From Theory to Practice: Interactive Training on the Lebanese Good Pharmacovigilance Practices (GVP) Guideline

November 2025

BRIEFING

Briefing – SciencePro Academy Pharmacovigilance Training (27–28 November 2025)

SciencePro Academy organized a two-day training dedicated to advancing the effective implementation of the Lebanese Good Pharmacovigilance Practices (LGVP) Guideline.

The Lebanese National Pharmacovigilance Program (LNPVP) team was invited as a key speaker, bringing substantial expertise across the LGVP modules and regulatory expectations.

This two-day training brought together key experts and representatives from national and bodies to strengthen pharmacovigilance practices and enhance collaboration across stakeholders.

Day 1 – Thursday, 27th November 2025

Day 1 Moderator: Dr. Amani Ghadban

Opening by Science Pro:

Dr. Rony Abboud (VP – Development and Compliance at Science Pro) started the session by introducing the training program and outlining its objectives, emphasizing its role in strengthening pharmacovigilance capacity. He also highlighted the importance of each module and set the stage for an interactive and practical learning experience.

Speaker: Dr. Rita Karam

Dr. Rita Karam, Director of the National Pharmacovigilance Program, delivered an in-depth progress update presentation, "Lebanese GVP Guideline: Progress and Module Updates," on core PV building blocks. Her session highlighted significant achievements in:

- Strengthening the national PV Quality System
- Advancing the PSMF/PSSF framework
- Enhancing Risk Management Plans
- Supporting the implementation of additional risk minimization measures

Her intervention set the strategic foundation for the workshop, reaffirming national commitment to strengthening PV standards and aligning practices with global expectations.

Module XV – Safety Communications : Speaker: Dr. Abeer Zeitoun

Dr. Abeer Zeitoun, clinical and technical manager, provided a thorough walkthrough of Module XV, clarifying the structure, purpose, and regulatory expectations of safety communication tools. She emphasized the importance of harmonized messaging, timely dissemination, and the alignment of communication materials with Lebanese regulatory requirements. Her presentation highlighted the central role of safety communications in protecting patients, ensuring transparency, and supporting informed clinical decisions.
She provided a detailed analysis of stakeholder feedback, demonstrating how comments were evaluated, categorized, and addressed. She showcased clear decision-making pathways, helping participants understand how national guidance evolves through consultation.

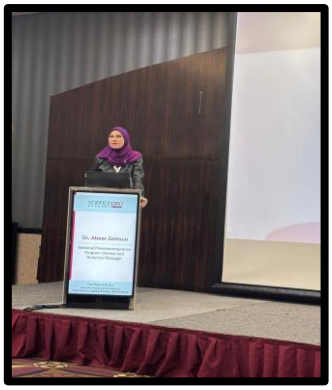
Module VI - Collection, management, and submission of reports of suspected adverse reactions to medicinal products: Speaker: Dr. Aya Ibrahim

Dr. Aya Ibrahim, clinical pharmacovigilance officer, presented a comprehensive overview of Module VI, breaking down the end-to-end process of collecting, managing, and submitting suspected adverse reactions. She clarified roles and responsibilities, timelines, and data management expectations. Her presentation focused on the foundations of high-quality reporting, accuracy, completeness, timeliness, and the importance of vigilance across the healthcare and industry ecosystem. She guided the participants through recurring industry questions and highlighted how stakeholder comments were addressed to enrich clarity, feasibility, and operational alignment. Her explanation demonstrated the collaborative nature of guideline development.

Day 2 Moderator: Dr. Randa Aoun, LPIA Representative

Module VII – Periodic Safety Update Reports (PSUR)

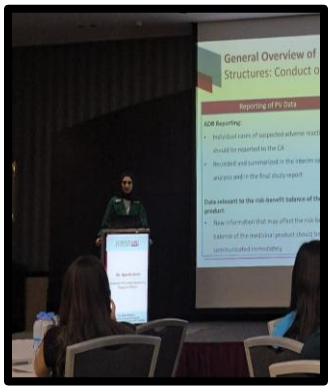
Speaker: Dr. Abeer Zeitoun



Dr. Abeer delivered a structured overview of PSUR requirements, focusing on report objectives, critical elements, and alignment with the Lebanese regulatory framework. She emphasized the importance of consistent benefit–risk assessment and the role of periodic reports in maintaining continuous product oversight. Her session included a deep dive into the most common industry errors and highlighted corrective measures, providing participants with clear guidance to strengthen future submissions.

Module VIII – Post Authorization Safety Studies (PASS)

Speaker: Dr. Aya Ibrahim



Dr. Aya provided a thorough explanation of PASS concepts, study types, and national expectations for planning, development, and execution.

She outlined the principles of scientific rigor, methodological transparency, and the importance of designing studies that are both impactful and feasible within the Lebanese health system. Her presentation addressed recurring stakeholder questions and clarified practical considerations for PASS implementation, reinforcing the value of structured guidance.

- **Ms. Maya Hobeika – Patient Safety Partner, Levant & Iraq, Roche**

  Presented an industry perspective on safety communications, focusing on the objectives and tools of safety communication and the local implementation of Direct Healthcare Professional Communications (DHPCs).

- **Dr. Stephanie Rached – Patient Safety Lead, Levant & Iraq, Roche**

  Shared insights on translating global safety communication strategies into local regulatory practice, supported by real-world examples and best practices.

- **Dr. Sara Bahr – Patient Safety Lead, Near East & UAE, Boehringer Ingelheim**

  Provided an in-depth overview of Periodic Benefit-Risk Evaluation Reports (PBRERs), covering report structure, benefit-risk evaluation, regulatory expectations, and best practices illustrated through practical examples.

- **Mrs. Martine Abi Khalil – Representative, KBP-Biomak**

  Explored the role of third-party service providers in strengthening pharmacovigilance compliance, highlighting outsourcing models, data quality assurance, and regulatory responsibilities.

- **Dr. Anil Mor – Head of Epidemiology Analytics and Innovation, Sanofi**

  Presented the MAH perspective on Post-Authorization Safety Studies (PASS), discussing study design, implementation challenges, and recommended best practices.

- **Dr. Amani Ghadban – Country Safety Head, Johnson & Johnson; PV Taskforce Lead, Lebanon Pharma Group**

  Moderated key sessions, facilitating dialogue between regulators and industry stakeholders and encouraging interactive discussion.

- **Dr. Randa Aoun – Chief Operating Officer, Holmed Group; Lebanese Pharmaceutical Importers Association Representative**

  Moderated Day 2 sessions, supporting collaboration between regulators, industry, and service providers to promote sustainable implementation of the LGVP framework.

- **Mrs. Joumana Jaber - SPIL Representative**
  Representing the Syndicate of Pharmaceutical Industries in Lebanon (SPIL), Mrs. Joumana Jaber delivered a dedicated speech on SPIL's pharmacovigilance experience, challenges

- **Dr. Hadir Rostom – Pharmacovigilance Consultant**

  Delivered multiple practical sessions on ADR case management, PSUR challenges, and PASS methodologies, using case studies to highlight common pitfalls, the role of local agents, and methodological considerations.