Royal Tulip Brasília Alvorada Hotel

Sep 25, 2024 8:00 AM - Sep 26, 2024 4:00 PM

Shtn - Trechno 01, Conj 1Bb - Bloco C, 40800-200 Brasília, Brazil

Latin America Annual Meeting

Take advantage of opportunities for networking and knowledge sharing with key stakeholders influencing the advancement and implementation of initiatives in Latin America.

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DAYS	HOURS	MINUTES	SECONDS

Print Agenda

Day 1 Sep 25, 2024

7:30 AM — 8:15 AM

Networking Breakfast

7:30 AM — 6:30 PM

Registration

8:15 AM — 8:30 AM

Welcome and Opening Remarks

8:30 AM — 9:45 AM

Session 1 Plenary: Regulatory System Strengthening: Updates on the Implementation of Good Regulatory Practices

This session will provide updates on Good Regulatory Practices in accordance with WHO guidelines, including the updates on the World Listed Authority (WLA), transitional WLAS status and the Global Benchmarking Tool (GBT) application. The objective of the session is to analyze current perceptions of key stakeholders regarding Good Regulatory Practices and their implementation in the regulatory field. The panel will include discussions regarding the challenges and obstacles identified in the implementation of Good Regulatory Practices and potential solutions or approaches to overcome them, also will identify existing opportunities for strengthening Good Regulatory Practices and improving the quality and safety of regulated products, both at the national and international levels. The discussions will facilitate the exchange of experiences and knowledge among regulators, industry, and other relevant stakeholders to promote collaboration and adoption of best regulatory practices, taking into account key elements of PAHO, and WHO regulatory system strengthening.

Learning Objective :

- Distinguish the key elements of regulatory system strengthening, including World Listed Authority (WLA), transitional WLAS status, and the Global Benchmarking Tool (GBT)
- Identify challenges, obstacles and potential solution or approaches of key stakeholders regarding the implementation of Good Regulatory Practices
- Explore about experiences and knowledge of relevant stakeholders to promote collaboration and adoption of best regulatory practices

Track: General Session

Session Chair(s)

Lawrence Liberti, PhD, RAC

Director, D.K. Kim International Center for Regulatory Science
The Kim Center/ USC DRQS, United States

Dr Liberti has worked in pharmaceutical regulatory affairs, communications and clinical R&D for the past four decades. From 2009 to 2021 he has served as the Executive Director of CIRS (the Centre for Innovation in Regulatory Science, Ltd, forming part of Clarivate Analytics). He has been actively involved in promulgating best practices in the regulatory aspects of medicines development, especially in the emerging markets. He received his doctorate in International Regulatory Policy through the WHO Collaborating Centre for Pharmaceutical Policy and Regulation, Utrecht University, where his research centered on expedited regulatory pathways with applicability in the emerging markets. He is a volunteer with the nonprofit Erudee Foundation.

Susan Zavala Coloma, MS, RPh

Specialist, Sanitary Evaluation of Pharmaceutical Products, Biological Products
DIGEMID, Peru

Susan Zavala is a Pharmacist with more than 10 years of experience, mainly in regulatory affairs. She has studied a Master in Biotechnology, as well a Master in Pharmaceutical Legislation and Intellectual Property. Over her more than 7 years at DIGEMID, she has work as a CMC reviewer of biological products, also, she has participated in the elaboration of regulation and procedures related to the sanitary register. Susan has participate as a speaker for several international events organized by MFDS, CASSS, DIA and PAHO. Currently, she is the coordinator of the reviewer CMC team of biological products.

9:45 AM — 10:30 AM

Refreshments, Exhibits, and Networking Break

10:30 AM — 12:00 PM

Session 2 Plenary: Latin America in Perspective: Projects and Priorities from Key Stakeholders in the Region

This session will present and discuss the latest regulatory updates from national regulatory authorities from Latin America, including projects, priorities, and initiatives in the short and medium term, in the area of pharmaceutical and medical devices. It will be formatted as a panel discussion, where regulators will provide insights on some pre-defined topics of general interest, before interacting with the audience. The objective is to promote active engagement of various stakeholders involved in regulation, such as industry, healthcare professionals, and civil society organizations, to foster constructive dialogue and address regulatory challenges in the region.

Learning Objective :

- Recognize strategies and advances from Regulatory Agencies towards strengthening regulatory systems
- Explore opportunities for collaboration among public, private, and academic sectors to advance regulatory agendas and promote regulatory harmonization

- Identify challenges and best practices in product and process regulation in LATAM to foster knowledge and experience sharing among regulatory agencies

Track: General Session

Session Chair(s)

Maria Antonieta Tony Roman, MPharm

Head Regulatory Policy Emerging Markets LATAM
Novartis, Mexico

Degree in Pharmacy, Master of Science (pharmacy) UNAM; Diploma in Clinical development and regulatory affairs, Universidad Anahuac; diploma in public health by the Swiss School of Public Health. 32 years of experience in various areas in the Pharmaceutical industry like R&D, quality, manufacturing, regulatory affairs and teaching. She has contributed in: BIRMEX, CDC, USA, Boehringer Ingelheim, Sanofi Pasteur and Novartis where she currently holds the position of Regulatory policy head, LATAM; has collaborated with regulatory authorities and associations of the pharmaceutical industry in the review and preparation of regulatory documents; coordinator of the Regulatory Affairs Committee of the Swiss-Mexican Chamber of commerce.

Elkiane Macedo Rama

Advisor to the International Affairs Office
Brazilian Health Regulatory Agency (ANVISA), Brazil

Elkiane is a Health Regulation Expert of the Brazilian Health Regulatory Agency - ANVISA. With 19 years of experience, she has served as a reviewer and advisor at ANVISA, initially in the Toxicology Office, and subsequently in the Biological Products Office. Recently, she has assumed advisory roles within ANVISA, first within the Directorate and presently in the International Affairs Office. She has been a member of ICH Q12 Expert Working Group and currently o currently serves on ICH Q6 as a Rapporteur Supporter. She holds a Pharmacy and Biochemistry Degree with specialty in Pharmaceutical Industry, a Master's degree in Toxicology, Postgraduate certificates in Toxicology, and in Health Regulation.

12:00 PM — 1:00 PM

Luncheon, Exhibits, and Networking Break

1:00 PM — 2:30 PM

Session 3, Track A: Regulatory Collaboration and Cooperation Initiatives Combined with Regulatory

Convergence & Harmonization

Regulatory collaboration and cooperation are becoming increasingly important, given the growth in regulatory procedures related to innovative therapies, or with post-registration changes and limited resources. In this session, we will learn about agreements and experiences; we will also discuss harmonization efforts, plans and challenges in the Latin American region, explore issues related to regulatory harmonization, resource allocation, and overcoming regulatory disparities among countries. Examine the role and contribution of various sectors, including industry and academia, in the evolution of ICH standards. Discuss how collaboration between regulatory agencies and these sectors can enhance the development and implementation of effective regulatory frameworks.

Learning Objective :

- Analyze the importance of collaboration and regulatory cooperation in the context of regional regulatory frameworks
- Identify the challenges and opportunities associated with collaborations and regional mechanisms
- Evaluate the implementation status of ICH guidelines in regulatory frameworks
- Analyze the challenges and obstacles faced in the adaptation and implementation of ICH guideline frameworks

Track: Track A: Regulatory

Session Chair(s)

Maria Antonieta Tony Roman, MPharm

Head Regulatory Policy Emerging Markets LATAM
Novartis, Mexico

Degree in Pharmacy, Master of Science (pharmacy) UNAM; Diploma in Clinical development and regulatory affairs, Universidad Anahuac; diploma in public health by the Swiss School of Public Health. 32 years of experience in various areas in the Pharmaceutical industry like R&D, quality, manufacturing, regulatory affairs and teaching. She has contributed in: BIRMEX, CDC, USA, Boehringer Ingelheim, Sanofi Pasteur and Novartis where she currently holds the position of Regulatory policy head, LATAM; has collaborated with regulatory authorities and associations of the pharmaceutical industry in the review and preparation of regulatory documents; coordinator of the Regulatory Affairs Committee of the Swiss-Mexican Chamber of commerce.

Leonardo Semprun Semprun, PharmD

Global Regulatory Policy Lead-LatAm
MSD, Panama

Leonardo Semprún is currently Senior Director, Global Regulatory Policy at MSD. In this role, Leonardo is responsible to define and execute a regional regulatory policy plan that addresses current and future needs, while also advocating for and anticipating regulatory change with LATAM-based regulators and multilateral organizations. He has worked with governments, regulators, trade bodies and other external stakeholders to shape regional regulatory policy. Leonardo' work in the industry spans over 20 years, across regulatory, quality, intellectual property and policy functions

Speaker(s)

PIC/S Journey in Latin America Towards Harmonization of CGMP Procedures

Representative Invited

MSD, Brazil

Juliana Perlow has aproximately 20 years of experience in local and multinational pharmaceutical companies working with regualtory affairs and regional CMC functions.

1:00 PM — 2:30 PM

Session 3, Track B: Challenges, Practices, and Governance in Pharmacovigilance and Technovigilance: Harmonization Efforts in Safety

The session will cover various important topics related to pharmacovigilance (PV) and technovigilance. It will provide an overview of the current legislations in place for these fields, highlighting the roles of both ICH and non-ICH members. Participants will also be informed about the ongoing PV harmonization projects aimed at enhancing global safety monitoring systems. The session will include discussions on the influential role of UMC (Uppsala Monitoring Centre) and its active participation in the field. Furthermore, the session will shed light on the electronic transmission of safety information, ensuring efficient and timely exchange of data. The IMDRF framework and regional initiatives will be explored in the context of improving pharmacovigilance and technovigilance practices. Lastly, the session will emphasize the importance of reliance in pharmacovigilance and technovigilance, promoting trust and collaboration among stakeholders to ensure the safety of medicines and medical devices.

Learning Objective :

- Know and understand the Pharmacovigilance and Technovigilance landscape in Latin America
- Understand the level of implementation of ICH and IMDRF principles in Latin America, including the harmonization status across the region for expedited reporting, aggregate reporting, and risk management
- To understand actions needed for reliance in the safety monitoring of medicines and medical devices

Track: Track B: Safety & Pharm

Session Chair(s)

Rosana M. Mastellaro, PharmD, RPh

Director, Technical Regulatory Affairs and Innovation
Sindusfarma, Brazil

Pharmacist, She is currently Director of Technical Regulatory Affairs and Inovation at Sindusfarma. She has worked for 17 years in the pharmaceutical industry. Specialist in Project Management. She acts in defense of the pharmaceutical industrial sector and coordinates regulatory convergence issues including

Pharmacovigilance. She is a member of the Brazilian Pharmacopoeia Management Committee and is responsible for the interface with Anvisa representing associated companies.

Josue Bautista, PharmD

GCP/PV Auditor
Novartis, Mexico

Industrial Pharmaceutical Chemist with 17 years of experience in the pharmaceutical industry. Founder and Member of #PharmacovigilanceEnEspañol. Founder of "JBA Farmacovigilancia". Advisor of the Pharmacovigilance Institute. Member and Mexico´s ambassador of the International Society for Pharmacoepidemiology (ISPE). Member of the LinkedIn program #LinkedInCreators. Pharmacovigilance Professor for Latin America. Ambassador for LATAM of the Global Pharmacovigilance Society (GPS). Invited coordinator of the Pharmacovigilance academic program at UNIBE. He collaborated with companies such as Wyeth, GlaxoSmithKline, Merck Sharp & Dhome and Pfizer. Currently, he works as a Global Auditor of Pharmacovigilance for Novartis.

1:00 PM — 2:30 PM

Session 3, Track C: Communicating Science, End-to-end Messaging and Storytelling: Innovative ways to Present Data

Translating data into valuable stories for internal and external customers is one of the biggest challenges in Medical Information. This session offers a comprehensive exploration of effective data communication strategies within the pharmaceutical industry. Participants will delve into diverse channels for data presentation, from traditional to digital platforms, and discover innovative data visualization techniques and storytelling methods to enhance engagement. The session also provides valuable insights into regional medical information operations, including case studies on challenges, successes, and tailored strategies. Engage in interactive discussions and leave with key takeaways to implement in your professional endeavors.

Learning Objective :

- Identify and analyze various channels used to present data effectively
- Evaluate and implement innovative techniques for presenting data in engaging ways
- Examine the operational experiences of regional medical information practices within pharmaceutical companies, in Latin America

Track: Track C: MASC

Session Chair(s)

Marta Avellar

Medical Information Head, Latin America and North America Medical Information

Takeda, Brazil

Marta Avellar, Medical Information Head for Latin America and Canada, at Takeda, brings 25 years of experience in the Pharmaceutical Industry. She has held leadership positions in Pharmacovigilance at Wyeth (now Pfizer), Janssen, and Shire (now Takeda) in Latin America. Marta spearheaded the implementation of Medical Information operations in the region and played a crucial role in integrating Medical Information after global mergers and acquisitions. Her passion lies in innovation, effective communication, and process excellence.

Speaker(s)

Current Status and Challenges for Medical Information in Latin America: Experience from a Pharmaceutical Company

Lizbeth González

Medical Information Lead
Takeda, Mexico

2:30 PM — 3:15 PM

Refreshments, Exhibits, and Networking Break

3:15 PM — 4:30 PM

Session 4, Track A: Regulatory Reliance Initiatives, Lessons Learned, and Best Practices

Necessary documentation is required for an effective and successful implementation of reliance mechanisms, considering the concept of risk prioritization in decision-making processes for marketing applications. The appropriate use of documents such as Public and Unredacted Assessment Reports, and Certificates of Pharmaceutical Products (CPP), among others will be shown. Attendees will gain insights on how to ensure ‘product sameness’ and discuss all relevant aspects to be considered, for example, same qualitative and quantitative composition, strength, pharmaceutical form, intended use, manufacturing process, suppliers of active pharmaceutical ingredients, and quality of excipients. Additionally, the scope of reliance beyond marketing applications, sharing how local practices related to the testing of pharmaceutical products are changing with the use of reliance will be discussed.

Learning Objective :

- Gain insights on risk prioritization models
- Explore decision-making practices necessary for the practical implementation of reliance models

- Clarify the concept of "sameness" in the context of regulatory agencies and outline the essential documentation required
- Examine the broader scope of reliance models, going beyond their applications in marketing authorizations

Track: Track A: Regulatory

Session Chair(s)

Susan Koepke, MBA

Head of Regulatory Affairs LATAM
EMD Serono, Inc., United States

Susan Koepke is a Regulatory Affairs professional with more than 25 years of experience in pharmaceutical industry. She works for EMD Serono Inc, healthcare business of Merck KGaA, Darmstadt, Germany. She is the Regulatory Affairs Head for Latin America based in Miami, FL, USA being responsible for innovative pipeline delivery as well as for life cycle management activities of established products in Latin America.

Diego Alexander Salas, LLM

Regulatory Affairs Director
FEDERACION LATINOAMERICANA DE LA INDUSTRIA FARMACEUTICA, A.C., Mexico

Specialist in Pharmaceutical Management and Pharmaceutical Market, with a master's degree in Intellectual Property and International Trade and a bachelor's degree in law. Experience as a University Teacher in the subjects of Pharmaceutical and Medical Ethics and International Trade. He has over 12 years of experience in technical Regulatory Affairs, Pharmacovigilance, and Regulatory Policy.

Speaker(s)

How reliance is changing local practices related to testing of pharmaceutical products

Joerg Garbe, PhD, MSc

Global Quality Manager & Policy Lead
F. Hoffmann-La Roche Ltd, Switzerland

Joerg has 20 years of experience in the pharmaceutical industry within different functions in the quality field for development and commercial products. He serves as Global Quality Manager in Roche Pharma Global Technical Operations overseeing Roche's global in-country testing activities. Joerg has been a contributing member in the industry via IFPMA/ EFPIA. As global Policy Lead, he co-/authored several publications and industry positions on in-country testing and Advanced Therapy Medicinal Products (ATMPs) and functions as scientific reviewer for several journals. Joerg received a PhD in biochemistry from the University of Hannover/Max-Planck-Institute of Biochemistry, Germany.

3:15 PM — 4:30 PM

Session 4, Track B: Pharmacovigilance Inspections in Latin America – Current Scenario, Expectations and Trends

In this session, speakers will discuss the current scenario for Pharmacovigilance Inspections in Latin America, considering the main concerns, trends and the expectations from the Regulatory Bodies for the Pharmacovigilance systems for the regulated sector.

Learning Objective :

- Recognize the main trends and concerns for Pharmacovigilance Inspections in Latin America
- Understand the Regulatory expectations for the Pharmacovigilance Processes set-up for the regulated sector in Latin America
- Identify opportunities for Pharmacovigilance processes alignments/improvements considering the lessons learned from Pharmacovigilance Inspections in Latin America

Track: Track B: Safety & Pharm

Session Chair(s)

Arthur Bueno, PharmD, MBA

Country Safety Head Back-Up
Sanofi Brazil, Brazil

Arthur is an experienced Pharmacist with more than 16 years of experience in Patient Safety & Pharmacovigilance. Currently Country Safety Head Back-Up at Sanofi Brazil. His carreer started at Takeda Brazil, where he acted in roles of increasing responsibility within local/regional/global PV operations organization (including oversight of ICSRs management, PBRER management, RMP management, Audits/Inspections, Pharmacovigilance Agreements, etc). Arthur also worked for CROs (IQVIA (formes Quintiles) and LabCorp (former Covance)), including Local, Regional and Global Projects for Pharmacovigilance and Patient Safety.

Josue Bautista, PharmD

GCP/PV Auditor
Novartis, Mexico

Industrial Pharmaceutical Chemist with 17 years of experience in the pharmaceutical industry. Founder and Member of #PharmacovigilanceEnEspañol. Founder of "JBA Farmacovigilancia". Advisor of the Pharmacovigilance Institute. Member and Mexico´s ambassador of the International Society for Pharmacoepidemiology (ISPE). Member of the LinkedIn program #LinkedInCreators. Pharmacovigilance Professor for Latin America. Ambassador for LATAM of the Global Pharmacovigilance Society (GPS). Invited coordinator of the Pharmacovigilance academic program at UNIBE. He collaborated with companies such as Wyeth, GlaxoSmithKline, Merck Sharp & Dhome and Pfizer. Currently, he works as a Global Auditor of Pharmacovigilance for Novartis.

3:15 PM — 4:30 PM

Session 4, Track C: Customer Engagement and Insights

To make the Medical Information service available to more health professionals, not only Key Opinion Leaders (KOLs), it is essential to implement a multi-faceted approach. This can involve leveraging various channels and different professionals to act as internal ambassadors of medical information. Adapting communication styles for different stakeholders, including healthcare professionals (HCPs) and non-HCPs, is fundamental to effective medical information dissemination.

Learning Objective :

- How to make the Medical Information service available to more health professionals, not only KOLs
- How other medical professionals – MSL, Medical Manager and non-medical professionals – Sales Force can be internal ambassadors of Medical information
- Adapting communication styles for different stakeholders: HCP and non-HCP

Track: Track C: MASC

Session Chair(s)

Barbara Nardi, PharmD

Global Director - Medical Communications
Thermo Fisher Scientific, Brazil

Barbara is a PharmD and holds a B.S. in Marketing and Business Management, with 18+ years' experience in the pharmaceutical industry supporting businesses with technical and medical expertise. Barbara has worked in several areas (Medical, Pharmacovigilance, Quality, Compliance, Customer Service and Marketing) in different industries such as Sanofi, Sanofi Pasteur, Biogen and Local Brazilian CRO. Barbara joined PPD in June 2017 and is currently a Director of Operations, working with different global clients, including Latin America, US, Europe and APAC.

Speaker(s)

Enhancing Medical Information Services: Medical Information Solutions for HCPs with LATAM as a Key Player

Ana Carolina Adame

Takeda, Brazil

Ana Adame is Brazilian, hailing from Rio de Janeiro and currently residing in São Paulo. She is a pharmacist with a Master's degree in Research, Development, and Management in the Pharmaceutical Industry, as well as an MBA in Leadership and Innovation. Ana began her professional journey at GSK, specializing in Medical Information and Scientific Support. In 2017, she made the transition to Takeda, where she took on a crucial role overseeing Medical Information and Customer Service in Latin America. Currently, Ana leads the management of Medical Information

content for Vaccines, Oncology, Neuroscience, and Immunology, in addition to various key activities related to Global Medical Information across Latin America & Canada.

4:35 PM — 5:50 PM

Session 5, Track A: Management of Product Lifecycle: Challenges and Suggested Solutions

In this session, participants will gain a comprehensive understanding of the challenges and constraints caused by delays in the implementation of PACs (post-approval changes) in the pharmaceutical industry. The session will provide an in-depth analysis of the impact on the supply of medicines to patients and explore suggested solutions to develop processes for implementing changes efficiently. Participants will also have the opportunity to identify and discuss the opportunities and challenges faced by regulators and the industry in implementing reliance, particularly in the context of PACs. Additionally, the session will delve into the effect of regulations on global PACs registration strategies, allowing attendees to develop a strategic approach to navigate this complex landscape.

Learning Objective :

- Identify the challenges and constraints caused by delays in the implementation of PACs in the pharmaceutical industry
- Suggest solutions for creating processes for implementing changes efficiently in the context of PACs
- Explore the effect of regulations on global PACs registration strategies and identify strategic approaches for navigating this complex landscape

Track: Track A: Regulatory

Session Chair(s)

Flavia Firmino Ribeiro, PharmD

Director Reg Global CMC
Pfizer, Brazil

Flavia is the Regulatory Advisor for Latin America in Global CMC at Pfizer since 2017. She holds accountability for partnering with manufacturing organizations and Regulatory Affairs while providing regional regulatory expertise to CMC Product Strategists, addressing strategic issues, contributing to the development of policies and positions on draft regulations and external engagement on CMC topics. Based in Brazil, she has over 20 years of experience in Quality, Regulatory and CMC areas and held leadership positions in Regulatory Conformance, Quality Operations and Regulatory Affairs.

Juliana Leite-Schnell

Director
Abbvie, United States

Juliana Leite-Schnell is a PharmD and regulatory affairs professional with 20 years of experience including drug development & established products across multiple geographies. Earlier in her

career she held several regulatory affairs positions in her home country Brazil. In May 2005 she joined AbbVie as a member of the Brazilian regulatory team and in 2009 transitioned to the Latin America team located in the US. In 2016, Juliana became the US & Canada Immunology lead for the original NDA of RINVOQ®. In 2019 she became a global regulatory lead and worked in different therapeutic areas such as rheumatology, gastroenterology, and dermatology. In June 2023 she transitioned back to Latin America as the Area Head for regulatory affairs.

Daniela Bravo

Regulatory Policy and Intelligence Manager
AbbVie, Brazil

Daniela Bravo is the Regulatory Policy and Intelligence leader for Latin America at Abbvie. She has a Master and a PhD degree in Health Sciences and previous experiences in regulatory affairs working at the Brazilian Health Authority (Anvisa) and the pharmaceutical industry.

Speaker(s)

How Product Supply is Impacted by Delayed Implementation of PACs

Representative Invited

Merck Sharp & Dohme Farmaceutica Ltda, Brazil

Reliance Implementation in the context of PACs – barriers & enablers

Representative Invited

Merck, Switzerland

Isabelle has joined Merck KGaA since 2005 where she has held growing managerial roles in RA and RA CMC as Head of Department. She currently is Head of International Global Regulatory & Scientific policy at Merck and as such actively engaged in international regulatory policy as member of IFPMA since 2014, representative at ICH TrSC, EFPIA and PhRMA ICH WG. Prior to joining Merck, she has worked for several Companies in areas of small and large molecules including in Clinical Development for Servier Laboratories, and assumed various manufacturing site managerial responsibilities within Sanofi GMP QA & RA. Isabelle holds a MSc and a Pharm. D from Lyon (France) coupled with an MBA from Paris (EAP) High Business School.

4:35 PM — 5:50 PM

Session 5, Track B: New Era for Signal Detection

In this session, we will Navigate the new era of pharmacovigilance, exploring innovations in signal detection across various sources and products. We will discuss the impact of innovative signal detection approaches on patient safety.

Learning Objective :

- Gain insights on regulatory considerations, methods and types of initiatives in the LATAM Region
- Examine the integration of multi-modal data sources and products for comprehensive signal detection and validation
- Recognize common challenges/traps and ways out in the new era of pharmacovigilance
- Evaluate case studies and success stories showcasing the impact of innovative signal detection approaches on patient safety

Track: Track B: Safety & Pharm

Session Chair(s)

Gislaine Villarta Capeleti Dib, PharmD

Pharmacovigilance Manager
PGA Farma, Brazil

Patient Safety Manager at PGA Farma responsible for supporting activities related to patient safety, in clinical trials and post marketing activities, for different pharmaceutical companies with the objective to help them reach their internal process with high performance and quality according to requirements from differenece healthy authorities. Professional with over 20 years of experience in pharmacovigilance in national and international pharmaceutical industry, working on different kind of operations like Pharmacovigilance, Technovigilance, Cosmetovigilance and Nutrivigilance owith process related to clinical development and postmarketing.

Yoon Jeon (Jamey) Kim, MSc, RPh

Cluster Pharmacovigilance Lead for Latin America
MSD, Panama

Yoon Jeon (Jamey) Kim, the Director and North Cluster PV lead for Latin America at MSD, has 23 years of experience with the company. She provides strategic leadership for cluster countries (Colombia, Ecuador, Venezuela, Central America, and the Caribbean), with an extensive background in pharmacovigilance, regulatory affairs, and clinical trials. Additionally, she chairs the post-approval safety monitoring program review committee within the company. Previously, she held roles as Country PV lead and Regulatory manager at MSD Korea. She is a pharmacist with a master's degree in pharmaceutical technology and a bachelor's degree in pharmacy from Ewha Womans University in South Korea.

4:35 PM — 5:50 PM

Session 5, Track C: Innovation in Artificial Intelligence (AI) and Technology for MASC

This session will dive into the realm of AI and technology applications in the medical information landscape. Participants will explore the definition and practical applications of AI in daily activities, examine real cases from Latin America, assess the trending digital landscape, and discuss how Medical Information (MI) can leverage technology advancements. Legal and compliance considerations will also be addressed to ensure ethical and regulatory adherence in the evolving technological landscape of medical information.

Learning Objective :

- Define AI and explore its practical applications in MI daily activities
- Analyze real cases from Latin America to understand the implementation of AI in MI
- Evaluate the digital landscape to determine trends and opportunities for MI involvement and contribution
- Examine legal and compliance considerations related to the use of AI and technology in the MI field

Track: Track C: MASC

Session Chair(s)

Marta Avellar

Medical Information Head, Latin America and North America Medical Information
Takeda, Brazil

Marta Avellar, Medical Information Head for Latin America and Canada, at Takeda, brings 25 years of experience in the Pharmaceutical Industry. She has held leadership positions in Pharmacovigilance at Wyeth (now Pfizer), Janssen, and Shire (now Takeda) in Latin America. Marta spearheaded the implementation of Medical Information operations in the region and played a crucial role in integrating Medical Information after global mergers and acquisitions. Her passion lies in innovation, effective communication, and process excellence.

Patricia A. Vieira, PMP

MI Content & Cross-Therapy Area Lead, Emerging Markets and China Medical Informa
Pfizer, Brazil

Patricia is a PharmD with 20 years' experience in R&D within pharmaceutical industry. She is passionate about innovation applied to healthcare, with solid experience in medical information, project management, medical affairs, and regulatory affairs. Currently, she is responsible for medical information content-related activities across all therapy areas in Emerging Markets and China Medical Information at Pfizer.

5:50 PM — 6:50 PM

Networking Reception

Day 2 Sep 26, 2024

7:30 AM — 8:15 AM

Networking Breakfast

7:30 AM — 4:30 PM

Registration

8:15 AM — 9:30 AM

Session 6 Plenary: Advancements in Patient Safety and Centricity in the Pharmaceutical Industry: Empowering and Engaging Better Healthcare

Effective communication strategies with patients are crucial to combat misinformation, enable stakeholders to make informed decisions, and enhance their experience with medicinal products. By providing accurate and clear information, addressing concerns, and promoting health literacy, patients can be empowered to take an active role in their healthcare.

Learning Objective :

- Gain insights on methods to bring patients at the core of their decision-making process in the pharma industry
- Identify the importance of having the patient's perspective as a crucial of pharma industry strategy
- Identify opportunities for e-labeling initiatives to inform better outcomes for patients

Track: General Session

Session Chair(s)

Raphael Elmadjian Pareschi, PharmD, MBA

Patient Safety Lead/ Head of Pharmacovigilance Brazil
Roche, Brazil

Raphael has more than 16 years of experience in Pharmacovigilance, beginning at Sanofi Brazil, where he acted in roles of increasing responsibility within local PV organization, responsibilities including oversight of case management, PSUR management and RMP management. Raphael also worked for Johnson & Johnson as associate manager, with responsibility for 18 countries within Latin America in processes like PSURs, PV Agreements, oversight of reporting to Health Authority and of contracts with vendors and business partners. Also worked at MSD Brazil as Associate Director with experience in PV and Quality & Compliance for PV and Regulatory for Americas. Since Aug.2022 Raphael is Head of PV Brazil at Roche.

Barbara Nardi, PharmD

Global Director - Medical Communications
Thermo Fisher Scientific, Brazil

Barbara is a PharmD and holds a B.S. in Marketing and Business Management, with 18+ years' experience in the pharmaceutical industry supporting businesses with technical and medical expertise. Barbara has worked in several areas (Medical, Pharmacovigilance, Quality, Compliance, Customer Service and Marketing) in different industries such as Sanofi, Sanofi Pasteur, Biogen and Local Brazilian CRO. Barbara joined PPD in June 2017 and is currently a Director of Operations, working with different global clients, including Latin America, US, Europe and APAC.

Susan Koepke, MBA

Head of Regulatory Affairs LATAM
EMD Serono, Inc., United States

Susan Koepke is a Regulatory Affairs professional with more than 25 years of experience in pharmaceutical industry. She works for EMD Serono Inc, healthcare business of Merck KGaA, Darmstadt, Germany. She is the Regulatory Affairs Head for Latin America based in Miami, FL, USA being responsible for innovative pipeline delivery as well as for life cycle management activities of established products in Latin America.

Speaker(s)

9:30 AM — 10:15 AM

Refreshments, Exhibits, and Networking Break

10:15 AM — 11:30 AM

Session 7, Track A: CTD/eCTD and Cloud-based System Solutions: Future Vision

In this session, speakers will discuss the future vision and potential enhancements of CTD and eCTD for regulatory submissions. The session will explore advancements in technology and best practices that can further improve the effectiveness and acceptance of these formats. Participants will also have the opportunity to recognize the importance of digital ways of work including eCTD implementation, without ignoring the different challenges and numerous advantages.

Learning Objective :

- Recognize eCTD's foundational significance and assess its adaptability and inherent limitations amidst rapid technological advancements in the cloud era
- Identify how cloud platforms can address eCTD's limitations, fostering enhanced information

Track: Track A: Regulatory

Session Chair(s)

Flavia Firmino Ribeiro, PharmD

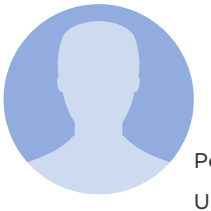
Director Reg Global CMC
Pfizer, Brazil

Flavia is the Regulatory Advisor for Latin America in Global CMC at Pfizer since 2017. She holds accountability for partnering with manufacturing organizations and Regulatory Affairs while providing regional regulatory expertise to CMC Product Strategists, addressing strategic issues, contributing to the development of policies and positions on draft regulations and external engagement on CMC topics. Based in Brazil, she has over 20 years of experience in Quality, Regulatory and CMC areas and held leadership positions in Regulatory Conformance, Quality Operations and Regulatory Affairs.

Representative Invited

AstraZeneca, United States

Jorge Azar is currently Senior Area Regulatory Director for Latin America with 25 years' experience on different roles at local, regional and global level in the Regulatory Affairs field, including product strategy, regulatory policy and intelligence. Jorge earned a degree in Pharmacy and a master's degree from Universidad Central de Venezuela.



Representative Invited

Merck Serono Limited, United Kingdom

Pedro holds a degree in Pharmaceutical Science (PharmD), a Master in Organic Chemistry from the University of Lisbon in collaboration with Imperial College in London and a PhD in Orphan drugs and Rare diseases from the University of Sheffield. Currently, he is working as a Director for Global Regulatory & Scientific Policy at Merck, mainly focus on regulatory intelligence, strategy and policy. He is the liaison for the China and Latam region concerning regulatory and policy topics. Previously, he worked at EMA for 12 years in different departments (regulatory affairs, assessment, authorisation of medicines, veterinary, orphan drugs, paediatrics, peer review and quality). Beforehand, he was working at INFARMED as a pharmaceutical assessor.

Speaker(s)

10:15 AM — 11:30 AM

Session 7, Track B: Risk Management and Communication as a Cornerstone of Safety Strategy

Engage in a strategic dialogue on risk management and communication as the cornerstone of safety strategy. This session focuses on driving safety initiatives through clear communications and risk management and empowering teams with effective risk communication strategies and effectiveness measures.

Learning Objective :

- Discuss the trends in Risk Management Plans (RMPs)
- Gain insights about development, distribution, and monitoring techniques for risk minimization activities
- Evaluate regional challenges in RMP and risk management strategy customization
- Case studies of effective risk minimization in Latin America

Track: Track B: Safety & Pharm

Session Chair(s)

Gislaine Villarta Capeleti Dib, PharmD

Pharmacovigilance Manager
PGA Farma, Brazil

Patient Safety Manager at PGA Farma responsible for supporting activities related to patient safety, in clinical trials and post marketing activities, for different pharmaceutical companies with the objective to help them reach their internal process with high performance and quality according to requirements from differenece healthy authorities. Professional with over 20 years of experience in pharmacovigilance in national and international pharmaceutical industry, working on different kind of operations like Pharmacovigilance, Technovigilance, Cosmetovigilance and Nutrivigilance owith process related to clinical development and postmarketing.

Raphael Elmadjian Pareschi, PharmD, MBA

Patient Safety Lead/ Head of Pharmacovigilance Brazil
Roche, Brazil

Raphael has more than 16 years of experience in Pharmacovigilance, beginning at Sanofi Brazil, where he acted in roles of increasing responsibility within local PV organization, responsibilities including oversight of case management, PSUR management and RMP management. Raphael also worked for Johnson & Johnson as associate manager, with responsibility for 18 countries within Latin America in processes like PSURs, PV Agreements, oversight of reporting to Health Authority and of contracts with vendors and business partners. Also worked at MSD Brazil as Associate Director with experience in PV and Quality & Compliance for PV and Regulatory for Americas. Since Aug.2022 Raphael is Head of PV Brazil at Roche.

Speaker(s)

Addressing Safety Needs in Tropical Diseases: Guidelines for Laboratory Tests and Vaccination Schedules in Colombia

Jeimmy Molano, MPH

Patient Safety Partner
Roche, Colombia

Jeimmy is a bacteriologist and clinical scientist with a master's in Public Health with emphasis in Global Health. She has 5 years of experience in pharmacovigilance (PV) and 3 years in medical information. She worked on the PV and Medical Information team at Roche Colombia and is currently dedicated to PV and risk management. She has led processes including ICSRs management, health authority reports, PV agreements, medical information management, digital communication on safety information, signal management, healthcare professional training and risk management. Recently she has been involved in addressing safety needs from therapeutic areas by providing evidence-based solutions to address safety uncertainties in the healthcare ecosystem.

10:15 AM — 11:30 AM

Session 7, Track C: Areas of Focus and Skills: Training, Medical Information as a Strategic Partner and Internal Communication

Placing Medical Information (MI) as a strategic partner involves recognizing its potential to contribute to organizational goals and decision-making processes. By leveraging strategic data in a highly regulated environment, MI can become a valuable tool for generating insights and driving evidence-based decision making.

Learning Objective :

- Gain insights on how to position MI as a strategic partner
- Identify how other departments can use the MI information and its impact on Regulatory Affairs, Clinical Trials and Quality
- Adapt communication styles for different stakeholders such as HCPs and non-HCPs

Track: Track C: MASC

Session Chair(s)

Barbara Nardi, PharmD

Global Director - Medical Communications
Thermo Fisher Scientific, Brazil

Barbara is a PharmD and holds a B.S. in Marketing and Business Management, with 18+ years' experience in the pharmaceutical industry supporting businesses with technical and medical

expertise. Barbara has worked in several areas (Medical, Pharmacovigilance, Quality, Compliance, Customer Service and Marketing) in different industries such as Sanofi, Sanofi Pasteur, Biogen and Local Brazilian CRO. Barbara joined PPD in June 2017 and is currently a Director of Operations, working with different global clients, including Latin America, US, Europe and APAC.

Vivienne Carduz Castilho, AHIP, RAC

Medical Affairs Manager
Libbs Farmacêutica, Brazil

Vivienne has a degree in Pharmacy and Biochemistry from Universidade Paulista, a specialization in Clinical Pharmacology from the Brazilian Institute of Development and Hospital Research (IPH), and a Certificate Course in Principles and Practice of Clinical Research from Harvard Medical School – USA/Brazil - 2009. She has over 27 years experience in the pharma industry, leading teams in clinical research for Schering do Brazil and Novartis. She is currently the Medical Science Manager at Libbs. She has nine years experience as a Study Coordinator at Dante Pazzanese Hospital of Cardiology. She has experience as a team manager in Clinical Research, Bioequivalence, Medical Science Liaison, Medical Communications and Medical Information.

11:30 AM — 12:30 PM

Luncheon, Exhibits, and Networking Break

12:30 PM — 1:45 PM

Session 8, Track A: Regulation of Medicinal Products for Rare Diseases in Latin America

This session will discuss the need to adopt regulatory framework, pathways, and tools to allow for timely access to medicinal products for rare diseases. Attention will be drawn to regulatory tools to prioritize or expedite the assessment and registration of treatments benefitting patients with rare diseases in Latin America. A discussion of international best practices and regional trends in the regulation of treatments for rare diseases, and how to bridge regulatory gaps through fostering discussions among regulators and industry representatives, will also be covered.

Learning Objective :

- Recognize concepts and international best practices in the regulation of rare diseases
- Identify current regulatory trends in Latin America
- Understand the potential for evolving regulatory frameworks to facilitate greater access to innovative therapies for rare diseases
- Capture the essence of a case study illustrating the use of priority registration pathway in Brazil

Track: Track A: Regulatory

Session Chair(s)

Viktoria Magyar, LLM, MSc

Doctoral Student, Department of Regulatory and Quality Sciences
USC Alfred E. Mann School of Pharmacy and Pharmaceutical Sciences, United States

Over 15 years of experience in law, finance, and corporate compliance. Worked for numerous small and mid-sized law firms, renewable energy companies, before launching MGC Associates LLC, a fully integrated pharmaceutical and medical device consulting partnership. Current area of focus and specialty is regulatory and quality sciences pertaining to medical devices, in vitro diagnostics, and digital health technologies in Latin American and Caribbean regions. She is currently working towards her Doctorate in Regulatory Sciences (DRSc) at USC.

Sonia Viejobueno, LLM

US and Latin America Policy Lead, Global Regulatory Policy and Intelligence
Johnson & Johnson Innovative Medicine, Argentina

Sonia has over 15 years of professional experience in the biopharmaceutical industry. As legal counsel specialized in commercial, business, and corporate law, she has provided extensive legal advice to pharmaceutical companies in the Latin America region, including pharmaceutical law, intellectual property, business transactions, regulatory matters and healthcare compliance. She joined Johnson & Johnson in 2016 as Latin America Lead for Global Regulatory Policy & Intelligence and later expanded her role to cover U.S. policy work on Cell & Gene Therapies. She holds a Master of Laws degree on International Trade Law from the University of South Africa and a Law degree from the University of Buenos Aires, Argentina.

Speaker(s)

12:30 PM — 1:45 PM

Session 8, Track B: Technological Advancements and Data Utilization Opportunities in Pharmacovigilance

In this session, speakers will discuss the current scenario for technological advancements and how it can support pharmacovigilance operational activities. Within this scenario, data utilization opportunities and limitations will also be discussed and explored from a pharmacovigilance point of view, considering opportunities for business and regulatory submission.

Learning Objective :

- Identify how most recent technological advancements can support pharmacovigilance operational activities
- Understand the current real-world data/real-world evidence utilization scenario in Latin America for pharmacovigilance, including opportunities and limitations
- Recognize opportunities and limitations for pharmacovigilance data utilization for business and regulatory submissions

Track: Track B: Safety & Pharm

Session Chair(s)

Arthur Bueno, PharmD, MBA

Country Safety Head Back-Up
Sanofi Brazil, Brazil

Arthur is an experienced Pharmacist with more than 16 years of experience in Patient Safety & Pharmacovigilance. Currently Country Safety Head Back-Up at Sanofi Brazil. His carreer started at Takeda Brazil, where he acted in roles of increasing responsibility within local/regional/global PV operations organization (including oversight of ICSRs management, PBRER management, RMP management, Audits/Inspections, Pharmacovigilance Agreements, etc). Arthur also worked for CROs (IQVIA (formes Quintiles) and LabCorp (former Covance)), including Local, Regional and Global Projects for Pharmacovigilance and Patient Safety.

Yoon Jeon (Jamey) Kim, MSc, RPh

Cluster Pharmacovigilance Lead for Latin America
MSD, Panama

Yoon Jeon (Jamey) Kim, the Director and North Cluster PV lead for Latin America at MSD, has 23 years of experience with the company. She provides strategic leadership for cluster countries (Colombia, Ecuador, Venezuela, Central America, and the Caribbean), with an extensive background in pharmacovigilance, regulatory affairs, and clinical trials. Additionally, she chairs the post-approval safety monitoring program review committee within the company. Previously, she held roles as Country PV lead and Regulatory manager at MSD Korea. She is a pharmacist with a master's degree in pharmaceutical technology and a bachelor's degree in pharmacy from Ewha Womans University in South Korea.

12:30 PM — 1:45 PM

Session 8, Track C: Outsourcing Clinical Operations, Hybrid Model Approach in Clinical Trial Execution

This session will explore the hybrid model approach to outsourcing clinical operations in clinical trial execution. Participants will gain insights into the benefits and challenges of combining in-house and outsourced resources to optimize clinical trial efficiency and effectiveness. Real-world examples and best practices will be discussed to highlight how this model can enhance flexibility, scalability, and quality in clinical operations.

Learning Objective :

- Describe the essential components of a hybrid model and provide practical strategies for successful implementation
- Outline and evaluate the key benefits and potential challenges associated with the components and structure of a hybrid model in clinical operations
- Illustrate the application of the hybrid model through real-world examples and case studies, showcasing successful implementations and lessons learned

Track: Track C: MASC

Session Chair(s)

Ricardo Uribe, MBA

Head of Clinical FSPx Americas
Fortrea Clinical Development Mexico, S. De R.L. de C.V., Mexico

As Head of Clinical FSP for The Americas at Labcorp, Ricardo oversees clinical teams of professionals in over 12 countries in North and Latin America. With over 20 years of experience in clinical research, he started his career working in Regulatory and Quality areas, then moved to Clinical Monitoring and Project Management. In 2009 he created from scratch and managed a Site Management Organization in Mexico that leaded him to jump to the CRO business in 2011. Passionate about developing professionals and innovative applications for clinical research, his career has been a complete journey. He regularly participates as speaker in different congresses and as trainer in Global Events presenting Latin American Clinical Research Advantages.

Mercedes Lopez, MA

Regional Operations Manager, Latin America
WCG Clinical, United States

Mercedes is originally from Mexico and holds a bachelor's degree in economics, a master's degree in Inter-American studies and PhD work in Latin American Culture and Education and PhD work in Organizational Leadership studies. Mercedes has trained and presented compelling information to National Cancer Institute directors throughout Latin America and influenced their participation in clinical research. Now, as a Regional Operations Manager for Latin America, Mercedes is focused on the development of Clinical Research professionals in Latin America and is confident in her capacity to convocate and connect with people of different cultures and interests to continue growing the network of clinical research sites and CRCs.

1:45 PM — 2:30 PM

Refreshments, Exhibits, and Networking Break

2:30 PM — 3:45 PM

Session 9 Plenary: Fostering Multisector Partnership: Strengthening Regulatory Capacity for Sustainable Health Systems in the Americas

The session focuses on the rationale and importance of building regulatory capacity in the Americas to promote and protect public health. National regulatory systems play a crucial role in ensuring the quality, safety, and efficacy of health technologies. However, evolving scientific advancements, globalization, and diverse product landscapes pose challenges in effectively overseeing these technologies. One of the goals of regulatory capacity building is to improve access to safe, effective, and innovative medicines. Inefficient regulatory systems can hinder access to quality medical products.

This session aims to galvanize mutual expertise and experience-sharing among regulators in the Americas, fostering a collaborative network to sustain robust regulatory agencies and for advancing regulatory practice to meet the potential of novel treatments, vaccines, diagnostics, and medical devices. The session explores strategies for enhancing regulatory capacity through collaboration, knowledge sharing, and fostering initiatives for joint work and collaboration. It discusses challenges, opportunities, and best practices in capacity building efforts, aiming to identify ways to promote collaboration and joint initiatives among regulators, universities, and industry stakeholders. By leveraging capacity building efforts, participants can enhance their ability to work together, share resources, and address common challenges in regulatory systems strengthening.

Additionally, the session engages in a discussion on existing models of capacity building in regulatory systems. By analyzing and comparing these models, participants can identify best practices, lessons learned, and innovative approaches that can be applied to strengthen regulatory systems in the Americas. This discussion aims to foster collaboration and knowledge exchange among participants, promoting the adoption of effective capacity building strategies that support collaborative initiatives.

Learning Objective :

- Discuss capacity building models for regulatory systems strengthening, identifying best practices and lessons learned
- Highlight the importance of robust regulatory systems in promoting public health and ensuring access to safe and effective health technologies
- Explore strategies for enhancing regulatory capacity through collaboration, knowledge sharing

Track: General Session

Session Chair(s)

Leonardo Semprun Semprun, PharmD

Global Regulatory Policy Lead-LatAm
MSD, Panama

Leonardo Semprún is currently Senior Director, Global Regulatory Policy at MSD. In this role, Leonardo is responsible to define and execute a regional regulatory policy plan that addresses current and future needs, while also advocating for and anticipating regulatory change with LATAM-based regulators and multilateral organizations. He has worked with governments, regulators, trade bodies and other external stakeholders to shape regional regulatory policy. Leonardo' work in the industry spans over 20 years, across regulatory, quality, intellectual property and policy functions

Duglas Rodriguez Calderon, MSc

Head of LATAM Regulatory Policy, Global Regulatory Policy & Intelligence
Roche, Panama

Duglas holds a Bachelor of Science degree in Biology with specialization in Molecular Biology, Biochemistry and experience in preclinical biochemical research. He adds to his career more than 12 years of experience in Regulatory Affairs in multinational companies such as P&G, J&J and Roche. With an

extensive knowledge of the LATAM regulatory landscape for consumer products, medical devices and pharmaceuticals, he recently has worked on strategic approaches to cooperate with regulators to strengthen the regulatory systems and has played leadership roles in industry associations like FEDEFARMA. Duglas currently holds the position of Head of LATAM Regulatory Policy part of the Global Regulatory Policy & Intelligence group at Roche Diagnostics.

3:45 PM — 4:00 PM

Closing Remarks