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

Print Agenda

Day 1 Sep 25, 2024

7:30 AM — 8:15 AM — Ballroom 1 and 2

Networking Breakfast

7:30 AM — 6:30 PM — Foyer, Outside Ballroom 1

Registration

8:00 AM — 9:00 AM

Welcome and introduction to the workshop and its goals

Welcome and introduction to the workshop and its goals

Session Chair(s)

Theresa Test Keeny

Sr. Manager, Meeting Operations
DIA, United States

8:15 AM — 8:30 AM Ballroom 3

Welcome and Opening Remarks

8:30 AM — 9:45 AM Ballroom 3

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 served as the Executive Director of CIRS. He is the Director of the DK Kim International (USC DRQS) and has been actively involved in promulgating best regulatory practices 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. 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 14 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 10 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 national and international events organized by DIGEMID, MFDS, CASSS, DIA and PAHO. Currently, she is the coordinator of the reviewer CMC team of biological products.

Speaker(s)

WLA and Regulatory Capacity Building

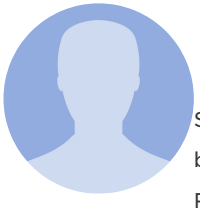
Antonio Barra Torres, MD

President Director
ANVISA, Brazil

Mr. Barra, President-Director of Anvisa, graduated in Medicine from Foundation Souza Marques in 1986 and had his residency in Vascular and Endovascular surgery done at Marcílio Dias Naval Hospital (HNMD) in Rio de Janeiro. MBA in Health Services Administration at Federal University of Rio de Janeiro, in 2012. In 1987 joined Brazilian Navy as a medical officer. In 2015 he was promoted to the rank of Rear Admiral, the second highest rank in the Medical Corps. Retired from the Navy in February of 2019, was approved by the Brazilian Senate to the position of Anvisa's Director in July of the same year. He was later confirmed as President-Director in October 2020. In March 2023, was appointed as ICMRA's second vice-chair.

Global Supply Chain Integrity Priority Work Area

Sarah Venti, JD



Regulatory Counsel, CDER, Office of Compliance
FDA, United States

Sarah Venti is a Regulatory Counsel at the U.S. Food and Drug Administration (FDA). Sarah has been with the FDA since 2013, first in the Center for Tobacco Products, then in the Office of Regulatory Affairs, and now with the Center for Drug Evaluation and Research (CDER). Sarah is in CDER's Office of Compliance where she focuses on policy and compliance issues related to prescription drugs and the pharmaceutical supply chain, including the implementation of the Drug Supply Chain Security Act. Sarah graduated with her J.D. from American University's Washington College of Law in 2010.

Implementation of Good Regulatory Practices: Actions to Promote Advancement

Mario Alanis, PhD

Senior Advisor
Erudee Foundation, Frpath, Mexico

Mario Alanis has domestic and international, public sector experience in health regulation, economic analysis, social policy and international trade negotiations. Proven track record of successfully leading teams working on complex, sensitive issues with governments, multilateral organizations, non-governmental organizations and the pharmaceutical and medical device industry. Currently he collaborates as Senior Advisor to the Center for Innovation in Regulatory Science, (CIRS) participating in diverse strategic projects for the Latin American Region. He concluded a Ph.D. in Economics at the University of Pennsylvania and the Bachelor program at the TEC de Monterrey in Mexico.

9:45 AM — 10:30 AM Ballroom 1 and 2

Refreshments, Exhibits, and Networking Break

10:30 AM — 12:00 PM Ballroom 3

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 Roman, MPharm

Head Regulatory Policy LaCan
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, MSc

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.

Speaker(s)

Latin America in Perspective: Projects and Priorities of Regulatory Authorities

Luis Rodrigo Pineiro, MA

Director of Institutional Relations
ANMAT Ministry of Health, Argentina

BA in Advertising MA in ORGANIZATION COMMUNICATION MANAGEMENT Attended the PhD in PUBLIC AFFAIRS, POLICIES AND GOVERNMENT program. He is the current director of the Office of Institutional Relations of ANMAT.

He has worked for ANMAT since 1994. Among other functions, he was the Head of the Observatory and the Coordinator of the Institutional Communication Program. From 2014 to 2019, he was a Member of the Subgroup of Communication on behalf of ANMAT at the Pharmaceutical Cooperation Scheme (PIC/S). He participated in several talks and congresses. He is a professor at the Master´s of Science in Regulatory Science of Buenos Aires University, a MSc program jointly developed by the School of Pharmacy and Biochemistry and ANMAT.

Latin America in Perspective: Projects and Priorities from Key Stakeholders in the Regional

Ana Carolina Moreira Marino Araujo, PharmD

Head of the International Affairs Office
ANVISA, Brazil

Ana Carolina Marino is Head of the International Affairs Office at ANVISA. Holds a permanent position at ANVISA as goverment employe, Health Regulatory Expert, since March 2007. Has experience in both technical and management roles: Advisor at the Fourth Directorate/ANVISA; Head for Inspectorate and Law enforcement department; Manager for the Medical Device Inspectorate and Law Enforcement Department; Manager for the Drugs Post Approval Changes Office. Pharmacist with a degree from the University of Brasília (2002), and postgraduate qualifications in Health Regulation and Surveillance (2009) from Fiocruz and Pharmaceutical Technology (2012) from the Federal University Fluminense. Represented Anvisa in ICH, PICs, IMDRF and MDSAP.

Progress, Cooperation and Quality

Jaime Alberto Cevallos Palacios

Risk Profile Technical
ARCSA, Ecuador

Jaime is a dedicated healthcare professional from Ecuador, currently serving as the Director of Risk Profile Technical Direction for the National Agency for Regulation, Control, and Sanitary Surveillance. He holds multiple master's degrees in Public Health and Health Institution Management, alongside a medical degree. Over the years, He has held various leadership roles and is committed to ensuring equitable access to healthcare. He has participated in several training workshops and seminars focused on health management and quality assurance. He is passionate about improving community health outcomes.

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

Miriam Jackeline Jackeline Loera Rosales

Commissioner of Evidence and Risk Management
COFEPRIS, Mexico

Master's degree in Science from the Centre for Research and Advanced Studies of the National Polytechnic Institute, and a Bachelor's degree in Pharmaceutical Biochemistry, with a specialisation in toxicological sciences, Ms. Miriam Jackeline Loera Rosales is the current Commissioner for Evidence and Risk Management at the Federal Commission

for the Protection against Sanitary Risks (COFEPRIS), where she addresses topics such as pharmacovigilance, environmental health, occupational health, and the management of sanitary risks in the Mexican population.

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

Maria del Pilar Hernández Svendblad, MHS

Head of the Records and Registrations Operations Office
Sanitary Regulation Superintendency, El Salvador

Mrs. Hernández has 11 years of experience at the National Directorate of Medicines, with 7 years in the pharmaceutical product market authorization area and 3 years as the coordinator of the Clinical Research Committee, as well as overseeing the Institutional Journal of Regulatory Sciences, Consciencia Sanitaria. She currently serves as Head of the Clinical Trials Unit (Ad Honorem) and Head of the Operations Office for Registration and Marketing Authorization at the Superintendency of Sanitary Regulation. She is responsible for providing technical support for decision-making by the Intendant of Registration and Marketing Authorization, as well as designing, coordinating, and executing plans to improve the efficiency of regulatory processes.

12:00 PM — 1:00 PM Ballroom 1 and 2

Luncheon, Exhibits, and Networking Break

12:15 PM — 12:55 PM

Roundtable Discussions: Driving Progress: Reliance in Action for Latin America

This interactive roundtable will explore the evolving role of reliance, collaboration, and convergence in Latin America. Participants will engage in meaningful discussions about their experiences with reliance, addressing challenges, and exploring the opportunities that lie ahead. By reflecting on these key areas, participants will work together to shape future roundtables and workshop topics, ensuring they are aligned with the needs and aspirations of the region. The roundtable will also highlight potential pathways to strengthen reliance, collaboration, and convergence initiatives and drive positive change in Latin America's drug and device development landscape. Topic for Day One: Reliance | Topic for Day Two: Collaboration & Convergence

Learning Objective :

- Explore personal experiences with reliance by sharing both successes and challenges faced from regulatory agencies and industry
- Identify key challenges to progress to better understand the region-specific obstacles to reliance-initiatives

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- Collaborate to define a vision for the future of reliance in Latin America, focusing on opportunities for growth and development

Session Chair(s)

Representative Invited

DIA, Switzerland

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1:00 PM — 2:30 PM Ballroom 3

Session 3, Track A: Exploring the Present and Future of Regulatory Cooperation, Collaboration and Convergence

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: Regulatory

Session Chair(s)

Maria Antonieta Roman, MPharm

Head Regulatory Policy LaCan
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, 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)

Exploring the Present and Future of Regulatory Cooperation, Collaboration and Convergence

Ana Carolina Moreira Marino Araujo, PharmD

Head of the International Affairs Office
ANVISA, Brazil

Ana Carolina Marino is Head of the International Affairs Office at ANVISA. Holds a permanent position at ANVISA as goverment employe, Health Regulatory Expert, since March 2007. Has experience in both technical and management roles: Advisor at the Fourth Directorate/ANVISA; Head for Inspectorate and Law enforcement department; Manager for the Medical Device Inspectorate and Law Enforcement Department; Manager for the Drugs Post Approval Changes Office. Pharmacist with a degree from the University of Brasília (2002), and postgraduate qualifications in Health Regulation and Surveillance (2009) from Fiocruz and Pharmaceutical Technology (2012) from the Federal University Fluminense. Represented Anvisa in ICH, PICs, IMDRF and MDSAP.

Regulatory Collaboration and Cooperation: Convergence & Harmonization

Luis Rodrigo Pineiro, MA

Director of Institutional Relations
ANMAT Ministry of Health, Argentina

BA in Advertising MA in ORGANIZATION COMMUNICATION MANAGEMENT Attended the PhD in PUBLIC AFFAIRS, POLICIES AND GOVERNMENT program. He is the current director of the Office of Institutional Relations of ANMAT. He has worked for ANMAT since 1994. Among other functions, he was the Head of the Observatory and the Coordinator of the Institutional Communication Program. From 2014 to 2019, he was a Member of the Subgroup of Communication on behalf of ANMAT at the Pharmaceutical Cooperation Scheme (PIC/S). He participated in several

talks and congresses. He is a professor at the Master´s of Science in Regulatory Science of Buenos Aires University, a MSc program jointly developed by the School of Pharmacy and Biochemistry and ANMAT.

Exploring the Present and Future of Regulatory Cooperation, Collaboration and Convergence

Margarita Contreras Olvera

Official of International Affairs Office
COFEPRIS, Mexico

Margarita Contreras Olvera es Licenciada en Relaciones Internacionales por la Universidad del Valle de México, con la Especialidad finalizada en Derecho Sanitario, impartida por la Universidad Autónoma de México, 2022-2023. Desde el 2004, se desempeña en el área internacional de la Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS), en el puesto de Verificador o Dictaminador Especializado A, en la atención de los compromisos internacionales en materia de regulación sanitaria de medicamentos, vacunas y sustancias controladas, mediante la vinculación con agencias sanitarias de otros países, foros y organismos internacionales, así como con las distintas dependencias a nivel federal.

Regional Collaboration and Engagement through ICH – IFPMA's role

Flavia Firmino Ribeiro, PharmD

Global Regulatory Policy Lead Latin America
Eli Lilly and Company, Brazil

Flavia Firmino is the Global Regulatory Policy Lead for Latin America at Eli Lilly and lead science-based and efficient global regulatory policy initiatives in the region by developing policy positions, assessing, and engaging in external stakeholder groups, and representing Lilly on relevant external work groups with the goal of effecting and leading policy change in the region and beyond. She has a wide range of experience in the strategic and tactical aspects of regional regulatory CMC, including CMC-specific knowledge of requirements in Latin America with a detailed understanding of submission requirements.

PIC/S in Latin America: Harmonization of cGMP Procedures

Juliana Perlow

Executive Director, Regulatory Affairs CMC – Latin America
MSD, Brazil

Juliana Perlow is currently Executive Director at MSD, where she leads the International CMC - Latin America team. In this role, Juliana is responsible for leading the regional strategy and execution of regional CMC post-approval variations and initial registration submissions for both small molecules and large molecules, including biologics and vaccines. A pharmacist with specialization in clinical pharmacology and project management, she also has an MBA. Juliana has more than 25 years of experience in pharmaceutical industries working in regional regulatory CMC and regulatory affairs functions. Juliana co-chairs the ISPE Latin America Regulatory Quality Harmonization Committee.

Regulatory Collaboration and Cooperation Initiatives Combined with Regulatory Convergence and Harmonization

Maria del Pilar Hernández Svendblad, MHS

Head of the Records and Registrations Operations Office
Sanitary Regulation Superintendency, El Salvador

Mrs. Hernández has 11 years of experience at the National Directorate of Medicines, with 7 years in the pharmaceutical product market authorization area and 3 years as the coordinator of the Clinical Research Committee, as well as overseeing the Institutional Journal of Regulatory Sciences, Consciencia Sanitaria. She currently serves as Head of the Clinical Trials Unit (Ad Honorem) and Head of the Operations Office for Registration and Marketing Authorization at the Superintendency of Sanitary Regulation. She is responsible for providing technical support for decision-making by the Intendant of Registration and Marketing Authorization, as well as designing, coordinating, and executing plans to improve the efficiency of regulatory processes.

1:00 PM — 2:30 PM

Room MN

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 :

- Gain insights on the Pharmacovigilance and Technovigilance landscape in Latin America
- Examine 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
- Evaluate the actions needed for reliance in the safety monitoring of medicines and medical devices

Track: Pharmacovigilance

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.

Gislaine Villarta Capeleti Dib, PharmD

Patient Safety 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 different healthy authorities. Professional with over 20 years of experience in Patient Safety in national and international pharmaceutical industry, working on different kind of operations like Pharmacovigilance, Medical devices, Cosmetovigilance and Nutrivigilance with activities and management related to clinical development and post marketing.

Speaker(s)

Challenges, Practices, and Governance in Pharmacovigilance and Technovigilance - Harmonization Efforts in Safety

Simone de Oliveira Reis Rodero, RAC

General Manager, Regulation and Health Surveillance
ANVISA, Brazil

Head of the Post-Marcket Surveillance Office at the Brazilian Health Regulatory Agency (ANVISA). Holds a permanent position at ANVISA as goverment employee, Health Regulatory Expert, since March 2005. Graduated in Pharmaceutical Sciences from the University of Brasília - UnB (2004), Specialist in Bioethics from the University of Brasília - UnB (2005), Specialist in Health Surveillance from the Oswaldo Cruz Foundation - FioCruz (2007) and Specialist in Data Science and Artificial Intelligence from Hospital Alemão Oswaldo Cruz - HAOC (2023).

Challenges, Practices,and Governance in Pharmacovigilance and Technovigilance

Miriam Jackeline Jackeline Loera Rosales

Commissioner of Evidence and Risk Management
COFEPRIS, Mexico

Master's degree in Science from the Centre for Research and Advanced Studies of the National Polytechnic Institute, and a Bachelor's degree in Pharmaceutical Biochemistry, with a specialisation in toxicological sciences, Ms. Miriam Jackeline Loera Rosales is the current Commissioner for Evidence and Risk Management at the Federal Commission for the Protection against Sanitary Risks (COFEPRIS), where she addresses topics such as pharmacovigilance, environmental health, occupational health, and the management of sanitary risks in the Mexican population.

Challenges, Practices, and Governance in Pharmacovigilance and Technovigilance - Harmonization Efforts in Safety

Kelly Elizabeth Serrano Mestanza

Head of Pharmacovigilance Team
DIGEMID, Peru

1:00 PM — 2:30 PM Room GH

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: 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.

Viviane Arid De Lima, PharmD, MBA

Medical Information Lead, Emerging Markets & China
Pfizer, Brazil

Viviane brings over 26 years of Medical Information (MI) experience to her role as Regional Lead for Pfizer in Emerging Markets and China. As part of the Global MI Leadership team, she has been instrumental to evolving MI practices, from establishing global processes and regional contact centers to pioneering digital channels like chatbots and WhatsApp. Passionate for innovation, she has been involved with exploration of GenAI for MI use cases. At the core of her work is a dedication to patient-centric strategies, ensuring that the voice of the customer informs company decisions. Viviane holds a Bachelor's in Pharmacy-Biochemistry, an MBA in Marketing, and a post-graduate certificate in Management. She is based out of São Paulo, Brazil.

Speaker(s)

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

Ana Carolina Monteiro Adame, PharmD, MBA, MS

Sr. Medical Information Manager, Latin America & Canada
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.

The Value of Collaboration between MI & MSL

Isabel Bretas, PharmD

Medical Information Associate Director
PTC Therapeutics, Brazil

Pharmacist, MBA, over 15 years of expertise in the medical area of rare diseases pharmaceutical industry. Solid experience as Medical Information and Customer Services head, leading both internal and third-party teams. Background in Pharmacovigilance, Medical Projects and field medical activities as MSL. Currently as Medical Information Associate Director for Americas at PTC Therapeutics.

2:30 PM — 3:15 PM Ballroom 1 and 2

Refreshments, Exhibits, and Networking Break

3:15 PM — 4:30 PM Ballroom 3

Session 4, Track A: Empowering Reliance: Tools and Insights for Enhanced Regulatory Practices

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. The use of documents such as Public and Unredacted Assessment Reports and Certificates of Pharmaceutical Products (CPP) as tools to guide reliance decision-making by regulatory agencies will be discussed. 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 in decision-making
- Explore decision-making practices necessary for the practical implementation of reliance models
- Clarify the concept of "sameness of product" and outline the essential documentation required for effective reliance implementation
- Examine the broader scope of reliance models, going beyond their applications in marketing authorizations

Track: Regulatory

Session Chair(s)

Susan Koepke, MBA

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

Susan Koepke is an accomplished Regulatory Affairs professional with more than 25 years of experience in the pharmaceutical industry. With a background in industrial pharmacy and an MBA, she brings a unique blend of expertise to her role at EMD Serono Inc, the healthcare business of Merck KGaA, Darmstadt, Germany. As the Regulatory Affairs Head for Latin America, based in Miami, FL, USA, she spearheads the innovative pipeline delivery and oversees life cycle management activities for established products across the Latin American market. Her wealth of experience and leadership are instrumental in driving regulatory excellence while advocating for best science and evidence-based decision making regulatory framework.

Diego Alexander Salas, LLM

Regulatory Affairs Director
Federación Latinoamericana de la Industria Farmacéutica, 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)

Reliance as a Tool to Promote Stronger Regulatory Systems

Patricia Oliveira Pereira Tagliari, LLM, MPH

Associate Director of the Second Directorate
ANVISA, Brazil

Patricia Oliveira Pereira Tagliari holds a master's degree in Public Health (Global Health and Health Diplomacy) from the National School of Public Health (2014), specializations in Health Regulation and Surveillance (2010) and Health Law (2007), both from Fiocruz, and a degree in International Affairs from the University of Brasilia (2004). She is currently a government employee, specialist in health regulation and surveillance, at the Brazilian Health Regulatory Agency - Anvisa. From April 2020 to the present date, Ms. Tagliari has served as Associate Director at Anvisa. Prior to that, she served as Advisor at Anvisa's Office of Inspection and Health Surveillance and as the Head of Anvisa's International Affairs Office.

Appraisal of Public Assessment Reports (PARs) as Tools to Guide Reliance Decision-making by Regulatory Agencies

Juan Ramón Lara

Senior Research Analyst
Centre For Innovation In Regulatory Science, Mexico

Juan is a Senior Research Analyst at the Center for Innovation in Regulatory Science. He holds a Bachelor's degree in Pharmaceutical-Biological Chemistry and has diverse experience in quality assurance, production, R&D, and regulatory affairs. Juan supports a wide range of regulatory science research projects to advance international regulatory policy development. Previously, he worked at IQVIA, where he supported pharmaceutical industry projects across Mexico and Central America on market access and regulatory landscape. Prior to that, he worked at the Federal Commission for the Protection of Health Risks (COFEPRIS, NRA of Mexico), where he supported projects to streamline scientific reviews and comply with regulatory timelines.

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 extensive 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. He is engaged as conference speaker and in numerous workshops/capability buildings with regulators from around the globe.

3:15 PM — 4:30 PM Room MN

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: Pharmacovigilance

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.

Speaker(s)

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

Raphael Elmadjian Pareschi, PharmD, MBA

Patient Safety Lead/ Head of Pharmacovigilance Brazil
Roche, Brazil

Raphael has more than 17 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.

Pharmacovigilance Inspections in Latin America: Current Scenario, Expectations and Trends – Scenario for Brazil

Flavia Neves Rocha Alves, MPH

PV Department Leader
ANVISA, Brazil

Flávia Neves Rocha Alves holds a degree in Pharmacy-Biochemistry from the University of São Paulo (1995), a master's degree in Public Health (Planning and Management of Health Services) from the National School of Public Health/Fiocruz (2004) and a specialization in Health Surveillance from Fiocruz (2008). She holds a permanent position at ANVISA as government employee, Health Regulatory Expert, since April 2005, having worked in different areas: medicines marketing authorization, pharmacopeia, toxicology, inspection, regulation. She currently holds the position of Head of Pharmacovigilance at the Brazilian Health Regulatory Agency (ANVISA).

Pharmacovigilance Inspections in Latin America – Current Scenario, Expectations and Trends

Xiomara Vega Cruz, MHS

Head of the National Pharmacovigilance Center
Ministry of Health of Costa Rica, Costa Rica

Graduate in Pharmacy and Master in Health Management. I began my work at the Ministry of Health in 2005 in the area of ??Pharmacovigilance. Coordinator of the National Center for Pharmacovigilance and Technovigilance. I have 21 years of professional experience. Since 2008 I was appointed as Coordinator of the National Center for Pharmacovigilance, the governing body in charge of dictating the guidelines for Pharmacovigilance at the national level and since 2014 I have coordinated the National Pharmacovigilance Commission, a technical advisory body for decision-making regarding the safety of medicines in the country. As of 2018 I was appointed coordinator of the National Center for Technovigilance.

Pharmacovigilance Inspections in Peru: Current scenario, Expectations and Trends

Kelly Elizabeth Serrano Mestanza

Head of Pharmacovigilance Team
DIGEMID, Peru

3:15 PM — 4:30 PM Room GH

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 :

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

Track: 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)

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

Lizbeth González, MSc

Sr. Medical Information Manager
Takeda, Mexico

I was born in Mexico City, and hold a BSc. in Biomedical Sciences, a MSc. in Biochemistry and further specialized in Pharmacoeconomics. With a background in Medical Information and Safety gained in CROs such PPD and ICON, I took on the role of Medical Information Lead at Shire, now Takeda, for Latin America in 2017. Ever since, I have played a pivotal role co-leading the transformation of medical information services in LATAM. I have contributed implementing custom responses, developing content tailored for the region, and actively participating in digital projects to keep streamlining medical information processes. I have also nurtured relationships with internal stakeholders across the region, fostering stronger collaborations.

Customer Engagement and Insights: MedInfo's Role in the Medical Affairs Strategy Medical Manager's View

Monalisa Bocchi, MD, MS

LatAm Senior Medical Manager
Merz Aesthetics Latam, Brazil

Physician graduated from UNICAMP, São Paulo, Brazil, with a master's degree in Gerontology. Clinical experience in palliative care and over 11 years of experience in the pharmaceutical industry, working in various areas including Medical Affairs, Clinical Research, Innovation, and Portfolio and Pipeline Management. Formerly worked at multinational and national companies including Abbott and NC Pharma. Currently responsible for MedInfo, Clinical Studies, and Medical Scientific Communication at Merz Aesthetics in a Latin America role.

Cross-team Collaboration in Customer Engagement: MedInfo & Field Medical

Carolina Martinez Bonaldi, MSc

Oncology MSL Head
Daiichi Sankyo Brasil, Brazil

Medical Affairs executive with 14 years of experience in pharma industry, from different leadership positions under Medical Affairs organization at Amgen and DS: MSL Mgr, Medical Excellence & Capabilities Mgr, Field Med. Value & Access Mgr, Medical Mgr and MSL Head. She has strategically developed and transformed Field Med. Teams local, regional and globally and led matrixed and dynamic teams, partnering cross-functionally as the bridge between R&D and commercial to enhance business impact and scientific knowledge. Pharmacist with master degree in Oncology, Carolina brings also 5 years of clinical experiency from Oncology Day Care Center, Hospital and Clinical Research Site as Study Coordinator.

4:35 PM — 5:50 PM

Ballroom 3

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: Regulatory

Session Chair(s)

Flavia Firmino Ribeiro, PharmD

Global Regulatory Policy Lead Latin America
Eli Lilly and Company, Brazil

Flavia Firmino is the Global Regulatory Policy Lead for Latin America at Eli Lilly and lead science-based and efficient global regulatory policy initiatives in the region by developing policy positions, assessing, and engaging in external stakeholder groups, and representing Lilly on relevant external work groups with the goal of effecting and leading policy change in the region and beyond. She has a wide range of experience in the

strategic and tactical aspects of regional regulatory CMC, including CMC-specific knowledge of requirements in Latin America with a detailed understanding of submission requirements.

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.

Speaker(s)

How Product Supply is Impacted by Delayed Implementation of PACs

Gloria Bocardo

Prin. Scientist, Regulatory Affairs-CMC
Merck Sharp & Dohme Farmaceutica Ltda, Brazil

Gloria Bocardo is currently Director - Regulatory Affairs CMC at MSD, where she is part of the International CMC LATAM team. In this role, Gloria is responsible for developing CMC regional regulatory strategies for new marketing applications and post-approval changes for both small and large molecules, and for ensuring awareness of regional regulatory policy trends in the region, partnering with Regulatory Affairs and trade associations to pursue priority advocacy plans on CMC topics. She has over 23 years of experience in the pharma industry, in areas spanning Regulatory Affairs CMC, Technical Operations and Quality.

Global Frameworks for Post-Approval Changes in Biological Products

Isabelle Colmagne-Poulard, PharmD, MBA, MSc

Head, International Global Regulatory & Scientific Policy
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.

Management of Product Lifecycle: Challenges and Possible Solutions

Patricia Oliveira Pereira Tagliari, LLM, MPH

Associate Director of the Second Directorate
ANVISA, Brazil

Patricia Oliveira Pereira Tagliari holds a master's degree in Public Health (Global Health and Health Diplomacy) from the National School of Public Health (2014), specializations in Health Regulation and Surveillance (2010) and Health Law (2007), both from Fiocruz, and a degree in International Affairs from the University of Brasilia (2004). She is currently a government employee, specialist in health regulation and surveillance, at the Brazilian Health Regulatory Agency - Anvisa. From April 2020 to the present date, Ms. Tagliari has served as Associate Director at Anvisa. Prior to that, she served as Advisor at Anvisa's Office of Inspection and Health Surveillance and as the Head of Anvisa's International Affairs Office.

4:35 PM — 5:50 PM Room MN

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: Pharmacovigilance

Session Chair(s)

Gislaine Villarta Capeleti Dib, PharmD

Patient Safety 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 different healthy authorities. Professional with over 20 years of experience in Patient Safety in national and international pharmaceutical industry, working on different kind of operations like Pharmacovigilance, Medical

devices, Cosmetovigilance and Nutrivigilance with activities and management related to clinical development and post marketing.

Yoon Jeon (Jamey) Kim, MSc, RPh

Director, Cluster Pharmacovigilance Lead
Merck & Co., Inc., Rahway, NJ, USA, Panama

Yoon Jeon (Jamey) Kim, the Director and North Cluster PV lead for Latin America at MSD, has more than 20 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 Affairs 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.

Speaker(s)

Handling Multiple Data Sources and Large Databases in Signal Evaluation

Mariângela Luchezi, RPh

Sr Associate - Clinical Surveillance
Eli Lilly and Company, Brazil

Mariângela is a dedicated pharmacist with nearly 10 years of experience in the pharmaceutical industry, having made significant contributions at companies like Roche and Eli Lilly. While she has worked in the Medical Affairs department, her career has been largely devoted to pharmacovigilance, with a focus on right to operate documents, regulatory requests tied to new drug applications and post marketing setting, and the signal management process. Ensuring patient safety is at the core of her professional and personal commitments.

Signal Detection in High Social Media Exposure Scenario

Stefania de Azevedo Fraletti

Quality Assurance Manager and Interim Director of Quality Assurance, Pharmacovig
Novo Nordisk, Brazil

Quality Assurance Manager at Novo Nordisk Pharmaceuticals Brazil; Twelve years of experience in the pharmaceutical industry, working with Quality Management Systems and Pharmacovigilance, as well as their tools and requirements; Extensive experience in Quality and Safety processes within the business, team management, and supervision of third parties; Currently serving in the interim management of Pharmacovigilance, Customer Service (SAC), and Scientific Information Service (SIC) departments.

Case Study of Automation in Signal Detection Implemented by a Brazilian Public Laboratory

Marcelo Eiji Koike, PharmD, MBA

Pharmacovigilance Specialist
Instituto Butantan, Brazil

Marcelo has extensive experience in Public Health and Pharmacovigilance. Over his 15+ year career, he has actively contributed to public health initiatives, including his work with the pharmaceutical program at the Municipal Health Department of São Caetano do Sul. Since 2012, he has been dedicated to the Clinical Trials and Pharmacovigilance Center at Instituto Butantan. Through his work in Pharmacovigilance, he has become deeply involved in the clinical safety of vaccines, both for vaccines developed in-house and those arising from technology transfer process. Currently Pharmacovigilance Specialist, he has actively contributed to the implementation and strengthening of safety signal detection process at Instituto Butantan.

4:35 PM — 5:50 PM Room GH

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: 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.

Speaker(s)

Analyze Real Cases from Latin America to Understand the Implementation of AI in MI

Lara Lopes Facó, DVM, PhD, MSc

Medical Information Coordinator
Libbs Farmacêutica, Brazil

I hold a bachelor's degree in veterinary medicine and a master's and a doctoral degree in the same field from the University of São Paulo, Brazil. I have carried out research on various aspects of veterinary medicine, such as mechanical ventilation, critical care medicine and pain management. Since 2019, I have been working as a medical information coordinator at Libbs Famaceutica. In this position, I am in charge of providing precise and current information on the company's products and services to health professionals, customers, and regulatory agencies.

Artificial Intelligence in Medical Information: Legal and Compliance Implications

Gustavo Swenson Caetano, JD, LLM

Partner
Mattos Filho, Veiga Filho, Marrey Jr. e Quiroga Advogados, Brazil

Gustavo is a specialist in transactional, regulatory and intellectual property matters related to the life sciences, health, food, agribusiness, technology and biotechnology industries. He represents local and international clients on contractual matters, including on licensing, collaboration, development and contracts of similar nature. He also advises and represent clients before regulatory and government agencies, such as the Brazilian Health Regulatory Agency, the Brazilian Agency of Supplementary Health, and the Ministry of Agriculture, Livestock, and Food Supply. He works with healthcare compliance and legal matters involving privacy and personal data protection.

5:50 PM — 6:50 PM

Ballroom 1 and 2

Networking Reception

Day 2 Sep 26, 2024

7:30 AM — 8:15 AM | Ballroom 1 and 2

Networking Breakfast

7:30 AM — 4:00 PM | Foyer, Outside Ballroom 1

Registration

8:15 AM — 9:30 AM | Ballroom 3

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 17 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 an accomplished Regulatory Affairs professional with more than 25 years of experience in the pharmaceutical industry. With a background in industrial pharmacy and an MBA, she brings a unique blend of expertise to her role at EMD Serono Inc, the healthcare business of Merck KGaA, Darmstadt, Germany. As the Regulatory Affairs Head for Latin America, based in Miami, FL, USA, she spearheads the innovative pipeline delivery and oversees life cycle management activities for established products across the Latin American market. Her wealth of experience and leadership are instrumental in driving regulatory excellence while advocating for best science and evidence-based decision making regulatory framework.

Speaker(s)

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

Claudia Echeverria, MEd

Chapter Lead Patient Experience (Patient Advocacy, Patient Solutions)
Roche, Brazil

Claudia is a speech therapist with a masters degree in Educational Psychology. At Roche, she leads a Patient Experience team working closely with Patient Communities. Prior to Roche, she has held roles in corporate settings and as a consultant, focusing on brand Patient Partnership, Patient Centricity, especially in Market Access, Patient Advocacy, Advocacy, Health Policy and Patient Support Programs including digital strategies. Claudia is recognized for her contributions to thought leadership, sharing insights through articles, speaking engagements, and mentorship programs. She believes a Patient Inclusive Mindset within her company is a relevant factor to the achievement of our vision focused on improving customer/patient experience.

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

Verônica Stasiak Bednarczuk, MBA, MSc

Founder and CEO & PhD Student on HTA / Patient Involvement
United For Life Institute & Federal University of Parana, Brazil

Master and PhD student in Pharmaceutical Sciences with an emphasis on Health Technology Assessment / Patient Involvement at Federal University of Parana; MBA in Public Policies and Social Rights; Psychologist; Diplomatura Health Literacy y empoderamiento. Founder and CEO of United for Life Institute (NGO for Cystic Fibrosis, Rare and Respiratory Diseases); Consultant at Supera Consulting; Speaker. Member of the ISPOR; Brazilian Study Group on Cystic Fibrosis and Universidad del Paciente y la Familia. She was late diagnosed with Cystic Fibrosis at the age of 23, and, since then, has dedicated herself to studying and working on the subject, also focusing on public policies, HTA and Advocacy.

9:30 AM — 10:15 AM Ballroom 1 and 2

Refreshments, Exhibits, and Networking Break

10:15 AM — 11:30 AM Ballroom 3

Session 7, Track A: The Future of Regulatory Submissions: CTD, eCTD, and Cloud-based Systems

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
- Evaluate the criticality of adopting emerging data standards and strategies for more efficient management of regulatory submissions

Track: Regulatory

Session Chair(s)

Flavia Firmino Ribeiro, PharmD

Global Regulatory Policy Lead Latin America
Eli Lilly and Company, Brazil

Flavia Firmino is the Global Regulatory Policy Lead for Latin America at Eli Lilly and lead science-based and efficient global regulatory policy initiatives in the region by developing policy positions, assessing, and engaging in external stakeholder groups, and representing Lilly on relevant external work groups with the goal of effecting and leading policy change in the region and beyond. She has a wide range of experience in the strategic and tactical aspects of regional regulatory CMC, including CMC-specific knowledge of requirements in Latin America with a detailed understanding of submission requirements.

Jorge Azar

Senior Area Regulatory Director for Latin America
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.

Speaker(s)

Anvisa's Expectations about the eCTD Implementation

Leonardo Santos, PhD

Advisor of the General Office of Medicines
ANVISA, Brazil

Leonardo Santos is a pharmacist, PhD in Immunology from University of Bahia, Brazil. He is a health regulation specialist from The Brazilian Health Regulatory Agency (ANVISA) since 2014. He worked with the evaluation of Chemistry, Manufacturing, and Controls (CMC) of pharmaceuticals for post-approval changes. After spending almost four years working with health control of pharmaceuticals, medical devices, food, and cosmetics importation in different positions, he is now an assistant in the general Office of Drug Products leading the process of eCTD implementation.

SAHPRA's eCTD Journey

Christelna Reynecke, MBA, RPh

Chief Operating Officer
South African Health Products Regulatory Authority (SAHPRA), South Africa

Christelna is the COO of South African Health Products Regulatory Authority (SAHPRA). She holds a Master of Business Administration (MBA) from Edinburgh Business School (Heriot Watt University) and a BPharm Degree from the University of the North West. Before joining SAHPRA, Christelna spent 13 years in the Pharma Logistics sector in Quality Assurance/Regulatory Compliance and Logistics Operations roles and developed an appreciation for the value Lean Six Sigma approaches, tools and process improvement can have for organisations. The first 8 years of her career in the Retail and Courier Pharmacy sector solidified the passion for prioritizing patient well-being and out-of-the box thinking.

The Future of Regulatory Submissions: Dossiers in the Cloud

Cesar Vinces

Sr. Director Regulatory Innovation & International Policy
Accumulus Synergy, United States

Cesar serves as Interim EU & International Policy Lead at Accumulus Synergy within Regulatory Innovation. He engages with industry experts, national regulators, and global organizations to foster policy changes and develop strategies that enhance regulatory frameworks, promoting industry collaboration through a cloud-based data exchange model. Cesar supports efforts that permit the adoption of the Accumulus platform by both sponsors and regulators. Additionally, he leads a Topic Group Digitalization in Regulatory for IRISS, pushing forward industry-wide digital advancements. Cesar has over two decades of experience, the last 12 years he spent in Submissions Management leadership roles within Regulatory Operations at Pfizer.

10:15 AM — 11:30 AM Room MN

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: Pharmacovigilance

Session Chair(s)

Gislaine Villarta Capeleti Dib, PharmD

Patient Safety 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 different healthy authorities. Professional with over 20 years of experience in Patient Safety in national and international pharmaceutical industry, working on different kind of operations like Pharmacovigilance, Medical devices, Cosmetovigilance and Nutrivigilance with activities and management related to clinical development and post marketing.

Raphael Elmadjian Pareschi, PharmD, MBA

Patient Safety Lead/ Head of Pharmacovigilance Brazil
Roche, Brazil

Raphael has more than 17 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 a Country with Tropical Diseases

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.

Risk Management and Risk Minimization Activities – EU Experiences and Evolution of Safety Management Systems

Priya Bahri, PhD, RPh

Senior Lead (Pharmacovigilance and Risk Management Guidance and Policy)
European Medicines Agency, Netherlands

Priya Bahri, RPh, PostGradDipEpi, PhD, at EMA since 1996, is now EMA's Lead Pharmacovigilance and Risk Management Guidance and Policy. In this role, she also instigates research and regulatory frameworks for risk communication, stakeholder engagement for pharmacovigilance and implementation of risk minimisation in healthcare. Pro bono, she is active in the learned societies ISoP and ISPE and as associated researcher at Utrecht University. She is the editor of the Springer textbook "Communicating about Risks and Safe Use of Medicines - Real Life and Applied Research".

Risk Management Plan and Risk Minimization Activities in Brazil

Flavia Neves Rocha Alves, MPH

PV Department Leader
ANVISA, Brazil

Flávia Neves Rocha Alves holds a degree in Pharmacy-Biochemistry from the University of São Paulo (1995), a master's degree in Public Health (Planning and Management of Health Services) from the National School of Public Health/Fiocruz (2004) and a specialization in Health Surveillance from Fiocruz (2008). She holds a permanent position at ANVISA as government employee, Health Regulatory Expert, since April 2005, having worked in different areas: medicines marketing authorization, pharmacopeia, toxicology, inspection, regulation. She currently holds the position of Head of Pharmacovigilance at the Brazilian Health Regulatory Agency (ANVISA).

10:15 AM — 11:30 AM Room GH

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: 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.

Speaker(s)

MedInfo as a Strategic Partner throughout Drug Lifecycle

Gabriela Pacheco De Oliveira, PharmD

Medical Information Lead
Ache Laboratorios, Brazil

Gabriela is a PharmD with a specialization in Pharmaceutical Medicine from Sírio-Libanês and a Leadership certification from Harvard Business School. With over 10 years of experience in Medical Information, Medical Communication, and Medical Writing, she currently leads the Medical Information department at Aché Laboratórios Farmacêuticos, Brazil. Throughout her career, Gabriela has significantly contributed to the expansion and

development of the Medical Information and Medical Communication roles within the company, enhancing their strategic contribution on the drug lifecycle—from feasibility to regulatory, marketing, and post-marketing stages.

Specific Areas of Focus and Skills: Training, MI as a Strategic Partner & Internal Communication

Gustavo Tiguman, PharmD, PhD

Health Technology Assessment Partner (Value Strategy & HEOR Manager)
Roche, Brazil

Gustavo holds a degree in Pharmacy-Biochemistry from the University of São Paulo (USP) and earned his PhD in Pharmacoepidemiology and Public Health from the State University of Campinas (UNICAMP). Gustavo brings over 10 years of experience in the pharmaceutical industry, having worked in Medical Affairs, Clinical Research, Medical Information, and Market Access in different companies, such as Roche, IQVIA, Teva Pharmaceuticals, and PPD/Thermo Fisher Scientific. Currently, he works as a Health Technology Assessment Partner (Value Strategy & HEOR Manager) at Roche, focused on the value proposition strategy for pricing and reimbursement of medicines in the Brazilian healthcare system.

11:30 AM — 12:30 PM Ballroom 1 and 2

Luncheon, Exhibits, and Networking Break

11:45 AM — 12:25 PM

Roundtable Discussions: Driving Progress: Reliance in Action for Latin America

Speaker(s)

Representative Invited

DIA, Switzerland

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12:30 PM — 1:45 PM Room GH

Session 8, Track A: 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: Regulatory

Session Chair(s)

Ricardo Uribe, MBA

Region Head, Clinical Network - Latin America
Fortrea Clinical Development Mexico, S. De R.L. de C.V., Mexico

With over 20 years of experience in the pharmaceutical industry, Ricardo brings a deep understanding of clinical research to his role as Head of Clinical Operations for Latin America at Fortrea. His career has spanned both large pharmaceutical companies and CROs, providing him with a comprehensive perspective on drug development. Ricardo has held leadership positions across diverse therapeutic areas, overseeing clinical teams in multiple countries. Passionate about driving operational excellence and delivering high-quality clinical trials, he is dedicated to advancing patient care through innovative research.

Mercedes Paloma 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.

Speaker(s)

Real-World Applications: Case Studies of Successful Hybrid Clinical Trials

Suely Kumagai Inoue, MBA, RPh

Executive Manager, Clinical Development
Eurofarma Laboratorios SA, Brazil

Suely Inoue currently serves as the Clinical Development Executive Manager at Eurofarma Labs, a Brazilian company, and she is dedicated to establishing the clinical strategy and generate clinical development plans, clinical data and documentation to support new products marketing authorizations in all Latin American countries. With over 30 years of experience working for different pharma companies (B-MS, Abbott, Amgen and Eurofarma), she cumulated experience in Regulatory Affairs, HEOR and Clinical Operations/ Clinical Development in different therapeutic areas. She holds a BSc. in Pharmacy and Biochemistry from the University of Sao Paulo and MBA from the Fundaçao Instituto de Administraçao (FIA).

Diversity in Hybrid Clinical Trials

Beatriz Rocha, MD, PhD

Chief Regulatory Liason Officer
Fortrea, United States

More than 35 years of professional experience that spans from academia and government to industry. It includes clinical practice in anesthesia and pain management, clinical and basic research in behavioral pharmacology, and regulatory affairs during the last 20 years, first at Merck Research Laboratories in 2001 and subsequently at Covance/LabCorp/Fortrea since 2013. In clinical she developed the oral morphine program for cancer pain, and as a behavioral pharmacologist, worked in animal models of drug abuse. Became Head of Global Regulatory Affairs, Product Development and Market Access Consulting in 2018, and since 2024 is serving as Fortrea's Chief Regulatory Liaison Officer.

Managing Vendors (ie. Patient Recruitment/Retention, CROs, Courier, etc) in a Hybrid Model

Waleuska Spiess

Clinical Operations Portfolio Leader
Roche, Brazil

Waleuska Spiess is a PharmD with more than 25 years´ experience in Clinical Research. She started at Pfizer as a CRA and increased her responsibilites in the area of Project Management and People Development which is really her passion. She has experience working in CRO environment where she had opportunity to learn and focus on Customer experience. She is currently Clinical Operations Portfolio Leader working locally and globally in Pharma Development Clinical Operations Group and Country Therapeutic Area Lead for Immunology, Opthalmology, Neuroscience and CardioMetabolism at Roche Brazil.

12:30 PM — 1:45 PM

Ballroom 3

Session 8, Track A: Regulation of Medicinal Products for Rare Disease: Challenges and Opportunities

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: 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.

Cammilla Horta Gomes, MA, MPharm

Latam Regulatory Policy Lead
Roche, Brazil

Specialist in Global Health and Health Regulation, with a Master's Degree in Development and International Cooperation. Broad experience in regulatory policy, both as regulator in ANVISA and industry, leading or contributing to bilateral and multilateral negotiations, harmonization and convergence initiatives. Specialized knowledge and activities in liaising with government agencies, international and regional organizations, industry and other stakeholders in the area of health regulation. Current role in Roche as Regulatory Policy Lead for Latin America.

Speaker(s)

FDA Regulatory Considerations for Drug Development in Rare Diseases

Daniela Varela Luquetti, MD, PhD

Lead Clinical Analyst, CDER
FDA, United States

Dr. Daniela Varela Luquetti completed her medical and clinical genetics training in Brazil. She pursued additional experience in research through a PhD in Epidemiology and Public Health (Brazil) and the Certificate of Public Health Genetics at the University of Washington (UW, Seattle). She joined the faculty at the School of Medicine of the UW in 2013 becoming an Associate Professor in 2019. At the UW, she designed and conducted multi-center studies on the genetic and non-genetic causes of craniofacial congenital conditions. In 2021, she joined the FDA in the Division of Rare Diseases and Medical Genetics as a clinical reviewer providing her 20 years' experience as a clinical scientist in rare diseases.

Rare Disease in Brazil: Case Study

Raquel Pinheiro, MBA, RPh

Regulatory Affairs Sr. Manager
Johnson & Johnson, Brazil

Raquel is a highly experienced professional with over a decade of expertise in the regulatory field, specializing in the development and implementation of robust strategies for the successful launch of innovative medicines in Brazil. With a deep understanding of the patient's needs and the importance of access to innovative treatments, she have consistently focused her efforts on prioritizing patient well-being throughout the regulatory process. Throughout her career, she exhibited a genuine passion for leading and empowering teams, fostering a collaborative and driven environment that enables individuals to thrive. She is dedicated to navigating complex challenges ensuring regulatory compliance while propelling the advancement of treatmen

Speaker

Claudia Saidman, DrMed, MD

Director of Clinical Research and Management of the Medicines Registry
ANMAT Ministry of Health, Argentina

I am physician specialized in internal medicine, pharmacology, medical audit and forensic medicine. I am teacher for pharmacology at University of Buenos Aires Medical School. I have worked for 31 years at ANMAT - Argentinean Administration Food Drugs and Medical Technology - and currently I am Director of Clinical Research and Management of the Medicines Registry, leading the evaluation and commercialization approval of medicines.

Speaker

Marlene Esquivel, RPh

Department of Biological and Radiopharmaceuticals
DINAVISA, Paraguay

Química Farmacéutica, egresada de la Universidad del Norte. Con más de 10 años de experiencia en el Ministerio de Salud Pública y Bienestar Social. Actualmente Jefa Interina del Departamento de Medicamentos Biológicos y Radiofármacos. Dirección Nacional de Vigilancia Sanitaria - DINAVISA 2016 - 2021 Jefa del Centro regional de Vacunas - Programa Ampliado de Inmunizaciones - MSP y BS. Con capacitación permanente local e internacional en biológicos.

Speaker

Indhira Johanna Bernuy Zagaceta

Executive Director of Pharmaceutical Products
DIGEMID, Peru

Speaker

Karina Cuadra, RPh

Head of Evaluation Sector
Ministry of Public Health - Uruguay , Uruguay

Pharmaceutical Chemist graduated from the Faculty of Chemistry of the University of the Oriental Republic of Uruguay. Drug Evaluator Chemist of the Drug Department of the Ministry of Public Health from 2006 to 2019, specialized in the evaluation of Biotechnological Drugs (training carried out at the Spanish Agency for Drugs (AEMPS) among others). Head of the Evaluation Sector of the Drug Department of the Ministry of Public Health from 2019 to date. Technical Director of the Comisión para el Control de Clidad de Medicamentos, official drug quality control laboratory since January 2020 to date.

12:30 PM — 1:45 PM Room MN

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: Pharmacovigilance

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

Director, Cluster Pharmacovigilance Lead
Merck & Co., Inc., Rahway, NJ, USA, Panama

Yoon Jeon (Jamey) Kim, the Director and North Cluster PV lead for Latin America at MSD, has more than 20 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 Affairs 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.

Speaker(s)

Current Scenario for Technological Advancements / AI in PV Activities

Simone de Oliveira Reis Rodero, RAC

General Manager, Regulation and Health Surveillance
ANVISA, Brazil

Head of the Post-Marcket Surveillance Office at the Brazilian Health Regulatory Agency (ANVISA). Holds a permanent position at ANVISA as goverment employee, Health Regulatory Expert, since March 2005. Graduated in Pharmaceutical Sciences from the University of Brasília - UnB (2004), Specialist in Bioethics from the University of Brasília - UnB (2005), Specialist in Health Surveillance from the Oswaldo Cruz Foundation - FioCruz (2007) and Specialist in Data Science and Artificial Intelligence from Hospital Alemão Oswaldo Cruz - HAOC (2023).

Real-world Data for Pharmacovigilance in the Context of Regulatory Decision Making

Juhaeri Juhaeri, PhD

Vice President and Global Head, Epidemiology and Benefit-Risk Evaluation
Sanofi, United States

Juhaeri Juhaeri, Ph.D., is Vice President and Global Head of Epidemiology and Benefit-Risk at Sanofi. An epidemiologist and statistician, he has held global leadership roles in Medical and Pharmacovigilance functions for more than two decades in the pharmaceutical industry. A passionate leader, he has built and developed different new teams at Sanofi and led successful programs leading to products' approval and maintenance. He has led different working groups in various public-private partnerships in benefit-risk evaluation, pharmacovigilance, real-world evidence, and patients. He holds adjunct faculty positions at the School of Public Health, University of North Carolina Chapel-Hill and at IPB University, Indonesia.

Real World Data Usage in Safety - Cases from Latin America

Guilherme Julian, MS

Emerging Markets Evidence Generation Lead, Senior Director
Pfizer, Brazil

Pharmacist graduated in Faculdades Oswaldo Cruz, with a master's degree in Psychobiology from UNIFESP, specialist in Clinical Research from Harvard Medical School. More than ten years working in health consultancy focused on evidence generation, health economics and market access, with 90+ publications in national and international conferences and journals. Currently, working as Evidence Generation Lead for Emerging Markets at Pfizer.

1:45 PM — 2:30 PM Ballroom 1 and 2

Refreshments, Exhibits, and Networking Break

2:30 PM — 3:45 PM Ballroom 3

Session 9 Plenary: Fostering Regional Initiatives to Enhance Regulatory Capacity and Strengthen Health Systems

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, 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

Global Head of LATAM Regulatory Policy, Global Regulatory Policy & Intelligence
Roche, United States

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 13 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 medical devices and pharmaceuticals, he works on strategic approaches to cooperate with regulators to strengthen the regulatory systems, playing actives roles at different regulatory/health working groups on industry associations like AdvaMed. Duglas currently holds the

position of Global Head of LATAM Regulatory Policy part of the Global Regulatory Policy & Intelligence group at Roche.

Speaker(s)

Opportunities for International Harmonization & Regulatory Convergence: Regulatory Perspectives

Michelle Limoli, PharmD, RPh

Associate Director, International Programs
FDA, United States

Michelle Limoli is the Senior International Health Science Advisor in FDA's CBER. She is responsible for coordinating and collaborating on activities and strategic programs with various international organizations and governments, as well as within the CBER. During her career at FDA, she has coordinated activities in various harmonization and multilateral initiatives such as ICH, VICH, ICCR, GHTF, IMDRF, APEC RHSC, OECD, and WHO. Michelle joined CBER after having worked in the Center for Drug's international programs, and the Office of the Commissioner, where Michelle served as the Director of FDA's Europe Office. Michelle is a clinical pharmacist with both hospital and community pharmacy experience.

Americas RISE for Health

Patricia Wu, MBA

Chair, Health Working Group
Americas Business Dialogue, United States

Patricia Wu is Senior Vice President at Access Partnership, a global public policy advisory firm, where she supports leading health and life sciences companies navigate the policy landscape throughout the Asia Pacific and Latin American regions. Additionally, Patricia serves as the Chair of the Health Working Group for the Americas Business Dialogue, which is the private sector voice before the Inter-American Development Bank on health issues. Previously, Patricia was Vice President and Managing Director at C&M International and has held positions at The Estée Lauder Companies and J.P. Morgan. She holds an MBA from Harvard Business School.

America Rise for Health: Regulatory Training

Jared Auclair, PhD

Interim Dean and Professor
Northeastern University, United States

Jared R. Auclair, Ph.D. is currently the Interim Dean College of Professional Studies, Vice Provost Research Economic Development and Director of Bioinnovation in the Office of the Provost at Northeastern University. As Vice Provost Research Economic Development, Dr. Auclair works to strengthen the bonds between our education and research missions. As Director of Bioinnovation, Dr. Auclair works to leverage important University activities around biotechnology, bringing together experts from a wide range of disciplines and backgrounds to advance the expansion of Northeastern life sciences programs.

Speaker

Augusto Bencke Geyer, MSc

Health Regulatory Expert, International Affairs Office
ANVISA, Brazil

Augusto Geyer holds a Pharmacy Degree, a specialization in Sanitary Law, and a Master's Degree in Materials Science and Engineering. Currently, he serves in the International Affairs Office at ANVISA. He held the position of Head of the Medical Devices Office, where he led strategic initiatives to enhance the regulatory framework for medical devices in Brazil, contributing to the development and implementation of policies to ensure the safety and efficacy of medical devices. Since 2005, he has consistently represented the agency in various international technical working groups and committees. His efforts have been instrumental in aligning Brazil's regulatory practices with global standards and facilitating international cooperation.

Speaker

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 served as the Executive Director of CIRS. He is the Director of the DK Kim International (USC DRQS) and has been actively involved in promulgating best regulatory practices 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. He is a volunteer with the nonprofit Erudee Foundation.

3:45 PM — 4:00 PM Ballroom 3

Closing Remarks