PHARMACEUTICAL CONSULTANCY SERVICES

IBA CEE Center for Executive Education Institute of Business Administration

Operational Excellence Consulting

ONE-DAY SEMINAR:

Exporting Medicine from Pakistan to PIC/s Countries, WHO Qualification & cGMP Regulatory Requirements

March 6th, 2018 in Lahore and March 7th, 2018 in Karachi Pakistan

The seminar

Pharmaceutical Consultancy Services (PCS), the Center for Executive Education IBA/CEE and Operational Excellence Consulting (OEC) organize the one-day seminar: Exporting Medicine from Pakistan to PIC/s Countries and WHO Qualifications, cGMP Regulatory Requirements.

Expert speakers from Pharmaceutical Consultancy Services (PCS) will provide insight into cGMP requirements, WHO Qualification and Exporting Medicine from Pakistan.

As the Drug Regulatory Authority of Pakistan (DRAP) is moving to get PIC/s pre-accession it should be easier for Pakistani companies to export their products to the world's largest markets. This seminar will benefit companies seeking to export to the United States, Europe or the countries covered by PIC/s.

Before a Pakistani company is allowed to export to any of the markets above it will be subject to regulatory inspection against the Good Manufacturing Practices (GMP) guidelines.

Every organization has their own view on these practices and has a distinct inspection approach. Understanding the practical implications of these differences can be extremely difficult.

The program

Start - End	Subject
09.00	Why Do We Do GMP
	International GMP Requirements
11.00	Coffee & Tea Break
	The PIC/s Framework & How Regulators Inspect
	Pharmaceutical Quality Systems (PQS)
13.00	Lunch
	Production Under GMP
	Documentation & Data Integrity
15.00	Coffee & Tea Break
(very short)	PIC/s Audits by PCS & OEC, Helping Your Company Get Ready
17.00	Q&A Session and Closing Notes

PIC/S World Health Organization FDA U.S. FOOD & DRUG ADMINISTRATION EUROPEAN MEDICINES AGENCY

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During the seminar industry, experts will elaborate on the requirements and expectations of PIC/s & WHO inspectorates. Practical examples will be provided as well as theoretical guidance to help your company take the first steps toward international regulatory compliance.

Target group

This seminar will be extremely beneficial for representatives of Pakistani companies who are seeking to export their products across borders. These companies may include producers of Finished Products and Active Pharmaceutical Ingredients (API) or Excipients.

Organizations who support the Pakistani pharmaceutical industry may also find this seminar useful for better understanding the increased requirements that will be placed upon them by the pharmaceutical industry.

Practical Outcomes will Include:

- A better understanding of the international regulatory requirements,
- Useful pointers for upgrading your Quality Management System (QMS) to global GMP requirements,
- Insight into how regulatory authorities will inspect your organization and against which criteria,
- Knowing which regulations apply to your company and where to find them,
- The latest trends in the pharmaceutical industry such as Quality Culture, Data Integrity, and Serialization.

Registration & more Information

Seminar Fee

The fee per person for this seminar is 35,000.- PKR ex. Taxes. These fees include; coffee, tea, lunch and course materials.
Participants will receive a certificate of attendance.

Registration

Email your full name, function, company, address and payment details to info@pcs-nl.com, marehman@iba.edu.pk or ceeinfo@iba.edu.pk. Please ensure that the payment reaches the IBA/ CEE Office before commencement of the program because seat in the program will only be reserved once the fee is received.

Payment can be made via cheque / bank draft payable to the "Institute of Business Administration, Karachi" at the following address: Center for Executive Education (CEE) IBA, City Campus, Garden/Kayani Shaheed Road, Karachi.

For online payments via credit cards:
https://onlinepayment.iba.edu.pk/

About the Organizers

Pharmaceutical Consultancy Services (PCS) has twenty-seven years of experience with helping companies pass FDA, WHO, PIC/s or EMA inspections.

Together with Operational Excellence Consulting (OEC), one of Pakistan's most esteemed strategic consulting organizations, a practical and cost-effective approach can be implemented to guide your company up to (and beyond) any regulatory inspection.

IBA/CEE The Center for Executive Education (CEE) at IBA, Karachi, is the core department of the institute that provides Executive Education to all public and private sector organizations. It was established in 2004 and aims at helping organizations gain a competitive advantage by developing their most important resource - their people.

PCS Experience

Notable Projects

- Serum Institute of India (Pune). Support in the design and construction and implementation of quality systems for three new buildings including two vaccines and one sterile finished dosage form. FDA Approved.
- China Vaccine Project, Design Qualification, QA support and training for three vaccine and biotech manufacturing plants in China. WHO Qualified.
- Developing Countries and Vaccine Manufacturers Network (DCVMN) helped organize and train at a number of training courses to promote the development of local pharmaceutical industries in China and Brazil.
- Selecting suitable suppliers of API's, processors of intermediates and packagers of finished products for an Australian generics organizations launching a new product. These audits are being performed in Spain, Australia, Bangladesh and Canada. All inspections are conducted against the EudraLex Volume 4.
- GAP-assessment for a Chinese biotechnology company in a BSL-3 facility including CAPA recommendations.
- WHO Pre-Qualification assessment for a Chinese manufacturer of pharmaceuticals including CAPA recommendations and assisting in the subsequent upgrade efforts.
- Nine-day auditor certification training programs provided to one of the largest pharmaceutical organizations in India, in three subsequent sessions. The auditors were part of the corporate auditor team, performing supplier inspections.
- The supply of an Interim Head Corporate Quality Assurance to two medium-sized pharmaceutical production organizations in India. Additionally, to guide these organizations through WHO-inspections and to assess their QMS through a 4-person quarterly audit. WHO Qualified.
- Design Qualification of a Biotech Facility in South Korea.
- Great number of audits conducted against FDA, WHO and EMA regulatory requirements over the past few years.

Vision for Pakistan's Pharmaceutical Industry

We are expecting the Pakistan pharmaceutical industry to become a key player in the international field of medicine. Following the PIC/s accession it will be easier for Pakistani organizations to export their medicine. We are committed to aiding the Pakistani organizations in this goal.

PCS and OEC will continue providing seminars on general GMP topics to help further advance your level of compliance. In addition PCS and OEC can provide consultancy and audits to assist you in becoming compliant with organizations such as the; U.S. FDA, European Medicines Agency (EMA), WHO and PIC/s.

For further details, please contact
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