



ROFEL SHRI G.M. BILAKHIA COLLEGE OF PHARMACY, VAPI

NAAC Accredited B++ Grade Institution &Approved by Pharmacy Council of India

A Constituent College of Rajju Shroff ROFEL University, Vapi

ROFEL Namdha Campus, Vapi – Namdha Road, P.B. No.11, Vapi (West) – 396 191, Dist: Valsad (Gujarat)

Tel: 9727723722 – 42 – 62; Email: info@rofelparmacy.ac.in; Website: rofelparmacy.ac.in

Ref. No. ROFEL/Pharm/

Date:

Report on Two days online Refresher Course for Registered Pharmacist sponsored by GSPC

Event: Two days online Refresher Course for Registered Pharmacist sponsored by GSPC

Date and Venue: 25, 26/11/2023, Online Zoom Meeting

Total Beneficiary: 241 Registered Pharmacists

Summary Report:

ROFEL Shri G.M. Bilakhia College of Pharmacy – A constituent college of Rajju Shroff ROFEL University has organized two days online Refresher course sponsored by Gujarat State Pharmacy Council for registered pharmacists on 25th and 26th November, 2023 on virtual Platform using zoom meeting. Gujarat State Pharmacy Council has made refresher course mandatory for all registered pharmacist with the aim to help pharmacist to acquire knowledge of recent trends. There were in all 400 registration received during the course amongst them 241 successfully attended all the session, appeared for the examination and duly submitted the feedback form also. Therefore the e-certificates based on monitoring of attendance and examination was issued to 231 registered pharmacists only.

The inauguration ceremony commenced with Saraswati Vandana. Dr. Kishor Dholwani – Principal, Sardar Patel College of Pharmacy, Bakrol, Anand - guest of honor inaugurated the refresher course and in his inaugural address he welcomed the gathering and explained the importance of the course and pharmacist in community health care.

Dr. Arindam Paul – I/C Provost of Rajju Shroff ROFEL University and Principal of ROFEL Shri G.M. Bilakhia College of Pharmacy welcomed the gathering and honoured the dignitaries. In his keynote address he explained the need for updating and enriching the knowledge for the professional competence and career advancement to face the challenges. Dr. Ankita Patel Course Coordinator also welcomed the delegates and encourage participant to actively participate in all sessions. Ms. Bijal Patel Course Co-Coordinator gave a brief overview of the schedule.



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Dr. Arindam Paul delivering his welcome keynote address

First guest talk was delivered by Dr. Bhavin Vyas – Head of Department of Pharmacology and Pharmacy Practice and Associate Professor, Maliba Pharmacy College, Bardoli. He delivered a talk on “Flavors Collide – Unraveling the secrets of food – drug interaction”. He gave a very informative session on different foods which are showing their interaction with different drugs.



Dr. Bhavin Vyas delivering a session on Flavors Collide



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Vitamin B3 (Niacin)

- Alcohol**
 - Niacin can cause flushing and itchiness.
 - Consuming alcohol along with niacin might make the flushing and itchiness worse.
 - Consuming alcohol with niacin might also increase the chance of having liver damage.
- Anti gout drugs**
 - Taking large doses of niacin might worsen gout and decrease the effectiveness of Antigout drugs (Allopurinol, Probenecid, Sulfinpyrazone).
- Antidiabetics**
 - Long-term use of niacin might increase blood sugar.
 - By increasing blood sugar, niacin might decrease the effectiveness of diabetes medications.
 - Monitor blood sugar closely.
 - The dose of diabetes medication might need to be changed.
- Statins**
 - Niacin can adversely affect the muscles.
 - Statins can also affect the muscles.
 - Taking niacin along with these medications might increase the risk of muscle damage.

Participants: 233, Q&A, Chat, Share Screen, Pause/Stop Recording, Polls, Raise Hand, Apps, Whiteboards, More, End

Dr. Bhavin Vyas explaining role of Vitamin B3

Dr. Dhiren Shah – Principal, CK Pithawala Institute of Pharmaceutical Science and Research, Surat shared his expertise knowledge on the topic “Introduction to Novel Drug Delivery System”. He explained the classification of NDDS, different routes of administration, advantages – disadvantages and different challenges of NDDS. His knowledge about Novel Drug Delivery System taught all participants to think like a researcher.

C.K PITHAWALA INSTITUTE OF PHARMACEUTICAL SCIENCE AND RESEARCH (216), SURAT

**Introduction
To
Novel Drug Delivery System (NDDS)**

PRESENTED BY:
Dr. Dhiren P. Shah
Principal
CKPIPSR, SURAT

Participants: 217, Q&A, Chat, Share Screen, Pause/Stop Recording, Polls, Raise Hand, Apps, Whiteboards, More, End

Dr. Dhiren Shah delivering a session on Introduction to NDDS



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3D Printing

- 3D-printing technology has been used to design customized personal medication to provide maximal therapeutic benefits for patients.
- In addition, 3D printing has been used to manufacture drug delivery systems and biomedical devices to establish a paradigm shift in the healthcare industry.
- Benefits of 3D-printing technology include high flexibility for customizing different geometrical shapes and sizes, low production cost, and negligible unit variability, among others.
- Thus, 3D printing is valuable for the design and fabrication of diverse drug delivery systems for therapeutic applications, and development of artificial tissues and organs for biomedical applications.

Dr. Dhiren Shah explaining 3D Printing during his session

Dr. Lalji Baldaniya – Principal, Faculty of Pharmacy, Marwadi University, Rajkot delivered a talk on the topic “Regulation of Medical devices in India”. His presentation truly navigated the significance of medical devices in India. He explained the classification of medical devices. He also overviewed the basic regulatory requirement required for manufacturing, repackaging, relabeling and import of devices globally.

REGULATION OF MEDICAL DEVICES IN INDIA

DR. LALJI BALDANIYA
Professor and Principal,
Faculty of Pharmacy, Marwadi University

PRESENTED AT
GSPC-sponsored two-day online refresher course for
the Registered Pharmacists
Organized by ROFEL Shri G. M. Bilakhia College of
Pharmacy, ROFEL University, Vapi, Gujarat, India.

November 25, 2023

Dr. Lalji Baldaniya delivering his expertise knowledge on the topic Regulation of Medical devices in India



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Manu and Anand: Medical device regulations in India

growth rate and is expected to touch \$50 billion by 2025.^[1,4] The devices distributed in various segments differ in terms of market share in India. Largest segment is of the medical instruments and appliances (34%), followed by diagnostic imaging devices (3%), consumables and implants (19%), and patient aids and others (16%).^[1]

Approximately 70% of medical devices in India are imported.^[4] This gap in import vs. manufacturing provides a big opportunity to medical device manufacturers to fulfill this gap by indigenous manufacture and sales. Currently, the medical device development process is very complex and is time-consuming. Its approval is one of the most structured processes, which is highly regulated and governed by Indian Medical Device Rules (IMDR) 2017^[5] and Medical Devices (Amendment) Rules, 2020.^[6] These rules cover various aspects of device-related regulations, including classification, registration, manufacturing and import, labeling, sales, and post-market requirements, etc. The process of device development from conceptualization to post-marketing surveillance (PMS) is explained in Figure 1.

requirements and guidelines. While the drug regulations in India are well established for decades, a well-defined regulation for medical devices was missing for long. Nevertheless, the Indian regulatory regime for medical devices has recently been very active.^[10] Medical Devices and Diagnostics Division of Central Drug Standard Control Organisation (CDSCO) has developed structured regulations for medical devices, IMDR which was released in January 2017 and came into force from January 2018.^[5] IMDR was amended in February 2020 as “Medical Devices (Amendment) Rules, 2020” and came into force in April 2020. The 2020 amendment was released with an addition of “registration of certain medical devices”.^[6] Though many of the medical devices still continue to be controlled as drugs under the Drugs and Cosmetics Act, 1940, the advent of the IMDR and other supporting guidelines has paved the way for India to move its first step towards enhanced patient safety with respect to medical devices. Future amendments of IMDR can focus on fulfilling the gaps that would have equated these regulations with that of MDR and IVDR of EU, which

Dr. Lalji Baldaniya explaining status of Medical devices in India

Dr. Biren Shah – Professor SNLCP, Umrah gave a brief overview on the topic “Medication Error”. He highlighted the main challenges faced by Pharmacist during prescription handling. He also explained prescriptions and medication orders are the primary means by which prescribers communicate with pharmacists regarding the desired treatment regimen for a patient. He discussed about the problems involved with medication and problems encountered by pharmacist in handling prescription. He emphasized that, there is a need for uniform Medication policy in India.

MEDICATION

ERROR

BY
DR. BIREN N. SHAH
PROFESSOR & HOD
SNLPCP. UMRAKH

Dr. Biren Shah delivering his post session on topic Medication Error



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CRITICAL THINKING

- You have given Mrs Veena her medication including cough Elixir. She asks you ,Now you didn't give me any Codeine ,did you? I am allergic to it .
- You reply that there is no codeine in her medication.
- After returning to the medication room, you think again and recheck the bottle of the cough elixir and find that it contains Codeine.

Dr. Biren Shah making all participants to critical think on the case study on Medication Error

Dr. Vaishali Thakkar – Professor and Research Coordinator, Anand College of Pharmacy, Anand shared her expertise knowledge on the topic “Alcohol – Induced Dose Dumping Modified Release Formulation”. She gave a informative presentation on current status of alcohol-induced dose dumping and the need for regulatory harmonization in handling this challenge.

Alcohol-Induced Dose Dumping Modified Release Formulations

Presented by:
Dr. Vaishali T. Thakkar
Professor and Research coordinator
Pharmaceutics department

Two day Refresher course for Registered Pharmacist

Dr. Vaishali Thakkar delivering a session on Alcohol – Induced Dose Dumping Modified Release Formulation



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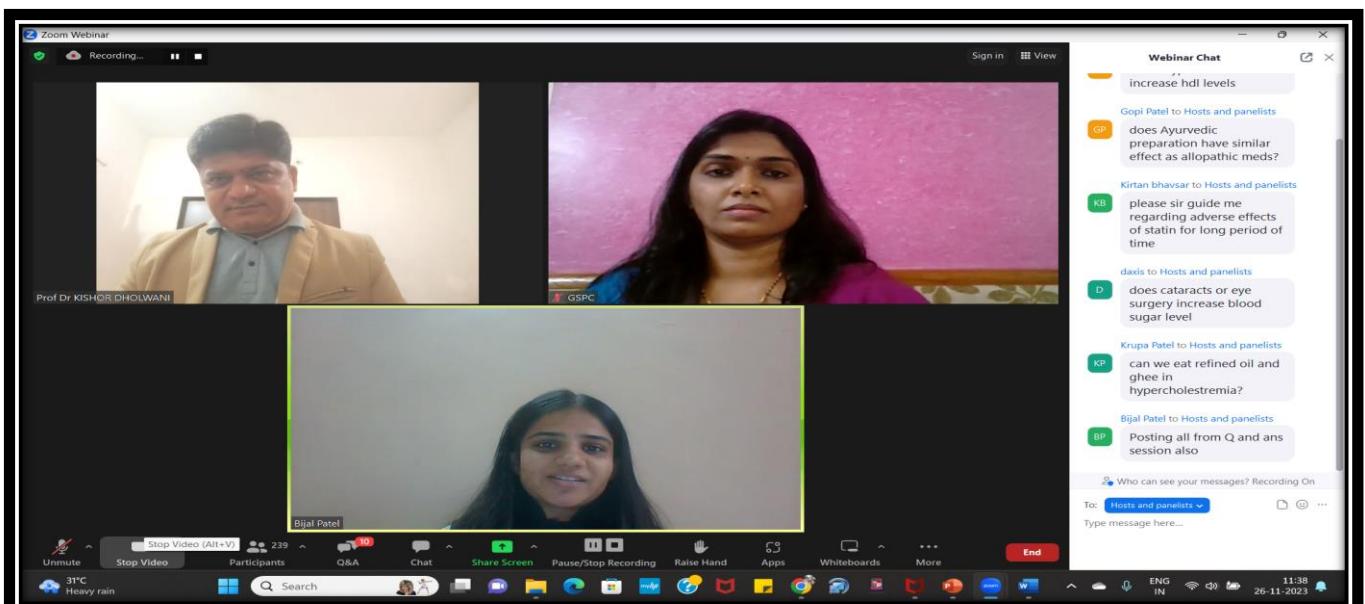
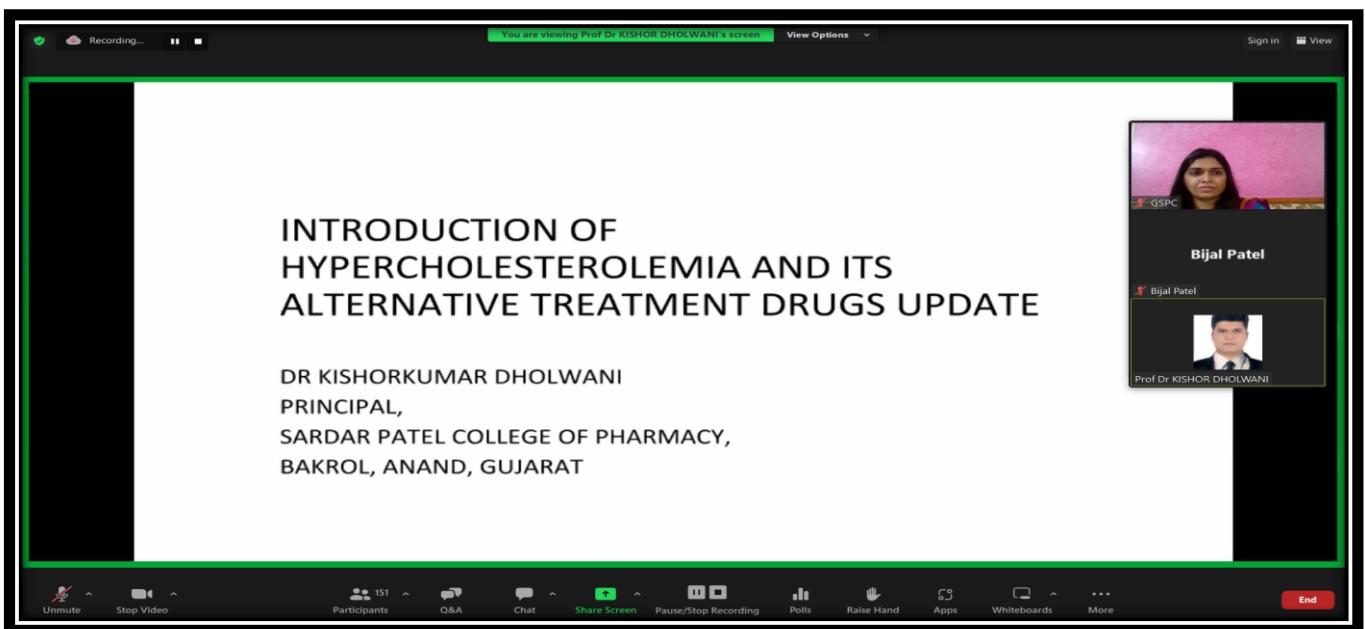
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Dr. Kishor Dholwani – Principal, Sardar Patel College of Pharmacy, Bakrol, Anand delivered a talk on the topic “Introduction of Hypercholesterolemia and its alternative treatment drugs update”. His session explained causes, risk factors, symptoms associated with hypercholesterolemia. He also gave a brief overview about the treatment used to cure it.



Dr. Kishor Dholwani delivering his expertise knowledge on the topic Introduction of Hypercholesterolemia and its alternative treatment drugs update and solving the Q and A session by the participants



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Dr. Pravin Tirgar – Director, School of Pharmacy, R.K. University, Rajkot gave a brief overview on the topic “Essentials of ADR and its Reporting”. He explained how to report ADR and how to fill ADR forms. He also delivered online authentic applications for reporting of ADR.

“GSPC Sponsored
Refresher Course for Pharmacist-2023”

**Essential of
Adverse Drug Reactions (ADR)
and
It's Reporting**

Dr. Pravin R. Tirgar
Ph.D., M. Pharm (Pharmacology)
Principal and Professor,
School of Pharmacy,
R K University, Rajkot, Gujarat

RKUNIVERSITY

Dr. Pravin Tirgar delivering a talk on the topic Essential of ADR and its Reporting

(I) Non-drug factors:

(a) Intrinsic to the patients:

Age:

Elder: Alteration in physiological function, aging and disease state.
e.g.T1/2 of diazepam

Neonates: Different pharmacokinetic.
e.g. Chloramphenicol - Gray baby syndrome.

Gender/Sex:

Female: More susceptible
Chloramphenicol – aplastic anemia (2 times common)
Phenylbutazone – agranulocytosis (3 times common)

Race/Genetics:

e.g. **Acetylators:** Isoniazid – liver toxicity

Dr. Pravin Tirgar explaining the risk factors associated with ADR



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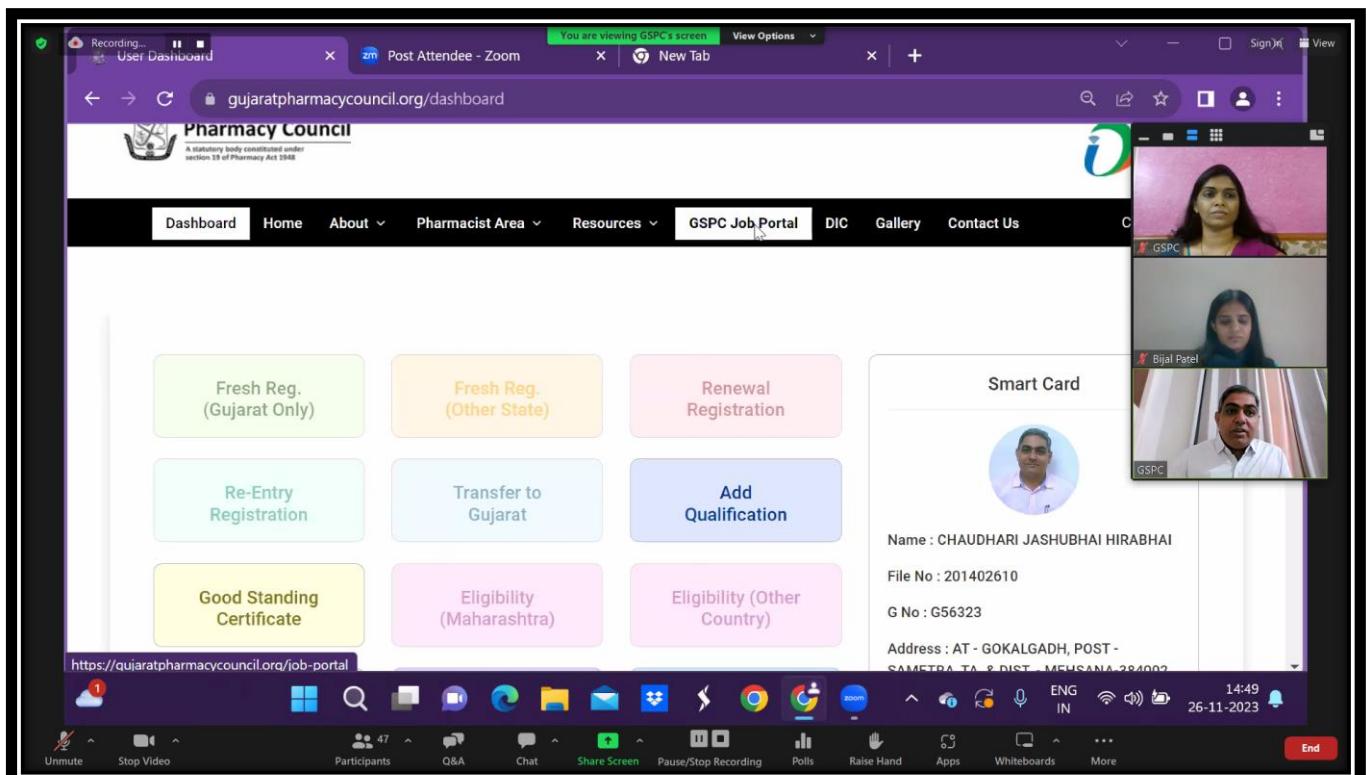
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The valedictory function was graced by the presence of Mr. Jasubhai Chaudhary – Registrar, Gujarat State Pharmacy Council. In his keynote address he highlighted the activities and efforts put by the state pharmacy council. He congratulated all registered pharmacists for participation in online refresher course and gave information about the new initiatives started by GSPC. He emphasized about the paperless system adopted by the council which has helped in organizing and tracking the files. In addition to it he explained about the online process for renewal of license.



Mr. Jasubhai Chaudhary explaining in brief about online renewal and various activities provided by GSPC



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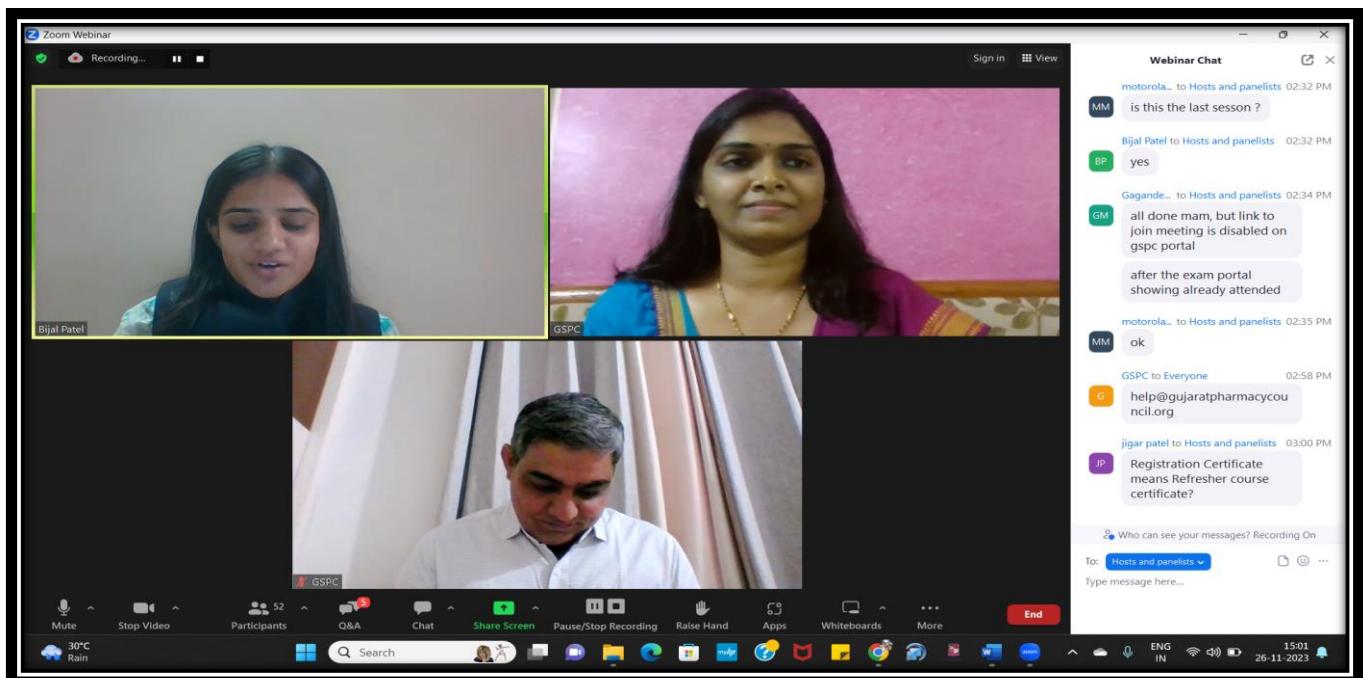
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Ms. Bijal Patel and Dr. Ankita Patel delivering vote of thanks

Ms. Bijal Patel proposed the vote of thanks thanking all eminent speakers for sharing their expertise and insights with us. Finally she expressed her gratitude to all esteemed delegates of the session for their presence and contribution to make this refresher course a great success.

Lastly it was pleased to see the active and enthusiastic participation of the participants in Question and Answer session held at the end of every session. The participants of the two days online refresher course also gave their feedback at the end of the session via google form link provided by the course coordinator. In addition to it the participants were systematically evaluated and graded through multiple choice questionnaires of 20 marks with 30 minutes of time duration. The participants who didn't appear or attempted the examination were not considered eligible for the e-Certificates.

The event was successfully accomplished by Course Coordinator – Dr. Ankita Patel and Course Co Coordinator Ms. Bijal Patel under the guidance of Course Director – Dr. Arindam Paul.

**Prepared By: Dr. Ankita Patel (Course Coordinator)
Ms. Bijal Patel (Course Co Coordinator)**