

## Topic of Seminar

### 'FACILITY QUALIFICATION FOR ORAL SOLID FORMULATION UNIT'

Drugs must be manufactured to achieve a predictable therapeutic response with highest quality levels. End product testing by itself doesn't guarantee the quality of the product. A properly designed system provides a high degree of assurance that every step and process has been properly evaluated before its implementation.

Oral solid dosage forms are one of the most common ways to deliver a drug substance. All pharmaceutical manufacturing processes comprise of a series of unit operations that includes machinery, methods, people, material, measuring systems and environmental conditions.

Regulatory bodies like US FDA ensure the quality of drug products by carefully monitoring compliance with Current Good Manufacturing Practice (CGMP) regulations. FDA encourages the use of modern pharmaceutical development concepts, quality risk management, and quality systems at all stages of the manufacturing process lifecycle. The facility qualification (FQ) qualifies the overall manufacturing / testing / production environment.

Regulatory agencies demand a product that not only meets its specifications but also require a process, procedures, intermediate stages of inspections and testing adopted to produce consistently similar, reproducible, desired results. This is to maintain and assure a higher degree of quality of food and drug products.

Qualification of systems and equipment is a part of process of validation. It is a requirement of pharmaceutical regulating agencies like FDA's good manufacturing practices. This seminar shall focus primarily on the layout of facility, infrastructure designing and process development. The target audience includes personnel from the industry and researchers within the academic community. The following are some of the topics that shall be deliberated in the seminar:

1. Layout of building for solid dose formulation unit
2. HVAC for solid dose formulation unit
3. Process flow of material and personnel including 'IPQC'
4. Waste disposal

## Speakers

Eminent personalities from academia, regulatory agencies, and highly experienced personnel from pharmaceutical industry shall deliver the lectures.

## Registration Fee

- Rs 3000/- per delegate
- Rs 2000/- for SMPIC members
- Rs 800/- for students

The fee includes course material in the form of CD, lunch, refreshments, tea/coffee and excludes accommodation charges.

## On-site Registration

The on-site registration desk will be open on the day of seminar from 1.30 pm to 2.00 pm.



## SEMINAR ON



### 'FACILITY QUALIFICATION FOR ORAL SOLID FORMULATION UNIT'

11<sup>th</sup> January, 2017

SMALL AND MEDIUM PHARMACEUTICAL  
INDUSTRY CENTRE  
National Institute of Pharmaceutical Education and Research (NIPER)  
Sector-67, Near PCA Stadium, S.A.S. Nagar-160062. (Punjab)  
Phone: 0172-2292032, Fax: 0172-2214692, email: smpic@niper.ac.in

## Registration Form

Name Prof./Dr./Mr./Ms .....

Designation .....

Institute/Organization .....

Address .....

Mobile No. ....

E-mail .....

Amount Paid for Registration .....

DD No. & Date .....

## Registration Fee

Delegates	Rs. 3000/-
SMPIC Members	Rs. 2000/-
*Students	Rs. 800/-

*The last date for Registration is 6<sup>th</sup> January, 2017*

\*Students are required to attach ID Proof  
DD in favour of Director, NIPER, Payable at Mohali should be sent along with duly filled form.

### About SMPIC

Department of Pharmaceuticals, Government of India, announced the setting up of a dedicated centre for Small and Medium Pharmaceutical Industries (SMPIs) at Pharmaceutical Advisory Forum (PAF) on 23<sup>rd</sup> April 2008. This Centre called as SMPIC, offers practical trainings on analytical instruments and conducts seminars on issues of relevance to the Pharma industry like GLP, GMP & regulatory affairs. All these activities have been designed in consultation with SMPIs. This dedicated centre aims at creating a synergy between the industry and academia.

NIPER has successfully conducted 53 training programs under the World Bank sponsored "Capacity Building Project" during the years 2004 to 2008. These were meant for the technical staff from government testing laboratories, regulatory bodies, private testing laboratories and analytical as well as production staff from SMPIs.

### How to reach NIPER

NIPER, S.A.S. Nagar (Mohali) is situated near Chandigarh, that is well connected by air, rail and road. NIPER is about 11 km from Chandigarh International Airport, 14 km from Chandigarh Railway Station, 10 km from ISBT, Sector-17, Chandigarh and 5 km from ISBT, Sector 43, Chandigarh.

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### SMALL AND MEDIUM PHARMACEUTICAL INDUSTRY CENTRE



11<sup>th</sup> January, 2017



### National Institute of Pharmaceutical Education and Research (NIPER)

Sector 67, Near PCA Stadium, S.A.S. Nagar - 160 062, Punjab  
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