ClinAcademy and USEK Present:

The Premier Pharmacovigilance Executive Certificate

USEK | ClinAcademy By CLINGROUP

Since 2002

Who We Are

ClinAcademy By CLINGROUP
Since 2002

ClinAcademy inherits the unparalleled pharmacovigilance expertise that ClinGroup has cultivated over 23+ years across 60 countries in Europe, the Middle East, and Africa. As a unique health solutions provider, ClinGroup empowers healthcare industries and institutions by supporting their research and development programs, whether focused on diagnosis, treatment methods or products, or on establishing and maintaining effective systems and developing essential resources. With roots in its original French establishment 23 years ago, ClinGroup has grown into a thriving network across Africa and the Middle East, enriched by close collaborations with diverse stakeholders in the health sector.

USEK

The Holy Spirit University of Kaslik (USEK), founded in 1938 by the Lebanese Maronite Order, is Lebanon's first private, non-profit university established by Lebanese citizens. Rooted in Catholic values and committed to inclusivity, USEK offers American-style education with international accreditations, preparing students for global opportunities while remaining deeply connected to Lebanon. Its programs span major fields and integrate vocational specializations tailored to labor market demands, fostering a diverse community grounded in Christian humanism and dedicated to excellence, innovation, and respect for cultural and religious pluralism.

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About our Program

Are you a healthcare professional looking to make a real impact in patient safety?

Pharmacovigilance is the science and activities involved in the detection, assessment, understanding, and prevention of adverse effects or any other medicine/vaccine-related problem. Its primary goal is to enhance patient safety by monitoring and evaluating the safety and efficacy of medications throughout their lifecycle, from development to post-market surveillance.

This program provides practical training related to Pharmacovigilance Professional job functions and covers all the activities to promote successful studying of drug's adverse effects, compliance with EU and FDA standards as well as proper report building Individual Case Safety Report (ICSR), Periodic Safety Update Reports (PSURs) and real case studies.
The program also describes the statistical methods adapted to Pharmacovigilance, in addition to Cosmeto-vigilance, Materio - vigilance, and the proper use of the MedDRA.

Upon program completion, participants will be provided training certificates from USEK and ClinAcademy.

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Program Outline

- Introduction Pharmacovigilance System.
- Pharmacovigilance system Master File (PSMF) and Capacity Building
- Management of ICSRs (collection, evaluation, processing, and reporting)
- Preparation and submission of PSURs and other safety aggregate reports (RMPs, ACOs)
- Signaling & Risk Assessment
- PV Quality Management System
- PV in clinical trials - Cosmetovigilance- Materiovigilance
- Practical Module 1
- Practical Module 2

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Learning Outcomes

Get familiar with the role of the World Health Organization (WHO), Council for International Organizations of Medical Sciences (CIOMS)'s, as well as the EMA (European Medicine Agency), and the role of the Qualified Person for Pharmacovigilance **(QPPV).**

Acquire skill in how to build an **ICSR**, process cases, and perform a quality and medical review.

Become an expert in **PSURs** (Periodic Safety Update Report) and build a comprehensive risk management plan.

Master **Signal Detection and Management** along with key data mining

methods and statistical methodologies

Establish robust frameworks for pharmacovigilance excellence, encompassing Standard Operating Procedure (SOP) development, PV center setup, optimization, and more.

Implement PV systems for clinical trials, manage Serious Adverse Effects (SAEs), and ensure vigilance across cosmetics and medical devices.

Receive invaluable practical experience in case studies, usage of MedDRA, and medical writing.

Career Opportunities

Clinical Data Coordinator (CDC) in pharmacovigilance	Product Safety Specialist
Drug Safety Manager or Director	Drug Safety Associate (DSA) or Scientist
Pharmaceutical Information Specialist	PV Professions: A collective term for various roles in Pharmacovigilance.
Pharmacovigilance Trainer	Qualified Person for Pharmacovigilance (QPPV)

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Beyond Pharmacovigilance Roles, Your Executive Certificate Opens Door to Diverse Career Opportunities in:

- Biotechnology Firms
- Clinical Research Organizations
- Regulatory Authorities
- Contract Research Organizations (CROs)
- Medical Device Companies
- Consulting Firms
- Pharmaceutical companies
- Government agencies
- Hospital and healthcare institutions
- Health authorities

Who Should Apply

1. Graduate, postgraduate degree in Chemistry, Biochemistry, Biology and Biotechnology
2. Graduate, postgraduate degree in Pharmacy Pharmaceutical Sciences or Medicine
3. Pharmacists, nurses, doctors and other healthcare professionals
4. Individuals looking for a career change
5. Patient Safety or Drug Safety Organization professionals
6. Regulatory affairs professionals
7. Clinical Research Associates (CRAs)
8. Biomedical Scientists / Biomedical Engineers
9. Public Health officials
10. Government and Non-Governmental Organizations (NGOs)
11. Medical Writers
12. Biostatisticians
13. Quality Assurance Professionals
14. Chemical Engineers

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Meet the International Experts

Dr. Nadia Cheaib

Founding President ClinGroup, QSI & DNCI

7 Times Forbes Top Leaders President Health Committee French Saudi Business Council.

Dr. Thomas Dobmeyer

Founder and former CEO at PharmaLex

Advisor at Ekwithree
Managing Partner at Yes Pharmaceutical Development GmBh Services.

Mr. Micheal Tsigkopoulos

Pharmacovigilance Consultant

Highly experienced professional with 26 years in pharmaceuticals and consulting, specializing in Pharmacovigilance and drug safety. Expertise includes conducting GVP audits and ensuring compliance with global regulations, with additional experience as an intracompany trainer for GVP and GCP practices.

Dr. Tintswalo Mashele

PV Deputy Director at National Department of Health

Overseeing the decentralization of the pharmacovigilance for public health programs.

And many others regional experts to be announced...

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Registration link: https://forms.office.com/r/9ffwmhPYXW
or scan the QR code

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