SPECTRUM PHARMATECH CONSULTANTS PVT. LTD.

raaj GPRAC Global Pharma Regulatory Affair Consultants

# PHARMA COUNSELING

## WHO SHOULD ATTEND ?

- B.Pharm
- M.Pharm
- B.Sc
- M.Sc
- Biotech
- B.Tech
- M.Tech
- Ph.D

Free Registration
Date : 15th October 2016
Venue : VES_Vivekanand College, Chembur.

## AGENDA

- ✓ **Pharmaceutical Industry, Current Scenario**
- ✓ **Understanding the opportunities available in the Pharmaceutical industry**
- ✓ **Importance of industrial job oriented courses like RA/QA/ Pharmacovigilance /Clinical Research/Patents Law/Medical writing/Pharmaceutical Management/Pharmaceutical documentation**

# Rajashri Survase-Ojha

**Mrs. Rajashri Survase-Ojha** is a senior RA professional, GMP consultant and Auditor and has over 25+ years of very versatile experience in pharmaceutical industry, starting her career **FROM Scientist** in R & D, Analytical & Formulation, QA-QM, till GLOBAL regulatory Affairs. Expertise in getting marketing approvals of Generics, **DRUG SUBSTANCE/DRUG PRODUCTS/medical devises/Neutraceuticals across the Globe.**

-**Rajashri is the FOUNDER and MD in Raaj GPRAC ['Raaj Global Pharma Regulatory Affairs Consultants] Thane-Mumbai since 2010 and completed 6 successful years as women Entrepreneurship and 20years in Pharma Industry.**

-She brings with her more than 2 decades of rich experience working for leading organizations like **SPECTRUM**,**COGNIZANT, Raaj GPRAC, FAMYCARE , NOVARTIS, GSK-TCS, GLENMARK, SANDOZ, Ciba-Geigy, UNICHEM Laboratories and LOCAL FDA, Bandra.**

She is **RAPS** qualified and also hold PG Diploma in Intellectual Property rights (IPR), Pharma Quality Management and is a Regulatory Submission expert of **CTD/eCTD/ACTD/NeeS formats**. She has **TRAIN the TRAINER**, **Six Sigma Green belt,** 7 habits of most effective people and Cornerstone leadership certifications.

-She has published more than 15 Articles and Research papers in reputed journals.

-She has Trained more than 6500 candidates till now on various aspects of **GLOBAL Regulatory Affairs [API/Formulations], Country-specific Submissions(USFDA, EMA, ASEAN, CIS, MHRA, ROW), Quality Assurance & COMPLIANCE, 21CFR PARTS, Clinical Research, Pharmacovigilance, Patents, Pharma Documentation and Pharma Management etc in Pharma industry.**

-Hands on expertise in Regulatory Affairs(RA) and 'Regulatory Intelligence'(RI) and setting up of new business process and operations of 'Regulatory Affairs' and 'Regulatory Information Management (RIM)' and Training centres across the globe.

-Competent, diligent & result oriented professional experienced in Strategic Management, New Organizational Set-ups, Project Management, Resource Management, Compliance Management , Regulatory Submission Management across the globe.

-Significant experience in Registration, Liasoning and marketing Approvals of pharmaceutical **Drug substance and Drug Products**.

-Handled submissions of **DMF/CEP/COS/ASMF, IND/CTA/IMPD/NDA/ANDA/ANDs/MAA** to different National & International Health Authorities. **Supported Regulatory Audits for USFDA, UK-MHRA, EdQM, TGA, SFDA, TFDA, MHLW, WHO and other local Health Authorities.** Project & Quality Management System within System Development Life Cycle (SDLC)

-**Computer Systems Validation(CSV)and FDA 21 CFR Part 11 adherence for all GxP Application, Eu Annex11, GAMP-5 etc.**

**-Quality and Compliance Assurance, DATA Integrity**

-She is also associated with many leading education institutes/colleges in India as a **'Guest faculty'.**

-She is a Visiting faculty Adjunct Professor at JSS University, NIPER, IIHMR, KLE,BCP,JJTU, MET, IIPM etc.

-**She is a member of IPA, DIA, IDMA, RAPS, TOPRA, OMICS, FIP, UBM, Global Compliance Panel, IMS, IBC, MARCEPS and Chaired many scientific sessions organized for National and International Conferences.**