SARASWATI INSTITUTE OF PHARMACEUTICAL SCIENCES

(Managed by Shree Saraswati Education Sansthan –Gujarat)

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Approved by the All India Council of Technical Education (AICTE) & Pharmacy Council of India (PCI), New Delhi

DATE: 30/10/2021

NAME OF SPEAKER	Mr. Ankit Trivedi
TOPIC	Overview of Post Approval Submission in Europe
DATE	30/10/2021
TIME	10:30 a.m. to 11:30 a.m.
NO OF ATTENDEE	100

Report

An online national webinar on "Overview of Post Approval Submission in Europe" was arranged by Saraswati Institute of Pharmaceutical Sciences at 30th October 2021 on zoom cloud App.

Very informative lecture was given by Mr. Ankit Trivedi, Assistant General Manager in Regulatory Department at Amneal Pharmaceutical. He explained very well about the Regulatory documents submission procedure of EU as well as US.

He also explained type IA variation , type IIA variation. what is the criticals and challenges while submission. He gave details about Review fees and procedure for it. He focused on what negative outcome and types IA of variation, Implementation Date depending on types of changes like Quality change, product information changes. He explained advantage of EU guidelines as compare to US by giving example as time table.

He also elaborate classification guideline, Guideline structure and discussed various case study for giving examples of type IA variation , Type IIA variation and grouping of variation, variation fees.

Students appreciated lots for this informative webinar.

Prepared By:

Mrs. Jigna T. Patel

Dr. Jinal L. Chaudhary

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