

A Brief Report on Industrial Expert Interaction series- 2023 Lecture I

(Enhancing interpersonal and professional skills)

Date: 21.07.2023

Name of the presenter:

Ms. Indu Nambiar
Local Patient Safety Lead
Boehringer Ingelheim India Pvt. Ltd.
Mumbai.



Title of the presentation:

Audits & Regulatory inspections

Program Organized by:

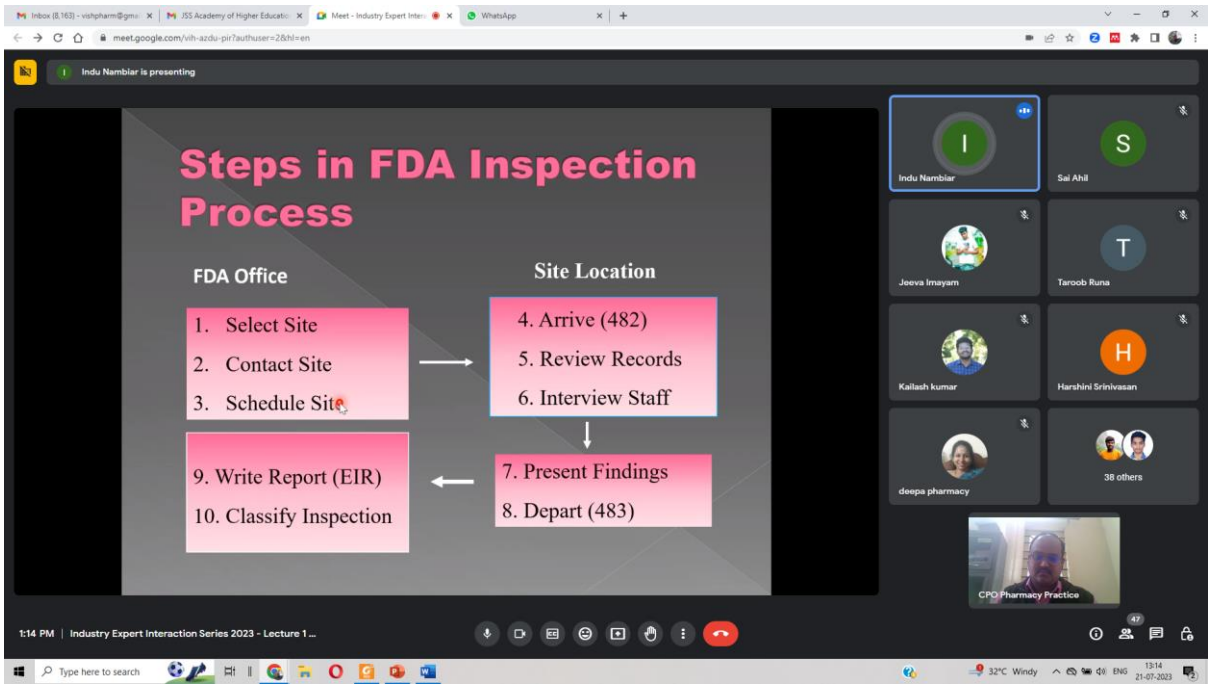
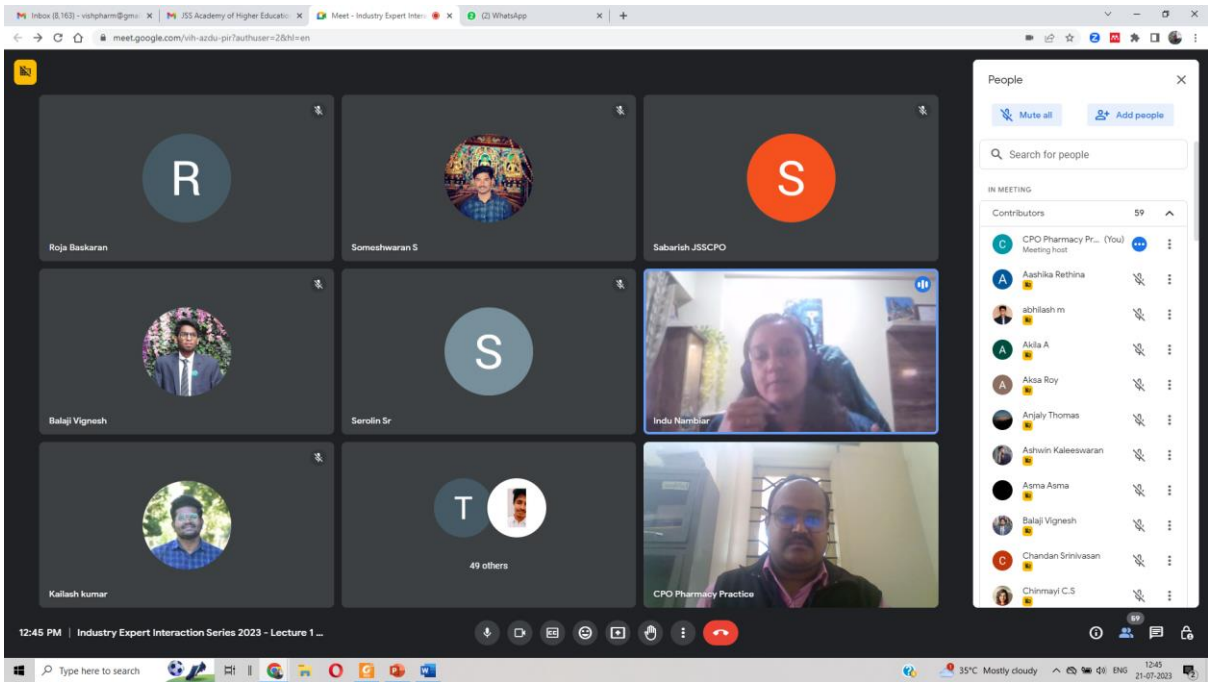
Dept. of Pharmacy Practice & Pharmacy Education Unit
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With an objective of enhancing interpersonal and professional skills of the students, Department of Pharmacy Practice in association with Pharmacy Education Unit, JSS College of Pharmacy, Ooty has planned to conduct Industrial Expert Interaction series. Industry expert interactions series provides a platform for budding Pharmacists to be aware of the skills required to enter profession and what Industry expects from the young graduates.

Ms. Indu Nambiar is a Home Science Graduate with Majors in Nutrition. She pursued her P. G Diploma in Dietetics, and is a registered Dietician and holds an MBA in Service Excellence from Welingar's. Ms. Indu started her career in the Pharmacovigilance field in 2006, when she joined Novartis India Ltd. as Executive – Drug safety & Epidemiology (DS&E). She is a life time member of Indian Society for Clinical Research (ISCR) and was instrumental in the formation of the PV working Group within ISCR in 2014. She was the Co-Chair for the PV council from its inception for 4 years (2015 – 2019). Ms. Indu is responsible for academic collaborations with major universities to co-ordinate, prepare the course, identify faculties, and conduct PV certification courses. She has received accolades from local and Global PV teams for many innovations in the field of Pharmacovigilance. Presently she is working as Local Patient Safety Lead, Boehringer Ingelheim India Pvt. Ltd., Mumbai.

The Industrial expert interaction series was hosted in online platform 'Google meet'. Ms. Indu started on the session with basics of audit and its purpose in clinical research. Further she explained the differences between audits and inspections. She also explained the various types of audits and inspections. She told many examples of clinical research scenarios where audits and inspections are conducted. She stressed on points like, whenever a sponsor or regulatory authorities suspect fraudulent activities or misleading information from clinical research, this usually attracts audits and inspections. Ms. Indu explained detailed about the how USFDA will perform the inspection.

Finally, Ms. Indu explained in-detail about the procedures involved before and after an audit is done. She told her insights about preparation of audit report followed by interaction with students for any doubts. The event was coordinated by Dr. S Ponnusankar & Mr. Vishwas H N. A total of 86 participants were present in the session. The report was drafted by Mr Vishwas H N.



Few Screen shots of the Industry Expert Interaction Series-Lecture I