



Dr. G. L. Jain

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Summary

- Well qualified with 32 Years of experience (2 years in chemical industry, 17 years in Biomedical Engineering, 9 years in Pharmaceutical/Medical Device industry and 4 years as consultant).
- Areas of Expertise:
 - Regulatory Affairs
 - Quality Assurance & Good Manufacturing Practices
 - Personnel and Training
 - Operations and Quality Management
 - Building Designs and Manufacturing setups
- Well versed with academia-industry-regulatory relationship
- Has high teaching, management, planning, organizing and leadership capabilities
- Was with USFDA for two months for training on various aspects of GMP/PMA/NDA and inspection
- Has been associated with Drugs Controllerate, India, in formulating GMP and inspection of manufacturing facilities and drafting Medical Device Regulation

Educational Qualification

- Ph. D. (Biomedical Engineering) 1987, IIT New Delhi
- M. Sc. Chemistry, 1976, University of Rajasthan, Jaipur

Consultancy & Training Projects

- **CONSULTANT to companies like:**

- Pharmaceutical Companies**

- PRESENT**

- GE Healthcare, UK & Bangalore
 - Yash Pharma, Roorkee
 - Unicure Pharma, Roorkee
 - Sahajanand Laser Technologies, Ahmedabad
 - IDPL, Gurgaon & Hyderabad
 - Goel Homoeo Pharma, Chittorgarh

- PAST**

- Retort Laboratories, Chennai (2005-06)
 - Western Drugs Pvt. Ltd, Udaipur (2004-06)
 - Cadila Pharma, Ahmedabad (1991-92);
 - Hindustan Latex Limited (1991-94);

- Medical Device Companies**

- PRESENT**

- Sahajanand Laser Technology, Ahmedabad

- PAST**

- Famy Care Ltd, Pune & Daman; (1995-97)
 - I.R. Surgicals, Hyderabad (2006-07)
 - Iscon Surgicals Ltd., Jodhpur (2007)

- Laboratories**

- PRK Pharmanalyst, Hyderabad
 - Central Institute of Plastic Engineering & Technology

- **IN-PLANT TRAINING COURSES:**

- Zydus Cadila Healthcare, Ahmedabad
 - Zydus Healthcare, East Sikkim
 - Alkem Laboratories, Daman (3Batches= Approx 80 Trainees)
 - GE Healthcare, Bangalore
 - USV Ltd., Baddi

- Akums Drugs & Pharmaceuticals, Haridwar
- Micro Lab, Bangalore
- Ahlcon Parenterals (India) Ltd., Bhiwadi
- True Pack, Bangalore
- Conducting WHO-GMP/QA Training Courses for last 20 years

Awards Received

- Gold Medal for standing first class first in M. Sc. Chemistry, University of Rajasthan, India
- National Research Development Corporation (NRDC) Republic Day 1990 Award for Invention
- National Technology Award 1990 for best invention for the handicapped by the Ministry of Welfare, Govt. of India
- President Rover Award 1972 by President of India
- President Scout Award 1969 by President of India

Professional Memberships

- Life Member & Ex-General Secretary: Society for Biomaterial & Artificial Organ (India)
- Life Member : Bio-Medical Engineering Society of India
- Life Member : Indian Pharmaceutical Association
- Member : Sub-Committee on IUD's & Tubal Ring :Task Force on the review of the Quality of Contraceptives : Ministry of Health & Family Welfare (MOH&FW), New Delhi
- Member: Expert Committee on Medical Device Regulation, MOH&FW, New Delhi.
- Member : MHD 3, Section Committee of Bureau of Indian Standards
- On panel of Circle of Experts, Evalueserve
- CDSCO Expert : For Audit of Pharmaceutical Manufacturing Units under NCB & ICB project

Professional Experience

TOTAL : 32 YEARS

Centre for Active Learning, Guidance & Solutions, Udaipur

Pharma & Medical Device Industries Training & Consultancy

April 2000-2006

Director, Corporate Channels India Pvt. Ltd. Udaipur, India : A Drug Manufacturing Company

Sept 97-March 2000

Vice-President (Operations), Famy Care Ltd. Goa, India

- Nature of Job : To independently run a drug plant with an annual capacity of more than 7 million Copper T 200B/380A production and having more than 70 employees

Sept 95-Sept 97

- Technical Consultant for Contraceptive Devices, medical devices, ISO 9000,
Nature of job : To provide consultancy in developing systems for ISO/GMP in medical device and drug industry.

Sept 1978- Sept 1995

Principal Scientific Officer Sr. Sc. Officer-I Sr. Sc. Officer-II
(Feb. 92 to Sept..95) (Dec.83 to Feb.92) (Sept.78 to Dec.83)

at Center for Biomedical Engineering
Indian Institute of Technology (IIT), New Delhi, India

- Nature of Job:
RESEARCH and DEVELOPMENT
 - Synthesis & Characterization of polymers.
 - Aids for the Handicapped.
 - Reproduction Bio-Engineering.
 - Equipment for Mass Health Care.
 - Expert system for Medical Devices.QUALITY ASSURANCE
 - Establishment of test facility.
 - Review of existing test Protocols / Methods and formulation of new Protocols/Methods of testing.
 - Test and Evaluation of Medical Devices.
 - QA/GMP/QC Training to manufacturers/regulatory agencies and users of medical devices
 - On-site training courses on QA/GMP/QC.

Sept 76 - Sept 78

Foreman, Shriram Chemical Industries, Kota, India

Additional Professional Activities

SIGNIFICANT CONTRIBUTION TO RESEARCH & DEVELOPMENT

Research and Development has primarily been focused on Reproductive Bio-Engineering, Rehabilitation Engineering and Medical Devices. The title are given below :

- Braille Duplication Sheet, Braille Duplication Machine
- Self Eye Testing Aid, - Artificial Cornea
- Evaluation of Temperature Sensation in Leprosy Patients
- Reduction of peripheral sensory threshold level
- In-vitro Fertilization-Embryo Transfer Set
- Portable weighing machine
- Tarnishing of Copper wire in Copper Ts- Problem and its solution
- New improved intra-uterine contraceptive device

TECHNICAL VISITS

• Copper T manufacturers

Population Council Licensees:

- Finishing Enterprises, USA
- Leiras Pharmaceuticals, Finland
- Ortho Pharmaceuticals, Canada

Others

- Famy Care Ltd., Goa & Daman, India
- Contech Devices, NOIDA, India
- SMB Corporation, Mumbai, India
- Hindustan Latex Limited, Trivandrum, India

• Tubal Ring manufacturers

- Cabot Medical Inc. (Kli) Philadelphia, USA
- Corporate Channels India Pvt. Ltd., Udaipur, India
- Famy Care Ltd., Daman, India
- Pregna International, Pune, India
- Surgiwear Ltd., Shahjahanpur, India

• Medical Device Manufacturers

- West Co., Philadelphia, USA
- DuPont, Philadelphia, USA
- 3 M Sarns, Detroit, USA
- Gabriel Sciences, Detroit, USA
- DIFCO, Detroit, USA
- Medical Research Lab, Chicago, USA

- **Sterilization facilities**
 - Medical Sterilization Inc., New York, USA (EtO, Gamma, EB, Steam)
 - Isomedics, New Jersey, USA
 - Johnson & Johnson, New Jersey, USA
 - ISOMED, Mumbai, India
 - Sterilization Technical Services, Rochester, USA
 - SRI for Industrial Research, New Delhi, India

- **Test Laboratories**
 - U.S. Testing Lab., New York, USA
 - Underwriters Lab, Chicago, USA
 - Sterilization Technical Services, Rochester, USA
 - Nelson Laboratory Inc., Utah, USA
 - Utah Biomedical Test laboratory, Utah, USA
 - FDA laboratories at Washington DC, Boston, USA
 - BSI labs. at Milton Keynes and Hemel Hempstead, UK

- **Regulatory and Funding agencies**
 - Food & Drugs Administration, USA
 - British Standard Institution, UK
 - Health & Welfare Canada, Ontario, Canada
 - GPA, World Health Organization, Geneva
 - National Medicines Control Organization, Finland
 - European Community for Standardization, Brussels
 - U N Population Funds (UNFPA), New York
 - The Population Council, New York, USA
 - Program for Appropriate Technology in Health (PATH & PIACT), Seattle, USA

Scientific Reports & Documents

For Ministry of Health & Family Welfare, Govt. of India

- Test Protocol for Copper T 200 B
- Test protocol for Tubal Occlusion Ring
- Assessment of Medical Device Industry in India
- Procedure for Condemnation of Laparoscope
- Technical Aspects of Copper T, Tubal Ring and MTP Suction Apparatus
- Sterilization of Copper T 200 B
- Draft Medical Device Regulation

For Bureau of Indian Standards

- Draft `Specification of Contraceptive Device – Tubal Ring (Now known as Indian Standard IS 13009 (1990)
- Draft `specification of Braille Duplication Sheet' (Now known as Indian Standard IS 13822 (1993)
- Draft `Specification of Braille Duplication Machine (Now known as Indian Standard IS 13837 (1993)

Organization of Workshops/ Training Courses

- Client-site Training Programs conducted on : Good Manufacturing Practices
- Coordinator, Medical Device Programme, WHO sponsored Workshop organized by CDSCO, New Delhi, Sept. 16-21, 2002
- First Regional Conference of IEEE EMBS & 14th Biomedical Engineering Society of India, New Delhi 1995
- International Conference on Life Style and Health, New Delhi 1995
- VII National Conference of Society for Biomaterials & Artificial Organs (India) New Delhi 1994
- Indian Pharmaceutical Congress, New Delhi 1993

Publications & Presentations

- **42 publications in National and International Journals**
- **TALKS/LECTURES DELIVERED**

Invited talks (48) at Training Programme under Capacity Building Project, organized by National Institute of Pharmaceutical Education and Research (**NIPER**), S.A.S. Nagar (Chandigarh), India on topics like

- Clean room concepts
- Sanitation & Hygiene
- QC: Facility, Environmental Condition, Health & Safety.
- GLP : Implementation and Non-compliances
- Clean Room Concepts in Microbiological Testing.
- Implementation of Revised Schedule `M' - Issues.
- HVAC System.
- Regulation of Medical Devices
- Personnel & Training
- Documentation, Raw Data, Archival
- Self Inspection & Internal Audit