CURRICULUM VITAE

PATEL NRUPESH SEVANTILAL

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10.7 years of experience in Bio-Pharmaceutical Company

CARRIER OBJECTIVE:

To work in Research and Development, Quality Control, Quality Assurance department where I can use my skills, knowledge and experience to attain a level of expertise and employer satisfaction, through which I can contribute substantially towards the growth of the company and extract some deep professional satisfaction as well.

CURRENT JOB:

Working in CADILA Pharmaceuticals, located at Dholka - Ahmedabad in Biotech-QC department as **Assistance Manager** since November-2014 to till date.

KEY DELIVERABLES:

- Allotment of work to subordinates, handling and analysis of Bulk product / Finished product / in-process samples / Validation samples / Developmental samples
- Managed team for handling department of IPQC testing / Drug Substance release / Drug Product release, Method Validation, IRS Qualification and Stability management.
- Preparation and review of various GMP/GLP document such as
  - Standard test Procedure (STP) and Product Specification
  - Method Validation Protocol and Method Validation report
  - Internal Reference Standard Qualification Protocol and its report
  - Stability Study Protocol and Report
  - Record of Analysis (ROA) of individual product
- Data Review: - Record of analysis (ROA), Logbooks entries, Preparation and Reconciliation records, Calculation sheets etc. for product batch release and qualification records.
- QMS document including Change control, Deviation, Out of specification, CAPA, third party analysis and retrospective report review.
- LIMS and SAP relative batch release QMS activity, Specification and material reconciliation etc. incorporate data review.
- Preparation of Technology Transfer document and its regarding document review.
- Aware with Document issuance, distribution and archival system.
- Experienced in handling the regulatory audit and customer audit, conduct the internal audit

International Project Management of Botulinum Toxin Type A

- Have been to South Korea for training of the project for a period of 1 month
- Analyzed Engineering batches, technology transfer batches, clinical trial batches and method validation of Botulinum Toxin Type A Drug Substance
- Preparation of Master Cell Bank of *Clostridium* for Botulinum Toxin Type A by techniques like
  - Microbial Identification
  - Sugar Fermentation Profile
  - Genomic Purity
  - Proteolytic Activity
  - Toxicity

Analytical Responsibility:

- Cell culture activities (In-vitro and In-Vivo study): Performed different techniques like In-Vitro Bioassay of rHu-GCSF, RFFIT of Rabies vaccine, Potency Assay of PC vaccine and Botulinum Toxin Type A, In-vivo bioassay of r-HuEPO
- Handling of techniques like HPLC, SDS-PAGE, Western Blot, IEF, HCP, cell culture assay, BET, Protein estimation methods, Chromogenic Assay
- Handling of animal based assays like Dose injection in animal, Isolation of Organ.
- Calibration of Different instruments (HPLC, Spectrophotometer, Balance, Deep Freezer, pH Meter, Micropipettes)
- Qualification of Internal Reference Standard (IRS) : Protocol and Report Preparation
- Maintenance of External and Internal Reference Standard Records

Performance Qualification/Verification & Validation Activities:

- Analytical method development and method validation by HPLC techniques (Assay, Related substances, Preservative contents, related excipients contents) for Formulation products, Finished Products, Intermediate stages samples, protein and bio-similar products.
- Method development and method validation for Identification, Estimation and Purity of protein samples (Formulation products, Finished Products, Intermediate stages) by SDS-PAGE, Western blot, Iso-Electric Focusing-Gel.
- Cleaning validation of different protein projects
- Aware with URS, DQ, IQ, OQ, PQ of Equipment & Utilities
- Hold Time Validation Study

Additional Activities:

- Archived implementation of Quality system in Laboratory – Qualification of equipment (IQ,OQ,PQ), SOPs, STPs, Specifications and Periodic calibration / qualification and logbooks
- Pharmacopeial evaluation and verification for product and method verification.
- Trend analysis of Stability samples, Drug substance and Drug Product samples.

ORGANIZATIONAL EXPERIENCE:

Name of Organization	Duration	Job Profile
Cadila Pharmaceutical Ltd. Dholka (Biologics)	Nov-2014 to till Date	Management and handling of different projects, QMS, Method validation, Internal Reference Standard Qualification
Sun Pharma Advance Research Company Ltd. Baroda	March-2014 to Oct-2014	Research and Development work Analytical Development Department
Zydus Biologics - Ahmedabad (Division of Cadila Healthcare Ltd.)	June-2010 to Feb-2014	QC- Batch release, stability and In process sample analysis and Validation of Recombinant Products
Concord Biotech Ltd. Dholka, Classical Fermented Product.	Nov-2009 to May-2010	Research and Development work Production basis.

ACADEMIC DETAILS

M.Sc. (Biotechnology) from Ganpat University, Mehsana, Gujarat in 2009 with 61%
B.Sc. (Biotechnology) from H.N.G.U, Patan, Gujarat in 2007 with 65%

PERSONAL DETAILS:

Name	: Patel Nrupesh S
Birth Date	: 30th December, 1986
Marital Status	: Married
Languages known	: English, Gujarati, Hindi
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