ARIF NAJIRAHMAD SHIKALGAR

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Quality Head Operation

Quality Assurance ◆ Quality Control ◆ Quality Audits ◆ System Management

Bulk Drugs, Nutraceutical and API Formulation Industry - FMCG

SNAPSHOT

- Chronicled success of over 26 years in Quality Assurance & Control, Quality Audit, System Management, and Quality functions for Bulk Drugs, Nutraceutical, Pharmaceutical and Formulation Industries
- Track record of attending several audit exposures; identifying & auditing the suitable Outsourcing facilities for supply of quality & quantity of API, Intermediates & formulations in defined time frame with cost efficiency.
- Vast knowledge of formulation development and analytical testing of Intermediates, Public health API & related formulations. In-depth understanding of USFDA, KFDA, TFDA, EU, BRCGS, ISO 22000, ISO 9001, ISO 14001 and OHSAS 18001. Comprehensively familiar on productions-fabrication process, elementary process and GMP process.
- Well organized with a successful track record that demonstrates self-motivation, creativity, and initiative to achieve corporate goals. Willingness to learn to keep abreast of new developments in the Medicinal chemistry field.
- Show dominant efforts in Project management and screening projects risks costs, review financial statements budget forecasting and business matrix for smooth operation.

COMPETENCY COVERS

Quality Management	Quality Control	Quality System	Quality Assurance
Quality Audits	Quality Review	Operational Effectiveness	Technology Transfer
Regulatory Submission	Regulatory Affairs	Equipment Qualification	Change Control
Plant Operations	Research & Development	Product/ Process Improvement	Documentation
Vendor Management	Compliances	Team Management	Training

- Standardization and application of modern, sophisticated instrumental analysis (UV-Vis, IR, GC, GC-MS, HPLC, AAS) as well as classical methods of analysis in the fields of pharmaceuticals, fine chemicals, intermediates, foods, natural products, pesticides, bio-chemicals, medicinal plants / extracts and related medicinal (Ayurvedic) products.
- Standardization / enrichment of herbal (medicinal plant) extracts with respect to active marker compounds.
- Method development for analysis of API's and preparation of quality specifications standardized API's.
- Auditing the facilities for maintaining the international standard.
- Auditing the external party's facility as an external Auditor behalf of BSI.
- Documentation SOP's, Specification, ATR, AWR, BPR, MPR (Raw Material, packing material and Finished Product).

RECOGNITION

- Certified Lead Auditor form BSI
- PCQI qualified
- Headed QA/QC and Regulatory department.
- Core Team Member for SAP (PP,QM & MM Module)

PRESENT ORGANISATION

Apr'06 Onwards — **OmniActive Health Technologies Ltd.**

Growth Path

Apr'06 – Apr'08	**Sr. Executive QA & QC**
Apr'08 – Apr'10	**Asst. Manager QA & QC**
Apr'10 – Oct'14	**Manager QA & QC**
Oct'14 – April'20	**Sr. Manager QA & QC**
April'20 – June'24	**Director Quality**
June'24 – Till date	**Sr. Director Quality**

As Sr. Director Quality in OmniActive Health Technologies Ltd. *New (Bulk/ Formulations) manufacturing facilities in Pune (Hinjewadi) Biotech Park & Hosur.*

- Dietary ingredient and supplement manufacturer. Successfully completed 21 CFR Part 111 compliance, 117 compliance, BRCGS, cGMP, Kosher, Halal, GMO, RSPO, Organic Certifications. Also, all plants were inspected by USFDA. (From 04th April 2006 to till date).

PREVIOUS ORGANISATION SERVED

Mar'05 to Mar'06 QA Executive Aarti Industries Ltd.

Totally new API manufacturing facilities in Tarapur MIDC. Under Team Leadership, Aarti has successfully completed USFDA/ISO Certifications.

Jan'05 to Mar'05 Q.C Executive KDL Biotech Ltd.

A WHO-GMP Certified Company, also having USFDA Involved in Bulk Drug manufacturing.

Oct'04 to Jan'05 Q.C Officer IPCA Laboratories Ltd.

A WHO-GMP Certified Company, UK MCA, TGA Involved in tablet/capsule manufacturing.

Jan'00 to Oct'04 Q.C Chemist Calyx Chemicals & Pharmaceuticals Pvt. Ltd.

A WHO-GMP Certified Company, also having USFDA Involved in Bulk Drug manufacturing.

Sep'99 to Dec'99 Q.C Chemist Fredun Pharmaceuticals Ltd.

A WHO-GMP Certified Company, UK MCA, TGA Involved in tablet/capsule manufacturing.

HIGHLIGHTS

- Analysed and troubleshoot product quality issues:
  - → Checking the quality of the product, handling sophisticated instruments.
  - → Interpretation in all analytical instruments.
  - → Corrective actions for audit findings and complete in a timely and effective manner.
  - → Different site and tooling daily activity highlight to management,
  - → Effective systems are used for equipment qualification; maintenance and calibration of all instruments.
  - → Instrument calibration matrix
- Engaged in:
  - → Investigating & resolving product complaints with the help of Q.C team.
  - → Releasing or rejecting raw materials, packing materials & finished product.
  - → Co-ordinating with the production people and daily planning in Q.C. Lab.
  - → Vendor approval.
  - → Calibrating & maintaining the history of instruments as per written procedure.
  - → Reviewing & approve quality related documents.
  - → Interpretation and investigation of OOS (Out Of specification) & OOT (Out of trend).
- Supervised operation to ensure that internal audits are conducted on an on-going basis followed by continual improvement activities
  - → Educating the subordinates for GMP Laboratories activities & quality related area.
  - → Training the Q.C & Production person for GMP, safety and housekeeping.
  - → Evaluation and certification of the products
- Conducted Management Review meetings to handle:
  - → Market complaint.
  - → Change control, Deviation system, CAPA, review and approval.
  - → FDA liaising and all related activities.
- Was accountable for handling:
  - → Laboratory setup, Qualification and performance testing of all equipment.
  - → Equipment and instruments qualification (DQ, IQ, OQ, and PQ)
  - → Regulatory audits like ISO, WHO, USFDA, TGA, MHRA, KOSHER, HALAL and cGMP etc.
- Played a key role to initiate implementation of QMS.
- Involved in strategic planning to prepare AOP.
- Instrumental in presenting stability study as per ICH guidelines.
- Budget handling and Capex, Opex handling.

EDUCATION

◆ 2010	Master of Science in Chemistry (M Sc.)	Madhurai Kamaraj University	1st Class.
◆ 1999	Bachelor of Science in Chemistry (B Sc.)	Shivaji University Kolhapur	2nd Class.

IT SKILLS

- Diploma in Computer Office Automation from C-DAC in 1999 with 'A' Division.
- Working knowledge in MS Word, Excel, PowerPoint & C Programming.
- ERP Modules Operation: I) QCS II) PRD (Production and Planning) III) INV (Inventory) IV) SLS (Sales).
- SAP implementation (QM Module) Version: ECC (Enterprise Central Component) 6.
- LIM's, Track wise operation.

INSTRUMENTS

- HPLC operation makes Dionex, Agilent, Waters, Shimadzu.
- TOC operation makes Shimadzu.
- PH meter, Auto Titrator makes Lab India.
- ABBE'S Refractometer, Polarimeter makes Rajdhani Scientific Instruments/ Rudolf.
- Gas Chromatograph, Spectro Photometer makes Shimadzu.
- HSS makes Perkin Elmer, Shimadzu.
- Electronic Balance Sartorius.
- Conductivity meter, Melting point apparatus, UV cabinate & Bulk Density apparatus.
- Karl Fischer titrator makes Veego matic-D.
- Stability Chambers
- ICP MS
- LC MS
- GC MS

TRAININGS/ SEMINAR/ SUMMIT

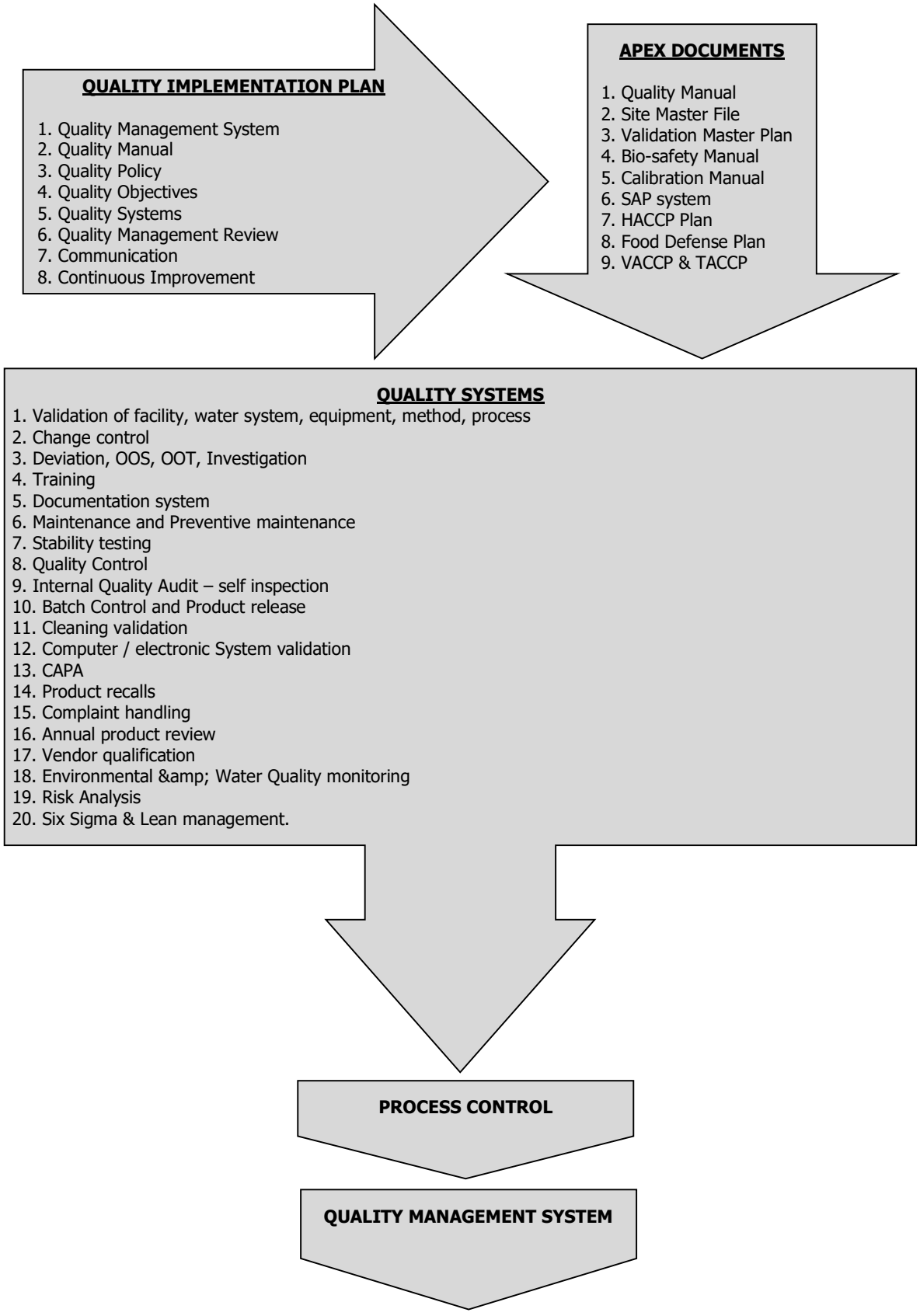
- ISO, cGMP Certificate training.
- Various seminars related to Instruments and Regulatory Affairs.
- USP ASM Summit.
- Provided various subject training related to Quality and regulatory to in house and other professional institutes.
- Completed Six Sigma training and projects on analytical variation reduction and yield improvement in beadlets manufacturing process.
- Training at NITIE (National Institute of Industrial Engineering) on "Managerial Skill of Technical Personnel".
- Attended Homi Mulla's training on RMP, MBR & MA (Related to business skill development).

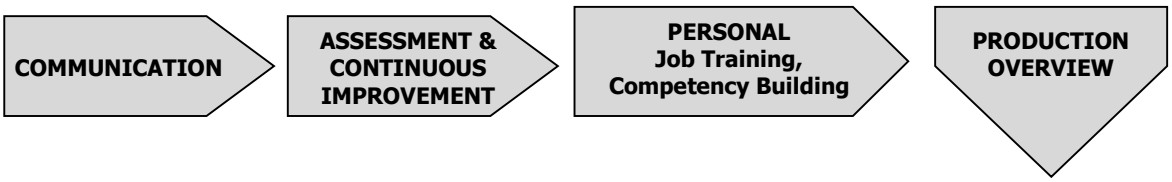
PERSONAL DETAILS

Date of Birth	09th September 1977.
Address	A/P: Chinchwad Tal: Haveli Sukhawani classic CHS, A-07, Near Talera Hospital. Dist : Pune. 411 033.
Passport No.	: T4412205
Nationality	: Indian

KNOWLEDGE COVERS

Established a bridge between R&D and GMP for smooth transfer of successful technology with the following QMS.





GENERAL GUIDELINES

Quality Manual	ISO 9001:2000 & WHO
Site Master File	TGA & PIC/S guidelines Schedule M of Drug; Cosmetics Act of India
Validation Master Plan	In-house (Based on Annex 15 and 18 EU guide to GMP)
Cleaning Validation	PIC/S and ICH Q7A
Area Qualification and Environmental Monitoring	Schedule M and Annex 1 EU Particle monitoring - ISO14644 Part-1 Personnel monitoring - USP
Facility Design	In-house (based on US-FDA; Schedule M)
cGMP (Drug Substance)	ICH Q7A (especially Chapter 18),
Food Ingredients and supplement Manufacturing	21 CFR 111 & 117
RM-PM Qualification	Schedule M, IP, BP, WHO-GMP, JECFA
Analytical Method Validation	ICH Q2 (R1)
Computer System Validation	Annex 11 EU

ICH GUIDELINES

Stability	Q5C, Q1A (R2), Q1D, Q1E, Q1F
Analytical	Method Validation Q2 (R1), Q2(R2)/Q14 EWG
Genetic Stability	Q5B
Specifications, test procedures & acceptance criteria for Biotech Products	Q6B
GMP for API	Q7
Quality Risk Management	Q9, Q9(R1) EWG
Pharmaceutical Quality System	Q10
Analytical procedure development	Q14, Q2(R2), Q14 EWG
Quality Management	ISO 9001:2008
Training	WHO-EDM Training Modules