ARTI MAKADIYA

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OBJECTIVE:

- Establish a career in the field of pharmaceutical/Biotech industry on the provision of quality support, in a technical environment where I can continue to increase my knowledge and responsibility.

PROFILE IN BRIEF:

- Having 7+ years of experience in Pharma/ Biotech industries.
- Having excellent presentation skill & convincing capacity
- Dedicated, hardworking & having strong sense of responsibility.
- Having good communication skills, team spirit, inter personnel skill & be self-motivated.
- Friendly, social & can mix with people.
- Self-motivated initiative & having pleasing manners.
- Perform all job functions in compliance with cGMPs and maintain accurate and legible laboratory records.

EXPERIENCE

❖ **Eurofins laboratories :**

Address: 2425 New Holland Pike,
Lancaster, PA 17601
Phone: 717-656-2300
Department: Extractables and leachables
Duration: 10-Jan-2020 - Present

Duties & Responsibilities:

Clinical SAS Programmer:

- Perform data manipulation, analysis and reporting of primarily clinical trial data.
- Program and generate tables, listings, and graphs (TLGs)
- Participate in the review of statistical analysis plans, table specification, develop specification for SDTM and ADaM data sets.
- Review, and comment on CRFs, annotated CRFs, and edit checks and related documents.
- Create SDTM and ADaM Datasets and related documentation.
- CDISC Expertise (SDTM and ADaM)
- Experience creating source and validation programs using SAS software for SDTM datasets, analysis datasets, and tables, listings, and graphs (TLGs) for multiple studies/products.
- Knowledge of integrating data across multiple studies or drug programs.
- Expertise in the development and use of system-level macro programs.
- Advanced knowledge of medical terminology, clinical trial methodologies, and FDA/ICH regulations.
- Ability to work independently with minimum oversight.
- Excellent written and verbal communication skills.

Sr Data Reviewer:

- Ensuring that the client receives quality data by reviewing laboratory data for accuracy, clarity, and adherence to GMP and/or GLP regulations and evaluating problems
- Applies GMP/GLP in all area of responsibility
- Diagnose problems, solve simple problems, and suggest solutions to complex problems in a professional area; perform complex calculations
- Keep oneself and peers abreast of current developments and trends in professional area by reading and understanding internal procedures, attending training sessions, by writing/revising SOPs (as required), and by assisting Group Leader/Principal Specialists in training new employees
- Perform review of scientific data, including, but not limited to standard preparation, calibrations, methodology, QC, sample data, integration review, compound evaluation, chemical identification, and other subjective review based on testing performed; perform complex calculations to verify results.
- Knowledge of ETQ, Lablinks, Empowers, ELN, eLIMS.

❖ **Amgen Biotech:**

Address: 40 Technology Way,
West Greenwich, RI 02817
Phone: 401-392-1200
Department: Quality Control – Critical Raw Materials
Title: Sr. QC Associate
Duration: 09-Mar-2015 to 05-10-2018

Duties & Responsibilities:

- Perform testing and data review for compendia methods like PH, Assay Titration, Moisture determination, ID Test, Heavy metals using USP, EP, JP, and ACS.
- Perform testing and data review for non-compendia methods.
- Perform Raw material testing using ICP-MS and NMR.
- Generate complete, accurate, and concise laboratory documentation using electronic systems and laboratory notebooks.
- Participate in laboratory investigations and audits as necessary
- Participate in the controlled document revision process as necessary in EDMS.
- Perform general laboratory housekeeping activities
- At all times, comply with safety guidelines, cGMPs and other applicable regulatory requirements
- Participate in transfer of method from different sites of Amgen to Rhode Island site. Creation of Verification of assessment document. Ordering the new reagents, uploading the safety sheets in internal system.
- Assist GC-MS method transfer from one lab to another
- Participate in lab 5S organization.

❖ **Mindlance Inc:**

Address: 80 River Street Fourth Floor
Hoboken NJ
Phone: 877-965-2623
Client: Amgen Biotech
40 Technology Way,
West Greenwich, RI 02817
Department: Analytical Sciences

Title: Process Development Associate
Duration: 04-Jan-2012 to 06-Jun-2013

Duties & Responsibilities:

- To quantitatively determine the concentration of drug product and in process samples using the HPLC instrument (Agilent/Waters), UPLC H class (Waters).
- To quantitatively assess the purity of drug product and in process samples by analyzing the level of clipped, dimerized & aggregated species using Size exclusion chromatography.
- Testing of drug samples for various protein methods using HPLC, qPCR, ELISA.
- Analytical testing of drug substances in support of process development studies and process characterization studies.
- Building Custom fields, Reporting method, Instrument methods and Processing method in Empower for new development projects.
- Transfer of various protein analysis methods from one lab to another lab. Also have a good hand of experience to develop a method for titer assay on HPLC & UPLC H class (Waters) and qualification of methods.
- Writing of transfer report, Protocol, Standard Operating Procedure, technical assessment report using the Enterprise document management system (EDMS).
- Analysis of various stability studies' samples using the HPLC.
- Knowledge of LIMS, EDM, ELN, Empower, Maximo, SAP etc.
- A280 measurements to quantify protein analytes in development and in-process samples by cuvette method.
- Data review of chromatographic test results and other electronic documents in EDM and ELN.
- Assist in Instrument maintenance and lab purchasing.
- Practice good laboratory technique in all laboratory operations.
- Comply with the company's Chemical hygiene Plan and Environmental policies when handling and disposing of chemicals.

❖ **A Division of On Assignment**

Address: 301 Edgewater Place, Suite 210,
Wakefield, MA 01880
Phone: 781-245-0387
Client: Bradford Personal care
200 Providence Street
West Warwick, RI 02893
Department: Analytical Development
Title: Analytical Chemist
Duration: 22-Aug-2011 to 23-Dec-2011

Duties & Responsibilities:

- Perform chemical analysis on raw materials, in-process materials, finished products or specialty chemicals using instrumentation and/or wet chemical methods.
- Analyze materials using standard wet chemical techniques that include, titrations (colorimetric/ potentiometric end points), specific gravity, and water content by Karl Fisher.
- Produce and maintain analysis records, laboratory reports and C of A's.
  Maintain sample retains of raw materials and finished goods.
- Provide analytical data to production and make basic recommendations on batch corrections when required.
- Assist the Analytical services team leader in the performance of instrumental analysis that includes chromatographic methods. To measure the OTC drug content in Soap Base using Waters HPLC.

- To check the appearance and color of the test samples with STD samples.
- To measure the transmission using FTIR Instrument.
- Assist the analytical services team leader with special projects, instrument maintenance and lab purchasing.
- Practice good laboratory technique in all laboratory operations.
- Comply with the company's Chemical hygiene plan and environmental policies when handling and disposing of chemicals.

❖ **The Davis companies:**

Address: 325 Donald J. Lynch Boulevard,
Marlborough, MA 01752
Phone: 1-800-482-9494
Client: Waters Corporation
177 Robert Treat Paine Dr,
Taunton, MA 02780-7266
Department: Quality Control Lab
Title: QC Lab Technician
Duration: 01-Feb-2010 to 05-Aug-2011

Duties & Responsibilities:

- Analysis of raw material and production samples through the various tests like Dryness check, %Carbon, Particle size, Surface area, Shape of particles, Water content in sample, PH meter, Titration etc.
- Handling and calibration of various instrument like HPLC, GC, TGA, LECO, Coulter multisizer, BET, Beta scientific Single Point Surface Area, Karl fisher, Spectroscopes, Auto titrator , PH meter, Balances.
- Use of the scientific data management system (SDMS), Nugenesis vision, SAP.
- Use of the various software like Pyris software for TGA, Leco 144 for Carbon-144, Tri-Star software for BET, Bachman for coulter multisizer, QC capture for Nikon Microscope, Tiamo software for Karl fisher & auto titrator, Empower for HPLC.
- Assist the Quality Senior with deviations, CAPAs, change control process review and detailed documentation of risk assessment analysis.
- Calibration of the HPLC system to check the various parameters like Flow check, Band spread, Detector test, Column temp test etc.
- To check the Cleanliness of oasis material (wcx, mcx) with the use of HPLC system.
- Order, stock, and receive, log and inventory lab supplies.
- Perform support work for QC laboratory including lab cleaning, equipment cleaning, preparation of reagents and solutions.
- Attend all required company training.

Relocation Break:

(India to USA): 01-Dec-2008 to 01-Jan-2010

❖ **M/s. Cadila Pharma**

Address: Cadila Pharmaceutical Ltd (CRO)
1389 Trasad Road
Dholka, Ahmedabad-387 810, India
Phone: 011-91 2714-220315
Department: BIO-ANALYTICAL Department (R&D)
Title: Research Associate
Duration: 18-Mar-2008 to 30-Nov-2008

Duties & Responsibilities:

- To check the method validation parameter like stock verification, matrix effect, recovery, all stability parameters, dilution integrity, P&A, aqueous linearity, sensitivity, specificity and homogeneity.
- Calculate the % CV, accuracy of the method validation parameter, calculate the ± change for the stability parameter.
- Write and revise basic laboratory SOPs, protocol, report for the validation and study also prepare a spiking chart.
- To analyzed study sample through various process like solid phase extraction, protein precipitations & liquid extraction.
- To detect the presence of an antibody or an antigen in a sample using ELISA Technique.
- Operation, maintenance experience with GC.
- Assist the leader in method development.
- Analysis of samples using UPLC (Waters) & HPLC (Agilent & Shimadzu).
- Calibration of pipettes.

❖ **M/s. Zydus Cadila Research Centre**

Address: Zydus Research Center
Sarkhej Bavla NH # 8A
Moraiya, Ahmedabad-382 213, India
Phone: 011-91 2717-250331
Department: BIO-PHARMACEUTICS (Drug metabolism & Pharmacokinetics)
Title: Research Assistance
Duration: 17-May-2007 to 10-Mar-2008

Duties & Responsibilities:

- Get a training of operation of HPLC (Agilent), UPLC (Waters).
- Collection of the blood from the mice, rat.
- Separation of plasma & serum from the blood and measure the drug concentration in the biological sample through various extraction procedures like liquid extraction, solid phase extraction, protein precipitations.
- To check the stability and homogeneity of formulation.
- Calculate basic mathematical calculation related to sample preparation like stock solution, serial dilution.
- To detect the presence of an antibody or an antigen in a sample using ELISA Technique.
- Operation, maintenance experience with GC.
- To check the method validation parameter like stock verification, matrix effect, recovery, all stability parameter, dilution integrity, P&A.
- Use of SDS-PAGE gel system for separation of broad range of proteins.
- To perform in vitro test like:
    - To check the stability of NCE in gastric & intestinal fluid.
    - To check the Log P & Log D of NCE.
    - To check the protein binding affinity of the drug

EDUCATION:

Bachelor of Pharmacy (B. Pham) - 2007
Saurastra University, Gujarat, India

Maternity Breaks:

June 2013-March 2015
June 2018-December 2019

Computer knowledge:

Chemstation for HPLC & Empower software for HPLC & UPLC, MS Office (Microsoft Word, Excel, Power Point), Microsoft Outlook, Internet technology, Auto data, Scientific Data Management System (SDMS), LMES (Laboratory Method Execution System), CIMS (Consumable Inventory Method System), LIMS (Laboratory Information Management System), ELN (Electronic Lab Notebook), EDMS (Enterprise document management system), SAP and Maximo, SAS 9.4, SQL, Knowledge of CDISC, SDTM and ADam.