

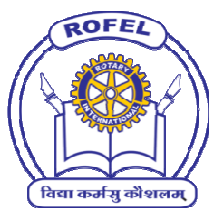
A Brief Report on Proceedings of

**GUJCOST Sponsored One Day National Seminar on
"Current Scenario and Scope of Drug Regulatory Affairs in
Pharma Industry"**

Venue: Auditorium, ROFEL-GIDC Campus, Chharwada Road, Vapi.

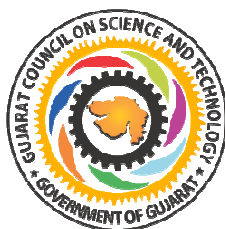
Date: 18th January 2020

ORGANISED BY:



**ROFEL SHRI G.M. BILAKHIA COLLEGE OF
PHARMACY**

ROFEL NAMDHA-CAMPUS, VAPI-NAMDHA ROAD, VAPI (W)- 396191 (GUJARAT)



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GUJARAT COUNCIL ON SCIENCE AND TECHNOLOGY(GUJCOST)

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PROCEEDING REPORT

One Day GUJCOST sponsored National Seminar was organized by ROFEL Shri G.M. Bilakhia College of Pharmacy, Vapi. The theme of the workshop was **"Current Scenario and Scope of Drug Regulatory Affairs in Pharma Industry"**. This Seminar was organized for the purpose of sharing the regulatory guidelines prevailing in pharma industry. A total number of 112 delegates participated in this seminar. The program schedule was as follows:

PROGRAM SCHEDULE:

DATE: 18th January 2020 (Saturday)		
TIME	TOPIC	SPEAKER
0830 to 0915	REGISTRATION AND BREAKFAST	
0915 to 1000	INAUGURATION	
1000 to 1115	Session-1: An Overview of Drug Approval Processes: IND & NDA	Mr. Pragnesh Donga Scientist - Quality Assurance & Regulatory Affairs, Zydus Research Centre (Cadila Healthcare Ltd.,) Ahmedabad
1115 to 1230	Session -2: Industrial Prospects of Drug Regulatory Affairs	Mr. Vijay Satapara CEO, Isazi Pharma and Techno Consultancy Pvt. Ltd. Vadodara
1230 to 1330	LUNCH	
1330 to 1430	Poster Presentation	
1430 to 1545	Session -3: Pharmaceutical prospects of dossier preparation	Ms. Bhumika Nayak, Assistant General Manager, Alembic Pharmaceuticals Pvt. Ltd., Vadodara
1545 to 1630	Certificate & Prize Distribution, Valedictory function	

PROCEEDING REPORT OF SEMINAR

DATE: 18TH January 2020

Registration of Delegates for Seminar (8.30 am to 9.15 am):



Inauguration Ceremony (9.15 am to 10.00 am)

The inauguration ceremony commenced with Saraswati Vandana by students, followed by lamp lighting by all dignitaries' present. As a part of tradition of Gujarat Technological University and being proudly affiliated with it, GTU Song was played. Floral welcome was given to all dignitaries and invited guests. Dignitaries present during the Inaugural function were:

- Dr. Abhay Deshpande, CEO- Global, Jai Research Foundation, Valvada
- Rtn. Bharat Patel, Trustee, ROFEL Trust
- Rtn. Praful Dewani, Trustee, ROFEL Trust
- Rtn. Dr. R.J. Singh, President, Rotary Club of Vapi
- Mr. Pragnesh Donga, Scientist - Quality Assurance & Regulatory Affairs, Zydus Research Centre
- Dr. Arindam Paul, Principal, ROFEL Shri G.M. Bilakhia College of Pharmacy, Vapi

Welcome address was given by **Dr. Arindam Paul**, Principal of college. He expressed his immense pleasure for the presence of delegates in commendable numbers. **Rtn. Bharat Patel, Trustee-ROFEL Trust** gave best wishes to the delegates of seminar and emphasized with his experiences, the importance and relevance of topics included in seminar for the students of pharmacy and society. **Dr. Komal Parmar**, Associate Professor and Coordinator of seminar briefed on the purpose of seminar. **Mr. Mittal Dalal**, Associate Professor gave brief introduction of the **Dr. Abhay Deshpande**, Chief Guest and Keynote speaker of the seminar.

Dr. Abhay Deshpande, CEO, JRF Global, Vapi during his keynote address, briefed with a powerpoint presentation on the following points:

- a) What is the role of regulatory guidelines in pharma industry
- b) What are key guidelines to be followed
- c) Scope of regulatory affairs etc.

The inaugural session ended with vote of thanks by Mr. Mittal Dalal followed by national anthem. Technical session started after a break of 10 mins.

Glimpses of Inaugural function:



Lamp Lighting by Dignitaries



Dignitaries and Delegates standing for National Anthem

Glimpses of Inaugural function:



Keynote address by Chief Guest, Dr. Abhay Deshpande
CEO, JRF Global, Valvada



Memento presented to Chief Guest, Dr. Abhay Deshpande
By Trustee of ROFEL Trust Rtn. Bharat Patel



Floral Welcome of Chief Guest, Dr. Abhay Deshpande
By Dr. Arindam Paul, Principal & Professor



Vision of ROFEL Trust by Rtn. Bharat Patel,
Trustee- ROFEL Trust



Dr. Komal Parmar, Associate Professor &
Coordinator of Seminar



Mr. Mittal Dalal, Associate Professor &
MOC of Inaugural function

Technical Sessions of Seminar

Technical Session 1:

Talk on "An Overview of Drug Approval Processes: IND & NDA" was given by **Mr. Pragnesh Donga**, Scientist - Quality Assurance & Regulatory Affairs, Zydus Research Centre (Cadila Healthcare Ltd.,) Ahmedabad. He explained drug approval process with minute details. Investigational New Drug Application (IND) and New Drug Application (NDA) in drug approval process was also explained in minute detail. Starting from basics of drug approval process, he covered detail requirements for IND and NDA approval process. He also briefed on electronic submission process thoroughly.



Technical Session 2:

Mr. Vijay Satapara delivered a talk on "Industrial Prospects of Drug Regulatory Affairs". The main focus was on dossier preparation. His talk was on various detailed aspects of common technical document. He illustrated the submission of dossier by eCTD by graphical illustrations of the software. Most delegates participated in the question answer session at the end of the talk. Dr. Arindam Paul, Principal and Professor felicitated Mr. Vijay Satapara with a memento and a certificate.



Lunch Time:



POSTER PRESENTATION SESSION

Post lunch poster presentation session was organised for the delegates. A total of 15 delegates presented their poster prepared on various topics of pharmacy. **Dr. Ashok Akbari**, Associate Professor, Shree Naranjibhai Lalbhai Patel College of Pharmacy, Umrakh judged the posters. Students actively answered the questions raised by the judge.



Technical Session 3:

A talk on "Pharmaceutical prospects of dossier preparation" was delivered by **Ms. Bhumika Nayak**, Assistant General Manager, Alembic Pharmaceuticals Pvt. Ltd. Vadodara. She covered the dossier preparation and submission process. She emphasized types of common technical documents to be applied in different countries.

She focused on registration and management of dossier. Content of dossier was discussed in detail. Overall lecture was quite informative and presented detailed description about dossier preparation and submission in pharma industry. At the end of talk, Dr. Hitesh Dalvadi, Associate Professor felicitated Ms. Bhumika Nayak) with a memento and certificate.



Valedictory Session:

Floral welcome of Rtn. Subhash Panchal, Trustee of ROFEL Trust was given by Dr. Komal Parmar, Associate Professor. He wished more such seminars should be organised by the college for the benefit of students and teachers. He also congratulated the organising team of college for successfully organising the Seminar.



Welcome of Rtn. Subhash Panchal, Trustee of ROFEL Trust
Rtn. Subhash Panchal, Trustee of ROFEL Trust
addressing the audience during Valedictory function

Certificate Distribution:



Rtn. Subhash Panchal, Trustee of ROFEL Trust distributed the certificate, memento and prize of Cash 1000/- to 1st (Mr. Rajesh Mourya) and 500/- to 2nd (Ms. Zalak Desai) winner of poster presentation.



Felicitation of Coordinator of Seminar; Dr. Komal Parmar and to Co-Coordinator; Dr. Hitesh Dalvadi
By Rtn. Subhash Panchal, Trustee of ROFEL Trust



Live Feedback by delegates of Seminar



Organising Team (Students Volunteers) of ROFEL Shri G.M. Bilakhia College of Pharmacy of GUJCOST Sponsored Seminar



Organising Team of ROFEL Shri G.M. Bilakhia College of Pharmacy of GUJCOST Sponsored Seminar