



Seema Dutt

Consultant, Regulatory Affairs

EXPERIENCE:

- Independent Regulatory Consultant India – 2011 to Present
- Manager, Regulatory Affairs - Bausch & Lomb Eyecare (India) Pvt. Ltd. – 2008 to 2011
- Executive, Regulatory Affairs – Johnson & Johnson Medical India - 2003 to 2006
- Executive, Regulatory & Scientific Affairs – Pharmacia India Pvt. Ltd. - 2000 to 2003
- Executive, Scientific Information - 1997 to 2000

AREAS OF EXPERTISE:

Devices:

- Ophthalmic devices
- Cardiovascular devices
- Orthopedic devices
- Wound care products and sutures
- Blood glucose monitoring devices

Drugs:

- Ophthalmic formulations
- Anti-cancer agents
- Anti-microbial and anti-inflammatory agents
- Human growth hormone
- Male & Female health products
- Vaccines
- Herbal formulations

Disciplines:

- Drugs & Cosmetic Act and Rules, India
- Site & Product Registration and Import licence applications for India
- Post Marketing Surveillance activities
- Regulatory & Quality compliance in warehousing and distribution
- Good Clinical Practices and ISO standards related to clinical trials with drug/device

EDUCATION:

- M. Pharmacy in Pharmaceutics, Mumbai University, Mumbai, India
- B. Pharmacy, S.N.D.T. University, Mumbai, India

PUBLICATIONS AND PRESENTATIONS:

- Dhaon BK, Singh OP, Gupta SP, Sharma DR and Bhutani S. Efficacy and safety of nimesulide transdermal gel versus Diclofenac and Piroxicam gel in patients with acute musculoskeletal condition. Indian Journal of Orthopaedics, 2000;34(4):288 - 292.
- Dhaon BK, Farooque MF, Sharma DR & Bhutani S. Open labelled clinical evaluation of local application of nimesulide transdermal gel in painful musculoskeletal conditions. Indian Journal of Orthopaedics, Apr 1998, 32(2): 75-78.