and qualification protocols and reports
- Shelf life setting and shelf life extension reports review and approval for DS and DP
- NDA documentation review

QA Consultant, LONZA Biologics, Hopkinton, MA 02/2012- 06/2012

- Manufacturing, Raw material and QC (Drug Substance, Drug product, API, Reference standard, Cell bank), Deviations, OOS , Non conformances Investigations review and approval, OOTs, Change Control and CAPA review and approval
- Review and approval of Equipment, Method transfer and method validation and qualification protocols and reports
- Release of raw material and solutions, Creating new Templates, Checklists
- Participation in validation and implementation of electronic systems
- Building Customer relations CMOs and CMC
- SOPs review for cGMP regulations, NDA Documentation review, Gap analysis
- Finding root causes for Investigations, Risk assessment of manufacturing equipment and recommending possible changes to Batch records based on different phases of clinical studies
- Reviewed IOQ of automated manufacturing equipment

Quality Engineer, Genzyme Allston, MA 10/2011- 12/2011

- Reviewed IOQ of automated manufacturing equipment
- OOT review
- Manufacturing validation protocols review and Quality SOP review for gaps

QA supervisor, Blue Stream Labs, Cambridge, MA 03/2010-09/2011

- Responsible for Managing reviewing and approving Quality systems (CAPA, Deviations, discrepancies, OOS/OOT and Change control, for drug substances, drug product, reference standard, equipment and analytical methods)
- Responsible for managing and conducting internal and external audits, vender qualification, quality agreements and supplier audits (scheduling and performing audits, authoring report, reviewing, following up, approving and maintained supplier files and audit logs)
- Responsible for Managing , author, reviewing and approving SOPs
- Responsible for reviewing and approving Method validation, software and equipment Validation Protocols, validation reports, IOQ, Managing documents management systems**.**
- Managing clients relations with QS discussions and solving issues
- Responsible for data review (stability, drug substance, drug product, in process, Raw material bulk,etc) and disposition (HPLC,SDS-PAGE,IEF,ELISA,LC/MS,UV-VIS, Potency, moisture analysis, N-terminal Sequence, immune blot etc), certificate of analysis
- Participated in QP, FDA and customer inspections and responding to audit observations.
- Responsible for quality metrics , facilitated and participated annual product review and MRB

Stability Specialist
Anika Therapeutics, Woburn, MA **9/2007-09/2009**

- Worked with Quality and Manufacturing in the root cause analysis and resolution of deviations, Out of Specification and Out of Tolerance investigations
- Significant contribution in the investigation and resolution of CAPAs and impact assessment related to QC and Manufacturing
- Developed, Authored, reviewed and approved Standard Operating Procedures
- Independently compiled stability reports that are required for regulatory submissions
- Authored, reviewed and performed validation protocols and reports
- Reviewed QC batch record, Maintained QC personnel training record files, equipment maintenance files
- Provided guidance to other analysts in prioritization of tasks, trouble shooting equipments, performance of assays
- Reviewed QC analytical and microbiological assays Analyzed stability data and authorized technical reports and interim summaries
- Drafted Certificates of Analysis for final product release, conducted internal audit and involved in FDA audit
- Coordinated outsource testing laboratories for raw material, release and stability testing
- Supported QA for complaints investigation
- Participated in MRB meetings,
- Responsible for Statistical analysis of product stability and metrics for Quality systems

QC Analyst II

CISUS-INC, Bedford, MA **10/2005-09/2007**

- Performed and authored reports and protocols of instrumentation IQ/OQ AND PQ
- Assisted with transfer of assays to and from CMOs, R&D, QC
- Executed and reviewed QC analytical assays, Method validations, trained other analysts, Reviewed QC analytical assays, SOPs
- Conducted continuous improvement meetings
- Reviewed Instrument troubleshooting and calibration, logbooks

University of Massachusetts, ***Research Assistant***
Amherst, MA **08/2004-7/2005**

- Assisted with the development of applications for nanoparticles in biological systems
- Investigated the binding of peptides to nanoparticles through CD and running fluorescence titrations of MMPC with peptides at various temperatures, concentrations and time, Purified peptides using HPLC

EDUCATION

Masters Degree in Chemistry

Attended seminars and webinars

- ASQ member
- PDA meeting, FDA New guidelines on process validation
- Effective Corrective and Preventive actions webinar
- Lab compliance Seminar "Raw Data in FDA Regulated Environments"
- cGMP practice in GXP environment
- Performing internal and external audit
- Method development and validation using Agilent HPLC system
- FDA investigations and inspections