

Institute of Pharmaceutical Management
'Escalating efficiency of pharma aspirants'



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Institute of Pharmaceutical Management [IPM] - an autonomous training institute established in 2007.

Services offered

Training programmes

GMP compliance

Regulatory consultancy

Founder members & designations:

Ms. Anagha Maharao- Managing director

Ms. Sheetal Mohidekar- Business development manager

Mr. Vidyesh Maharao- Director: Administration

Our motto '**Escalating efficiency of pharma aspirants**'

12th year of excellence in training and consultancy

Accomplishments-Training

- Conducting Regulatory Affairs courses at Borivali, Dombivli and Vashi
- Completed 58 Regulatory affairs batches
- About 4000 enrolments
- National and international enrollments from Spain, New York, UK, Japan South Africa, Vietnam, Oman, Dubai, Bangladesh, Johannesburg, Australia
- Participants are directors, consultants, corporate heads, general managers, team leaders, executives, officers and fresh graduates/post-graduates
- Students placed in renowned companies after course completion
- In-house training for company employees in various organizations and seminars involving candidates from multiple organizations [details on page 10]

Accomplishments- Consultancy

- Currently handling assignments involving updation of GMP and RA documents in various organizations in Mumbai, Patalganga, Surat, Pune and Nashik
- Audited US, Chinese and Indians organization to evaluate Quality System
- Advice on improvement of SOPs and data
- Filed DMFs and Dossiers with various regulatory agencies
- Helped companies in getting regulatory approvals
- Successfully restored CEP of Indian company`
- Reviewed revision/renewal applications for Europe and got approval

Mrs. Anagha Maharao – Founder & Managing Director



Qualification – M.Sc. Organic Chemistry, University of Mumbai

Professional experience - 30 years in QC, QA and RA of API and formulation companies

Present Profile

- Managing Director & Principal trainer at Institute of Pharmaceutical Management for QC, QA and RA courses since 2007
- GMP and RA Consultant to renowned pharmaceutical organizations for 10 years

Accomplishments

- Audited US, Indian and Chinese organizations to evaluate Quality System as per GMP guidelines
- Audited API, intermediate, starting material vendors and warehouse facilities
- Assisted pharma companies for facing regulatory inspections (EDQM, USFDA, WHO Geneva)
- Given guidance on DMF submissions to USFDA, EDQM, Health Canada, WHO etc
- Trained over 4000 pharma professionals on regulatory and GMP aspects
- Conducted seminars on 'Current regulatory requirements of DMF'
- Conducted 10 days regulatory affairs course at Astra-Zeneca, Bangalore
- Conducted training sessions on GMP, impurities, genotoxicity, PQR, change control, stability studies, good documentation, ICH Q11 etc in various organizations
- Felicitated on the eve of National conference on 'Women Entrepreneur of 21st Century: Trends and developments organized by University of Mumbai on 20th-21st November'09
- Published Indian patent (2006-06-16) on "Improved process for Zopiclone synthesis".
- Presented paper on "Studies on the application of hydrotropes as solvent media for some organic reactions" at ICCE 2005, Indore.
- Attended conventions like CPhI at Frankfurt, Paris & Spain and Informex at USA

Training programmes

- **Types**

- Classroom training at IPM locations – Dombivli, Borivali & Vashi
- Distance learning
- In-house training for company employees
- Seminars involving candidates from multiple organizations

- **Classroom at IPM locations – Dombivli, Borivali & Vashi**

IPM conducts 'Post-graduate Diploma in Regulatory Affairs [API & Formulation]'

Duration	6 months [Sunday batches]
Faculties	Subject matter experts
Study material	User friendly notes provided
Explanation	Includes case studies & videos
Evaluation	By written assessment
Certificate	On course completion

- **Distance learning/ E-learning**

'Post-graduate Diploma in Regulatory Affairs [API & Formulation]'

Features:

- Admissions open- all 365 days
- User-friendly notes, presentations and reference guidelines provided
- Students can listen to the webinar sessions on all RA topics
- Questionnaire based on common interview questions provided
- Time flexibility for attending assessments
- Certification after course completion

Regulatory Affairs syllabus highlights:

RA profession	Introduction	
ICH Quality guidelines	Analytical method validation, Stability, Impurities & Specification	
ICH M4Q CTD	Modules 1, 2, 3, 4 & 5, Bio-equivalence studies	
eCTD submission		
API	DMF preparation	
	Regulatory submission to: USFDA	Process flow, submission, review, Post approval changes
	Europe	ASMF, CEP-submission, review, Inspection, suspension, revision & renewal
	Other markets	WHO, Canada, Japan submissions
Formulation	Dossier preparation	
	Regulatory submission to: US, ANDA submission	Approval process, Hatch-Waxman & patent certification rules, ANDA Modules, QbR, ANDA submission and review, Labeling requirements, Post approval changes
	Europe	Marketing authorization procedures, Dossier- Modules, Labeling requirements, Variations
	Emerging markets, ACTD submission, India regulatory filings	

➤ **In-house training for company employees**

This training is conducted at company office or manufacturing site for its employees in India and abroad. Company may select the topics of their interest related to Analytical Data Review/ Quality Assurance / Regulatory Affairs. It may vary from 1 day to 7 days.

Salient features:

- Tailor-made program
- Course contents based on current approach of regulatory agencies
- Experienced industrial faculties
- Discussion with case studies
- Evaluation and certification

I. Analytical Data Review:

• **Forced Degradation Studies & Analytical Method Validation**

- Protocol
- Limits, interpretation and reporting
- Linking of solution stability and robustness to test method
- Use of data in designing specification
- Common regulatory deficiencies

• **Specification and COA – APIs, Finished Products**

- Designing specification in compliance with pharmacopoeia & regulatory norms
- Review of data generated for all the tests-reading of chromatograms/spectra & raw data
- Calculations & reporting
- COAs

• **Stability studies of finished pharmaceuticals as per ICH guidelines**

- Q1A- Stability testing protocols, requirements etc
- Q1B- Photostability studies
- Q1D - Bracketing and matrixing
- Q1E – Evaluation of stability data

• **OOS, Incidences & Data Integrity**

- **Characterization: Techniques used- IR, UV, Elemental analysis & MS, reading & interpretation, Polymorphism by XRD, IR & DSC - reading, interpretation and conclusion**

II. Quality Assurance

- Change control & deviation Management –root cause analysis
- Vendor qualification
- Review of batch records
- Training
- Technology transfer

- Designing specifications
- Product complaints and recalls
- Good documentation practices
- Corrective and preventive action

III. GMP

- Overview of sections, Specific sections of the guidelines
- Facing GMP audits
- Process validation
- Cleaning validation
- Software validation

IV. Regulatory Affairs

- DMF & Dossier Preparation
- ANDA, MAP, CEP, ASMF, USDMF
- ICH Quality guidelines Q1, Q2, Q3 & Q6 and Q11
- Handling deficiencies
- Selection of starting materials
- Review of DMF and Dossiers

V. Other areas

- Clinical research
- Pharmacovigilance
- BE studies
- Statistical analysis for QA, R & D and ADL
- Design of experiments
- QbD

➤ Seminars involving candidates from multiple organizations

- Statistics primer for pharma industry, ICH Q11, QbD at Satkar hotel, Thane
- Handling OOS at IDMA, Vadodara
- DMF preparation at Sitec Labs, Hyderabad

Our esteemed clients for in-house training programmes:

- Astrazeneca, Bangalore
- Novartis house [Shree Logistics], Bhiwandi
- FDC, Mumbai &Roha
- Polypeptides, Ambernath
- IDA Foundation, Mumbai
- Mehta API, Mumbai & Tarapur
- Elppe Chemicals Private Limited, Roha
- Doctors Analytical Laboratory, Navi-Mumbai
- Orex Pharma, Mumbai
- Omkar Speciality Chemicals Limited, Ambernath
- Encube Ethicals, Mumbai
- Maxim Pharmaceuticals, Pune
- Oregon Pharma, Mumbai
- Equinox Precision Technologies, Mumbai
- Blossom Pharma, Goa
- Bharat Parenterals, Gujarat
- Finorion, Mumbai
- Kores, Roha
- Griffon laboratories
- Hemmo pharma, Navi mumbai
- Pharma college in Palghar

Sponsors for our courses and seminars:

Concordia	Cipla
Abbott	Solvay
Astrazeneca	Novartis warehouse
Orion	USV
FDC	DKSH
Amdipharm Mercury Services	Watson
IDA Foundation	Unichem
RPG Life sciences	Thing pharma
USP Convention	Piramal Enterprises
Marico	Daewoong
Famycare	G.Amphray
Blue cross	Excel industries
Digvijaya	Alembic
Chiral Bio-sciences	RPG life sciences
Aristo Pharma	Alchem synthon
Aanjaneya Biotech	Milan Labs
Intertek	Amneal
Aarti Drugs	Elder
Acme Synthetic Chem	Sequent
Amoli organics	Neuland laboratories
Veer Chemie Private Limited	Biosynth
Nakodachemica	Jodas Expoin
Inogent Laboratories	Biochemical Life Sciences
Laxai-Avanti Life Sciences	Alkem
Griffon	Arihantanam & more
Fiabila	Schulke India

GMP compliance:

IPM helps those companies willing to enter in regulated and semi-regulated market for preparing documents, its implementation, training, facing audits and subsequent approval.

IPM will work from the ground level and bring the organization to comply with the desired regulatory standards in the areas of QC, QA, Process development, Plant design of industries related to the manufacture of API, Intermediates, Excipients and Finished Dosage Forms

Regulatory consultancy:

IPM helps client in regulatory compliance and registration services for various regulatory agencies for

- Regulatory strategies
- Guidance on quality data generation
- Medical writing
- Drug master files (CTD, eCTD)
- Dossier (CTD, ACTD, eCTD, NeeS, PDF)
