

PHARMACOVIGILANCE WEBINAR AUDIT AND INSPECTION

SEPTEMBER
8, 2023

UAE- 1:00 AM-3:30 PM

USA-5:00 AM-7:30 AM

INDIA-2:30 PM-5:00 PM

FR 11:00 AM.-1:30 AM

CHIEF SPEAKER



DR. SOMNATH BASU,
EX- DY DRUG CONTROLLER, INDIA

ORGANIZERS



ORIANE BISMUTH
LUCKY LINK



DR. CHINMAYA MAHAPATRA
GLOBAL PVS



MR. ALAIN KUT
AK CONSULTING

GUEST SPEAKERS



DR. AHMED
HEGAZY, UAE



DR. MANOJ
SWAMINATHAN, INDIA



DR. HADIR ROSTOM,
EGYPT



DR. JOSE ALBERTO
AYALA ORTIZ,
SPAIN



DR. BASSEM
TOEAMA, CANADA



DR. AMIT JADHAV,
UK

CHAIRS



DR. LUCA CARIOLATO
ASSOCIATE EDITOR,
JPADR



DR. RAJINDER K JALALI
CO-FOUNDER, GPVS
ADVISOR, JPADR



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MORE INFORMATION

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PHARMACOVIGILANCE WEBINAR

AUDIT AND INSPECTION

SEPTEMBER 8, 2023

TOPICS



DR. SOMNATH BASU, EX- DY DRUG CONTROLLER, INDIA

OVERVIEW OF PV INSPECTION FROM REGULATORY PERSPECTIVES



DR. AHMED HEGAZY, UAE

OVERVIEW OF PV INSPECTION
FROM REGULATORY
PERSPECTIVES



**DR. JOSE ALBERTO AYALA
ORTIZ, SPAIN**

AUDITS AND INSPECTIONS
FROM A PV AUDITOR AND
QPPV PERSPECTIVE



**DR. MANOJ SWAMINATHAN,
INDIA**

REMOTE PV INSPECTIONS /
AUDITS



**DR. BASSEM
TOEAMA, CANADA**

HOW DID THE NOVEL MRNA
COVID-19 VACCINES SHIFT
THE PARADIGM OF
VACCINOLOGICAL



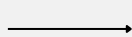
DR. HADIR ROSTOM, EGYPT

OPTIMIZING THE SCOPE OF PV
AUDIT/INSPECTION



DR. AMIT JADHAV, UK

PV AUDIT AND INSPECTION: A
PHARMACOVIGILANCE
PHYSICIAN PERSPECTIVE



PV AUDIT AND INSPECTION

OBJECTIVE

To share knowledge on the effective implementation of PV systems following regulatory guidelines.

UNIQUENESS

Uniformity in delegates
Direct interactions with PV Auditors
Networking

WHO CAN JOIN?

Pharmacovigilance
Associates/Managers/Directors -
Global Head - QPPV - LQPPV -
Pharmaceutical Industry

FEES

Pharmacovigilance Professionals <i>with e-certificate</i>	20 USD
Others (Quality Assurance Professionals/ Students/ Academia/ Clinical research Professionals) - <i>with e-certificate</i>	10 USD
Free (Join through You Tube Live Streaming) - <i>without certificate</i>	0 USD



CERTIFICATION

TWO WAYS OF PARTICIPATION :

- **FREE** THROUGH YOU TUBE LIVE STREAMING. **NO POSSIBILITIES OF QUESTIONS OR E-CERTIFICATE**
- **PAID** PARTICIPATION THROUGH ZOOM LINK. PARTICIPANTS WILL **INTERACT** WITH THE SPEAKERS AND WILL RECEIVE **E-CERTIFICATE** FROM GLOBAL PVS

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AGENDA

PHARMACOVIGILANCE WEBINAR: AUDIT AND INSPECTION



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TIME (INDIA)	SPEAKER	TOPIC	CHAIR PERSON	MODERATOR
2:30-2:40 PM		Welcome Address		Ms. Oriane Bismuth
2:40-2:55 PM	Dr. Somnath Basu, Ex-Dy Drug Controller, India	Overview of PV inspection from Regulatory perspectives	Dr. Rajinder K. Jalali	Ms. Oriane Bismuth
2:55-3:10 PM	Dr. Ahmed Hegazy, UAE	Overview of the common findings in PV audits and inspection	Dr. Rajinder K. Jalali	Ms. Oriane Bismuth
3:10-3:25 PM	Dr. Manoj Swaminathan, India	Remote PV Inspections / Audits	Dr. Rajinder K. Jalali	Ms. Oriane Bismuth
3:25-3:40 PM	Dr. Hadir Rostom, Egypt	Optimizing the Scope of PV Audit/Inspection	Dr. Rajinder K. Jalali	Dr. Chinmaya Mahapatra
3:40-3:55 PM		Break Time		
3:55-4:10 PM	Dr. Jose Alberto Ayala Ortiz, SPAIN	Audits and Inspections from a PV Auditor and QPPV perspective	Dr. Luca Cariolato	Dr. Chinmaya Mahapatra
4:10-4:25 PM	Dr. Amit Jadhav, UK	PV audit and inspection: A pharmacovigilance physician perspective	Dr. Luca Cariolato	Mr. Alain Kut
4:25-4:40 PM	DR. Bassem Toeama, Canada	How did the novel mRNA COVID-19 vaccines shift the paradigm of Vaccinovigilance	Dr. Luca Cariolato	Mr. Alain Kut
4:40- 4:50 PM		Interaction with Delegates, Q&A		Ms. Oriane bismuth
4:50-5:00 PM		Vote of Thanks		Dr. Chinmaya Mahapatra

MORE INFORMATION →

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