CURRICULAM VITAE

PERSONNEL PROFILE:

Name : Naishadh G. Doshi

Permanent Address : D-406,Pramukh Park, 132 Ft. Ring Road, B/H. Torrent Power House, Naranpura, Ahmedabad - 380013

E-mail : **naishadhdoshi@gmail.com**

Mobile : 9558176681, 9909964260 (R).

Gender : Male

Birth Day : 9th October, 1975.

Marital Status : Married

Bood Group : B_{+ve}

Language Known : English, Hindi, Gujarati.

Current organization: Cadila Healthcare Ltd.(Zydus Biologics).

Current Position : Manager - QC

Experience : 26 years

PROFESSIONAL EXPERIENCE:

Sr. No.	Name & Address of the Company	Position	Duration period
1.	Cadila Healthcare Limited (Zydus Biologics Unit)	Manager- QC	Feb – 08 to onwards
2.	Astron Research Center, Ahmedabad	Research Associate	Jun – 07 to Feb – 08
3.	Zydus Mayne Oncologies Ltd.	Officer – ADL (Oncology Lab)	Sep - 05 to Jun – 07
4.	Dishman Pharmaceuticals & Chemicals Limited, Bavla.	Officer – QC	Jan - 99 to Aug – 05
5.	Monokem Laboratory, Ahmedabad	Chemist-QC	Nov - 96 to Dec – 98

STRENGTH:

- Willingness to take up challenging assignment.
- Determination to ensure in such assignment by putting in best intellectual inputs, skills I have acquired so far.
- Utilizing my knowledge, talents, and skills for best of the work allotted.

ACADEMIC QUALIFICATION : M. Sc. (Chemistry)

MASTER OF SCIENCE (Chemistry)

Obtained : 56 %

University : Madurai Kamraj University, Madurai.

BACHLORE OF SCIENCE (Chemistry)

Obtained : 60 %

College : C. U. Shah Science collage, Ahmedabad.

University : Gujarat University, Ahmedabad.

PRESENT JOB DESCRIPTION:

Presently, working as Manager – QC (Raw Material & Packing Material) & GLP Activities for drug substances (API) and drug products (Injectable Formulations).

In Zydus Biologics I am looking after the Raw Material & Packing Material Lab, daily work distribution of the laboratory and the meeting the targets of the organization and department.

Work experience in API, Formulation

- Improve the quality system to compete with international requirement. (US/ EU etc.) I am monitoring the below mentioned JOB responsibility/activities.
- Lead the team of more than 10 nos. of members directly (Routine QC activity / GLP / documentation / compliance / reference / working standard management / procurement/Budgeting to comply the routine activity and regulatory requirement.
- QMS Compliance activity of Change Control, CAPA, Incident and Deviation.
- Handling Training Activity through Zytims Software.
- Annual Budget preparation of QC laboratory.
- Procurement activity of routine use chemicals and consumables.

Raw Material and Packing Material Laboratory and GLP related Work:

Monitoring activities of RM/PM release as per guideline of ICH, USP & EP.

- Preparation of Raw Material and Packing Material related Specifications , Standard Test Procedures as per respective Pharmacopoeia.
- Preparation of SOP of Instrument and system procedure respective to RM/PM analysis.
- GLP activities like Instrument qualification and Calibration.

DOCUMENTATION

- Preparation & updating the documents to comply various regulatory bodies (USP, EU, Tech. packages for customers).
- Handling of all QMS for change control, incident, OOT, OOS, planned/unplanned Deviation.
- Designing and preparation of Specification & Standard test procedure.
- Preparation of General test procedure as per EP/USP/IP/JP etc.
- Monitoring the activities of analyst qualification for new joiners/section rotation.
- Job description of QC personnel:
    - Preparation of JOB description. Organogram.
    - Analyst Qualification & OJT & cGMP training.

CALIBARTION & ANNUAL MAINTNANCE CONTARCT (AMC):

Monitoring the activities of External & Internal Calibration.

- Planning & execution of Master Calibration Schedule and Planner.
- Ensure the compliance regulatory requirements and also fulfill the Pharmacopoeial requirements for calibration.
- Indent, Purchase & Ensure the chemicals–reagents used for calibration are certified and traceable to recognize bodies such as NIST.
- All the instruments/analytical weights which are utilize for calibration of Instruments of quality control are calibrated & traceable to NPL, NABL accredited labs.
- Close coordination with all sections for internal calibration & third party for external calibration.

Annual Maintenance Contract (AMC).

- Monitoring the in house & external Preventive maintenance of Instruments and ensure alive for analysis.
- Planning & execution of AMC.
- Close coordination with all sections & third party for external calibration.
- Maintain records & ensure the compliance.

INSTRUMENTATION:

Familiar with various make sophisticated Instruments.

- Close monitoring the instruments. Helpful for base & additional advantages at the time of technical recommendations & compliance of regulatory requirements of instruments.
- Actively involved in Technical recommendation, qualification, & installation of various instruments.
- Familiar with various Network software with fully comply the 21 CFR part 11 compliance. Chromeleon-Dionex, Shimadzu-Lab Solution ,Tiamo Software etc.

List of major Instruments which are handled along with Mfg. as given below:

HPLC	-	Shimadzu, Dionex, Agilent.
Ion Chromatography	-	Dionex, Thermo fisher
GC-HS/GC	-	Perkin Elmer, Agilent
UV Spectrophotometer	-	Shimadzu
FTIR	-	Perkin Elmer, Shimadzu
Polarimeter	-	Jasco, Antonpar
Auto Titrator, Coulometer	-	Metrohm
KF Titrator	-	Metrohm

Laboratory Software Tools:

- Using SAP for Indenting laboratory items and RM,PM and Finished product release.
- Using LIMS for RM,PM and Finished product release, Calibration module, Column management module, Volumetric Solution module etc.
- TrackWise system for QMS activities like Change Control, CAPA, Deviation.
- Documentum Software using for SOP management.

AUDITS:

Actively involved in internal, Customer and Regulatory bodies audits. Faced once audit for USFDA,in Zydus Biologics. Represented as core team member for Regulatory audits from Quality control department.

1. USFDA
2. INVIMA
3. SRILANKA
4. WHO
5. Customer Audits (i.e. Torrent,Glenmark etc.)

BUDGETING ACTIVITIES

- Budgeting Activities of department (Capital / Revenue / Manpower) Preparation,

Planning & Execution.

- Direct consultation with Top Mgt. (GM/VP) for Budgeting Activities.

PRODUCTS HANDLED

Eprosartan Myselate, Omeprazole, Pantoprazole Na, Glimepiride, , Bupivacaine & Ropivacine HCl, Praguanil HCl, Chlorohexidine derivatives, CHG solution, Enoxaparin Sodium ,Fulvestrant, Oncological API like Doxorubicin HCl, Epirubicin HCl, Docetaxel ,Paclitaxel Biotech products like Filgrastim Solution, Erythropoietin etc.

PROCUREMENT & EXECUTION

Actively involved in activities of procuring the highly sophisticated Instruments in Lab.

- Active team member of Techno–Commercial discussion.
- Prepare & Proposed Technical Recommendation for Instruments.
- Monitoring the Procurement activities to compliance all regulatory requirements for US/EU/Customer etc.
- Monitoring the Procurement & Execution activities of
  Chemicals – Reagents, Glassware, PVC ware etc.
  Consumable – Spares & parts of Instruments.
  Reference Standard (USP/BP/EP/IP/JP and others).

COMPUTER LITERACY

- MS Office (Word, Excel, PowerPoint), Windows, Internet.
- Prompt internal communication through Lotus Note / Outlook.

VOCATIONAL TRAININGS

- Active participant in safety seminars and fire fighting seminars.
- Training on guidelines for industry on Manufacturing, Processing & Holding ofAPIs conducted by Dr.A.K.Sabharwal,President, Pharmaffiliates Asia.
- First Aid training conducted by ST.JOHN AMBULENCE BHAVNAGAR.
- Training on communication skills, Time management by HR department.

OTHER INFORMATIONS

FDA Approval	Gujarat FDCA Approval for Zydus.
Salary Expected	Negotiable
Reference	(i) Mr. Nimesh Thaker – Asst. VP (Reliance Biotech) Mobile – 8828437404 (Mumbai)

(ii) Dr. Rakesh Sinha – VP (Intas Biotech)
Mobile – 9866566923 (Ahmedabad)

DATE: **Naishadh Doshi.**