# HIREN PATEL

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### *Last assignment served as Senior research scientist, ADL, Xylopia (Zydus cadila).. Ahmadabad, India*

### *With 15+ years Multi-functional career span offers a*

### *Analytical development laboratory in Pharmaceutical (Both API and Formulation)*

### *Review of Analytical method validation and development, DMF of supplier and STP as per Quality control, Handling of Time-bound CRL, DRL and IR Response from USFDA, Co-ordination with RA and Quality control department for Analytical matters , Performing Mock-up Regulatory and GMP audits of API sites, Conducting of internal audits periodically.*

***Profile:*** *I would describe myself as highly motivated, innovative, decision-making and positive individual, who would thrive on challenges and has the ability to adopt with situation of stress and relate well with the people. I would like to seek a challenging position with a dynamic group with excellent growth opportunities in the field of Analytical.*

***Objective: To be known as a highly skilled and reputed*** *Analytical Leader who strenuously focus inline with the Organizational objectives & perform to serve the society.*

### *Professional Synopsis*

* Comprehensive exposure in providing leadership for management of activities pertaining to Analytical Development encompassing method development and validation, method transfer, reporting results and timely follow up with stakeholders.
* Skilled in development and validation of analytical methods for Oral Solid Dosage Forms as per the relevant guidelines of regulated markets like USP & ICH.
* Possess extensive knowledge on Dissolution Studies, Chromatographic Method Development, Stability Studies, Impurity profiling etc.
* Possess strong analytical, problem solving & organizational abilities. Possess a flexible & detail oriented attitude with an ability to work independently as well as part of a multidisciplinary team.
* Successful Preparation of Validation excel sheet for accurate result and save the time.
* Successful Preparation of Annual Product Quality Review (APQR) Review of BPCR, Change control, Deviations and OOS.
* Well acquainted with the various Documentation of TT-Analytical, AMV, Incidents and Change control, DMF, Cleaning Validation protocol & report.
* Familiar with various make sophisticated Instruments. (i.e. HPLC, GC, Dissolution, FTIR, UV spectrophotometer, Partical Size Analyzer, Polarimeter, ICP-OES and AAS, IC)

### *Notable Accomplishments (Across the career)*

* *USFDA Audit faced (thrice) at Xylopia (Zydus cadila) without any observation.*
* Visited the BioPharm, Inc. USA for Query respond to FDA agency of Nitrofurantioin Oral suspn 25 mg/5ml.
* Played Quality control lead role of developed the method and performing analysis of ethanol content in methanol as per USFDA Auditor needs at Unimark remedies ltd. Ahmadabad.
* Performed the specificity (forced degradation) study was repeated of Letrozole as per USFDA Auditor needs at Zydus cadila (zyfine).
* Represented the Our Analysis and Calibration System step by step, how to maintain working standard and reference standard, Incidents, Multimedia etc.. to USFDA Auditors in Xylopia( zydus cadila).
* Master Documents Review related to, Method validation protocol, Specification and STP’s

### *Key performance indicator*

* Insistence And Implementation Of Systems
* Adept At Independent Decision-Making
* Takes On The Responsibility And Accepts The Challenges
* Believe in Time Management
* Team Management
* Believe in Right-At-First-Time Approach
* Ability To Follow Prescribed And Detailed Procedures To Solve Problems
* Effective In Cross Functional Departments Relationships

### *Career History*

**Xylopia (Zydus cadila), Ahmedabad, India**

**Since 14th February 2011 to till date**

**Job Profile as Senior research scientist Analytical development (Formulation)**

* Day to day reporting to Associate director.
* Respond of the CRL, DRL and IR to FDA agency within timeline for analytical related.
* Plan of **validation and Verification for Drug substance, Drug Products** & trouble shooting of problems in the area of analysis.
* **Method validation protocol review of drug product** (Tablets, capsules, Oral powder and suspension) and Drug substance, like Blend Assay and Blend Uniformity, Assay by HPLC and UV, Dissolution, Related substance by HPLC, Residual solvent by GC and Cleaning validation.
* **Responding to the method related queries raised by quality control** department during method transfer.
* **Co-coordinating with vendors/suppliers on different technical (as per DMF)** and non technical issues related to product requirement.
* Validation of **excel sheet for calculation** with document.
* Maintaining the Lab complies and **Good Laboratory Practices** in the laboratory practices in the laboratory.
* Conducting the **weakly review meetings** with team members, discussion on critical issues and giving suggestions to complete the project in time.
* Conducting of **internal audits** periodically.
* Review of Specification and standard test procedures related to ADL.
* Review and **implementation of Pharmacopoeial changes** as per current pharmacopeias.
* **Impart training** like on job training, instrument handling & operation, working standard preparation, analytical method validation, how to refer pharmacopeia, recording of raw data in protocol, sampling of material & product etc.. to staff.

**Asence pharma (Asence Incorporated Group Company, USA), Baroda, India**

**Worked for 8 months from 13th July 2010 to 11th February 2011, majority in Quality assurance.**

**Job Profile as Asst. manager, Quality (API)**

* Day to day reporting to General Manager Quality.
* Preparation and review of Annual Product Quality Review (APQR) Review of **BPCR**, **Change control**, **Deviations and OOS.**
* **Review** of Specification and standard test procedures related to quality control.
* **Handling Market complaints returned**, recalled goods and response preparation.
* Conducting of **internal audits/self inspections** periodically.
* Ensuring trace ability of documentation through **archival system**.
* Handling of **Retain** sample.
* Review and **implementation of Pharmacopoeial changes** as per current pharmacopeias.
* To evaluate quality and stability of the finished Drug substance and carry out gap analysis from overall quality angle at the location and keep the corporate head informed.

**Zydus cadila (Zyfine), Ahmedabad, India**

**Worked for about 2 years from 02nd Sep, 2008 to 9th July 2010 majorly in Validation Cell and Quality control.**

**Job Profile as Officer, Quality control (API- Oncology)**

* Day to day reporting to Sr. Executive-Quality control.
* As per ICH and CQA guide. Perform the **Analytical method validation activity** like preparation of Validation protocol , validation report and annexure
* Online update the **reference standard through web / catalogue** & ensure all reference standard alive at all time for analysis
* Design & maintain a **system of working / reference standard Inventory & Consumption record** with traceability.
* **Preparation of Validation protocol** like analytical method validation, cleaning validation, Excel spreadsheet validation and calculator validation and also performed the all type validation.
* Planning & **Execution of master calibration** record
* All Others instrument / analytical weight which are utilize for calibration of instruments of calibrated & traceable to NPL
* Monitoring the In house & **External Preventive Maintenance** of instruments and ensure alive for analysis.
* Maintenance records & ensure the compliance
* **Active involves in various audits** , Like USFDA , WHO , Customer Audits
* Preparation of **stability protocol, charge the sample in stability chamber and prepare the stability summary** report.
* Related activity of stability like assign the retest period etc.

**Unimark Remedies Ltd, Bavala, Ahmedabad,India.**

**Worked for about 2 years from 7th AUG, 2006 to 01st Sep 2008 majorly in Quality control.**

**Job Profile as Officer, Quality control API**

* **Analysis and Release** of Raw Material , Packing material , Reaction Monitoring Sample, Intermediate and Finished Product.
* Maintain the record of reference **standard and working standard.**
* Review of **working standard protocol, in process protocol, Raw material Protocol & Calibration** record.
* **Corresponding with QA** and Plant for its related problem.
* Verification of analytical methods for new products by H.P.L.C. as per ICH Guideline, like check the parameter for Accuracy, Linearity, Limit on Detection and Limit of Qualification.
* Instrument **Calibration & Trouble Shooting of H.P.L.C**.
* **Intermediate and finish product analysis** by H.P.L.C.
* Good pharmacopoeia knowledge.
* I have an **exposure in USFDA Team**, like check and correct the Analytical worksheet reports, calibration Records, clean laboratory and labeling and demonstration of HPLC Assay Analysis with complete Document.

**Glenmark Phrmaceutical Limited, Ankleshwar, India.**

**Worked for about 2.5 years from 16th May, 2004 to 21st July 2006 majorly in Quality control.**

**Job Profile as Jr. Officer, Quality control (Formulation and API)**

* I know to **handle various sophisticated lab instrument** like HPLC, GC, UV spectrophotometer, FTIR, Polarimeter, Malvern Particle Size Analyzer, Autotitrator etc
* I have knowledge of formulation analysis of pellets. (Like Itraconazole pellets & Esomeprazole pellets). Dissolution profile by U.V and HPLC method.
* I have adequate **knowledge related cGMP**.
* I have adequate experience related wet analysis.
* Calibration and maintenance of analytical instruments as per schedule.
* To enter all the **analytical data and indent the requirements in SAP** (System application and product of data processing )

### *Computer Skills*

*Expert in handling any kind of application to latest versions of MS Office, SAP, BSS and Surfing related to all Global Regulatory Sites and Regulatory/Quality guidance*

### *Educational / Technical Qualifications*

***M. Sc (Industrial Chemistry) from*** *North Gujarat University, Patan, Gujarat, 2004.*

***B. Sc (Industrial Chemistry) from*** *North Gujarat University, Patan, Gujarat, 2002.*

### *Personal Information*

***Permanent Address:*** *D-703, Abhilash, Behind Nirma University, Malabar county road, Vaishniodevi circle, Tragad, Ahmedabad -382470, Gujarat, India.*

***Date of Birth:*** *08th June 1982*

***Languages:*** *Gujarati, Hindi and English*

***Hobby :*** *Music, swimming and sports*

***Key Personal characteristics:*** *Leadership, Decisive, Analyzer, Proactive, Independence, Alert, Sensible, Committed, Disciplined*

***Sports Activities:*** *I have participated in Basketball, Soft ball, Chess&. Hand ball.I have participated in Glenmark Cricket Rolling trophy & Pharma Cricket Rolling trophy.and also I have state level certificate*

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***References will be furnished on request***

***Hiren Patel***

