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WORKSHOP ON "PHARMACOVIGILANCE - PRACTICE AND PROSPECTS"

Introduction :

Pharmacovigilance is the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects. It is an integral part of health care delivery system that begins with the clinical trial and continues throughout the life of the drug.

It is critical to ensure the continued safety of drugs, as information on potential harms of a drug is incomplete when the drug is launched.

India is now being recognized as the 'Global pharmacy of Generic Drugs' & has distinction of providing generic quality drugs at affordable cost. India is also emerging rapidly as a big exporter of the medicines and a hub of Global Clinical trials & a destination for Drug Discovery & Development.

This workshop is conceptualized to provide an understanding of the basic concepts of pharmacovigilance and their application for collection and processing of adverse events, detection and evaluation of safety signals, and planning risk management strategies. Current scenarios in pharmacovigilance in India as well as internationally will be reviewed.

Contents

- Basics of Pharmacovigilance Seriousness, severity, causality and labeling of adverse events
- Adverse drug reactions (ADRs) mechanisms, risk factors and early detection
- Drug-Drug interactions (DDIs)
- Safety databases-Collection, entry and retrieval
- MedDRA dictionary and coding, other standard coding dictionaries
- Differences in drug safety evaluation in Clinical development products vs. marketed products
- Causality and correlation in drug safety data - Bradford-Hill criteria
- Signal detection
- Issue analysis reports, Regulatory safety reports, PSUR, PBRER
- Regulatory affairs relating to Pharmacovigilance in India
- Legal aspects and ethics in drug safety
- Product labels
- Real-life scenario of drug safety in standard global pharmaceutical companies
- Drug safety scenario in India - offshoring, business and commercial aspects, future prospects

Facilitator of the workshop

- **Dr. Sudhir Bansod,** Consultant in Drug safety and Medical affairs in Switzerland and Germany.
- **Dr. Santanu K. Tripathi,** Prof. & Head, Clinical Pharmacology, School of Tropical Medicine, Kolkata
- **Dr. S. P. Dhaneria,** Prof. & Head, Pharmacology AIIMS, Raipur
- **Dr. Prem Nyati,** Prof. & Head, Pharmacology, Index Medical College, Indore
- **Dr. Sachin Kuchya,** Asst. Prof., Pharmacology, NSCB Medical College, Jabalpur
- **Dr. Sukanta Sen,** Ex. Asso. Prof., Pharmacology, IMCHRC, DM Clinical Pharmacology post doctoral trainee

Who should attend?

Graduates and post graduate doctors and faculty of allopathic as well as Alternative Medicine, Dentists, Pharmacists, Physiotherapists, Nurses, clinical researchers,

Pharmaceutical industry planners and all professionals who need to handle the medicines in benefit of the patients.

Registration Fee

1500/- for Medical/Dental/Nursing graduates/ post graduates & Faculty

3000/- for Pharmaceutical sponsored Deligates/Clinical Research Professionals

Hotel accomodation 1000/- day

Hostel accomodation 1000/- for 3 days (including of dinner also)

Registration fee includes workshop kit, lunch & refreshment.

Last date of Registration:

June 15.2013, 6 PM. (Subject to confirmation on first come first serve basis)

How to register?

Registration form can be downloaded from
http://www.indexgroup.co.in/ws.htm#
Interested participants may send their completed registration form to the registered office:
WORKSHOP ON PHARMACOVIGILANCE - PRACTICE AND PROSPECTS
Index Medical College: 104, Trishul Apartment, 5, Sanghi Colony, A. B. Road, Indore-452001
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Accommodation (Hostel):
Dr. B. M. Sabnis, Medical Director

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Mrs. Chitra Khirwadkar, Administrator

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Reception:
Dr. K. K. Saxena, Medical Superintendant

Registration:
Dr. S. M. Jain, Professor & Head of Microbiology

Valedictory Function & Stage:
Dr. V. K. Arora, Professor & Head of PSM

P.R.O.: **Dr. Piyush Singh**