Sr.No.	Training Modules	Topics to be covered
9	**In-process Quality Assurance(IPQA)**	1. Production Line Clearance
		2. In-process Quality Checks and Sampling procedures at each un it operations
10	**Product Analytical Techniques**	1. Introduction and overview of Product Analytical Techniques 2. HPLC
11	**Visit of Central Instrumentation Facility(CIL)**	1. Practicl Demonstration of different analytical instruments in Central instrumentation facility
12	**Tech-transfer and scale up techniques**	1. Procedure and steps involved from lab scale to commercial stage.
		2. Tech –Transfer methods/procedures
		3. Scale up batch studies, procedure and regulatory guidelines.
		4. Exhibit and validation studies, procedure and regulatory guidelines
13	**Pharmaceutical Validation/Qualifications**	1. Concept of Validation & Qualification along with relevant regulatory guidelines
		2. Process validation
		3. Equipment Validation(process & Packing)
		4. Utility Qualification(HVAC, Water System, Compressed Air)
		5. Cleaning Validation
		6. Computer System Validation(CSV)
		7. Product/Equipment Hold time studies
		8. Facility/Area qualification
14	**Quality Risk Management (QRM)**	1. Introduction & importance of to Risk Management study
		2. Risk Management methods & different tools
		3. Regulatory guidelines governing the QRM
13	**Current trends in Pharmaceutical products Import/export security system**	1. Pharmaceutical serialization system (Track and Trace) and E-pedigree.
		2. Indian DGFT regulation requirements & other countries (global) requirements
		3. Challenges for Pharma industries to implement the serialization system (Track and Trace) and E-pedigree.
		4. Qualification/ validation challenges of track and trace (e-pedigree, child parent relationship)

Contact Details

Technology Developement Centre-Dosage form (Formulation)
National Institute of Pharmaceutical Education & Research (NIPER)
(Department of Pharmaceuticals,
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S.A.S. NAGAR

TECHNOLOGY DEVELOPMENT CENTER (TDC)-DOSAGE FORM (FORMULATION)

(GMP MANUFACTURING PILOT PLANT FACILITY)

Pharmaceutical Industrial Training - Short Term Certification Training Programme

GOOD MANUFACTURING GMP PRACTICE

HIGHLIGHTS OF HANDS ON TRAINING

- Training will comprises of A) Audio & video class room training –for understanding the concepts. B) Hands on training with Equipment, Instruments, Process and System– more focus will be given.
- Daily progressive assessment, evaluation and interactive session.
- Training by experienced Pharma Industrial Experts, Drug regulators and NIPER faculties /Scientists.
- Participants will have the actual hands on experience by handling, operating and executing the each part of the system / equipment / Procedures with emphasis on different regulatory guidelines which is not possible in pharma industries due to their limitations.
- Pharma industrial visit during the training programme.
- Pharmaceutical Industrial Training Completion Certificate by the NIPER, SAS Nagar.

- Tailor-made training modules based on the course duration and request by the participants (Can be modified with the specific need of participants)
- The participants who completes this training will help in growth of the organisation along with development of their personnel skills. For the pharma students it will be help at the time of their employment as they are well trained as per the present industrial demands which can save the employer time for training.

Pharmaceutical Industrial training at TDC-Dosage form (Formulation)-NIPER

National Institute of Pharmaceutical Education and Research (NIPER) is the first national level institute in pharmaceutical sciences in India with a proclaimed objective of becoming a Centre of excellence for advanced studies and research in pharmaceutical sciences in India as well as abroad. NIPER has been ranked first by MHRD in NIRF-2018 ranking in pharmacy category.

The institute has a mission for creation of specialized Centers to cater the needs of pharmaceutical industries and other research and teaching institutes. As a part of this mission, NIPER has established 16 different central facilities including a GMP facility (OSD) i.e. Technology Development Centre (TDC)-Dosage form (Formulation) for pilot scale studies and Pharmaceutical Industrial Training of employees of small and medium scale Industries and Pharma students. These trainings are for the up gradation of information according to the skills required to the Pharma Industries and regulatory expectations.

NIPER is the only institute in India which is having the Pharmaceutical Formulation Manufacturing Pilot Plant facility (GMP Facility) of having 200 kg batch size capacity with the built up area of 24102 sft at institute level.

This GMP facility of NIPER dedicated for Pharmaceutical Industrial training is equipped with all required Oral Solid Dosage (Tablet) Manufacturing Equipment (Production & packing (Blister), in-process quality testing instruments and utilities along with HVAC system (14 no's) to maintain the production environmental conditions (DP, Temp & % RH), to prevent the Cross contamination and maintain the clean room concept with compliance to the cGMP requirements.

Joining hands in hands with the vision of Indian govt. for the quality education & skill development as per the requirement of the industries. NIPER, SAS Nagar shoulder the responsibilities to provide the Pharmaceutical Industrial Training to the employees of Small and Medium scale pharma industries and Bachelors/Masters students of pharmacy colleges across India. This training also helps to fulfill the gap between Industry and Academia and to provide the skilled manpower with high acceptability at various industrial sectors.

OUR PHARMACEUTICAL TRAINING PORTFOLIO...

Sr.No.	Training Modules	Topics to be covered
1	**Induction & Orientation**	1. Introduction to Pharma Industry.
		2. Role and responsibility of various departments in pharma industries
		3. Introduction to SOP, Importance & contents of the SOP, Validation Master Plan (VMP), Site Master File (SMF)
		4. Preparation of SOP, Validation Master Plan (VMP), Site Master File (SMF)
2	**Good Manufacturing Practices (GMP)**	1. cGMP training modules-Part 1
		2. cGMP training modules-Part 2
		3. cGMP Case Studies-Focus on cGMP & FDA inspection
3	**Men and material Flow in Pharmaceutical manufacturing premises**	1. Material Flow in to manufacturing premises: Raw material & API flow (Entry) and Finished product Exit procedures
		2. Man (personnel) Flow: Entry and Exit procedures (Gowning and de-gowning) & Change room Practices
4	**Good Documentation Practices(GDP)**	1. Importance of Good Documentation Practices(GDP) right from Drug development stage to Manufacturing process (Dossier filing, Pilot level, Production level, Packaging level, Quality control(QC), Quality Assurance(QA)
		2. Data integrity, Audit trial and its importance in Pharma industries
5	**Drug Regulatory Affairs in Pharma Industry**	1. Role of Drug Regulatory Affairs in Pharma Industry
		2. Dossier filing in different countries/regulatory authorities
6	**Intellectual Property Rights (IPR) /Intellectual Property Management (IPM)**	1. Patents searching database.
		2. Introduction and hands on training on various intellectual Property(IP) tools used in Pharmaceutical industry
7	**Pharmaceutical Clean room Concept & cross contamination**	1. Introduction to the HVAC System
		2. HVAC and clean room concept-Part 1
		3. HVAC and clean room concept-Part 2
8	**Quality Management System (QMS)**	1. Change Management System
		2. OOS,OOT ,deviation and incident handling
		3. Risk Management System and Various tools of Risk assessment
		4. Annual Product Review(APR)
		5. Various Regulatory documents review and Approvals
		6. Audit readiness & regulatory compliance.