KONERU LAKSHMAIAH EDUCATION FOUNDATION
(Deemed to be University, Estd. u/s. 3 of UGC Act 1956)

(DEEMED TO BE UNIVERSITY)

Ref: KLEF/RO/Pharmacy/2018-2019   **Date: 02-04-2018**

<u>**Orders of the Vice-Chancellor dt. 02-04-2018**</u>

CIRCULAR

Sub: Guest lecture on *"Pharmaceutical Analytical Method Validation Requirements Specifically for Brazil and Japan Markets for Regulatory Approvals"* dated 4th April 2018- **Reg.**

Ref: Letter dt. 02-04-2018 from **Dr. GSN Koteswara Rao,** Convener, KLEF College of Pharmacy.

<div align="center">***</div>

This is to inform that KLEF College of Pharmacy is organizing a **Guest lecture on** *"Pharmaceutical Analytical Method Validation Requirements Specifically for Brazil and Japan Markets for Regulatory Approvals"* which is beneficial to the Life Science (Pharma) students, faculty and researchers, as per the details given below.
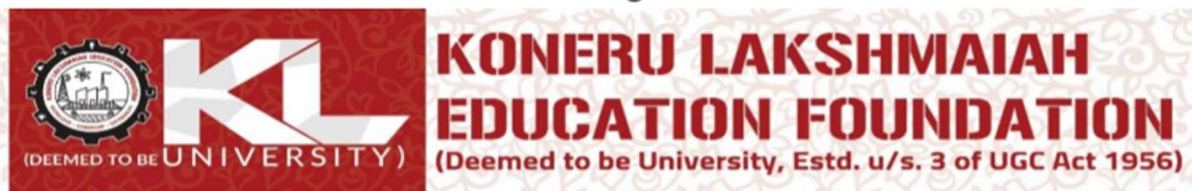
Resource person: **Mr. Pavan Kumar Katari**, Senior Research Scientist, Research and Development Wing, Mylan Laboratories Limited, Bollaram, Hyderabad.

Date & Time: 04-04-2018 from 11:00 a.m. to 12.30p.m.

All the students, faculty members and Ph.D scholars are invited to attend the Guest Lecture and acquire knowledge.

REGISTRAR

Prof. T. UMA MAHESWARA RAO
REGISTRAR

KL COLLEGE OF PHARMACY
Skill Activity Report April-2018

Date	04-04-2018
Resource Person	**Mr. Pavan Kumar Katari**, Senior Research Scientist, Research and Development Wing, Mylan Laboratories Limited, Bollaram, Hyderabad.
Guest lecture Title	***Pharmaceutical Analytical Method Validation Requirements Specifically for Brazil and Japan Markets for Regulatory Approvals***
Participants	B Pharmacy & Pharm D Students
Venue	R-309D
Organizing Member	**Convenor: Dr. G**SN Koteswara Rao

KLCP- Guest lecture- Chemistry

The pharmaceutical industry operates within a highly regulated environment to ensure the safety, efficacy, and quality of drugs. One critical aspect of this is the validation of analytical methods used to assess the quality and consistency of pharmaceutical products. Different markets around the world have their own regulatory frameworks, and understanding the specific requirements for analytical method validation is crucial for successful regulatory approvals. In this guest lecture, we will delve into the requirements for pharmaceutical analytical method validation in the Brazil and Japan markets.

Brazil Market:

Regulatory Overview: In Brazil, the regulatory authority responsible for overseeing pharmaceutical products is the National Health Surveillance Agency (ANVISA). ANVISA provides guidelines that outline the requirements for analytical method validation to ensure the quality and reliability of pharmaceutical products.

Method Validation Parameters: ANVISA emphasizes the validation of analytical methods for various parameters, including accuracy, precision, specificity, linearity, range, detection limit, quantification limit, and robustness. Each parameter must be carefully assessed to ensure that the analytical method is suitable for its intended use.

Documentation: Documentation plays a crucial role in method validation for the Brazil market. Detailed protocols, validation reports, and data demonstrating the method's performance against each validation parameter are required. These documents should be submitted as part of the regulatory filing to demonstrate the method's reliability and suitability.

Japan Market:

Regulatory Overview: Japan's regulatory authority for pharmaceuticals is the Pharmaceuticals and Medical Devices Agency (PMDA). PMDA provides guidelines for analytical method validation to ensure the quality and safety of pharmaceutical products in the Japanese market.

Validation Parameters: Like ANVISA, PMDA also emphasizes the validation of analytical methods for accuracy, precision, specificity, linearity, range, detection limit, quantification limit, and robustness. The guidelines provide specific acceptance criteria for each parameter, which must be met for successful method validation.

Lifecycle Approach: PMDA encourages a lifecycle approach to method validation, which includes validation during development, validation during routine use, and continuous verification throughout the product's lifecycle. This approach ensures that the method remains reliable and consistent over time.

Comparative Analysis: While both Brazil and Japan have similar validation parameters and expectations, there are nuanced differences in the specific requirements and documentation. Both markets emphasize the need for comprehensive documentation, data integrity, and a thorough understanding of the analytical method's performance characteristics.

Pharmaceutical analytical method validation is a critical component of regulatory submissions in markets like Brazil and Japan. Understanding and adhering to the specific requirements outlined by regulatory authorities such as ANVISA and PMDA are essential for obtaining regulatory approvals and ensuring the safety and quality of pharmaceutical products. As the global pharmaceutical landscape continues to evolve, staying up to date with these requirements is imperative for success in these markets.

In this guest lecture, we have explored the analytical method validation requirements for the Brazil and Japan markets, shedding light on the nuances and key considerations for regulatory approvals. This knowledge will undoubtedly contribute to the professional growth and success of individuals and organizations operating within the pharmaceutical industry.

The students of B Pharmacy and Pharm D Programs got benefited from this guest lecture.
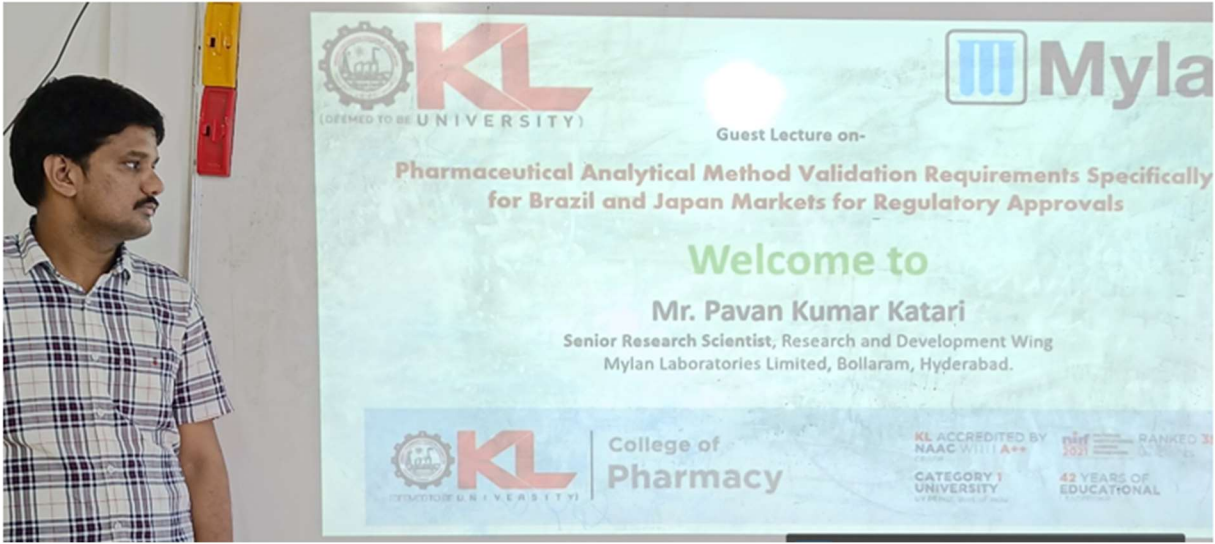
Total number of Registered: **66.**

Total number of participants: 65.
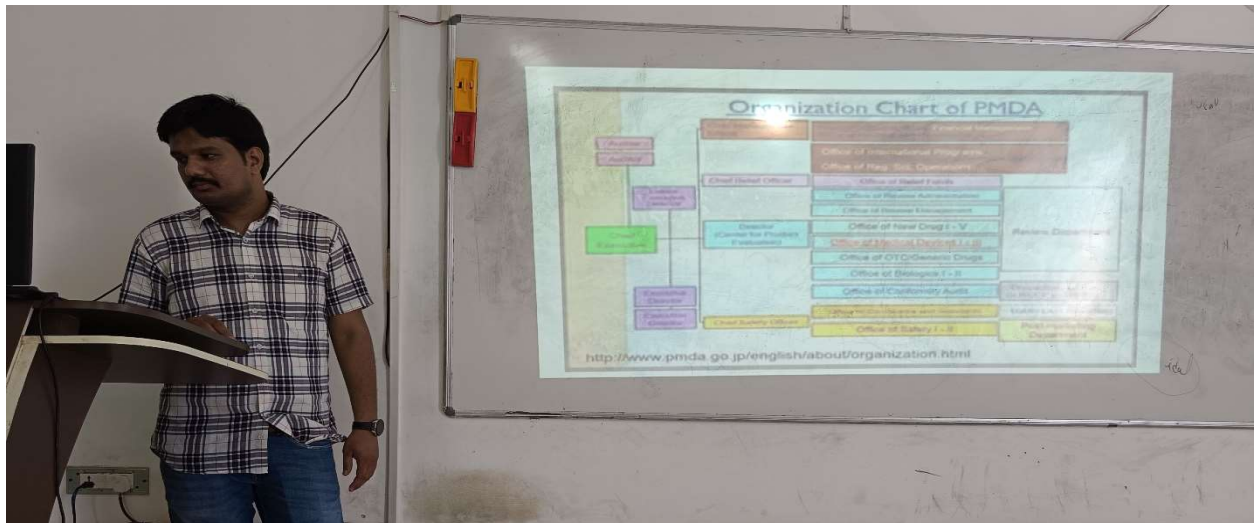
Prof I/c. Skill
KL College of Pharmacy

Principal PRINCIPAL
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(Deemed to be University)
Green Feilds, Vaddeswaram-522502
Guntur District, Andhra Pradesh.

Photographs of the Guest Lecture:

Resource Person Addressing the Participants, dated 4th April 2018

Speaker briefing about the PMDA Rules and Regulations, dated 4th April 2018

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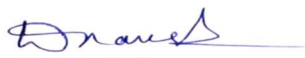Green Feilds, Vaddeswaram-522502
Guntur District, Andhra Pradesh.

FACULTY LIST:

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S.No	Emp. ID	Name of the Faculty	Designation	Department
1	5470	Dr. SUBRANSHU PANDA	PRINCIPAL	PHARMACY
2	5419	Dr.K UMA SANKAR	PROFESSOR	PHARMACY
3	4866	Dr.SIVA PRASAD PANDA	ASSOC.PROF.	PHARMACY
4	5465.	Dr.S N KOTESWARA RAO G	ASSOC.PROF.	PHARMACY
5	4460	Dr.ALAVALA RAJASEKHAR REDDY	ASST.PROF.	PHARMACY
6	4918	Dr. UTTAM PRASAD PANIGRAPHY	ASST.PROF.	PHARMACY
7	5085	Ms. GADE KALYANI	ASST.PROF.	PHARMACY
8	5304	Mr. VENKATA GOPAIAH	ASST.PROF.	PHARMACY
9	5306	Ms.NALLAPATY SRI LAKSHMI	ASST.PROF.	PHARMACY
10	5728	Ms. NIGAMA CHANDRA	ASST.PROF.	PHARMACY

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K L E F
K L COLLEGE OF PHARMACY
LIST OF STUDENTS PARTICIPATED

S.No	REGDNO	NAME OF THE STUDENT	SIGNATURE
1	180180001	AASHISH KUMAR SHARMA	
2	180180002	DOKKU BINDU SAI LAKSHMI	
3	180180003	DEVINENI PRUDHVI KESHAVA	
4	180180004	DEVOJEET SARKAR	
5	180180005	GADDE SRIVALLI	
6	180180006	KAKURU BINDU HASINI	
7	180180007	L THIPPE SWAMY	
8	180180008	MEDHARA CHANDUVARDHAN	
9	180180009	MIKKILINENI DHEDEEPYA	
10	180180010	PARUCHURU GAGANA SRI	
11	180180011	THOTA CHAITNAYA KUMAR	
12	180180012	VURA APARNA REDDY	
13	180180013	VELAGA INDU	
14	180180014	KOLLIPARA VAISHNAVI	
15	180180015	NAINAVARAPU SUMAKSHARIKA	
16	180180016	AMAN KUMAR SNEHI	
17	180180017	AMBOJI PRAVEEN KUMAR	
18	180180018	KELVIN MUTHENGI MURITHI	
19	180180020	JOACHIM SULLE	
20	180180021	SALIM ALZAKWAN ABDALLAH SEIF HAMAD	
21	180180022	JACQUELINE KIDUMBA	
22	180180023	ADILI MSELUKA ZACHEO	
23	180180024	AHMED MOHAMED YOUSIF WADI	
24	180180025	EMMANUEL KWIZERA	
25	180180026	SLAHALDEEN JAMEELALLAH MOHAMMED ABDALLAH	
26	180180027	NCHIMUNYA HANJALIKA	
27	180180028	TRESOR KAYIRANGA	
28	180180029	ANWER MUSSA EDRESS	
29	180180030	MALIK HUSSEIN YAHIA ABDULRESOOL	
30	180180031	JOSEE UFITESE ARATETA CONSCIENCE	
31	180180033	G BHANU PRAKASH	
32	180180034	SHUBHAM KUMAR	
33	180180035	AMRUTHA VARSHINI	
34	180180036	AHMED OSMAN	
35	180180037	MOHAMEDELGMOGTABA ABDELRAHMAN	
36	180180038	NATASHA SWANA	
37	180180039	ANWER MUSSA EDRESS	

38	180180040	TANDEO BIBIAN	
39	180180042	MOHAMMED ABUBAKER ABBAS YASSIN	
40	180180043	MEHAD ABUZAR GUMMA KOKO	
41	180180044	GALILA MOATSIM ELAMEIN SAEED	
42	180180045	ABDULLAH MOHAMD	
43	180180046	CHINTALA BINDU	
44	180180047	GNANA PRASUNA	
45	180180049	NASRA ALLY MWIHUMBO	
46	180180050	EUGENE LAWRENCE YOWELLE	
47	180180051	GIFT SANGA	
48	180180052	ASALA MOHAMED ELBUSHRA HAMDI	
49	180180053	YVAN UJENEZA ISHIMWE	
50	180180054	DAVID MICHAEL	
51	180180055	SALOME NTULILWA JOSEPH	
52	180180056	BERNADINA PATRICK MOSHA	
53	180180057	GRACE PHILIP TESHA	
54	180180058	JACKSON JOSEPH NDAKIDEMI	
55	180180059	MAYADA KHALID ADAM OMER	
56	180180060	AMR MOUSTAFA MAHMOUD GHAZI SHALABI	
57	180180061	LILIAN ELIASSHAKA KACHWELE	
58	180189001	BETT FRANCIS KIPCHUMBA	
59	180189002	WANJIKU EVANSON GICHARU	
60	180189003	SIMIYU EMMANUEL WEKESA	
61	180189004	KARITU DENNIS KIRIMI	
62	180189005	JEPKIRUI SHERIFAH	
63	180189006	MOENGA KELVIN NYAEMA	
64	180189007	AHMED NASRA ADOW	
65	180189008	SADAM HASSAN IBRAHIM	

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