School of Pharmaceutical Sciences organises One Day Workshop on Pharmacovigilance Risk Management on 22\textsuperscript{nd} November, 2014 at Plot no. 23, Sector 32 Institutional Area Gurgaon, Haryana

In collaboration with:

Amarant Lifesciences Pvt. Ltd.
About the Workshop
Regulatory requirements towards adverse events and patient reporting has created a growth in the area of Pharmacovigilance. Increasing drug recalls due to safety concerns are driving the need for robust pharmacovigilance systems and pharmaceutical companies are now focusing strongly on drug safety management and pharmacovigilance.

One of the area that has emerged within pharmacovigilance is risk assessment and management of the adverse events. Risk management planning (RMP) has been initially developed in ICH regions for improved post-marketing drug surveillance. With fast evolving regulations worldwide to address drug safety, RMP will soon be adopted and implemented in various countries.

While there are lot of regulatory guidelines available for an individual, a workshop has been designed to guide new entrants into this area of Pharmacovigilance. Objective is to impart basic knowledge of this subject as well as provide a hands on training on specific elements of a RMP, so that you can develop the risk management plan to improve post-marketing drug safety surveillance within your organisations.

Objectives
- Evaluating and minimising risks through RMPs and other activities in the post-licencing phase
- What is a Risk Management Plan as per ICH, US and EMA requirements?
- How to write a risk management plan and the link with PSURs
- Risk management activities for generics/products with well-established use

Case Studies
Group Discussion/Q&A

Participants
Pharma Professionals or students with basic or intermediate knowledge of, and experience in, clinical safety and who are involved or interested in:
- Pharmacovigilance
- Drug safety
- Risk management
- Medical product safety assessment
- Regulatory affairs
- Clinical research
- Data analysis
- Medical information

It is also designed for professionals who work for:
- Clinical Research Organizations
- Academic Research Centres and Institutes
- Faculty Members
Program Director & Speaker

Ms. Bharti Khanna  
*Strategic, Regulatory and Scientific Consultant, New Delhi, India*

Ms. Bharti Khanna is M.Pharm. and MBA and has over two decades of experience in the Pharmaceutical Industry. Her primary area of expertise is in generic pharmaceuticals, where she provides strategic, regulatory and scientific consulting to clients interested in catering to the US, EU, Australia, Canada and other international markets. She has extensive experience in regulatory affairs, research & development, scale-up and technology transfer, manufacturing, project management, GMP and compliance, pharmacovigilance covering all activities from ideation to execution of launch of products.

Earlier to her work as a consultant, Ms. Khanna was Vice President, Research & Development for **Sentiss** leading the R&D Team. Prior to this she has worked in organizations such as **Ranbaxy** as Director Project Management and Regulatory Affairs and **Dabur** as Joint Director Regulatory Affairs. She also worked in production earlier in her career. She has talked on various subjects at national and international level and has imparted rigorous training and mentoring to young professionals in regulatory and compliance.

Keynote Speaker

Mr. Biswajit Kundu  
*Pharmacovigilance Professional, New Delhi, India*

Mr. Biswajit Kundu graduated as a Physiotherapist and is a holder of advanced diploma in Clinical research and Pharmacovigilance. He started working in clinical settings in physiotherapy department initially and from the past five years he is working as a pharmacovigilance professional having diversified experience in preparing different Aggregate Safety Reports including PBRER and Risk Management Plans for Regulatory submissions, database quality checks and medical review of ICSRs. He is currently working in **YES Regulatory Healthcare Services India Pvt. Ltd.** as a Medical Advisor and Team Lead, Pharmacovigilance. Prior to this Biswajit has worked in APCER and Cognizant.
About Apeejay Stya University

ASU is India’s 1st liberal arts and Meta University focused on Research and Technology. It is a seat of global learning that offers rich opportunities for innovative teaching learning, and research across disciplines. It is a part of India’s leading education group with 45 + years of excellence in education, 29 educational institutions across the country, more than 85 courses to choose from, over 32000 students and 2200 teachers, 60,000 strong alumni network, across pre nursery to doctoral level.

School of Pharmaceutical Sciences

The Programs of School of Pharmaceutical Sciences at ASU have been designed in collaboration with pharmaceutical organisations of repute. The newly launched R&D centre for pharmaceutical research will further ensure a holistic and experiential learning for students. The students at the School would be familiarized with the knowledge of formulation development from basic drug designing to final stages of clinical trials.

1. Internationally aligned curricula designed in collaboration with leading institutions & reputed pharmaceutical companies
2. State-of-art infrastructure & technology incubation facilities for Nanotechnology & Pharmaceutical Research
3. Industry-experienced faculty with avant-garde research in Pharma Sciences to their credit
4. Research opportunities at all levels including real-time projects such as designing & development of NDDS
5. Strong industry linkages for hands-on training & placement in varied pharma sectors including research, regulatory, manufacturing, marketing, clinical etc.
6. Online databases-Scifinder, Prowess & Emerald for Research & Development.
7. Sprawling Campus, Hi-tech teaching rooms, Hostel & Transportation facilities available.
REGISTRATION FORM

One Day Workshop
on
“Pharmacovigilance Risk Management”

On 22ND November, 2014
at, School of Pharmaceutical Sciences, ASU
Plot No.23, Sector 32, Gurgaon

In collaboration with: Amarant Lifesciences Pvt. Ltd.

Prof./Dr./Mr./Ms. ________________________________________________________________

Designation _________________________________________________________________

Institution/University _______________________________________________________

Mailing Address ____________________________________________________________

Tel: (Mobile) _______________________________________________________________

Fax. No. _________________________________________________________________

Email: ________________________________________________________________

Please Tick Relevant Box:

Faculty [ ] PG Student [ ] UG Student [ ]

Abstract Submission YES [ ] NO [ ]

Registration Fee: Demand Draft/Cash

Dated: ___________________________ Amount: ___________________________

Drawing Bank: ___________________________________________________________
Demand Draft shall be drawn in favour of “Apeejay Stya University” payable at “New Delhi”.

Registration Fee: till 15th November, 2014

Delegates from Academia/Industry/Institute : Rs. 2000/-
PG/PhD Student : Rs. 1000/-
After 15th November, 2014/Spot Registration : Rs. 4000/-

Pl. Note:

1. Registration fee does not include stay and transportation charges.
2. Last Date for Registration will be 15th November, 2014.
3. The photocopy of registration form can be used.

Date ______________   Signature_______________

Registration, Abstract submission and correspondence to be sent to the following:

Dr. Anupama Diwan (Organising Secretary)
Professor & Program Director,
School of Pharmaceutical Sciences
Apeejay Stya University
Plot no. 23, Sector 32, Institutional Area
Gurgaon, Haryana-122001
Office phone: (0124)-23833493 / 4286870-74
Mobile: 09958132224/09910350593
Email: anupama.diwan@asu.apeejay.edu