Topic of Seminar

'DOCUMENTATION REQUIREMENTS FOR REGULATORY COMPLIANCE'

Documentation provides information of all the processes employed during drug manufacturing. It is a key to GMP compliance and ensures traceability of all development, manufacturing, and testing activities. Pharmaceutical manufacturers must maintain proper records to maintain good documentary practices (GDPs) to comply regulatory requirements. The understanding of the regulatory requirements can be beneficial for pharmaceutical export. The Indian pharmaceutical industry has a broad spectrum of global exports of pharmaceuticals. The regulatory strategy for product development is essential before commencement of developmental work. The role of the regulatory authorities is to ensure the quality, safety, and efficacy of all drugs in circulation in the country. It not only includes the process of regulating and monitoring the drugs but also the process of manufacturing. One of the primary challenges for regulatory authority is to ensure that the pharmaceutical products are developed as per the regulatory requirements. This process involves the assessment of critical parameters during product development.

GMPs are the practices and the systems required to be adapted in pharmaceutical manufacturing. Substantial documentation and data are required for approval to import or manufacture new drug for marketing. This seminar shall provide an overview of the documentation requirements for regulatory compliance for export of pharmaceuticals. Various topics like Qualification and Validation Principles, Process validation, analytical method development, stability studies of Pharmaceutical products and Water Systems in Pharmaceutical industry shall be discussed by the experts. **The emphasis would be on providing an overview of the topics from the perspective of regulatory compliance. The participants will get an opportunity to learn/ enhance their knowledge on preparation of documents as per regulatory requirements on above topics at various stages of production of a drug molecule or API.** 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. Qualification and Validation Principles
2. Process Validation
3. Development of Analytical methods
4. Stability studies of Pharmaceutical Products
5. Water System in Pharmaceutical industry

Speakers

Eminent personalities from academia, regulatory agencies, (Dr. N Sharma, CDSCO, India) and highly experienced personel from pharmaceutical industry (Mr. D R Panda, GM, QA, Glenmark Pharmaceutical Ltd. and Mr. A P Gupta, Retd. Sunpharma Ltd.) 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, tea/coffee and excludes accommodation charges.

On-site Registration

The on-site registration desk will be open on the day of seminar from 8.30 am to 9.30 am.

SMPIC

SEMINAR ON

S.A.S. NAGAR

'DOCUMENTATION REQUIREMENTS FOR REGULATORY COMPLIANCE'

6th April, 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 .....

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Address .....

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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 31st March, 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 23rd 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.

Seminar on

‘DOCUMENTATION REQUIREMENTS FOR REGULATORY COMPLIANCE’

SMPIC

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NIPER S.A.S. NAGAR

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