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|  | **Basha Kanala** | **Location**: Ahmedabad, India.  **Contact**: +91 9618564764  **Language**: Telugu,English & Hindi  **E-mail**: [kanalabasha@gmail.com](mailto:kanalabasha@gmail.com)  [kanalabasha@rediffmail.com](mailto:kanalabasha@rediffmail.com)  **Skype ID** : kanalabasha |

**Snapshot:** Versatile, dynamic, accomplished Pharma/Biopharmaceutical industry Quality professional seeks a challenging assignment with a consistently growing firm to utilize skills & knowledge gained through professional experience, education and continual professional development to deliver outstanding results aligned to corporate goals and objectives.

**Professional Summary Overview**

* **Master of Science in Biochemistry**, NET qualified, having 13 plus years of experience working with reputable global Biopharmaceutical & life science companies of Biologics facilities in India & Abroad (Dubai), having exposure in the areas of Quality Control, Bio analytical, QMS and Compliance aspects.
* **Molecules worked upon:** Insulin Human, Darbepoetin alfa, Erythropoietin, Rituximab, Bevacizumab, Adalimumab, Trastuzumab, Ranibizumab, GCSF and Peg GCSF Drug substances and Drug products...

**Competency Matrix**

* **Quality Documentations** – Preparation, review and approving of SOPs, STPs, Specifications, Stability study protocols and reports, Analytical method validation protocols and reports.

Reviewing and approving of QC documents, analytical results and reports of in-process, raw materials, drug substance and drug product and final COA releases.

* **Laboratory Compliance** - Having expertise in performing all operational activities, smooth functioning of QC laboratory and ensuring Data integrity. Expertise in handling of Change controls, CRN, CCF, Incidents, (LIR), Deviations, OOS, OOT, Investigations and CAPA.

Ensuring the QC instruments Calibrations, PMP, Validations, Electronic data backup, restoration, audit trial verifications and Data integrity.

* **Regulatory Matters** – Skilled in preparing and reviewing all regulatory audit compliance reports related to product quality. Having exposure in managing compliance audits by multiple regulators – INVIMA - Columbia, CDSCO, PPB-Kenya, PICs - Ukraine, COFEPRIS - Mexico, MOH - Turkey, MOH - Algeria, MOH - Kyrgyzstan, MOH - Kazakhstan, FDA - Tanzania, MOH - UAE, SFDA - Saudi Arabia, MOH - Egypt, domestic and international customer audits.
* **Competency Training & Development** – Expertise in design, development & delivery of training programs & modules to build competency, skills & knowledge on current technologies and continual improvement techniques.
* **Cross functional activities** - Experience in internal and external audits, Involving in Technology transfers, coordinating with Manufacturing, QA, RA teams for technical discussions. Capable of coordinating equipment procurement, installation, validation & qualification, batch release and end user support.
* **Analytical Competency** - Familiar with complete QC analysis of therapeutic molecules from cell bank testing till final drug substance and drug products including in-process analysis. HPLC Assays, Related substances, SEC, CEX,peptide mapping, Agarose gel electrophoresis, PAGE, IEF, ELISA, DNA isolations, PCR, DNA

Fingerprinting and protein expression studies.

* **Familiar with**: LIMS, TRIMS and SAP systems.

**Education**

**M.Sc. Biochemistry** passed with Distinction 72 % from S.K.University, Andhra Pradesh, India

**B.Sc. Biochemistry** passed with Distinction 78 % from S.K.University, Andhra Pradesh, India

**Post graduate diploma** in Patents and Intellectual property rights from Osmania University.

**Professional Experience**

**Intas pharmaceuticals (Biopharma division) Ltd, Ahmedabad, India.**

*Intas Biopharmaceuticals is first EU certified company in India in Biologics facility.*

**Manager - Quality Control |Feb 2018 to current|**

**Responsibilities**

* Implement & manage the **Intas QC Quality Management System** at the site compliant with cGMP guidelines covering manufacturing, packaging, testing, documentation, storage & transportation of products.
* Develop & implement quality systems and validate all systems, methods, processes & equipment against applicable GMP protocols.
* Analytical assurance and monitoring of QC team in systematic functioning.
* Lead the investigations of OOS, OOT, and deviations management .s
* Lead the investigation of major deficiencies reported in processes & products (OOS, OOT, deviation management) to identify root causes and recommend effective corrective & preventive action (CAPA) action plans.
* Organize internal audits related to QMS and cGMP compliance, coordinate external audits by regulatory bodies. Preparation and review of audit compliance reports and ensure closing of all observations through effective CAPA.
* Develop & deliver training programs for staff across functions & levels to build & sustain a culture committed to QMS & cGMP compliance
* Coordinate all activities related to product release including all testing and documentation protocols to meet regulatory requirements.
* Involving in Technology transfers, coordinating with Manufacturing, QA, RA teams for technical discussions.
* Provide day-to-day as well as need based support in root cause analysis, problem solving, troubleshooting and implementation of effective CAPA.
* Design & deliver instructor led training programs covering all aspects of the quality assurance function.
* Responsible for review and release of drug products and drug substance in SAP.
* Review and approval of SOPs, STPs, Specifications, Stability protocols & reports, method validation protocols & reports, all kinds of analytical reports and COAs.

**Hetero Drugs Ltd (Hetero Biopharma), Jadcherla, Telangana, India Sep 2014 – Jan 2018**

**Deputy Manager – QC**

**Responsibilities**

* Leading the Product team executing the Batch release, Stability & Reserve sample management and Compliance related issues across the site.
* Planning, allotment and monitoring of work and supervising the QC team in systematic functioning.
* Preparation and review of SOPs, STPs, Specifications and all kinds of protocols and reports.
* Preparation, review and approval of all kind of analytical reports and COAs.
* Preparation and review of analytical method validation protocols and reports.
* Coordinating with other departments for technical discussions and follow up of technology transfers.
* Responsible for handling of Laboratory incidents (LIR), OOS, OOT, Change controls, CCF, CAPA, Risk assessment, impact assessments and market complaints.
* Responsible for reviewing of Audit trails in QC instruments as part of Data integrity.
* Review and checking of all raw data of analysis, logbooks and online temperature data.
* Monitoring and ensuring the calibration, validation, verification, Preventive maintenance, AMC, Electronic data backup and restoration of Instruments as per the schedules.
* Responsible for trouble shootings of analysis and instruments.
* Monitoring and ensuring the Stability management and Reserve/ Control samples management.
* Responsible for conducting internal audit of other departments as part of cGMP compliance.
* Auditing and qualifying the outside analytical laboratory.
* Representing in internal and external audits. Preparation and review of audit compliance reports.
* Responsible for review and release of drug products and drug substance in LIMS and SAP.
* Providing the SOP training in TRIMS and Qualifying the QC staff in analytical techniques.
* Planning for procurement of chemicals, glassware, Reference standards, HPLC, UPLC columns, Instrumental spares and other consumables.
* Successfully faced Regulatory Audits: INVIMA - Columbia, CDSCO, PPB-Kenya, and PICs - Ukraine, COFEPRIS - Mexico, MOH - Turkey, MOH - Algeria, MOH - Kyrgyzstan, MOH – Kazakhstan, T FDA Tanzania and NDA UGANDA.

**Julphar, Gulf pharmaceuticals Ltd, Ras Al Khaimah, Dubai, UAE | Dec 2011 – Aug 2014|**

*Julphar is a biggest pharmaceutical company in the Middle East and*[North Africa](https://en.wikipedia.org/wiki/North_Africa)*Region established in 1980*

**Quality Control**

* Supervising the QC team in systematic functioning of all activities. Reviewing of all quality control documents, results and reports of In-Process, Raw material and Finished products.
* Upstream analysis: Culture purity, viability, plasmid stability, protein expression studies for bacterial cell samples
* Recovery stage : Protein profiling quantitation of inclusion bodies, trypsin digest analysis
* Downstream stage: HPLC analysis of DEAE, Q sepharose and RP-HPLC chromatography fractions
* Process intermediates and impurity depletion studies and process mass balancing
* Insulin, Human (API) complete analysis as per USP and EUPhr pharmacopeia
* Chemical analysis: Raw material analysis as per pharmacopeia, water analysis and trending
* Compile, analyze data, and prepare graphs, reports and trending.
* Experience in analytical techniques: SDS-PAGE, HPLC, GC, Atomic absorption spectroscopy, UV-visible spectroscopy, protein estimations, peptide mapping ELISA, IEF, DNA quantifications.
* Preparation and review of SOPs, STPs, specifications, process validation protocols, cleaning validation protocols, Stability studies, Impurity depletion studies.
* Responsible for handling of Laboratory incidents (LIR), OOS, OOT, Change controls, CCF, CAPA
* Representing the department in all internal and external audits.
* Planning for procurement of chemicals, glassware, Reference standards, HPLC, GC columns, Instrumental spares and other consumables.
* Co-ordinating with manufacturing, QA and Regulatory affairs in smooth functioning of department
* Successfully faced Regulatory Audits: MOH - Turkey, MOH - Algeria, MOH - Kyrgyzstan, MOH - Kazakhstan, FDA - Tanzania, MOH - UAE, SFDA - Saudi Arabia and MOH – Egypt.

**Nagarjuna Innovation centre, NFCL, Hyderabad | Sep 2006 – Dec 2011 |**

**Scientist - Analytical**

**Responsibilities**

* Working closely with process development project team as process Analytical scientist to support analytical needs and engage in long-term collaboration such as setting up a strategy for process control and critical quality attributes and process mass balancing
* Strain improvement by genetic manipulations involving cloning, over expressions
* Familiarity with upstream and downstream biologics processing and analysis using HPLC, SDS PAGE,UV Spectroscopic methods
* Development of Analytical methods for in-process analysis
* Protein expression and enzyme assay studies of wild and recombinant microorganisms
* DNA Finger printing, PCR, RE digestion, Recombinant screening methods
* Protein and Isozyme profile study by SDS- PAGE & Data compilation
* Molecular biology techniques: DNA, plasmid Isolations, PCR, colony PCR, Agarose gel

electrophoresis, cloning and recombinant screening techniques

* Culture revival, MCB & WCB maintenance of E.coli, Yeast, Anaerobic microorganisms
* Preparation of SOPs, STMs, reviewing of batch records and making presentations
* Applying good laboratory practices during execution of all works.

**A.P.Rice Research Institute, Marteru, Acharya NG Ranga Agri. University Hyderabad**

**|Mar 2005 – Sep2006 |**

**Research Associate**

**Responsibilities**

* DNA fingerprinting based on microsatellite DNA markers& AFLP markers
* Protein profiling of different genotypes by SDS-PAGE
* Isolation, estimation and separation of fungal proteins by SDS-PAGE.
* Extraction and separation of fungal Isozymes by Native PAGE
* Molecular biology techniques: DNA, plasmid Isolations, PCR, colony PCR, Agarose gel electrophoresis, cloning and recombinant screening techniques

**Instruments handled**

* HPLC – Agilents 1200 & 1260 (Chem station,EZ Chrom,Open Lab chemstation)
* Gas chromatography – Agilents (6890, 7890
* UV-Spectrophotomater- Amersham Biosciences 6300
* Vertical Electrophoresis – Voefer Mini & Horizontal electrophoresis
* Atomic Absorption spectroscopy
* Refractometer
* Microanalytical balances
* Molecularbiolgy equipments , PCR Thermal Cycler & Microcentrifuges
* ELISA Reader –Zenyth 340

**Personal Information**

* Date of Birth: 26 July 1982
* Languages: Telugu, English, Hindi
* Nationality : Indian
* Passport No: R41660824
* Marital status : Married
* References : Shall be provided upon request
* Permanent Address: H.No. 6-88, Kota Street, OWK (post), Kurnool ( Dist), Andhra Pradesh, Pin 518122

**Declaration**

* I hear by declare that the information furnished above is true to the best of my knowledge .I will be responsible for any wrong information.
* Basha Kanala
* Place- Ahmedabad