

LALIT VAYA

EDUCATION

MD & DPM (psychiatry) 1979

K M School of Post-graduate Medicine & Research and VS Hospital, Ahmadabad, Gujarat.

MBBS:1972

RNT Medical College, Udaipur, Rajasthan.

PROFESSIONAL SKILLS

- Regulatory submissions, making presentations and defending the same for:
 - ❖ getting approval for clinical trials in India (IND)
 - ❖ getting permission for manufacturing and marketing in India (MMA)
- End to End Clinical Trial management
- Plan and execute product launch and promotional strategy
- Teaching subjects related to Pharmaceutical industry.
- Clinical Trial Protocol writing.
- Clinical Trial monitoring and GCP audit.

PROFESSIONAL EXPERIENCE

October 2012 onwards:

- Consultant in Clinical Research & Regulatory Affairs. Monitoring and Audit of clinical studies, Regulatory Liaisoning, GCP Training and technical inputs for promotional literature.
- Practicing Psychiatrist

October 2011 to October 2012:

- Chief Clinical Research Course Coordinator, Apollo Hospital Education & Research Foundation, Ahmedabad. Gujarat. India
- Consultant in Clinical Research & Regulatory Affairs. Audit of clinical studies being conducted for submissions to USFDA, EMEA and Canadian Regulatory Agency.
- Regulatory Liaisoning: submission to DCG-India for approval for IND and NDA and defending the same.
- Protocol writing
- Site Selection
- Trial Initiation, Monitoring, Audit and Close-out related Activities
- GCP Training

October 2008 to October 2009

- Pharmaceutical consultant
- Visiting faculty in Clinical Research and Clinical Pharmacology at Nirma University Pharmacy Institutes, expert on the board to conduct interviews for staff selection and expert on the panel for evaluation of Doctoral work.
- Campus Head as Principal (Ahmadabad campus), Institute of clinical Research India, (ICRI) Affiliated to Crenfield University, UK.
- Member, Curriculum Planning Committee of M S University, Vadodara, India for MSc in Biostatistics in Clinical Research.
- Establishment of Institutional Review Board and conduct of the proceedings at Sarvajanic College of Pharmacy, Mahesana, Gujarat, India
- Practicing Psychiatrist.

October 1994 to July 2008

Torrent Pharmaceutical Ltd at Torrent Research Centre.

Asst. General Manager and later General Manager--Clinical Research & Regulatory Affairs:

- **Introduction of new drugs:** Planned and supervised more than 50 Products across the therapeutic segments. The function involves getting Manufacturing permission and launch of the product. This requires sourcing of API to regulatory submission at various stages for Manufacturing permission and defending the same during the presentation before Drugs Controller General of India (DCG-I) for introduction of a new drug in India in all therapeutic categories and formulations i.e. Immediate Release and Modified Release. The team had 35+ members comprising of PGs in Pharmacology and Medicine, Pharmacists, Nursing and other disciplines for carrying out operations of a 30 bed BA/BE center.
 - Planned and supervised the execution of more than 40 Phase III Clinical Trials and an equal number of Post Marketing Surveillance studies for MAA submission in India and 100+ bio-equivalence studies for submission in India and abroad in all therapeutic segments.
 - Planned and conducted more than 200 new-product launch symposia. Assisted marketing in Planning product launch strategy including preparation of Visual Aid and Leave Behinds. Extensively interacted with Key Opinion Leaders.
 - **Audited CROs in UK, initiated and monitored first phase-I clinical trial of Torrent's NCE TRC4186. This was followed by similar exercise in India**
 - Established Institutional Review Committee at Torrent Pharmaceuticals Research Centre in 1997.
 - **Successfully organized and coordinated first ever audit of Clinical Pharmacokinetics Unit at Torrent Research Centre in 2003 by ANVISA, Brazil.**
 - Planned, initiated and monitored clinical trial of a contraceptive in China.
 - **Audited CROs for outsourcing Bio-equivalence studies in India, Eastern & Western Europe.**
 - Participated in the development of the Investigator Brochure and protocol for the phase-II trial of TRC4186
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POSITIONS & MEMBERSHIPS

- Founder member & Steering committee member of Forum for The Ethical Review Committees of India (FERCI) under the aegis of Indian Council of Medical Research (ICMR). Developed SOPs for Ethical review for FERCI.
- Worked with ICMR Committee on Clinical Trial Registry-India
- Life fellow of Indian Psychiatric Society
- Life fellow of Indian Association of Private Psychiatry
- Chairman CME committee and Award committee of Indian Psychiatric Society-Western Zonal branch.
- Exe. Committee member. Indian Psychiatric Society-Western Zonal branch.
- President for two terms 1981-82, 1982-83, & 1988-89 and General Secretary of Gujarat State branch of Indian Psychiatric Society.