



Priya Jambhekar

Regulatory / Quality, Clinical Operations

Summary. Drug development entrepreneur with extensive executive experience in Worldwide Regulatory, Quality, Clinical and Pharmacovigilance operations and at early and late stage development; product registration and commercial support. Areas of experience and expertise include:

- Managing Early Stage Companies
- GCP, GLP and GMP Quality Compliance
- Global Regulatory Strategy, Compliance and Operations
- Project Planning and Management
- Pharmacovigilance Operations and Reporting
- Clinical Trial and CRO Management
- Health Authority Interactions
- Business Development

Professional Experience

Accellent Partners
2015-present

PBS Regulatory Consulting Group LLC
Managing Director/President: 2007 – Present
Regulatory, Quality, Clinical Operations

Paramount Biosciences LLC
Sr. VP, Regulatory, Quality: 2006-2008

Alkermes Plc
Worldwide VP Regulatory, Government Relations: 2004 - 2006

Ethicon Inc.
Worldwide VP Regulatory: 2003 - 2004
Quality

Baxter Inc. (Anesthesia and Critical Care Group)
Head of Regulatory: 1996 – 2003

Bristol Myers Squibb Inc.
Manager Regulatory, Safety, Compliance: 1993-1996; 1988-1990

Block Drugs (GSK)
Manager Regulatory & Compliance: 1990-1993

Education/Certification

BSc, Karnatak University, India

M.Sc, Shivaji University, India

MS, St. John's University

RAC, Compliance Quality Certifications

Drug Development and Regulatory Experience

- Managed global Regulatory and Quality organizations in drugs, devices and biologics for small, medium and large size corporations
- Extensive experience working globally with health authorities including US, EU, Japan, China, ASEAN region, BRIC, Lat Am region, South Africa for early / late stage development, marketing approvals and post approval support
- Clinical trial operation management and Clinical trial supply management
- Sourcing and supply chain management for start ups
- Lectures on numerous regulatory topics at many professional organizations, including DIA and RAPS