VIJAYA INSTITUTE OF PHARMACEUTICAL SCIENCES FOR WOMEN
ENIKEPADU, VIJAYAWADA-521108.

Date: 15.07.2021

CIRCULAR

All the faculty and students are hereby informed to attend a one day webinar on **"IPR & Regulatory Guidelines in Different Countries"** which is to be held on 17-07-2021. All are requested to attend the webinar on **17th July 2021.**

Principal

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PIN - 521 108

Vijaya Institute of Pharmaceutical Sciences for Women
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VIJAYA INSTITUTE OF PHARMACEUTICAL SCIENCES FOR WOMEN

INSTITUTION'S INNOVATION COUNCIL
(Ministry of HRD Initiative)

ENIKEPADU, VIJAYAWADA – 521108.

A One-Day Webinar on

"IPR & REGULATORY GUIDELINES IN DIFFERENT COUNTRIES"

17th July 2021

10:00 to 10:15 AM
Webinar Inauguration
and Keynote Address

Dr. V. Sai Kishore,
Head of Pharmaceutics Dept.
Bapatla College of Pharmacy, Bapatla.
Time : 10:15 to 11:15 AM
Topic : **Regulatory Considerations in New Drug Development Process**

Mr. S. V. Suresh Babu,
Deputy Manager,
Regulatory Affairs, Eywa Pharma Pvt Ltd
Chennai.
Time : 11:15 AM to 12:15 PM
Topic : **Generic Drug Product Development, Regulatory Registration and Post Approval Changes**

Mr. I.V. Suman Kumar,
Senior Manager,
Regulatory Affairs, Eisai Pharmaceuticals
India Pvt Ltd, Visakhapatnam.
Time : 12:15 to 01:15 PM
Topic : **Regulatory Pathway for Generic Drugs in Japan**

Registration form link
https://docs.google.com/forms/d/e/1FAIpQLSeyeZKNjCnFJnGHRaVuGG0vQapbcOHPBJ63zzMeIhkD-wWpaA/viewform

Zoom link
https://us02web.zoom.us/j/2793613773?pwd=c3BGVTdwbHNacEh1TnJoWDHib1kv2209
Meeting ID : 279 361 3773 Passcode : ZzVJ8B

Youtube Link : https://www.youtube.com/channel/UCBLrYsTIY4xSqXKsxX7arUw

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Dr. Sivadasu Praveen	Mrs. P. Durga	Dr. S. Venkateswara Rao	Sri B.S Sri Krishna	Prof. K. Padmalatha
Programme Coordinator	Technical Incharge	Coordinator, IIC	Secretary	Principal

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Pharmacy Council of India, New Delhi & Affiliated to JNTU Kakinada
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Date: 19-07-2021

Name of the Programme:	A One-Day Webinar on **"IPR & Regulatory Guidelines in Various Countries"**
Date:	17-07-2021
Resource Person Details:	1. **Dr. V. Sai Kishore,** Head of Pharmaceutics Dept. Bapatla College of Pharmacy, Bapatla **Email:** voiceofsaikishore@yahoo.com **Contact Number:** +91- 94409 38249 2. **Mr. S. V. Suresh Babu,** Deputy Manager, Regulatory Affairs Eywa Pharma Pvt Ltd, Chennai. **Email:** **Contact Number:** +91-9591631362 **3. Mr. I.V. Suman Kumar** Senior Manager, Regulatory Affairs Eisai Pharmaceuticals India Pvt Ltd, Visakhapatnam. **Email:** **Contact Number:** +91-8008779191
Topics covered:	1. Regulatory Considerations in New Drug Development Process 2. Generic Drug Product Development, Regulatory Registration and Post Approval Changes 3. Regulatory Pathway for Generic Drugs in Japan

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A one day Webinar on **IPR & Regulatory Guidelines in Various Countries** was organized by Institution Innovation Council (IIC) of *Vijaya Institute of Pharmaceutical Sciences for Women* on 17-07-2021. **Dr. V. Sai Kishore**, Head of Pharmaceutics Dept. Bapatla College of Pharmacy, **Mr. S. V. Suresh Babu**, Deputy Manager, Regulatory Affairs Eywa Pharma Pvt Ltd, Chennai and **Mr. I.V. Suman Kumar**, Senior Manager, Regulatory Affairs, Eisai Pharmaceuticals India Pvt Ltd, Visakhapatnam were invited as Guest Speakers. **Prof. Dr. K. Padmalatha**, Principal was the convener of the webinar; **Dr. S. Venkateswara Rao** and **Dr. Sivadasu Praveen** were the coordinators of the webinar. The webinar was inaugurated by Mrs. V. Vishnu Vandana Devi and the keynote address was delivered by Mrs. B. Hemalatha.

Post inauguration **Dr. V. Sai Kishore** delivered a talk on **Regulatory Considerations in New Drug Development Process.** Where, the talk has begun with explaining the fundamental aspects of intellectual property and Regulatory affairs. Further, special emphasis was given on various regulatory aspects involved in developing a new drug or new drug product, different stages of pre-clinical and clinical trials and marketing strategies of the new drug product. Furthermore, delegates were detailed about various applications that are required to introduce a new drug into the market. By the end of session delegates gained knowledge about the challenges that are faced by pharmaceutical industries in developing a new drug or a new drug product and different applications that are required to be filed in various countries to introduce the drug or drug product in the market.

The second talk was given by **Mr. S. V. Suresh Babu** on **Generic Drug Product Development, Regulatory Registration and Post Approval Changes.** In this talk special emphasis was given on developing, registering and the changes that have to be made after approval. Generic drugs are medicinal products that can be manufactured and marketed by others than the innovator company after the original patents have expired. Different countries established different procedures in approving this generic drug products and the main aim of establishing this policies are to increase the global access to and regulation of generic drugs, reduce drug costs, and prevent drug shortages and supply disruption. Particularly, the availability of low-priced generic drugs is important to increase the economical access to drug treatment in low- and middle-income countries. By the end of talk delegates had got an access

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to information about development and registration process of generic drug products in different countries.

The third talk was given by **Mr. I.V. Suman Kumar** on **Regulatory Pathway for Generic Drugs in Japan.** Where, in this talk special emphasis on different regulatory guidelines followed by Japan to market the generic drugs. Generic drugs are interchangeable with original proprietary drugs, as they have the same active pharmaceutical ingredients, dosage forms, strength, quality, indications, effects, directions, and dosage. The cost of generic drugs is lower than original drugs, because the developmental cost is lower. The expansion of medical expenses is an important issue in many countries, including Japan, the USA, and Europe, and promotion of generic drugs has been demanded to solve this issue in Japan. Generic drug approval review in Japan is conducted by the Pharmaceuticals and Medical Devices Agency (PMDA), which reviews the equivalence of the original drugs from the viewpoint of quality, efficacy, and safety, based on documentation submitted by the generic drug applicants. From the session delegates gained knowledge about the different procedures that have to be followed to market a generic drug product in Japan.

Vote of thanks was given by Dr. Sivadasu Praveen. 250 participants attended the webinar, and it was conducted through the online platforms of zoom and you tube.

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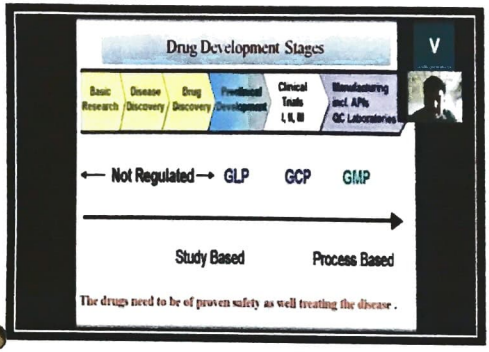
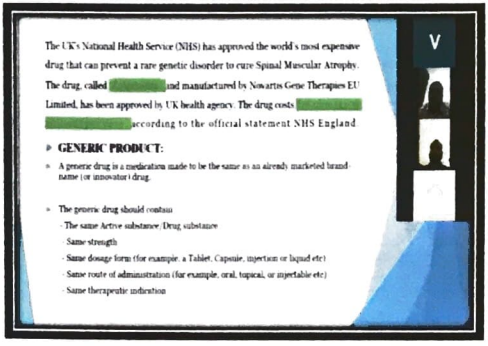
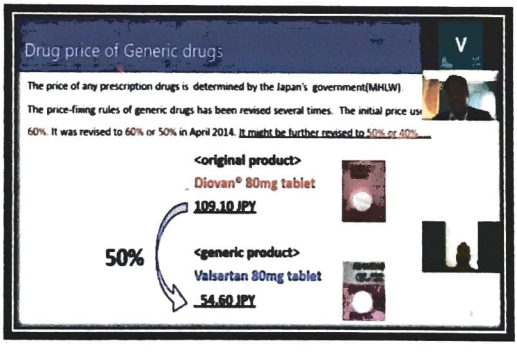


Dr. V. Sai Kishore giving a talk on Regulatory Considerations in New Drug Development Process on 17-07-2021



Mr. S. V. Suresh Babu giving a talk on Generic Drug Product Development, Regulatory Registration and Post Approval Changes on 17-07-2021



Mr. I.V. Suman Kumar giving a talk on Regulatory Pathway for Generic Drugs in Japan on 17-07-2021

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Certificate of Participation

This is to certify that Prof/Dr/Mr/Mrs/Ms Sivadasu Praveen has actively participated in the One day Webinar on "IPR & Regulatory Guidelines in Different Countries" held on 17th July 2021.

Dr. S. Venkateswara Rao
Coordinator, IIC

Sri B. Sri Krishna
Secretary, SRK Foundation

Prof. K. Padmalatha
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