



PRADEEP TYAGI

Senior Consultant, Regulatory Affairs

EXPERIENCE:

- Independent Consultant for Regulatory Affairs, Emergo (India) Consulting Private Limited - 1998 to present
- Regulatory Manager - Business Relations, Sun Pharmaceutical – 1987 to 1998

AREAS OF EXPERTISE:

Devices and Drugs:

- Drugs - all therapeutic Areas
- Diagnostics - Critical and Non-Critical
- Medical devices - Stents/DES/Heart valves/Cardiac Occluders/Intra ocular lenses/Orthopedic Implants/Dental Implants/Catheters/delivery systems/Bone cements/Sutures, etc.

Disciplines:

- Product registration of drugs and devices in India
- Compliance with Indian Drugs and Cosmetics Regulations as per Drugs and Cosmetics Act
- Approval for Drugs for Marketing in India (In all the Therapeutic Areas)(Form-45/46)
- Import of Drugs/Diagnostics/Medical Devices in India (Form-41 and Form-10)
- Approval for Global Clinical trial and Registration trial in India for Drugs and Medical devices
- Import of small quantity of Drugs for R&D purpose and for Personal use
- Approval for recombinant products/vaccines for marketing in India (Derbapoitein/Pegfilgrastim/insulin/Human Growth Hormone/Hepatitis-b vaccine)
- Interactions and meetings with DCG(I)

EDUCATION:

- B.Sc., Delhi University, India