

SPEAKERS

Dr. LINCY JAISON
MANAGER LEARNING AND DEVELOPMENT

Dr. KUMARI PRIYANKA
ASSOCIATE MANAGER- REGULATORY SOLUTIONS

Mr. IMRAN AHMAD KHAN
MANAGER- SAFETY OPERATIONS

REGISTRATION FEES - Rs.350/-

INCLUDES CERTIFICATE AND WORKING LUNCH

ORGANISING COMMITTEE

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Chancellor, PES University

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Prof. Dr. J. SARAVANAN
Principal, PES College of Pharmacy

Convener
Dr. R. SRINIVASAN
Head, Department of Pharmacy Practice.

Co-ordinators
Mrs. APURVA DEV
Dr. CHINNU JOHN

ORGANISED BY

INDEGENE LEARNING & DEVELOPMENT ACADEMY IN COLLABORATION
WITH PES COLLEGE OF PHARMACY

E mail: pescp@pes.edu Call : 080-26600741

A One Day Workshop
On

**REGULATORY & PHARMACOVIGILANCE LANDSCAPE
AN INDUSTRY PERSPECTIVE**

Indegene



WEDNESDAY, 10 OCTOBER 2018,

Venue: AV Room PES College of pharmacy, Bengaluru



PES

College of Pharmacy

Dear friends:

Greetings from PES College of Pharmacy.

REGULATORY & PHARMACOVIGILANCE LANDSCAPE - AN INDUSTRY PERSPECTIVE.

I have great pleasure in informing you about the first ever workshop in academic institutions.

Today's increasing pace of innovation in the clinical research industry is resulting in ever larger number of drugs and medical devices coming to the market every year. Despite the continued work during the past few decades towards harmonization of regulations across various ICH regions the fact remains that there are wide differences in regulatory bodies and the respective regulations they mandate. The developed economies have well established regulatory oversight bodies (like the FDA, EMA and PMDA) that have laid out clear pharmacovigilance functioning and reporting requirements. Many of the developing regions on the other hand are evolving their national regulators as well as their respective regulations. In order to successfully function across multiple markets, the pharmacovigilance and safety departments today face several unique challenges. This workshop will delve into some of these challenges and how they affect multiple roles within the pharmacovigilance and safety departments of clinical research organizations.

Many students aspire to work in industry in perspective field. In academia, the theoretical concepts are explained, while the practical aspects like structuring and framing of reports is not taught. Because of this, students will not be having orientation on how the regulatory and PV science works. Considering this we are bringing hands on training of these unknown concepts from highly experienced skilled professionals on respective field.

Dr. R. Srinivasan, Head,
Department pharmacy practice

This workshop will cover:

- The journey of a pharmaceutical product like a drug from molecule to market .
- The data generated at each stage of the product lifecycle and relevance of these data.
- Safety aspects of the product and importance of this to the company and to humanity.

SCHEDULE



10.00am to 10.30am	INTRODUCTION
10.30am to 11.00am	INTRODUCTION OF INDEGENE
11.00am to 12.30pm	REGULATORY REQUIRMENTS IN THE LIFE CYCLE OF PRODUCT
12.30pm to 1.00pm	Q&A AND SUMMARIZATION
1.00pm to 2.00pm	LUNCH BREAK
2.00pm to 3.30pm	OVERVIEW OF PHARMACOVIGILANCE
3.30pm to 4.00pm	ASSIGNMENT
4.00pm to 4.30pm	Q&A AND SUMMARIZATION
4.30pm to 5.00pm	CERTIFICATION AND CLOSURE