

A Report
on
Online Expert Lecture Series
on Various Topics of
Pharmaceutical Regulatory Affairs
Organized by
Graduate School of Pharmacy
10th & 11th July, 2021

GTU - Graduate School of Pharmacy has organized an online Expert Lecture Series on Various Topics of Pharmaceutical Regulatory Affairs on 10th & 11th July, 2021. The experts named Mr. Anil J. Pareek, Deputy General Manager-IRA, Mr. Ravindra S. Trivedi, Senior Executive, Regulatory Affairs and Mr. Subhdeep A. Chakraborty, Associate Manager, Dept. of IRA has been invited for the expert lecture series. The experts has enlighten notes on Theoretical knowledge on ICH CTD and eCTD Guidelines and International Regulatory markets of USA Drug Master Files, Regulatory Approval Process for Investigational New Drug, New Drug Application, Abbreviated New Drug Application and Supplemental New Drug Application. Emerging Market Registration of drugs in WHO through Prequalification program and ASEAN-Pharmaceutical Registration process.

Drug Development Process

PRE-CLINICAL RESEARCH

CLINICAL STUDIES

PHASE 1

PHASE 2

PHASE 3

SYNTHESIS AND PURIFICATION

ANIMAL TESTING

SHORT-TERM

LONG-TERM

INSTITUTIONAL REVIEW BOARDS

INDUSTRY TIME

IND SUBMITTED

NDA SUBMITTED

REVIEW

DECISION

SPONSORSHIP MEETING ENCOURAGED

EARLY ACCESS

SUPPORT E

SPONSOR ANSWERS ANY QUESTIONS FROM REVIEW

11:27 AM | Online Expert Lecture 1

Registration Process in ASEAN Countries

Country	Pre-clinical	Phase 1	Phase 2	Phase 3	Marketing
AP (Vietnam)	AP (Vietnam)	AP (Vietnam)	AP (Vietnam)	AP (Vietnam)	AP (Vietnam)
CA (Cambodia)	CA (Cambodia)	CA (Cambodia)	CA (Cambodia)	CA (Cambodia)	CA (Cambodia)
LA (Laos)	LA (Laos)	LA (Laos)	LA (Laos)	LA (Laos)	LA (Laos)
MY (Malaysia)	MY (Malaysia)	MY (Malaysia)	MY (Malaysia)	MY (Malaysia)	MY (Malaysia)
PH (Philippines)	PH (Philippines)	PH (Philippines)	PH (Philippines)	PH (Philippines)	PH (Philippines)
SG (Singapore)	SG (Singapore)	SG (Singapore)	SG (Singapore)	SG (Singapore)	SG (Singapore)
TH (Thailand)	TH (Thailand)	TH (Thailand)	TH (Thailand)	TH (Thailand)	TH (Thailand)
VN (Vietnam)	VN (Vietnam)	VN (Vietnam)	VN (Vietnam)	VN (Vietnam)	VN (Vietnam)

2:25 PM | Online Expert Lecture 2

WHO Regional Grouping

WHO Member States are grouped into 6 WHO regions

- Africa Region (AFRO)
- Region of the Americas (AMRO)
- South-East Asia Region (SEARO)
- Europe Region (EURO)
- Eastern Mediterranean Region (EMRO)
- Western Pacific Region (WPRO)

10:48 AM | Online Expert Lecture 3