

## **JAIRAJ (JAI) MEHTA**

### **SUMMARY**

Mr. Jai Mehta recently returned to JM Pharma, LLC, the consulting company he started ten years ago, and he is further building on it by adding development and testing services. He has been in the pharmaceutical industry for more than twenty years, and just left the management of Red River Pharma LLC, a development and manufacturing company he co founded along with the principals of JM Pharma's pharmaceutical marketing client company. He has had a successful consulting business and has held senior management positions at various pharmaceutical manufacturing firms. His responsibilities have included R&D, Clinical Research and Regulatory functions, with oversight of Quality and Validation disciplines as well. Mr. Mehta has filed and received numerous Drug (ANDA, IND and NDA) approvals from the FDA during his career in the industry.

Mr. Mehta has audited Active Pharmaceutical Ingredient (API), dosage form, repackaging, and clinical research facilities around the world for compliance to FDA's quality and compliance standards. Mr. Mehta's expertise encompasses product development, quality systems validation for bulk drugs and dosage forms which include sterile products including freeze-dried products, suspensions, solutions, and powders; oral solid immediate release and modified release products; and metered dose inhalers.

Mr. Mehta's regulatory expertise extends to U.S. FDA's cGMP, GLP, and GCP requirements for APIs, Clinical Research and finished dosage form manufacture, repackaging, development, and testing.

Mr. Mehta has a Bachelor's degree in Pharmacy and a Master's degree in Medicinal Chemistry from Bombay University and a Master's degree in Biopharmaceutics from the University of Illinois. He is a registered pharmacist in the states of Arizona and Illinois.

### **PHARMACEUTICAL INDUSTRY EXPERIENCE SUMMARY**

**EMPLOYMENT: JM PHARMA LLC – PHARMACEUTICAL CONSULTING,  
DEVELOPMENT AND TESTING COMPANY**  
Peoria, Arizona

**PART TIME - 1996 - 1998  
FULL TIME - 1998 – 2002  
FULL TIME 2005 - PRESENT**

#### **President**

JM Pharma provides technical and regulatory consulting to the pharmaceutical industry for the clinical research, dosage form and bulk drug industry. JM Pharma started up a development and analytical laboratory in 2005 as well. The areas of consulting include product development, Phase I – IV and BA/BE clinical research, API DMF development and filing, regulatory submissions, quality systems, facility audits, product, specifications and process upgrades, and batch certification. Outsourcing of product development and clinical research is also another area of business.

#### **Experience as a consultant:**

API, solid oral, repackaging, parenteral, Pen/Ceph facility audits  
Regulatory research ANDA Validity Assessment auditing, reconciliation of factual processes and practices with descriptions in the regulatory submissions.  
Alliance and joint venture development and management

Active membership of NAPM, NPA, and GPIA, GPHA scientific regulatory and clinical research committees

Presented training and educational seminars - day long workshops and presentations at own sponsored workshops, AAPS, NAPM, CBI, CHPA. Etc. sponsored events.

Outsource and manage product development  
Outsource and manage clinical research

EMPLOYMENT: RED RIVER PHARMA  
Shreveport, Louisiana

2002-2005

President, Founder, and Part Owner

Single handedly built from ground zero, with Mr. Mehta as employee #1, a development and manufacturing company for oral solids in partnership with marketing company, PamLab, LLC. A development and testing laboratory, housed in ~ 4,000 Sq. Ft. and a 20,000 Sq. Ft. manufacturing and packaging facility was developed over an eighteen months time, with a capacity to produce 500 million tablets, and employs 38 team members.

Experiences and Responsibilities at Red River Pharma:

Established development and quality control laboratory, quality and regulatory systems  
Designed, procured, and validated facilities, process and equipment for oral solids manufacturing and packaging.

Developed the infrastructure, and hired key employees including head of manufacturing, quality assurance, quality control, regulatory affairs, formulation, process and analytical development, human resources, and information technology staff totaling over 35 employees.  
Worked with local non-profit organizations, and Universities to develop educational and research programs, and took part in developing University research into viable business products as a member of advisory committees.

Successfully developed, validated and launched four new products in first year of commercialization.

Red River Pharma broke even at the end of its first full year of existence, and is on its way to be profitable in the second and subsequent years.

EMPLOYMENT: SIDMAK LABORATORIES, INC.  
East Hanover, New Jersey

1996 - 1998

Vice President, Regulatory Affairs

Responsible for compliance and submissions and other interactions with FDA on behalf of the company. Dosage forms included IR and MR solid oral capsules and tablets; metered dose inhalers; Ophthalmics - solutions, suspensions and ointments; and unit blistered dose packages. Jointly responsible for quality systems, process validation, cleaning validation, and clinical research management.

Experiences and Responsibilities at Sidmak:

Reduced the approval times of ANDA's below one year by overhauling approaches to specifications, and manufacturing parameters and controls. The format of the submissions was fine-tuned to be as reviewer friendly as possible.

Enhanced the quality conscious image of the company within the organization, and with the FDA.

Established clinical study monitoring programs, and enhanced overall clinical research management.

ANDA auditing- reconciliation of factual processes and practices against descriptions in the regulatory submissions.

**EMPLOYMENT: AKORN, INC.** 1991 - 1996  
(DBA- Taylor Pharmaceutical), Decatur, Illinois

Vice President, R & D and Regulatory Affairs 1994 - 1996  
Director, Research and Development 1991 - 1994

Responsible for product and process development, analytical development, stability, GMP compliance, defending all FDA inspections, all licensing, U.S. and international registration application submissions, process validation and quality systems.

**Experiences and Responsibilities at Akorn:**

Developed research and development and regulatory affairs programs from ground up - building laboratory and office areas, acquisition of instrumentation, hiring staff, etc.

Audit and assist foreign and domestic bulk drug substance manufacturers for their DMF approval, and FDA inspection.

Ophthalmic product and process development, process validation, technology transfer to production and QA/QC departments, analytical methods development and validation, R & D and commercial stability, ANDA, IND and NDA filing, labeling development, GLP maintenance, training and continuing education programs development.

Defend U.S. FDA's GMP and Pre-Approval Inspections of the sterile ophthalmic and injectables manufacturing facility.

Component sourcing and specifications; bulk drug substance and excipient sourcing and specifications; Developed other quality systems including finished product specifications; annual product review; documentation change control; container closure integrity testing, etc.

Interacted with FDA and trade associations like NAPM and GPIA to stay current with regulatory requirements.

**EMPLOYMENT: STERIS LABORATORIES** 1988 - 1991  
(Subsidiary of Schein Pharmaceuticals, Inc.)  
Phoenix, Arizona

Manager, Research and Development 1990 - 1991  
Manager, Sterile Product Development 1988 - 1990

Responsible for all four groups of R & D - Formulation Development, Analytical Development, R & D Products Support Services, and Pharmaceutical Technology.

**Experiences and Responsibilities at Steris Laboratories:**

Developed generic injectable, ophthalmic and otic products. Presentations included solutions, suspensions, lyophilized products in serum vials, plastic bottles, two compartment vials, and syringes.

Enhanced GLP's in the R & D laboratory to meet increased scrutiny of the FDA, and introduced standardized approaches to product development.

Developed testing methodologies for a metered dose inhaler product in conjunction with the manufacturer of the delivery system.

Improved existing products, especially suspension and freeze-dried products.

Jointly responsible for annual review of all products and resultant investigations and corrective actions.

**EMPLOYMENT: LYPHOMED, INC.** 1984 - 1988  
Melrose Park, Illinois

Section Head, Formulation Development 1986 - 1988  
Group Leader, Formulation Development 1985 - 1986  
Scientist II, Research and Development 1984 - 1985

Developed formulations and processes for all company facilities for injectable products, including solution, micro emulsion, and lyophilized products.

**Experiences and Responsibilities at LyphoMed:**

Developed solution and lyophilized injectable generic, orphan and proprietary products.

Developed medical devices working with device manufacturer.

***EDUCATION SUMMARY:***

M.S. in Pharmacy (Biopharmaceutics), 1984 - University of Illinois

M.S. in Pharmacy (Medicinal Chemistry), 1980 - University of Bombay, India.

Bachelor of Pharmacy, 1977 - University of Bombay, India.

***LICENSURE:***

Registered Pharmacist in Illinois and Arizona