Latin America Pharmacovigilance and Risk Management Strategies Workshop

November 11-12 | Virtual

PROGRAM COMMITTEE

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Pharmacovigilance Coordinator
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Merck S.A., Brazil

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Director of Regulatory Affairs
Sindusfarma, Brazil

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Bianca Passos, PharmD, MBA
Country Safety Head
Sanofi, Brazil

Michelle Rocha de Souza, MBA
Pharmacovigilance Coordinator,
Abbvie, Brazil

Overview

DIA's *Latin America Pharmacovigilance and Risk Management Strategies Workshop* is the leading resource to discuss the current safety, pharmacovigilance, and risk management strategies landscape in LATAM. Attendees will gain insight from biopharmaceutical industry experts and global regulatory agencies on current policies and guidances. The conference is aimed to stimulate discussion, foster collaboration, and enhance standardization of regulations to meet global compliance.

**The primary language is English, however simultaneous interpretation in English and Portuguese, will be available during this Workshop.*

Who Should Attend

Professionals involved in:

- Drug Safety/Pharmacovigilance
- Risk Management, including Risk Evaluation and Mitigation Strategies (REMS)
- Benefit-Risk Assessment and Communication
- Regulatory Affairs
- Medical Product Safety Assessment
- Clinical Research
- Pharmacoepidemiology
- Post-Market Studies and Real World Evidence Generation
- Customer Engagement Programs, including Patient Support Programs
- Medical Information
- Medical Communications
- Health Outcomes

Schedule-At-A-Glance

This agenda is listed in ET

DAY ONE | WEDNESDAY, NOVEMBER 11

10:15-10:30AM	**Welcome and Opening Remarks**
10:30AM-12:00PM	**Session 1:** PV Crisis Management
12:00-1:20PM	Break
1:20-3:00PM	**Session 2:** How to Communicate Signals and Risks Appropriately with the Patient in Mind?

DAY TWO | THURSDAY, NOVEMBER 12

10:00-11:30AM	**Session 3:** Real World Evidence
11:30AM-1:00PM	Break
1:00-2:40PM	**Session 4:** Key Regulatory Trends for Safety in Latin America
2:40-2:55PM	Closing Remarks

Learning Objectives

- Discuss pharmacovigilance crisis management and the best practices and challenges from both local and global companies
- Assess basic real world evidence study design considerations and describe the role of real world data in active safety monitoring and its strengths and limitations
- Analyze the importance of planning pharmacovigilance activities and risk minimization measures by keeping the patient in mindAmerica
- Discuss key aspects of country-level pharmacovigilance systems and the trends they possess, the challenges that they face and the efforts of convergence in the Latin America region

10:15-10:30AM

Welcome and Opening Remarks

Session Chair
Rosana Miguel Messias Mastellaro, RPh, Director of Regulatory Affairs, Sindusfarma, Brazil

Speaker
Robin Weinick, PhD, Senior Vice President and Managing Director, Americas and Global Program Officer, DIA Global

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10:30AM-12:00PM

Session 1: PV Crisis Management

Session Co-Chairs
Michelle Rocha de Souza, MBA, Pharmacovigilance Coordinator, Abbvie, Brazil

Deirdre McCarthy, MSc, Senior Director, Pharmacovigilance and Safety Operations, Allovir

In this session, attendees will hear from PV experts in both local and global companies on the specific challenges faced during the COVID-19 pandemic and the collaborations undertaken with regulators and trade associations. Following the presentations, we will engage in a 30-minute panel discussion on these topics, with active audience Q&A.

COVID-19 PV Crisis Management: A Global Company Perspective
Calvin Johnson, MSc, Head, International PV Operational Excellence, AbbVie Ltd., United Kingdom

COVID-19 PV Crisis Management: A Global Company Perspective
Gislaine Dib, PharmD, Pharmacovigilance Coordinator, Libbs Farmacêutica, Brazil

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12:00-1:20PM

Break

1:20-3:00PM

Session 2: How to Communicate Signals and Risks Appropriately with the Patient in Mind?

Session Co-Chairs
Gislaine Dib, PharmD, Pharmacovigilance Coordinator, Libbs Farmacêutica, Brazil

Bianca Passos, PharmD, MBA, Country Safety Head – Sanofi, Brazil

Risk Management aims to ensure that the benefit-risk profile of a medicinal product is managed optimally during the whole product lifecycle. Exploring existing and developing strategies to plan and optimize risk management activities for known and potential risks of approved product and properly quantify and characterize them over time are crucial for the success of a risk management cycle. This session will provide an overview on the importance of an effective strategy for risk communication to enable the general public and healthcare professionals to make informed decisions and protect themselves and their patients.

Speakers
Josue Bautista, PharmD, President, Mexican Drug Safety Society, Mexico

Walter Straus, MD, MPH, Associate Vice President, Therapeutic Area Head for Vaccines and Infectious Disease, Clinical Safety & Risk Management, Merck Research Laboratories

Manuela Rovani Grizoto, **PharmD**, Pharmacovigilance Manager, Sanofi, Brazil

Patricia Fonseca Agostini, RMP Manager and Manager Group, Novartis, Brazil

DAY TWO | THURSDAY, NOVEMBER 12

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10:00-11:30AM

Session 3: Real World Evidence

Session Co-Chairs

Natalia Hristov, PharmD, Regional Pharmacovigilance Manager - a.i. Head of Americas Merck S.A., Brazil

Gislaine Dib, PharmD, Pharmacovigilance Coordinator, Libbs Farmacêutica, Brazil

This session will expose how data collected for the purpose of pharmacovigilance can also contribute with the decision-making when evidence is needed. Explore real-life examples from Latin American companies that have addressed regulatory or strategic needs through data generated from safety databases. This session will also consider the point of view from the regulatory agency when assessing the response to requirements by using data from safety databases.

The Use of Safety Database to Generate Real World Evidence

Guilherme Julian, Director, Real World Insights, Latin America IQVIA, Brazil

Case Study - Safety Data Generation Based on the Safety Database as Real World Data

Karen Sacomam Barbosa, RPh, Pharmacovigilance Coordinator, Ache Laboratorios Farmaceuticos, Brazil

Perspective From Regulator Concerning the Use of Safety Database to Generate Evidences

Gustavo Mendes Santos, MPharm, General Manager of Medicines and Biological Products, ANVISA, Brazil

11:30AM-1:00PM

Break

1:00-2:40PM

Session 4: Key Regulatory Trends for Safety in Latin America

Session Co-Chairs

Raphael Elmadjian Pareschi, MBA, Associate Director, Pharmacovigilance Brazil, MSD, Brazil

Michelle Rocha de Souza, MBA, Pharmacovigilance Coordinator, Abbvie, Brazil

Rosana Miguel Messias Mastellaro, RPh, Director of Regulatory Affairs, Sindusfarma, Brazil

This session will review key aspects of country-level pharmacovigilance systems and their trends. Explore the perspectives from various Health Authorities and the pharmaceutical industry which includes convergence efforts to discuss future challenges of pharmacovigilance.

Speakers

Fernanda Simioni, MPharm, Specialist Health Surveillance - Pharmacovigilance, ANVISA, Brazil

Janet Hormbrey, DrMed, MRCP, MSc, FFPM, AVP Global Pharmacovigilance, Merck & Co, Inc.

Melissa Truffa, RPh, Director, Policy and Strategy Evaluation, Pharmacovigilance Excellence, Abbvie

2:40-2:55PM

Closing Remarks

Session Chair

Rosana Miguel Messias Mastellaro, RPh, Director of Regulatory Affairs, Sindusfarma, Brazil