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WEBINAR FOR CELEBRATING

4Th NATIONAL PHARMACOVIGILANCE WEEK

On

"Building ADR Reporting Culture for Patient Safety"

www.pgims.org.in

Campus : Chandrakona Town, Paschim Medinipur, West Bengal, Pin - 721201

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OUR CHIEF GUEST

DR. SWAPNANIL MISTRY

BMOH, Chandrakona Rural Hospital

Topic : BUILDING ADR REPORTING CULTURE FOR PATIENT SAFETY

OUR EMINENT SPEAKERS

Dr. SUBRATA CHAKRABORTY

**FORMER GM Dr. REDDY'S LABORATORY,
FORMER VICE-PRESIDENT- CIPLA & FKB.
PRESENTED CONSULTANT & INDUSTRY
RESOURCES PERSON**

Topic : INDUSTRIAL EXPERTISE IN VARIOUS FIELDS

Mr. AVIJIT GHOSH

**ASSISTANT DRUG CONTROLLER (ADC),
DEPT. OF DRUGS CONTROL,
NCT OF DELHI**

Topic : REPORTING ADRs & DEVELOPMENT OF MEDICAL DEVICES IN PHARMACEUTICAL INDUSTRY

Dr. NIRANJAN SHARMA

**DIRECTOR LaSante FORMULATION
PHYTOCHEM HEALTHCARE**

Topic : GMP & RELATED DEVELOPMENT

REPORT ON THE WEBINAR FOR CELEBRATING 4TH NATIONAL PHARMACOVIGILANCE WEEK

P.G Institute of Medical Sciences the department of pharmacy of GOPSAI AVINANDAN SANGHA has Organizingd a webinar for celebrating **4th National Pharmacovigilance Week 2024 on "Building ADR Reporting Culture for Patient Safety" between 17th September2024 to 23rd September 2024**, through the Google meet platform.

The inauguration ceremony of **4th National Pharmacovigilance Week 2024 held on 18th September 2024 in seminar hall** (ML SCHROFF SEMINER HALL) of P.G Institute of Medical Sciences. The inaugural ceremony started with a warm welcome of the dignitaries. This step towards **4th National Pharmacovigilance Week 2024 celebration** was encouraged with kind support of Patron Dr. Pravas Ghosh (Chairmen, P.G.I.M.S); Convener Dr. Karunamoy Bhattacharya (Principal, I.S.T.); Organizing Secretary Dr. Biplab Kumar Chakra (Principal, P.G.I.M.S.); Joint Secretary Mr. Tapan Chakraborty (T.P.O. of P.G.I.M.S.); Coordinators Mr. Nilanjan Adhikari (O.I.C. & Asso. Prof. Dept. of Pharmacology, P.G.I.M.S) and Mr. Samyadip Singharoy (Asso. Prof. Dept of Pharmacology, P.G.I.M.S) shared the dais along with the chief guest of the inaugural function Dr. Swapnanil Mistry (BMOH, Chandrakona Rural Hospital). The students, faculty members as well as staff of P.G Institute of Medical Sciences grace the seminar by their valuable presence. The introduction speech was given by Dr. Biplab Kumar Chakra (Principal, P.G.I.M.S.). After the introduction, our chief guest and all the dignitaries lightened up the lamp and they are felicitated with Uttorio and flower bouquet by our respected faculties.

DR. SWAPNANIL MISTRY

BMOH, Chandrakona Rural Hospital

Chief Guest Dr. Swapnanil Mistry (BMOH, Chandrakona Rural Hospital) started his speech with the introduction of ADR (Adverse Drug Reaction) and its importance. He also addressed the students regarding the types of ADR. He focused specifically on ADRs and explained that the problem occurs after drugs taken by patients and the impact on boundary conditions, as well as how to aware about ADR for patent and how to report ADR to reporting center or help line, about pharmacovigilance team and how they work, deferent type of ADR and the existence of solutions and their validity.

The Oath taking was held with full enthusiasm which marks the purpose of the ceremony. We received good response from the audience and also they gave very good feedback. After the Oath taking , Event concluded with a vote of thanks to the Patron Dr. Pravas Ghosh (Chairmen, P.G.I.M.S); Convener Dr. Karunamoy Bhattacharya (Principal, I.S.T.); Organizing Secretary Dr. Biplab Kumar Chakra (Principal, P.G.I.M.S.); Joint Secretary Mr. Tapan Chakraborty (T.P.O. of P.G.I.M.S.); Coordinators Mr. Nilanjan Adhikari (O.I.C. & Asso. Prof. Dept. of Pharmacology, P.G.I.M.S) and Mr. Samyadip Singharoy (Asso. Prof. Dept of Pharmacology, P.G.I.M.S), Faculty members, participants and other officials for their active support for making the program to be successful.

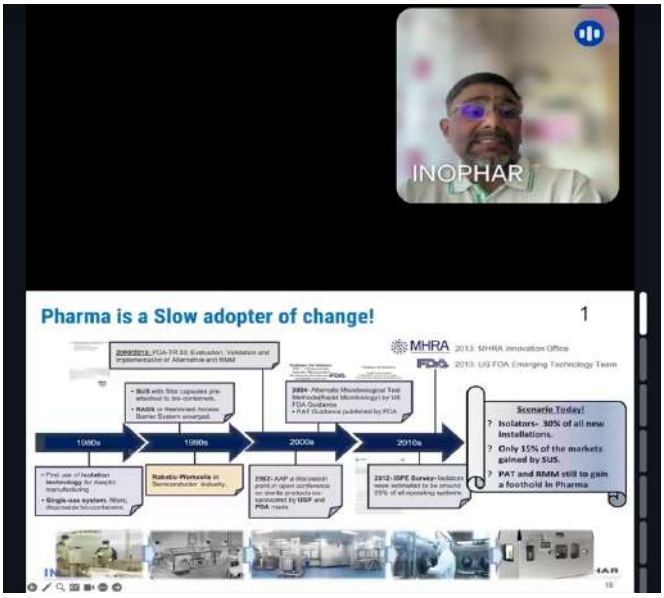
Dr. SUBRATA CHAKRABORTY

FORMER GM Dr. REDDY'S LABORATORY,
FORMER VICE-PRESIDENT- CIPLA & FKB.
PRESENTED CONSULTANT & INDUSTRY RESOURCES PERSON

Second day of Webinar on **"Building ADR Reporting Culture for Patient Safety"** was Organized on 19th of September 2024 by the P.G Institute of Medical Sciences. Dr. Subrata Chakraborty the former GM Dr. Reddy's Laboratory, former Vice- President- Cipla & FKB was the speaker of the day. The webinar was focused mainly on the **"Industrial Expertise in Various Fields"**.

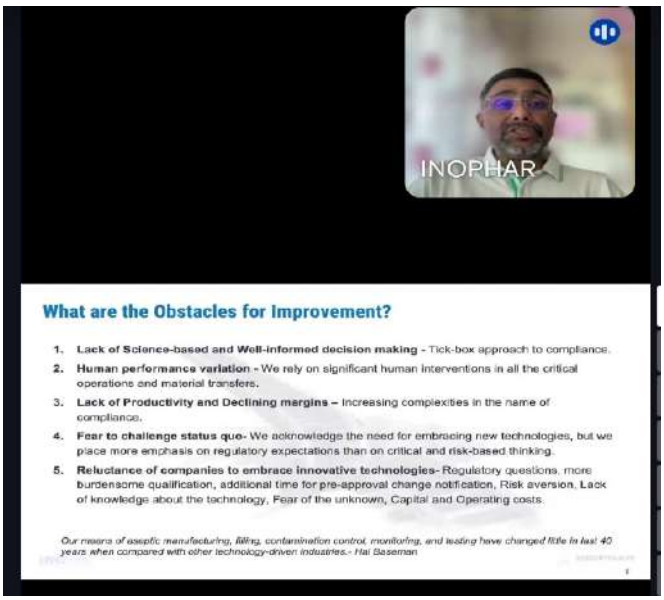
A broad range of disciplines, each possessing its own set of best practices, technologies, and abilities contribute to industrial expertise. Webinar was hosted by and Mr. Samyadip Singharoy (Asso. Prof. Dept of Pharmacology, P.G.I.M.S). The main aim of this webinar was to enlighten the students about the Industrial performa & It generally refers to the abilities, experience, and proficiency that people or organizations have in work environments. Technical expertise, an awareness of production procedures, and acquaintance with instruments and equipment across a range of industries may serve as examples of this.

The eminent speaker of the day Dr. Subrata Chakraborty shared his thought from the perception of an industry expert. He presented about manufacturing segment regarding production for hundred of years, pharmaceuticals have been utilized to treat medical conditions. In the early days of medicine, a wide range of illnesses and traumas were treated with plants and herbal remedies. Today, a multibillion dollar global business exists around the drawn-out and difficult process of proving a compound's safety and effectiveness and getting it from the laboratory into the hands of people in need.



Pharmaceutical companies are always looking to develop novel, cutting-edge therapies that will extend and improve people's lives. Pharmaceutical businesses develop, produce, sell, and deliver these therapies on a daily basis all around the world. This article examines some of the industry's major accomplishments and explains the significance of pharmaceutical companies for patients, society, and the life sciences sector.

He further spoke about the About R&D a new medication or medical device must have precise, timely clinical and business insights at every stage of its development for the process to be as successful as possible. Pharmaceutical businesses lose years of valuable time and billions of dollars due to the "life science insight gap" in R&D when they do not have them. Issues with traditional virtual meetings, one-time events with erratic attendance, and erratic engagement were among the difficulties made worse by the COVID-19 epidemic. There is inefficient gathering, sharing, or utilization of crucial information. Researchers and developers have been forced by the insight gap to come up with innovative, productive ways to interact virtually. Reduce the duration. To promote complete attendance and involvement, convenient asynchronous sessions are arranged across days or weeks, sometimes in tandem with live webcasts. Say goodbye to wasting time on individual session scheduling that result in sporadic participation or a few loud individuals controlling the conversation. As fresh ideas and feedback are exchanged, additional data points are acquired. Observe the most recent developments. More participation results in more current responses to new information on scientific trends and research. Choose the appropriate specialists early on in the development process locating and choosing the appropriate individuals, not just the customary list but also up-and-coming experts, to assist you in avoiding the knowledge vacuum and provide you with the new insights required to produce outcomes. Download our white paper, "Best Practice Guide: Transforming Insights into Business Value," to find out more about how pharmaceutical companies can begin using insights management. He also describe about Disruption accelerated by COVID-19 and also about the facing Obstacles for improvement of Pharmaceutical industry.



There was a Q&A session where Dr. Subrata Chakraborty answered many questions of the Attendees. He also explained and gave various examples too. In addition to that, he suggested various applications and skill sets for the attendees to work on.
In the end, Respected Principal Dr. Biplab Kumar Chakra, P.G.I.M.S. gave the Vote of Thanks. He thanked Dr. Subrata Chakraborty for sparing his time from his busy schedule and sharing his insightful and informative knowledge about the "Industrial Expertise in Various Fields" to the attendees' present. He also thanked the Patron Dr. Pravas Ghosh (Chairmen, P.G.I.M.S); Convener Dr. Karunamoy Bhattacharya (Principal, I.S.T.), Joint Secretary Mr. Tapan Chakraborty (T.P.O. of P.G.I.M.S.); Coordinators Mr. Nilanjan Adhikari (O.I.C. & Asso. Prof. Dept. of Pharmacology, P.G.I.M.S) and Mr. Samyadip Singharoy (Asso. Prof. Dept of Pharmacology, P.G.I.M.S), Faculty members, participants and other officials for their enthusiastic cooperation in ensuring the program's success.

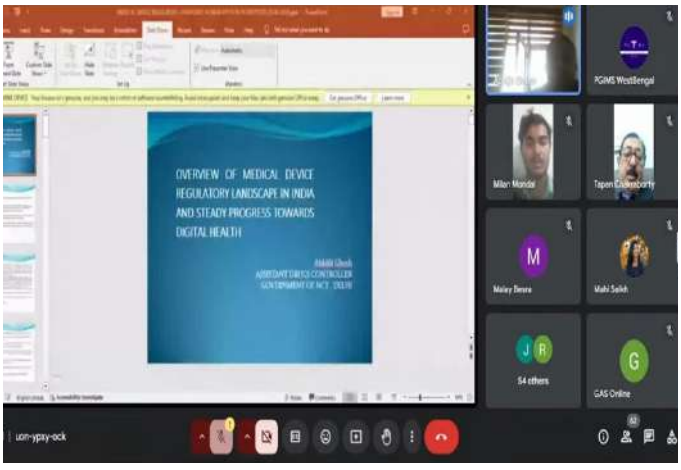
Mr. AVIJIT GHOSH

ASSISTANT DRUG CONTROLLER (ADC),
DEPT. OF DRUGS CONTROL,
NCT OF DELHI

The third day of a webinar on "**Building ADR Reporting Culture for Patient Safety**" was Organized by the P.G. Institute of Medical Sciences on September 20, 2024. The day's speaker was Mr. Abhijit Ghosh, the Assistant Drug Controller (ADC) from the NCT of Delhi's Department of Drug Control. Regarding **"Reporting ADRs & Development of Medical Devices in Pharmaceutical Industry,"** he offered his opinions. In the pharmaceutical sector, developing medical devices and disclosing Adverse Drug Reactions (ADRs) are essential to guaranteeing efficacy and safety. The main goal of this webinar was to educate the students on the advancements in medical device development within the pharmaceutical industry.

Under the Drugs and Cosmetics Act 1940, regulations pertaining to medical devices officially came into effect on January 1, 2018, that regulate clinical research, device manufacturing, importation, sales, and distribution in India. The Central Government used the powers under section 12 and section 33 of the Drugs and Cosmetics Act 1940 to make the said Rules.

He also talked about how, following an online periodic meeting with medical device association members, CDSCO announced the classification of 26 categories of medical devices under sub-rule (3) of Rule 4 of the Medical Devices Rule. This classification was based on the intended use, risk associated with the device, and other parameters specified in the First Schedule of the Medical Devices Rule 2017 and compared with the global classification system of the USFDA, EU, JAPAN, and Singapore. A public notice listing the "Classification of Medical Devices" is accessible on the CDSCO web page. CDSCO classified 60 medical devices related to software under sub-rule (3) of Rule (4) of MDR. The classification was based on the device's associated risk as well as the medical purposes that the device was intended to treat, diagnose, cure, mitigate, or prevent.
He also discussed the Medical Devices Online Portal, which is operational for accepting applications for the granting of Manufacturing, Import, Retention, Loan, Test, and Post-Approval modifications licenses as well as Clinical Investigation of Medical Devices and Clinical Performance Evaluation of In-vitro Diagnostic Devices.

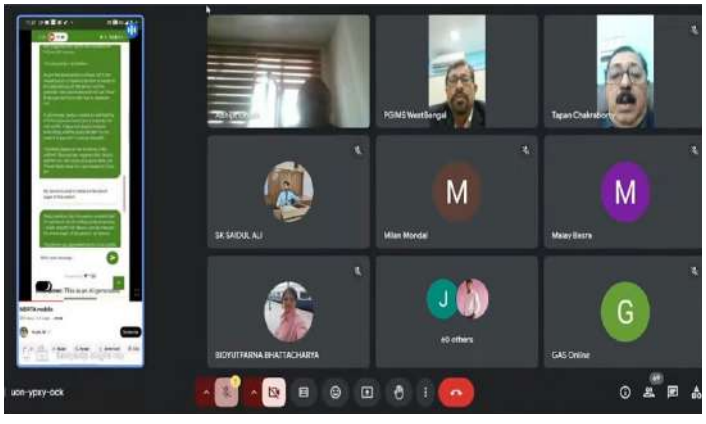


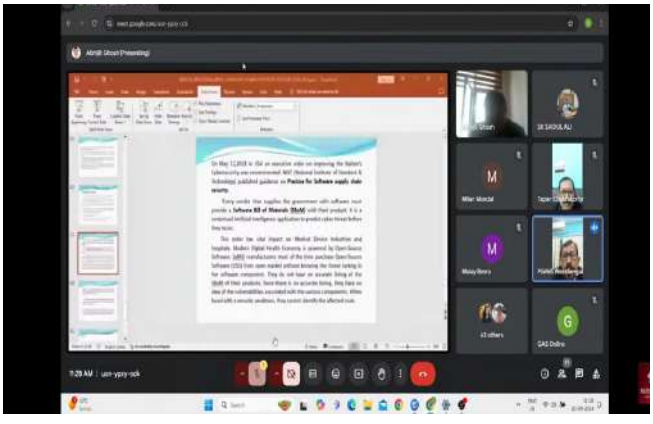
medical device, including an in vitro diagnostic device. Preserve the availability, confidentiality, and integrity of the health data that SaMDs process (CIA Triad: The cornerstone of any security framework). The long-term viability of a medical device manufacturer's goods, services, and solutions depends on the idea of security built in, or end-to-end, from design to production to support. An essential pillar of the device life cycle is the integration of cyber security into the design and deployment phases. Strong guidelines and practices for Following the guidelines outlined in ISO 14971, the "Zero Trust Security Model," or "Never trust always verify," can be used to detect and remediate emerging vulnerabilities in SaMD. Determine all potential threats to cyber security, analyze the related risk, put controls or mitigations in place to bring risks down to a manageable level, then keep an eye on and assess how well the mitigation measures are working.

He continued by discussing an executive order to strengthen the countries cyber security was suggested on May 12, 2021 in the United States. The National Institute of Standards and Technology, or NIST, released guidelines on software supply chain security practices. Each software supplier to the government is required to include a Software Bill of Materials (SBOM) with their offering. This application of contextual artificial intelligence forecasts cyber threats before they happen. The Medical Device Industry as well as hospitals will be greatly impacted by this regulation. Open-Source Software drives the contemporary digital health economy. Open-Source program (OSS) is typically purchased by SaMD manufacturers from the open market, oftentimes without their knowledge of potential security risks associated with the program. Their SBOM listings for their products are inaccurate. Their ignorance of the vulnerabilities linked to the different components stems from the lack of an exact listing. They are unable to recognize the code that is impacted by a security flaw.

During the Q&A session, Mr. Abhijit Ghosh provided answers to a number of queries from the attendees. Furthermore, he recommended a range of possibilities and expertise that the attendees should focus on.

The vote of thanks was finally given by Honorable Principal Dr. Biplab Kumar Chakra, P.G.I.M.S. He expressed his gratitude to Mr. Abhijit Ghosh for taking time out of his hectic schedule to speak with the attendees about "Reporting ADRs & Development of Medical Devices in Pharmaceutical Industry" and to share his insightful and educational expertise. Additionally, he expressed gratitude to the Patron Dr. Pravas Ghosh (Chairmen, P.G.I.M.S.); Convener Dr. Karunamoy Bhattacharya (Principal, I.S.T.); Joint Secretary Mr. Tapan Chakraborty (T.P.O. of P.G.I.M.S.); Coordinators Mr. Nilanjan Adhikari (O.I.C. & Asso. Prof. Dept. of Pharmacology, P.G.I.M.S.) & Mr. Samyadip Singharoy (Asso. Prof. Dept. of Pharmacology, P.G.I.M.S.), Faculty members, participants, and other officials for their motivated collaboration to ensure program achievement.





Dr. NIRANJAN SHARMA

DIRECTOR LaSante FORMULATION
PHYTOCHEM HEALTHCARE

The last day of a webinar on "Building ADR Reporting Culture for Patient Safety" was Organized by the P.G. Institute of Medical Sciences on September 20, 2024. The day's speaker was Dr. Niranjan Sharma, the Director of La Sante Formulations Private Limited in the division of Phytochem Healthcare. Regarding “GMP & Related Development” he offered his opinions. GMP refers to the procedures and laws that ensure goods are manufactured consistently and under strict quality control, particularly in the food, pharmaceutical, and cosmetics industries.

Our eminent speaker discussed about Good Manufacturing Practices (GMPs), which is a collection of guidelines, guidelines documents, and directives developed by international organizations and institutions in partnership with the pharmaceutical industry and multiple national regulatory bodies across various regions and nations.
The primary goal of GMPs is to ensure the highest levels of safety, quality, and efficacy in any process that involves the manufacturing of health products. GMPs are regulations that control a drug's supply, distribution, and manufacturing. Getting marketing authorization (MA) requires it. This review's objective is to map pharmaceutical regulation, manufacturing, distribution, and consumption.

He discussed how it is intended to show and provide the General/Current State of GMP for Medicinal Products for Human Use? emphasizing the importance of a continuous update, regulatory harmonization, its adoption, and monitoring/inspection. This will help to achieve, through greater consensus, the continuous evolution of quality assurance, safety, and efficacy. The regulatory harmonization of GMP for human use drugs and stricter compliance monitoring by the relevant authorities are made possible by the close cooperation of multiple national and international organizations. Since the middle of the first half of the 20th century, all parties concerned in the pharmaceutical and health industries have been trying to design, comprehend, and apply GMP principles.

He highlighted The guidelines for GMP for Medicinal Products for Human Use, which are issued by national and international organizations and institutions, such as the US Food and Drug Administration (FDA), the World Health Organization (WHO), the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), and the Pharmaceutical Inspection Co-Operation Scheme (PIC/S), were cited as needed in compliance with the directives from the European Commission (EC).

He pointed out the crucial roles of Good Manufacturing Practices (GMP) are essential to public health because they guarantee that goods, especially food, medicine, and pharmaceuticals, are manufactured and managed consistently in accordance with quality standards. Here are some salient features of their significance: Safety Assurance, Product Quality, Regulatory Compliance, Risk Management, Public Trust, Worldwide Health, Continuous Improvement :

He also highlighted that Assuring that products fulfill the necessary safety, efficacy, and quality criteria throughout the production process is the primary responsibility of quality control (QC) under good manufacturing practices (GMP). Standards of Operation for Quality Control Systems (SOPs), Quality Management System (QMS), Examination of Raw Materials, Real-Time Monitoring, In-Process Testing, Batch Release, Stability Testing, Record-keeping and Documentation Traceability. In conclusion, GMP is critical to protecting public health since it guarantees the efficacy, safety, and quality of goods that people use on a regular basis. At the time question-and-answer session, Dr. Niranjan Sharma addressed several questions asked by the participants. In addition, he conclude, GMP is critical to protecting public health since it guarantees the efficacy, safety, and quality of goods that people use on a regular basis.

At last, Honorable Principal Dr. Biplab Kumar Chakra, P.G.I.M.S., offered the vote of gratitude. He was appreciative of Dr. Niranjan Sharma's willingness to take a break from his busy schedule to talk with the attendees about "GMP & Related Development" and to impart his knowledge and wisdom. Further, he expresses feelings of gratitude to the following individuals: Patron Dr. Pravas Ghosh (Chairmen, P.G.I.M.S.); Convener Dr. Karunamoy Bhattacharya (Principal, I.S.T.); Joint Secretary Mr. Tapan Chakraborty (T.P.O. of P.G.I.M.S.); Coordinators Mr. Nilanjan Adhikari (O.I.C. & Asso. Prof. Dept. of Pharmacology, P.G.I.M.S.) & Mr. Samyadip Singharoy (Asso. Prof. Dept. of Pharmacology, P.G.I.M.S.); Faculty members, participants, and other officials for their enthusiasm collaboration to make sure the program's achievement