Manish Bhatkar

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PHARMACEUTICAL INDUSTRY PROFESSIONAL & TECHNICAL/ GMP CONSULTANT

EXECUTIVE SUMMARY

- Tremendous Integrity, Foresight and Leadership Ability.
- An accomplished pharma professional with hands on experience in all technical aspects and functional area(s) related to pharmaceutical products manufacturing.
- Around 25 years comprehensive experience in:
  - Pharmaceutical technical operations, including **quality, manufacturing, conceptualization, designing, creation, qualification, validation and operation of world class pharmaceutical manufacturing facilities** for top ranking pharmaceutical organizations in India and abroad**.**
  - Handling all aspects of pharmaceutical operations management, including obtaining approval from the regulatory agencies, such as **USFDA, MHRA, TGA, etc**.
  - **Investigation, troubleshooting and resolution of complex technical problems** originating from the shop floor and / or from business environment.
  - Conceptualization, development, establishment, management and continuous improvement of **quality systems, such as quality policies, systems, procedures, guidelines** etc.
  - Development of a **high performing and sustainable team / organizations**.
  - Understanding and interpretation of **regulatory and GMP compliance rules, regulations and guidelines** for cost effective implementation within the organization.
  - **Technical consulting** to pharmaceutical industry for development and / or improvement of manufacturing facilities and quality systems.
  - Adopting, working and managing in **different cultures and geographies**.
  - Working with and under **consultants prominently known** in the pharmaceutical industry.
- Extensive experience and expertise in:
  - Handling all aspects of **management of manufacturing units**, including obtaining relevant licenses and approvals both Indian and US.
  - Structuring **production budget and judicious deployment of resources** to achieve max. operational efficiency.
  - **International manufacturing experience** (UK / US / Japan).
  - Providing input to the topmost management and influencing **capital investment and asset utilization decisions**.
  - Identification of potential **cost reduction** areas / ideas and implementation of plans.
  - Development of **business risk mitigation** strategies / plans and management.
  - Technical / commercial **negotiations** with vendor's / suppliers and technical agreements.
  - Preparing and leading the manufacturing organization for **regulatory / customer inspections, such as USFDA, MHRA, WHO, TGA, ANVISA, NIP, PMDA** etc. More than 50 inspections faced and managed.
  - **Resolution of regulatory issues**, such as **technical queries** on submission documents, GMP deficiencies, inspectional observations **(483's, warning letter)**.
  - Preparation and review of the **technical & / or regulatory submission documents**, such as **ANDA, DMF, regulatory submission dossier, changes, development / technology transfer / qualification / validation / batch manufacturing related documents.**
  - **Conceptualization, design, qualification and validation** of pharmaceutical products manufacturing equipment, facilities, processes and systems.
  - **Technical due diligence, inspection, assessment and audit** of products / brands / technologies for acquisition, contractors, suppliers, distributors and vendors.
  - Leading and management of complex **technology transfer projects**.

Creation of world class (USFDA/MHRA) facilities	New Product Development (Pharma /APIs)	Procurement
Regulatory exposure for EU, US, Japan	International Sales	Exports
Operations / Plant Management	Budgets / Strategic Planning	Logistic & Supply Chain
Production Planning / Scheduling	Liaison, Licenses, Approvals	Quality Assurance / QC / TQM

CAREER OVERVIEW

JEFF YUEN AND ASSOCIATES INC., USA	***Associate***, 2016 – Present
DR. REDDY'S LABORATORIES LIMITED, Hyderabad, India	***Head, Technical Services – Sterile Dosage Forms***, 2015–2016
DR. REDDY'S LABORATORIES LIMITED, Hyderabad, India	***Sr. Director, Formulation Technical Operations***, 2014–2015
ZYDUS CADILA, Ahmedabad (based at St. Louis, Mo., USA)	***VP, Technical Services***, 2012–2014
LUPIN LIMITED, Mumbai, India	***Sr. GM, Technical Services***, 2009–2012
DABUR PHARMA LTD. (NOW FKOL), Sahibabad, India	***Global Head, Quality,*** 2007–2009
DABUR ONCOLOGY PLC., Bordon, United Kingdom	***Production Manager & Site Head***, 2004–2008
PHARMAPLAN INDIA LTD., Delhi, India	***DGM, Validation & GMP Compliance***, 2000–2004
RANBAXY LABORATORIES LTD., Gurgaon, India	***Assistant Manager, Corporate QA***, 1999–2000
LUPIN LABORATORIES LIMITED, Mandideep, India	***Sr. Officer, Production***, 1992–1999

PROFESSIONAL DEVELOPMENT

- Completed several development programs in India, Germany, UK & USA in technical & regulatory developments, leadership development, team building, strategic planning, ISO 9001:2000 and train the trainer.
- Conducted technical workshops, addressed seminars and technical sessions at various pharmaceutical conferences and technical / professional development programs etc.
- Attended numerous international conferences, meetings, and seminars.
- Member of several professional bodies, ISPE, PDA and Indian Pharmaceutical Association.

PROFESSIONAL EXPERIENCE

REDLOTUS PHARMTECH PRIVATE LIMITED, INDIA
Founder & CEO

JEFF YUEN AND ASSOCIATES INC., USA
Sr. Associate Present

Providing consultancy, advisory and technical services in the following areas/ functions through RedLotus (A Technical Services Company):

- QA & GMP Compliance: (a) Quality Management System – Design & Effectiveness Reviews, (b) GMP Audits – Process Design, Review & Performing (Vendors, Suppliers, Service Providers, Mock Regulatory Inspections, Data Integrity, Sterility Assurance), (c) GMP Risk/ Gap – Analysis & Mitigation Plans, (d) Training – GMP Compliance, QMS, Data Integrity, Special – Sterility Assurance
- Regulatory: (a) Regulatory Filing Document – Preparation and Reviews, (b) Regulatory Compliance Issues – Response Strategy and Response Drafting/ Preparation/ Review, Issue Resolution Remediation Plan
- Technical Due Diligence: (a) Assessment of Client Identified Target – Organization, Facilities, Systems, Products, Processes and Resources for Capacities, Capabilities, Competence, Performance & Compliance with Current Regulations, (b) Gap Analysis – Identification of deficiencies and gaps in compliance and provision of remediation plans, (c) Assessment of Systems & Controls – Management Controls and Management Personnel Capabilities
- Qualification and Validation: (a) Development – Qualification Policies, Strategy, Validation Master Plan, Qualification & Validation Protocols & Reports, Sterility Assurance Plans, Cleaning Validation, Computer System Validation, Process Validation, Sterilization/ Bio- decontamination Process, Media Fill, Analytical Methods (Chemistry & Microbiology), (b) Reviews and Gap Analysis – Regulatory Compliance, Suitability & Adequacy, Sterility Assurance, Media Fills, Trend Analysis, Statistical Process Analysis, Annual Product Reviews, (c) Guidance & Training – Qualification & Validation, Sterility Assurance, Media Fills, Aseptic Manufacturing, (d) Investigations – Failures Investigation, Guidance, Reporting, Review and CAPA (product testing, stability, environmental monitoring, market complaints, sterility, media fill etc.) and Position Papers, (e) Execution
- Training: (a) General & Specific Training – GMP & Compliance, Qualification & Validation, Quality Management Systems, Continuous Process Improvement, Sterility Assurance, Sterilization Processes etc, (b) Custom Training – Depending upon the specific customer need.
- Design & Engineering: (a) Development – Conceptual Facility Design, User Requirement Specifications (Facility, Equipment & Critical Support Systems), Factory Acceptance Testing, Facility/ Equipment Maintenance Plan and Processes, Instrument Calibration Plan and Processes, (b) Reviews and Gap Analysis – Facility Design, Equipment & Critical Support System Design and Specifications, Facility/ Equipment Maintenance Plan and Processes, Instrument Calibration Plan and Processes.
- Mentoring & Advisory: (a) Manufacturing Philosophy and Strategies, (b) Strategic advisory and/ or mentor role, (c) Mentor teams/ chosen professionals to meet challenges of operations and business, (d) Consulting role in project overviews and management, (e) Providing strategies for setting-up pharmaceutical business right from concept to operation, (e) Operational excellence.

DR. REDDY'S LABORATORIES LIMITED, Hyderabad, India
Sr. Director & Head, Technical Services – Sterile Dosage Forms

(Reporting to Executive VP – Formulation Technical Operations, Team Size – 50) Sep 2015 – Aug 2016

Leading technical services team (sterile dosage forms) in; (a) technology absorption, (b) technology transfer, (c) conceptualization of industrial scale manufacturing process(s)/ equipment/ facility, (d) qualification and validation of; manufacturing process, support processes (like cleaning, sterilization, process simulation tests – media fills), equipment, facilities and critical support systems (like water system, environment, compressed gases), (e) continuous process verification, (f) product robustness monitoring and continuous improvement, (g) troubleshooting, (h) investigation and failure root cause analysis, (i) resolution of regulatory issues (like regulatory query response, inspectional observation response and remediation).

Key Achievements

- Resolution of FDA 483 critical observations as well as the warning letter for sterile dosage forms manufacturing facility FTO-7.
- Setting up of a robust technical services delivery organization and processes.

DR. REDDY'S LABORATORIES LIMITED, Hyderabad, India
Sr. Director, Formulation Technical Operations

(Reporting to Executive VP – Formulation Technical Operations, Team Size – approx. 800) June 2014 – Sep 2015

Providing capability and supply assurance to fulfil market requirements and ensure proactive planning for adequate volume and opportunistic leverage in the markets. Ensuring seamless linking of market requirements with operations through alignment of all critical aspects like Product Selection, Capacity Planning, Technology Absorption, Technology Selection, Capex, Supply Chain and Manufacturing.

Key Achievements

- Turning around the Baddi site operations with respect to productivity, efficiency improvement and CoPE reduction.

ZYDUS CADILA, Ahmedabad (based at St. Louis, Missouri, USA)
Vice President, Technical Services

(Reporting to President Quality, Team Size – 20) Jun. 2012 – May 2014

Leading & Supporting new acquisition [Nesher Pharmaceuticals (USA) LLC] in development, improvement and establishment of technical operations processes (Manufacturing, Engineering, Quality, Validations, Supply Chain, IT Systems etc.)

Key Achievements

- Detailed process mapping of more than 150 processes and gap analysis. This resulted in improvement with respect to efficiency, productivity, GMP compliance & simplification thus helping the consent decree remediation work.

LUPIN LIMITED, Mumbai
Sr. General Manager, Technical Services

(Reporting to President – Technical, Team size - 80) Nov. 2009 – May 2012

Play a key part (technical) in; (a) all acquisitions and expansion plans of overseas locations, (b) leading & coordination between multiple functions and sites located in different geographies to enable site transfer of existing products and launch of new products from Lupin to overseas locations and vice versa, (c) coordination and management of business risk mitigation plans, (d) development, establishment and management of corporate validation group & processes in the organization, (e) leading and driving cost reduction initiatives for Japan manufacturing facility, (f) Alternate vendor development programs – cost reduction, (g) providing support / guidance to the business development teams for identification and / or evaluation of technical aspects of a new / prospective business initiative / target, (h) working with manufacturing sites in resolution of complex quality related issues, (i) quality audits of prospective vendors / contractors.

Key Achievements

- Established functional organization for inter site technology transfers, particularly from Japan to India.
- Successfully completed technology transfer projects from Japan.
- Guiding the site to prepare for the Japan regulatory inspection (achieved first PMDA / MHLW approval).
- Successfully identified & implemented potential cost reduction areas for Japan manufacturing facility (circa 60 Mn JPY saving will be achieved in this FY).
- Completed technical due diligence for two potential large acquisition targets. One deal out of these two is already closed.
- Developed and established a high performing team and a sustainable technical services delivery system

DABUR PHARMA LTD., (NOW FRESENIUS KABI ONCOLOGY LIMITED), Delhi
Global Head, Corporate Quality

(Reporting to CEO, Team size – 150, multi location /global) Apr. 2007* – Nov. 2009

Responsible for; (a) establishing, improvising and leading the global quality (includes R&D, QA & QC) team, (b) quality and GMP compliance in all facilities at Baddi-DF (India), Kalyani-API (India), Bordan-DF (UK), contract manufacturer's-DF (India) and R&D, (c) development of quality metrics and reporting to key stakeholders, (d) conducting management reviews of process performance, product quality and pharmaceutical quality systems and escalation where necessary, (e) global quality resource and budget planning / management / control, (f) leading the quality council, (g) global vendor / contractor quality management, control & technical / quality agreements, (h) identification and implementation of ideas / areas for continuous process performance, product quality and quality systems improvement, (i) planning, organization and leading regulatory inspection / audits and resolution of inspectional observations, (j) identification, definition and setting of annual quality objectives for the organization (includes budget and performance).

Key Achievements

- Developed and implemented corporate quality structure, team, policies, guidelines, processes and systems.
- Obtained regulatory approvals (USFDA, MHRA, TGA, EDQM, ANVISA, NIP etc.) for Kalyani-API (India) Bordan-DF (UK) and Baddi-DF (2 units). More than 20 regulatory inspections / audits handled.
- Managing regulatory inspections and resolving inspectional & regulatory observations.
- Resolution of FDA warning letter for UK aseptic manufacturing facility.
- Conceptualized world class manufacturing facility at Baddi for advanced markets in Solid Oral and Sterile dosage forms – aseptically manufactured and lyophilized for cytotoxic, Oncology products with containment capability.
- Obtained several LRM approvals for the Baddi (old), Cytotoxic, Oncology products manufacturing facility.
- Created and Filed Drug Master Files (DMF) for Oncology API's.
- Automation of Quality Processes.
- Created Abbreviated New Drug Application (ANDA) and obtained approvals for Oncology drug products.
- Developed a highly effective and high performing corporate QA team.

DABUR ONCOLOGY PLC., Bordon, United Kingdom
Site Head & Production Manager

(Reporting to Global Head –Manufacturing, Team size – 120) Oct. 2004 – Jan. 2008*

Responsible for; (a) site operations management at Bordon, United Kingdom, the site is involved in the manufacturing of licensed and specials category oncology, cytotoxic products manufactured using aseptic manufacturing process, (b) production, quality, engineering, regulatory, HSE & GMP compliance, (c) supply chain, HR, general administration and site P&L, (d) technology transfer, new product registration and market launch, (e) vendor / contractor management, technical and commercial agreements, (f) site operations and capital expenditure budgets, (g) continuous process / product improvement and cost reduction, (h) leading site leadership team.

Key Achievements

- Streamlining site operations and complete site turnaround from a non-performer to a performer.
- Planning & execution of manpower redundancy plans (2 times reducing from 120 to 60 – resulting in 56% site operational budget reduction).
- Establishment of supply chain for US / Europe markets including products sourced from India (own & contracted sites).
- Technology transfers, new aseptically manufactured product introduction and product filing on time, including one para IV candidate.
- Resolution of complex technological problems resulting in product quality, process and profitability improvement (yield improvement by 28%).
- Obtained USFDA and MHRA approvals for the Bordon, UK, Cytotoxic, aseptically manufactured oncology drug products manufacturing site.
- Developed and established a highly effective and high performing team and a succession plan.

PHARMAPLAN INDIA LTD., Delhi, India
DGM, Projects

(Reporting to Director – Technical, Team size - 6) May 2000 – Sep. 2004

Responsible for; (a) developing conceptual engineering designs, (b) establishment, development & management of validation & GMP compliance business and team, (c) acquisition, management and closing of projects in validation & GMP compliance, conceptual designing, basic engineering, quality systems inspection, GMP audits and technical

* *Overlapping responsibility to cover the transition / succession plan for a period of about 8 months*

consulting, (d) participation in the business development / strategy meetings and development & implementation of plans, (e) internal compliance as per ISO 9001:2000 standards.

Key Achievements

- Establishment of validation & GMP compliance business (contributing almost 50% of the company turnover).
- Acquisition and completion of more than 20 validation / GMP compliance, GMP audits / mock inspections / quality systems inspection, consulting and concept designing projects for variety of pharmaceutical projects (Sterile/ Non-sterile DF, API, Biotechnology, Oncology).
- Development and implementation of project time and cost management system / software.
- Obtained ISO 9001:2000 approval.
- Key in establishing Pharmaplan as a brand in the pharmaceutical consulting space in India.
- Developed a highly effective and high performing team and a profitable validation & GMP compliance business.

RANBAXY LABORATORIES LTD., Gurgaon, India
Assistant Manager, CQA

(Reporting to Controller – CQA) May 1999 – May 2000

Responsible for; (a) GMP compliance audits of all Ranbaxy' and contract manufacturing sites in India and abroad, (b) review and approval of product development & technology transfer reports, (c) providing technical support and guidance to the manufacturing sites, (d) market complaint investigation, (e) SOP / process harmonization

Key Achievements

- Audited all key dosage forms manufacturing facilities (domestic and international, In-house and contract).
- Lead Ranbaxy Dewas site team to get first MHRA (formerly MCA) approval for the aseptically manufactured sterile formulation.
- Played key role in the standardization and harmonization of quality systems and processes across the organization.
- Reviewed and assessed product development report / technologies for site transfer.

LUPIN LABORATORIES LIMITED, Mandideep, India
Sr. Officer, Production

(Reporting to Plant Manager, Team size – 75) Jul. 1992 – Apr. 1999

Responsible for; (a) daily production planning, line supervision, packaging and dispatch activity of sterile (aseptic process) and solid oral dosage forms, (b) completion of batch manufacturing and packaging records, (c) deviation, non-compliances and complaints investigation and closure, (d) preparation of periodic production and inventory control reports, (e) preparation of plant operational and capital expenditure budgets, (f) GMP compliance in the plant, (g) handling GMP audits and resolution of inspectional observation and / or deficiencies, (h) plant human resources / personnel management, (i) development and executions of validation master plans and protocols, (j) Management of plant technical / utility services, (k) monitoring and control of process improvement and cost reduction projects.

Key Achievements

- Designing, Commissioning, Qualification & Validation of new facility for manufacturing of sterile formulations – aseptic process [first in Asia to get MHRA (MCA at that time) / USFDA approval].
- Start-up of oral solid dosage forms manufacturing facility.
- Qualification & Validation of sterile & oral solid dosage forms manufacturing facility and processes.

ACADEMIC / PROFESSIONAL QUALIFICATIONS

Department of Pharmaceutical Sciences, Nagpur University, Nagpur

Bachelor of Pharmacy, First Class 1990

Master of Pharmacy (Pharmacology), First Class 1992