RESUME

Rahul Bhanudas Unde

CQA Manager - Pharmaceutical

Mobile No. : +91-9767424078, +91-9657969961

Email ID : rahul_unde@rediffmail.com

Current address : 1. Navi - Mumbai.

2. Flat No. 401, Digambara Residency, Moshi, Pune.

Permanent address : A/P : Loni Kd, Taluka : Rahta, District : Ahmednagar, Maharashtra, India, Pin : 413713.

OBJECTIVE

To work as a task-oriented Quality Assurance specialist in pharmaceutical, Chemical or relevant industry wherein, I can put all my acquired skill and abilities to the optimum use to bring out the best for the company and myself.

BASIC INFORMATION

Qualification : M. Sc Analytical Chemistry

Total Year of Experience : 20+ Years in Pharmaceutical Quality (10 Years in QC and 10 years in QA)

Current Organization : Kilitch Drugs (I) Ltd, Navi- Mumbai.

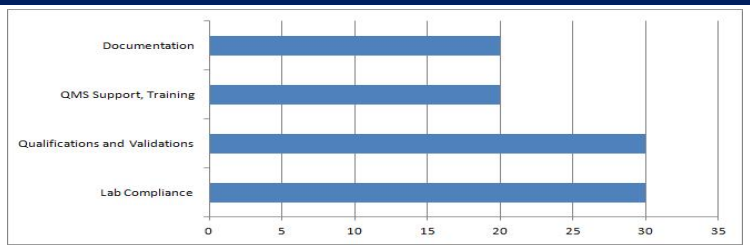
Current Designation : **CQA Manager**

DOSEGE FORMS WHERE IN I HAD WORK

- Tablets, Capsule, Syrup, Dry Syrup, Injectable.
- APIs, Key starting materials
- Excipients and packing materials

EXPERIENCE SUMMERY

EXPERIENCE SUMMARY



SKILLS

- 21 CFR Part 11, Data integrity, Audit Trail, Computer System Validation, GAMP5.
- Document preparation, Review & Approval of SMF, VMP, SOP's, BMR, Specifications and test procedures.
- IPQA, APQR, Quality Risk Management, Regulatory / customer support.
- Self-inspection and Audit Compliance, Finish good Inspection of CM Sites at CQA.
- RM/PM Vendor Qualification, Auditing Contract Manufacturing sites, Review of Technical agreements.
- Market Complaint Handling.
- Validation and Qualifications, Calibrations, Technology Transfer.
- Product Development Plan, Report, Method Development Report (PDP, PDR, MDR)
- Quality Management System (QMS), NCR/CAPA, Change control, OOS Investigations.
- Developing Quality culture through GMP, GLP, GDP, ALCOA principles, Training at all over site.
- QC sample Testing, Instrumentation and compliance.

COMPANY PROFILE

Organization	Location	Designation	From	To	Experience
Kilitch Drugs (I) Ltd	Navi - Mumbai	Manager CQA	Aug - 25	Till Date	
Alpha-Pharma	Kalyan	Manager QA	May - 24	Aug - 25	1 Y 3 M
Self Employed	--	Freelance QA Consultant	Jul - 22	May - 24	1 Y 8 M
Baxter International	Bengaluru	QA Associate - III	Apr - 20	Jul - 22	2 Y 3 M
Sai Life Sciences	Pune	Asst. Manager - QA	Jan - 15	Mar - 20	5 Y
Wockhardt	Aurangabad	Sr. Officer- QC	Jan -11	Dec - 14	4 Y
Harman Finochem	Aurangabad	Officer - QC	Feb - 07	Jan - 11	4 Y
Encore Healthcare	Paithan	Officer - QC	Jan - 06	Feb - 07	1 Y
Alkem Lab	Daman	Officer - QC	Jun - 04	Jan - 06	1 Y 6 M

EDUCATIONAL PROFILE

Qualification	University	College	Year	%
M.Sc (Analytical Chemistry)			2004	II Class
B. Sc		Vikhe Patil College, Loni,	2000	II Class
H.S.C	Pune	Ahmednagar, Maharashtra.	1997	II Class
S.S.C			1995	I Class

TRAINED ON

- 21 CFR Part 11, Data integrity awareness, CSV, Good Documentation Practices.
- Quality inspections, How to face or conduct Audits.
- Stability study, Chromatographic Practices.
- EU-GMP, 21 CFR Part , 210, 211, ISO 9001-2015

SOFTWARE/COMPUTER EFFICIENCY

- Analytical laboratory Software (Empower 3, Metrohm, Chromeleon….)
- Track-wise (QMS), SAP, ECOM, TcU (Document Management).

JOB PROFILE

KILITCH DRUGS (I) LTD

49 Years Pharma Manufacturing organization having 5 WHO approved manufacturing units in India and Ethiopia. Specifically catering for Africa and ROW Market. Head office in Mumbai.

- **Designation:**
  Corporate Quality Assurance Manager
  (Handling team of 4 - 5 person)
- **Reporting to:**
  GM - Corporate Quality
- **Responsibilities:**

➢ RM/PM Vendor Qualification, Auditing Contract Manufacturing sites.
➢ Market Complaint Handling.
➢ Finish good Inspection of CM Sites at CQA
➢ Support new greenfield project of Kilitch drugs at Khopoli.
➢ SOP Harmonization

MEGHDOOT CHEMICALS (ALPHA PHARMA-HEATHCARE)

MEGHDOOT CHEMICALS (ALPHA-PHARMA HEALTHCARE)

Pharma formulation unit with GMP - Schedule M Approval., Manufacturing Tablets.
ALPHA group of company having two Manufacturing Units. Meghdoot, Kalyan and another is Zenzi Pharma Murbad, which is EU-GMP. Engaged in manufacturing of Tablets and Injectable

- **Designation:**
  Manager QA
  (Handling team of 2 - 4 person)
- **Reporting to:**
  Plant Head
- **Responsibilities:**

➢ Establish, Implement and ensure the Quality Management System (QMS).
➢ Review and approval of Annual Product Quality (APQR).
➢ Conduct Management Review Meeting (MRM).
➢ Hosting Regulatory/Customer Audits.
➢ Review and Approval of MFR, BMR/BPR, Change control, Deviation, OOS, CAPA.
➢ Conduct Internal Audits as per schedule.
➢ IPQA Activities.
➢ Vendor Qualification, Validation and Qualification.
➢ Ensure Batch has been produced, controlled and release as per requirements.
➢ Monitor overall plant GMP compliance.
➢ Training.
➢ System Improvement and SOP Harmonization.
➢ Interviewing new candidate.

- **Achievements:**

➢ Got opportunity to implement the systems as per revised schedule M and WHO Guideline.

FREELANCE QUALITY CONSULTANT

PHARMA QUALITY

- **Designation:**
  Working as a freelance Pharma Quality Consultant
- **Responsibilities:**
  Supports in providing pharma quality services like,
  - ➢ cGMP, SOPs
  - ➢ Documentation
  - ➢ Validation and Qualification
  - ➢ Audits
  - ➢ Data Integrity remediation, 21 CFR Part 11,

BAXTER

Baxter International, Bengaluru is supporting to the other Baxter facilities with respect to technical queries, development and Validations.
It is the 90 years old US Based Multinational Pharma Especially involved in Injectable manufacturing.

- **Designation:**
  Quality Associate- III, Equivalent to Dy. Manager/ Manager (Global Corporate)
- **Reporting to:**
  Manager – Quality
- **Team Members:**
  Working independently and reports to Manager QA.
- **Responsibilities:**
  - ➢ Provide Supports in QMS activities to various Baxter Global Business Units.
  - ➢ Support Design, Qualification and Validation of the New Laboratory Facility as well as supporting systems and instrumentation.
  - ➢ Assures that Sustaining Products (SPO) and New Product Development (NPD) activities meet Quality System Requirements.
  - ➢ Supports and supervise to Reference Standard Global Team at Syngene.
- **Achievements:**
  - ➢ Got Opportunity to work with the Multinational like Baxter.

SAILIFE SCIENCES LTD

Sailife Sciences Ltd., Pune, Maharashtra is ISO 9001-2015, USFDA Approved well reputed Formulation Research and Pilot Bio Batch Manufacturing for clinical trial center. Involved in the development of Injectable and OSD Dosage forms.
Organization is having four business units. All the API Facilities are USFDA Approved Manufacturing and CRAMS.
Company had its corporate office at Hyderabad, India.

- **Designation:**
  Asst. Manager QA (Joined as Sr. Executive & Promoted to Asst. Manager)
- **Reporting to:**
  General Manager – QA
- **Team Members:**
  Working independently and reports to General Manager QA.
- **Responsibilities:**
  - ➢ Computer System Validation (CSV) implementation and compliance.
  - ➢ Finding Data Integrity lapses in the systems and their remedial measures.
  - ➢ Review of Analytical Method Validation Protocols and Reports.
  - ➢ Qualification & Validation of Products, Processes, Systems/Facilities
  - ➢ Review of Stability studies,Technology Transfer Documents.
  - ➢ Preparation and Review of SOPs, Validation Master Plan, Site Master File.
  - ➢ QMS Implementation, Change control, Non-Conformance/CAPA, OOS.
  - ➢ Review & Approval of JOS, Products Development Plan, Report (PDP, PDR, MDR).
  - ➢ Document Control.
  - ➢ Ensures Calibration & Maintenance of Equipment & Instruments.
  - ➢ Vendor/ Service Providers Qualification & Review of Quality Agreements.
- **Achievements:**
  - ➢ Successfully Completed USFDA Audit in 2016, 2017, 2018 for different units.
  - ➢ Set New Analytical Validation Lab at Pune complying to 21 CFR part 11.
  - ➢ Certified Internal auditor for all SAI's API Units at Hyderabad.

WOCKHARDT LTD

Wockhardt Limited, Aurangabad is regulatory Approved unit. Facility is engaged in manufacturing of Tablets, Capsules and liquid Injectables.

Well-known pharma having multiple API and formulation manufacturing facilities in India and abroad.

- **Designation:**
  Sr. Officer Quality Control (Joined as officer & Promoted to Sr. Officer)
- **Reporting to:**
  Asst. Manager – Quality Control
- **Team Members:**
  Of Raw material and Finished goods team.
- **Responsibilities:**
  - Work allocation, Review of Raw and packing material, Finish goods Reports.
  - Train and guide new associates on GMPs and carry out Analyst Qualification.
  - Carry out investigation.
  - Carryout Technology transfer of analytical methods.
- **Achievements:**
  - Identify GAPs in current procedures/ practices with respect requirements.

HARMAN FINOCHEM LTD

Harman Finochem Ltd,
One of the largest manufacturer of Metformin HCL along with several other APIs & Formulation unit located at Aurangabad.
Company having three API manufacturing units, with WHO, USFDA, EU GMP, PMDA, TGA, ANVISA regulatory approvals.

- **Designation:**
  Officer Quality Control
- **Reporting to:**
  Asst. Manager – Quality Control
- **Team Members:**
  Of HPLC and GC sections.
- **Responsibilities:**
  - Analysis of Key starting material, APIs & Stability Samples.
  - Analytical Method Validation of API.
  - Calibration of Analytical Instruments like HPLC & GC.
  - HPLC, GC Column Management, Standards and Samples management
  - Stability chamber and stability sample management.
- **Achievements:**
  - Successfully completed USFDA audit.

ENCORE HEALTHCARE PVT LTD

Encore

Encore Health care Paithan, Maharashtra manufactures Tablets, Capsules and syrup.

Loan licensing unit having WHO Approval. Manufacturing the products for reputed Pharma like, Nicholas Piramal, GSK, J&J, Fulford.

- **Designation:**
  Officer Quality Control
- **Reporting to:**
  Asst. Manager – Quality Control
- **Responsibilities:**
  - Analysis of starting materials, In-process, Finish goods & stability samples.
  - Calibration of analytical instruments like, Dissolution apparatus, Balance, Polarimeter, UV spectro photometer, FTIR…. etc.
  - Preparation, standardization of Volumetric solutions, Reagents, Indicators.
- **Achievements:**
  - Participated in WHO Audit, As a loan licensing (LL) manufacturing site, got opportunity to fulfill requirements of different clients.

ALKEM LABORATORIES LTD.

ALKEM

Multinational Formulation Manufacturing unit at Daman, engaged in manufacturing of Tablets, Capsules, Syrup, Dry Syrups, Injectable.
Facilities are approved with regulatory authorities like MHRA, MCC.

- **Designation:**
  Officer - Quality Control **(**Joined as Trainee & Promoted to Chemist)
- **Reporting to:**
  Asst. Manager – Quality Control
- **Responsibilities:**
  - Sampling and Testing of Raw, Packing Materials, Finish & stability samples.
  - Calibration of instruments like, pH Meter, Polarimeter, ….etc.
  - Water Analysis.
- **Achievements:**
  - GMP Awareness, Handling of different Analytical instruments,

AUDIT FACING

- **Regulatory Audit:**
  WHO-GMP, USFDA (5 times), MHRA (3 Times)
- **Client Audits:**
  Cipla, Emcure, Lupin, Kinedex, Alkem, Abbott, Sun, Amneal, Akorn.

COMMUNICATIONS

Language	Oral	Written	Understanding
English	Good	Good	Good
Hindi	Good	Good	Excellent
Marathi	Excellent	Excellent	Excellent

PERSONAL INFORMATIONS

Marital Status	Married
Spouse	Nilima Rahul Unde (Housewife)
Date of Birth	14th August 1979

DECLARATION

I, hereby state that the information compiled above are precise and accurate to my knowledge.

Rahul B. Unde