



PHARMACEUTICALS EXPORT PROMOTION COUNCIL OF INDIA
(Set up by Ministry of Commerce & Industry, Govt. of India)



A workshop on Pharmaceutical Quality Assurance /Quality Control (QC/QA)

MODULE - I

DAY 1 – 11th OCTOBER 2019

Time	Title of presentation	Speaker
Inaugural Session		
9:00-09:30 Hrs.	Registration of Participants	
9:30-10:30 Hrs.	Conference inauguration	Dr Shashi Bala Singh , (NIPER Hyderabad) Mr. Udaya Bhaskar , (Pharmexcil) Dr. D Roy , (NIB)
TEA BREAK (10:30-10:45 Hrs.)		
Session 1		
10:45-11:15Hrs	Pre Training Assessment	Dr. D Roy , NIB
11:15-13:00 Hrs	Good Manufacturing Practices and Quality Systems: An Overview <ul style="list-style-type: none"> • Impact of regulatory observation on existing and new product approvals • Data Management & application of Statistical process controls for higher compliance • Pharmaceutical Quality Management Systems • Quality Risk Management 	Dr. D. Roy , NIB
Lunch Break (13:00-14:00 Hrs.)		
Session 2		
14:00-15:30 Hrs	Good Manufacturing Practices and Quality Systems: An Overview <ul style="list-style-type: none"> • Good Manufacturing Practices & Comparative Review of Various International Norms 	Dr. Chandrashekar , Vice President, Sanofi Aventis
TEA BREAK (16:00-16.15Hrs)		
16:15-17:00 Hrs	Case studies	Dr. D. Roy , NIB

DAY 2 – 12th OCTOBER 2019

Time	Title of presentation	Speaker
Session 3		
9:00-10:30 Hrs.	Pharmaceutical “Quality by Design” (QbD): An Introduction and Applications	Dr. Premnath Shenoy , Former Director, Regulatory Affairs, Astra Zeneca
TEA BREAK (10:30-11:00 Hrs.)		
11:00-13:00 Hrs.	Validations including Process, Analytical, Cleaning & HVAC <ul style="list-style-type: none"> • Validation Master Plan • Approaches to Process Validation • Cleaning Validation • Analytical Method Validation • Packaging Validation • Laboratory & Electronic Data Management 	Dr. A. Nagarjuna , Vice President-Quality, Sanofi Aventis

Lunch Break (13.00-14.00 Hrs)		
Session 4		
14.00-15.30 Hrs	HVAC, Water System & Compressed Air System Validation Technology Transfer Validation of GMP related computerized System	<i>Speaker will be updated soon</i>
TEA BREAK (15:30-16:00 Hrs)		
15.45 -17.00Hrs	Case Studies	

DAY 3 – 13th OCTOBER 2019

Time	Title of presentation	Speaker
Session 5		
9.00-11.00 Hrs	Introduction to Quality Management System <ul style="list-style-type: none"> Quality Management System Annual Product Quality Review (APQR) Managing Incidents 	Dr Premnath Shenoy
Tea Break (11.00-11.15Hrs)		
Session 6		
11:15-13:00 Hrs	QMS <ul style="list-style-type: none"> Approach to Categorization of Deviations Deviation & Change Control Corrective & Preventive Action (CAPA) Technical Report Writing – Use of Fishbone diagram and Pareto Charts 	Dr. D. Roy NIB
Lunch Break (13:00-14.00Hrs)		
14:00-15:30 Hrs	Case studies	Dr. D. Roy Dr. Premnath Shenoy
Tea Break (15.30-15.45Hrs)		
15.45- 17.00Hrs	Sum up of Three Days program	

Module II

DAY 1 – 18th OCTOBER 2019

Time	Title of presentation	Speaker
Session 1		
09:00-11:00 Hrs	Good Laboratory Practices <ul style="list-style-type: none"> An overview of GLP Material Management & Sampling Procedures Lab Instruments & Controls Documentation & Records 	Dr. Lakshmana Murthy, USP India Dr. D. Roy, NIB Mr. Chandranan, NIB
Tea Break (11:00 – 11.15 Hrs)		
11:15 -13:00 Hrs	Lab Compliance w.r.t Data management and Data integrity	Dr. Lakshmana Murthy, USP India

Lunch Break (13:00 – 14.00 Hrs)		
Session 2		
14.00 – 15.30 Hrs	Effective Method Development for analytical methods for Assay and Purity of drugs & Risk Management in Analytical Methods	<i>Speaker will be updated soon</i>
Tea Break (15.30-15.45 Hrs)		
15:45-17:00 Hrs	Innovations and Updates on Chromatographic Technologies	<i>Speaker will be updated soon</i>

DAY 2 – 19th OCTOBER 2019

Time	Title of presentation	Speaker
Session 3		
9:00-13:00 Hrs.	Stability studies and Impurity profiling: Regulatory Perspectives	Prof. Saranjit Singh, NIPER-Mohali
TEA Break (11:00 -11.15Hrs.)		
11:15-13:00 Hrs	Stability studies and Impurity profiling (<i>Session Continues</i>)	
Lunch Break (13:00-14:00 Hrs)		
Session 4		
14:00-15:45Hrs.	National Regulatory Requirements <ul style="list-style-type: none"> • Application for Manufacturing License (Form-25, 25-A, 28 & 28-A) • Application for Test License (Form-29) • Application for Registration Certificate (Form-41) & Import License (Form-10) 	CDSCO/DCA officials <i>Speaker will be updated soon</i>
TEA Break (15:45 -16.00Hrs.)		
16:00-18:00Hrs.	Regulatory Filing & Drug Registration <ul style="list-style-type: none"> • DMF Types • CTD modules • Outline on Dossier filing for USA, EU & ROW • Post Approval Changes 	<i>Speaker will be updated soon</i>

DAY 3 – 20th OCTOBER 2019

Time	Title of presentation	Speaker
Session 5		
9:00-11:00 Hrs.	Market opportunities & Challenges <ul style="list-style-type: none"> • Pharmexcil role in Export promotion • Government schemes for Export Promotion • Market dynamics • Avenues & Challenges for exploring the markets of USA, EU, AFRICA, ASEAN & LAC 	<i>Speaker will be updated soon</i>
Tea Break (11:00-11:30 Hrs)		



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11:30 -13:30Hrs	Market opportunities & Challenges (Session Continues)	
Lunch Break (13:30-14:30 Hrs)		
Session 6		
14:30-16:00 Hrs	Post Training Assessment Certificate Distribution Valedictory Function	Dr. D. Roy NIB

Workshop Registration Fee

Category	Module I	Module II	Both module I and II
Student	2000	2000	3000
Academia	4000	4000	6000
Industry	7500	7500	12000

Note: 18% GST extra on workshop registration fee

Bank account details:

Account name: NIPERH RESOURCES

Account no: 37787539689

Bank Name: State Bank of India

Branch: IDPL Colony Branch

Address of the Bank: Kukatpally, Hyderabad- 500037

Account Type: Saving A/C

MICR Code: 500002326

IFSC Code: SBIN0020245

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