NH Buenos Aires City

Sep 29, 2025 11:00 AM - Oct 01, 2025 12:00 PM

Bolívar 160, C1066AAD Buenos Aires, Argentina

Latin America Annual Meeting

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

Print Agenda

Day 1 Sep 29, 2025

8:00 AM — 12:00 PM

DIA Latin America Annual Meeting Reliance Pre-Conference Workshop

11:00 AM — 6:00 PM Gaudi Foyer

Registration

1:00 PM — 1:15 PM Gaudi

Welcome and Opening Remarks

1:15 PM — 2:45 PM Gaudi

Session 1 Plenary: Strategic Insights from Latin America Authorities

This session will provide the latest regulatory updates from national regulatory authorities from Latin America, including projects, priorities, and initiatives in the short and medium term, and delve into the priorities that dominate the regulatory agenda, shedding light on the strategic goals and objectives set forth by LATAM authorities. Attendees will gain valuable insights into the plans that are being formulated to address emerging challenges and opportunities within the regulatory framework.

Learning Objective :

At the conclusion of this session, participants should be able to:

- Gain an understanding of the key priorities that dominate the current regulatory agenda set by LATAM authorities
- Explore the specific strategic goals and objectives that have been established to guide regulatory efforts in the region
- Explore opportunities for collaboration among public, private, and academic sectors to advance regulatory agendas and promote regulatory harmonization

Track: General Session

Session Chair(s)

Flavia Firmino Ribeiro, PharmD

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.

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. 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.

Speaker(s)

Strategic Perspectives of Latin American Authorities

Estefania Mariel Gerez, MPA

Professional from the National Institute of Drugs
ANMAT Ministry of Health, Argentina

Estefania Gerez holds a Bacherlor´s Degree in Biochemistry and Pharmacy with a Master's Degree in Public Administration. She has worked in the public sector (INAME-ANMAT) for 12 years, and her experience in the international regulatory field includes participation and collaboration in regulatory projects and as ANMAT's representative before harmonization and convergence organizations such as PAHO/WHO, IPRRP, and ICH.

Strategic Insights from ANVISA

Elkiane Macedo Rama, MSc

Associate Director of the 3rd Directorate
Brazilian Health Regulatory Agency (ANVISA), Brazil

Elkiane is a Health Regulation Expert and currently serves as the Associate Director of the Third Directorate at the Brazilian Health Regulatory Agency (ANVISA). With over 20 years of experience, she has held various roles at ANVISA, beginning as a reviewer and advisor in the Toxicology Office and later in the Biological Products Office. More recently, she has taken on advisory positions within the agency, including in the Directorate, the International Affairs Office, and the General Office of Cosmetics and Sanitizers. Elkiane holds a degree in Pharmacy and Biochemistry with a specialization in the Pharmaceutical Industry, a Master's degree in Toxicology, and postgraduate certificates in both Toxicology and Health Regulation.

Strategic Perspectives of the Sanitary Regulation Superintendency of El Salvador

María del Pilar Hernández Svendblad, MSc

Head of the Operations Office for the Registration and Market Authorizations Int
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 Sanitary Regulation Superintendency. 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.

Speaker

Jose Crisostomo

Head of Marketing Authorization for Biological Products
Institute of Public Health of Chile, Chile

Speakers

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.

2:45 PM — 3:15 PM Gaudi Foyer

Refreshments, Exhibits, and Networking Break

3:15 PM — 4:30 PM Gaudi

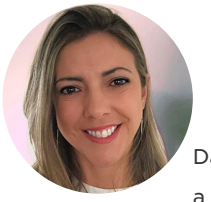
Session 2, Track A: Navigating Regulatory Reliance: Practical Insights and Applications Beyond Initial Marketing Authorization Application

Regulatory reliance initiatives are increasingly becoming vital in the global landscape, promoting more efficient and harmonized approaches to the approval of medicinal products. While commonly focused on medicines marketing authorization, the scope and benefits of regulatory reliance extend to essential areas such as post-approval changes, Good Manufacturing Practice (GMP) certification, clinical trials applications, medical devices authorizations and local batch release. This session will delve into how expanding reliance beyond medicines marketing authorization can streamline regulatory processes, enhance collaboration among stakeholders and support the timely availability of safe and effective medical products for patients in Latin America.
Learning Objective :

- Identify broader applications of regulatory reliance across various regulatory areas
- Describe the regulatory reliance landscape in Latin America, including key challenges and opportunities beyond initial marketing authorization
- Evaluate how regulatory reliance initiatives streamline regulatory processes, contribute to the availability of safe and effective medical products and justify the importance of collaboration among regulatory bodies

Track: Regulatory/Clinical

Session Chair(s)



Daniela Bravo, DrSc, MBA, MSc

Regulatory Policy and Intelligence Latam Associate Director
AbbVie, Brazil

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

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)

Efficient Implementation of Regulatory Reliance: An Industry Perspective

Sérgio Cavalheiro Filho, MPharm

Manager, Regulatory Affairs
IFPMA, Switzerland

Sérgio develops policy and advocacy on complex regulatory issues at IFPMA, with a focus on system strengthening, manufacturing quality, and regulatory reliance. He also played a key role in establishing the Fight the Fakes Alliance, shaping its governance and fostering multi-sectorial collaboration. He brings a creative, solution-oriented perspective to policy development, working across diverse viewpoints to shape pragmatic approaches that strengthen regulatory frameworks. Before joining IFPMA, he worked in late-stage drug formulation and development and as a community pharmacist in Portugal. He holds a Diploma in Management of Clinical Trials from the University of Geneva and a MSc in Pharmaceutical Sciences from the University of Coimbra

Speaker

Magda Bujar, PhD, MSc

Associate Director, Regulatory Programme and Strategic Partnerships
Centre for Innovation in Regulatory Science (CIRS), United Kingdom

Dr Magda Bujar is Associate Director, Regulatory Programme and Strategic Partnerships and has over 12 years' experience working in Regulatory Policy and Science. She has co-authored a number of publications and has presented and chaired at major scientific meetings including those of the Drug Information Association (DIA) and International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Prior to joining CIRS, Magda carried out research spanning scientific, engineering and policy issues regarding the development of medicines. She received her Master of Science in Biochemical Engineering from University College London (UCL) and a Doctor of Philosophy from the University of Hertfordshire.

Navigating Regulatory Reliance: Practical Insights and Applications Beyond Initial Marketing Authorization Application

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.

Reliance's Strategic Projection in ANMAT

Andrea Ricchiutti, RPh

Head of the Regulatory Inspction Service
ANMAT Ministry of Health, Argentina

Ms. Andrea Ricchiuti is the at the Head of the Regulatory Inspction Service at the National Institute of Drugs (ANMAT, Argentina). She is a member of the technical Subcommittee of the Argentinean National Pharmacopeia for both active ingredients and final products. She also holds the position of Mercosur Inspector of medicines with a focus on GMP. Ms. Ricchiuti previously held the position of Chief of Service for Drugs Marketing Authorization within the Office of Risk Monitoring and Management. Prior to this role, she served as a Quality Control Analyst, Inspector and Evaluator in the registration and post-registration processes of medicines. Ms. Ricchiuti earned her Bachelor´s degree in Pharmacy from the University of Buenos Aires.

3:15 PM — 4:30 PM G. Leopardi

Session 2, Track B: The Future of Pharmacovigilance Professionals, Training, and Education in a Digitally Evolving World

This session will focus on the evolving role of pharmacovigilance (PV) professionals in the context of a rapidly digitizing world. As technologies such as artificial intelligence (AI), machine learning (ML), automation, and big data analytics transform the field of pharmacovigilance, there is an increasing need for PV professionals to adapt and acquire new skills. This session will explore the future of PV roles, training, and education, with an emphasis on local and regional initiatives to upskill professionals to thrive in a digital landscape.
Learning Objective :

- Recognize how the field of PV has been transformed over the years by technologies such as artificial intelligence (AI), machine learning (ML), automation, and big data analytics

- Understand the future of PV training and education, to upskill PV professionals to thrive in a rapidly digitizing world
- Identify opportunities for current and future PV roles, considering both local and regional digital landscape perspectives

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.

Betty Duarte, PharmD, MBA

Pharmacovigilance Director CAN & LATAM
Pfizer, Costa Rica

Pharmacist with 14+ years of experience in the pharmaceutical industry, specializing in Pharmacovigilance across Latin America and Canada. Currently Sr Director at Pfizer, leading regional safety operations and supporting global services. I hold a Master's and Business Analytics (Machine Learning & AI). Passionate about team leadership, regulatory compliance, and academic mentorship—having taught at Universidad de Iberoamérica and led collaborative projects with health authorities and international groups.

Speaker(s)

Evolution of Pharmacovigilance and Training Offered by the Uppsala Monitoring Centre

Salvador Alvarado Lopez, MD, MPH, MSc

Regional Pharmacovigilance Manager
Uppsala Monitoring Centre, Sweden

Dr Alvarado has worked since 2018 at the Uppsala Monitoring Centre (Uppsala, Sweden),which is the World Health Organization-Collaborating Centre responsible for supporting the Program for International Drug Monitoring(WHO-PIDM), his current position is Regional Pharmacovigilance Manager. Dr Alvarado graduated as a medical doctor from the National Autonomous University of Mexico, has a Master´s degree in Public Health with a major in Health Economics and Policy, from the Karolinska Institute(Stockholm, Sweden), and Master´s degree in Pharmacovigilance and Pharmacoepidemiology from the University of Alcalá (Madrid, Spain). Dr Alvarado provides Pharmacovigilance support to Ministries of Health and Regulatory Authorities around the world.

The Global PV Landscape

Ana Aymes, PharmD, RPh

Sr Director Safety Information Management

Pfizer, United States

Ana Aymes is a pharma executive with over 30 years of experience in Regulatory, Clinical Research and Development, Medical Writing and Pharmacovigilance. It is through her experiences that she has obtained the skill sets to see data as fields of information and thereby now is the Head of Safety Solutions, Information Management, responsible of the eco-system of tools for Pfizer Worldwide Safety. Since Covid, the need to use technology to accelerate Safety operations has quickly advanced. Ana has led many digital automations in pharmacovigilance with a focus on quality, accuracy and benefits for the patient. It is natural now to be on the edge of AI use in pharmacovigilance, changing the way pharmacovigilance is processed and assessed.

The Future of Pharmacovigilance Professionals, Training, and Education in a Digitally Evolving World

Andreia Freitas, PGDip

Local PV Network Manager
iVigee, Brazil

Experienced professional with 14 years of expertise in pharmacovigilance across Latin America, with a career spanning multinational pharmaceutical companies and service providers. Holds a postgraduate degree in Organizational Psychology and People Management, with a strong focus on leadership, team development, and empathetic communication. Skilled in ensuring compliance with both local and global procedures and legislation, overseeing pharmacovigilance and quality systems, and managing audits and inspections. Experienced in delivering training to local teams and across Latin America.

4:40 PM — 5:55 PM Gaudi

Session 3, Track A: From Principles to Impact: The Benefits of Implementing Good Regulatory Practices in Latin America

This session will explore the implementation and impact of Good Regulatory Practices (GRPs) in Latin America, highlighting institutional experiences from ANMAT and ANVISA. Through real-world examples and regional insights, speakers will examine how GRPs—such as transparency, stakeholder engagement, evidence-based decision-making, and regulatory impact assessments—are strengthening regulatory systems and advancing public health objectives. The session will also feature key findings from the Latin American Regulatory Practices Observatory, a study conducted by INNOS, offering data-driven insights into the progress and gaps in GRP adoption across the region. Finally, panelists will reflect on challenges and opportunities for embedding GRPs across the regulatory lifecycle and promoting convergence.
Learning Objective :

- Define key elements of Good Regulatory Practices (GRPs)
- Identify examples of GRP implementation in Latin American regulatory authorities
- Apply GRP principles to strengthen processes within their own regulatory frameworks
- Discuss methods for integrating impact assessments and public consultations in regulatory decision-making

Track: Regulatory/Clinical

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.

Diego Alexander Salas, LLM

Regulatory Affairs Director
Federación Latinoamericana de la Industria Farmacéutica, A.C., Mexico

Current Director of Regulatory Affairs at FIFARMA, the Latin American Federation of the R&D Pharmaceutical Industry. He is responsible for leading regulatory policy and regulatory intelligence for the Federation in the region. Specialist in Pharmaceutical Management and Pharmaceutical Market, holding a master's degree in Intellectual Property and International Trade, as well as a bachelor's degree in law. Member of the Steering Committee of the Pan American Network for Drug Regulatory Harmonization (PARF Network), part of the Organizing Committee for the DIA Latin America Annual Conference, and has over 14 years of experience in Regulatory Affairs, Pharmacovigilance, and Regulatory Policy both in Latin America and Globally.

Speaker(s)

From Principles to Impact: The Benefits of Implementing Good Regulatory Practices in Latin America

Estefania Mariel Gerez, MPA

Professional from the National Institute of Drugs
ANMAT Ministry of Health, Argentina

Estefania Gerez holds a Bacherlor´s Degree in Biochemistry and Pharmacy with a Master's Degree in Public Administration. She has worked in the public sector (INAME-ANMAT) for 12 years, and her experience in the international regulatory field includes participation and collaboration in regulatory projects and as ANMAT's representative before harmonization and convergence organizations such as PAHO/WHO, IPRRP, and ICH.

How Are We Regulating? Insights from the Latin American Regulatory Practices Observatory

Carlos Felipe Escobar Roa, MD

Director
Institute for Health Foresight and Innovation (INNOS), Colombia

Dr. Carlos Felipe Escobar Roa is the Director of HUB iEX, the Health Innovation and Entrepreneurship Hub at Universidad El Bosque, and leads INNOS, the Health Foresight and Innovation Institute, a joint initiative by AFIDRO and El Bosque. A medical doctor specialized in Otolaryngology and Head and Neck Surgery, with a Master's in

University Management and executive training at Harvard Business School. He has held leadership roles including President and Vice President at El Bosque and has consulted for national ministries and international universities on health and higher education innovation.

The Role of Good Regulatory Practices (GRPs) in Supporting Better Regulatory Outcomes: The ANVISA Experience

Thalita Antony de Souza Lima, MPA

Assessor of the Cabinet of the Director President
Brazilian Health Regulatory Agency (ANVISA), Brazil

Thalita Lima, Ms. Assessor of the Cabinet of the Director President at the Brazilian Bachelor's degree in Nutrition from the University of Brasilia (UnB), postgraduated degrees in Food Quality and in Regulation and Health Surveillance from the Oswaldo Cruz Foundation (Fiocruz), and Master in Public Administration by Getúlio Vargas Foundation (FGV). Ms Lima has been a government employee at ANVISA for 20 years. During this time, she hold leadership positions such as General Manager at Food Office for 6 years, and Chief Advisor for Better Regulation, for the last 3 years. Recently, in June 2025, she was appointed as assessor of the cabinet of the Director President at the Brazilian Health Regulatory Agency, position she currently hol

4:40 PM — 5:55 PM G. Leopardi

Session 3, Track B: Unlocking Deeper Safety Insights with Real-World Evidence in Pharmacovigilance

In this session, we will explore the pivotal role that real-world data (RWD) and real-world evidence (RWE) play in enhancing pharmacovigilance (PV) practices. Integrating RWD and RWE into pharmacovigilance activities offers innovative approaches to monitoring drug safety and effectiveness, providing comprehensive insights into drug performance in diverse patient populations and real-world settings.
Learning Objective :

- Describe the pivotal role of Real-World Data (RWD) and Real-World Evidence (RWE) in enhancing modern pharmacovigilance practices
- Identify innovative approaches for integrating RWD/RWE into pharmacovigilance activities to monitor drug safety and effectiveness
- Explain how the use of RWD/RWE generates comprehensive insights into drug performance within diverse patient populations and real-world settings

Track: Pharmacovigilance

Session Chair(s)

Raphael Elmadjian Pareschi, PharmD, MBA

Patient Safety Lead/ Head of Pharmacovigilance Brazil
Roche, Brazil

Raphael has more than 20 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.

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. 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.

Speaker(s)

Challenges in Generating Real-World Evidence (RWE)

Flávia Moreira Cruz, PharmD

Specialist at Pharmacovigilance Officer (GFARM)
ANVISA, Brazil

Flávia Moreira Cruz is a Pharmacist and Specialist in Health Surveillance and Regulation who has worked at ANVISA since 2005. Her experience spans marketing authorization, traceability/anti-counterfeiting, and package inserts and labeling. Since 2016, she has focused on pharmacovigilance, supporting the national ICSR management system and leading Brazil's implementation of VigiFlow (VigiMed) in partnership with the Uppsala Monitoring Centre (UMC), while advancing the use of PV databases and analytics. She represents ANVISA in international fora, including the ICH E2B(R3) and ICH E2D(R1) Working Groups, and the CIOMS Working Group XIV on Artificial Intelligence in Pharmacovigilance.

Real World Data Usage in Safety in Latin America – The Importance of Open Data

Guilherme Julian, MS

RWD Partnerships 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 RWD Partnerhips Senior Director .

Unlocking Deeper Safety Insights with Real-World Evidence in Pharmacovigilance

Ana Fajreldines

Head of the Quality and Patient Safety Department
Hospital Alemán, Argentina

Ana is the Head of Department: Quality, Patient Safety, and Accreditation for Hospital Alemán, Buenos Aires. She has a Phd in Biomedical Sciences, Austral University, an MBA from European Business School (EUDE), a Master's in Healthcare Management and Administration from Favaloro University and a Master's Degree in Clinical Pharmacy and Monitoring from University of the Peoples of Europe.

5:55 PM — 6:40 PM Gaudi Foyer

Networking Reception

Day 2 Sep 30, 2025

8:00 AM — 4:15 PM Gaudi Foyer

Registration

8:30 AM — 9:45 AM Gaudi

Session 4, Track A: Innovative Trial Designs: Accelerating Access Through Smarter Evidence

Innovative clinical trial designs are transforming the way we generate evidence by making studies more adaptive, efficient, and patient-centric. In Latin America, the adoption of methodologies such as platform trials, master protocols, adaptive designs, and decentralized clinical trials (DCTs) is gaining traction—offering opportunities to accelerate access to innovative therapies and strengthen regional research capabilities.

This session will feature a range of perspectives—including regulators, clinical operations experts, and academic leaders—who will present case studies and experiences implementing innovative designs in the region. Topics will include how flexible methodologies have been applied to real-world clinical research in oncology and rare diseases, the evolving regulatory landscape supporting these approaches, and lessons learned in managing operational complexity and ethical oversight.

Attendees will also explore how stakeholder collaboration, digital tools, and infrastructure development are critical enablers for the wider adoption of these models. The session will conclude with a dialogue on how Latin America can enhance its readiness and leadership in the global transition toward smarter, more resilient clinical research frameworks.

Learning Objective :

At the conclusion of this session, participants should be able to:

- Define core concepts of adaptive, platform, and decentralized clinical trial designs
- Apply practical examples of these designs to their own regulatory or operational contexts
- Assess key regulatory and infrastructure needs for implementing innovative methodologies in Latin America
- Promote stakeholder collaboration to scale up research innovation across the region

Track: Regulatory/Clinical

Session Chair(s)

Diego Alexander Salas, LLM

Regulatory Affairs Director
Federación Latinoamericana de la Industria Farmacéutica, A.C., Mexico

Current Director of Regulatory Affairs at FIFARMA, the Latin American Federation of the R&D Pharmaceutical Industry. He is responsible for leading regulatory policy and regulatory intelligence for the Federation in the region. Specialist in Pharmaceutical Management and Pharmaceutical Market, holding a master's degree in Intellectual Property and International Trade, as well as a bachelor's degree in law. Member of the Steering Committee of the Pan American Network for Drug Regulatory Harmonization (PARF Network), part of the Organizing Committee for the DIA Latin America Annual Conference, and has over 14 years of experience in Regulatory Affairs, Pharmacovigilance, and Regulatory Policy both in Latin America and Globally.

Marcela Garrot, RPh

Associate Director, Principal Clinical Site Lead LATAM
Merck Group, Argentina

Marcela is the Principal Clinical Site Lead for LATAM at Merck. As a pharmacist with 25 years of diverse experience in the biopharmaceutical industry and contract research organizations (CROs), she specializes in clinical trials and has a strong track record in both global and regional leadership roles. Currently, she oversees and engages in the delivery of operational activities for trials conducted in LATAM within Global Development Operations at Merck. Marcela is deeply passionate about advancing healthcare in the LATAM region, driven by her commitment to improving patient outcomes and ensuring access to innovative treatments.

Speaker(s)

Speaker

Laura Traversi, MD

Head of Clinical Trials Department
ANMAT Ministry of Health, Argentina

Current position: Head of Clinical Trials Department at Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT), Argentina. Joined ANMAT in 2012 to evaluate Clinical Pharmacology Trials of different pathologies. Since 2018, coordinates the Clinical Trials Department. Graduated as Medical Doctor from the University of Buenos Aires. Pediatrician with a Pediatric clinic residency held at Pedro de Elizalde Children's General Hospital in Buenos Aires. She has a Master in Clinical Pharmacological Research and a specialization in Clinical Pharmacology.

Speaker

Leonardo Semprun, PharmD

Global Regulatory Policy Lead-LatAm
MSD, Panama

Leonardo Semprún is the Global Science & Regulatory Policy Leader for Latam at MSD, where he leads the definition and execution of regulatory policy plans that address the current and future needs of the region. With over 20 years of experience in the industry, he has held key roles in regulation, quality assurance, intellectual property, and policy, collaborating with governments, regulators, academia, and multilateral organizations to influence regional policy-making. Additionally, he is co-chair of the Regulatory Affairs and Pharmacovigilance group at FIFARMA, where he drives important initiatives in the field of regulation and drug safety.

Speaker

Mariel Peitiado, PharmD

President
Cámara Argentina de Organizaciones de Investigación Clínica (CAOIC), Argentina

Mariel Peitiado is a pharmacist with 30+ years in the pharmaceutical industry, specializing in clinical trials. She began in regulatory affairs and quality control, later joining Quintiles in 2001 to lead Quality Assurance for Latin America. In 2011, she became Director of Clinical Operations for Argentina, and in 2020, Regional Head of Clinical FSP and GSM at IQVIA. Since 2023, she has served as President of CAOIC, Argentina's CRO Association.

8:30 AM — 9:45 AM G. Leopardi

Session 4, Track B: Risk Management and Communication with Patient Perspective

This session focuses on the importance of incorporating the patient perspective into risk management and communication strategies in pharmacovigilance (PV). By emphasizing patient-centric approaches and facilitating effective communication between the pharmaceutical industry, governments, and patients, we can improve drug safety and efficacy and ensure that patient needs and concerns are addressed in a comprehensive risk management framework.
Learning Objective :

- Implement transparent messaging, tailored communication methods and diverse channels to communicate to patients
- Evaluate the role of digital tools in risk communication and how to leverage them to engage with patients
- Recognize examples of successful risk management and communication initiatives incorporating the patient perspective
- Identify mechanisms to incorporate patient feedback into risk management processes to improve safety outcomes

Track: Pharmacovigilance

Session Chair(s)

Gislaine Villarta Capeleti Dib, PharmD

Operational Manager
PGA Farma, Brazil

Gislaine Capeleti is a licensed pharmacist and seasoned Operations Manager with over two decades of experience in the pharmaceutical industry, specializing in Patient Safety. Currently serving as Operational Manager at PGA Farma, she leads initiatives that support clinical trial and post-marketing safety activities for a diverse portfolio of pharmaceutical companies . Her mission is to help organizations optimize internal processes with high performance and quality, in alignment with regulatory requirements from local and global health authorities. Throughout her career, Gislaine has built a strong reputation for excellence in pharmacovigilance and has expanded her expertise to include medical devices, cosmetovigilance, and nutrivigilance.

Lina Valero, MD, MBA, MSc

Regional PV Head LATAM
Opella Healthcare, Colombia

Dr. Lina Valero is a multinational leader with over 9 years of experience in the pharma industry. A medical doctor with a focus on Public Health, Master's in Epidemiology and Business Management. Passionate about Pharmacovigilance, Clinical Research, Medical Engagement, and People Development, Dr. Valero currently serves as PV Head for the LATAM region at Opella Healthcare, formerly part of Sanofi. Her expertise spans clinical trials and post-marketing surveillance across biologicals, general medicines, vaccines, and beyond. As an international speaker in Europe, North America, and LATAM, Dr. Valero is recognized for her strategic, patient-centered approach and her commitment to advancing global collaboration in healthcare.

Speaker(s)

Evolving RMPs: Digitalization, Effectiveness and Challenges, with a Focus on Patients

Julieta Pilar Boned

Patient Safety- Local Risk Management Plan Manager
Novartis Argentina, Argentina

Julieta Boned is the Patient Safety RMP Manager at Novartis Argentina, where she leads the local implementation and oversight of Risk Management Plans (RMPs). In this role, she ensures alignment with global commitments and regulatory expectations while collaborating with cross-functional teams such as Regulatory Affairs and Global Product Teams. With over a decade of experience in the healthcare and pharmaceutical sectors, including clinical trials and local vigilance, Julieta brings a solid foundation and is committed to contributing to patient safety and continuous improvement through collaborative and pragmatic approaches.

Pharma Companies' Partnership and the Prioritization of Patient Safety

Ana Paula Lima Denger, PharmD, MBA

Pharmacovigilance Manager
AbbVie, Brazil

Ana Paula is a pharmacist and a specialist in people management, with over 13 years of experience in Pharmacovigilance at Eli Lilly and AbbVie Brazil. Throughout her career, she has held positions of increasing responsibility and currently serves as Pharmacovigilance Manager and National Qualified Person for Pharmacovigilance at AbbVie Brazil.

Risk Management and Communication with Patient Perspective

Roberta Eleonora Anido

Patient Advocate
FADEPOF, Argentina

Founder and President of the Association to Help Patients with Primary Immunodeficiency since 2005 due to her eldest daughter's primary immunodeficiency diagnosis. Roberta is also a board member of the International Patient Organisation for Primary Immunodeficiencies since 2007, responsible for the LATAM national members organisations. She is founder and currently Secretary of the Argentine Federation of Rare Diseases since 2024, Vice-chair from 2018 to 2020 and Chair from 2020 to 2024. She is a member of the Ibero-American Alliance for Rare Diseases & Rare Disease International. In 2014 she received an Honorary Diploma in “Recognition of her committed action in the defense of human rights” by the Honorable Senate of the Argentine Nation.

9:45 AM — 10:30 AM Gaudi Foyer

Refreshments, Exhibits, and Networking Break

10:30 AM — 11:45 AM Gaudi

Session 5, Track A: Orphan and Rare Disease Management: Are Patients In LatAm Getting the Advanced Therapies They Need?

As the identification of rare diseases become more sophisticated, so too do their therapies. The growing focus on advanced medicinal therapeutic products (ATMPs), biologics and specialized gene therapies for orphan diseases poses not only challenges during development but also for their regulatory assessments. This session will investigate challenges such as the use of early clinical data and decisions from other NRAs based on phase 2 or small, yet fit-for-purpose datasets. Is import testing of ATMPs being optimized or are products which are developed in precious small quantities being needlessly wasted? What do patients expect from developers and regulators to meet their unique needs?
Learning Objective :
At the conclusion of this session, participants should be able to:

- Define the scope of rare diseases in LatAm
- Characterize the similarities and diversities among regulatory approaches to assess rare disease therapeutics
- Identify opportunities to optimize regulatory approaches to the efficient review of rare disease therapeutics
- Understand the needs of patients affected by these rare diseases

Track: Regulatory/Clinical

Session Chair(s)

Carolina Sian, PharmD, RAC

Regulatory Affairs Director
CAEME, Argentina

Carolina is Regulatory Affairs Director at CAEME (Argentine Chamber of Innovative Medicines) with over 20 years of experience in the pharmaceutical and biopharmaceutical industry, locally and internationally. She is Academic Director of the International Diploma in Regulatory Affairs, member of the Regulatory Affairs Expert Committee of SAFYBI and active in FIFARMA's Regulatory and PV Working Group. She also serves on the Board of AsAF, is a founding member of Pharmacovigilance en español, and represents the Argentine pharmaceutical industry at ICH through IFPMA. Carolina holds degrees in Pharmacy and Biochemistry with a focus in Biotechnology from UBA, as well as national and international postgraduate qualifications in Regulatory Affairs.

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.

Speaker(s)

Orphan and Rare Disease Management: Are Patients In Latam Getting the Advanced Therapies They Need?

Roberta Eleonora Anido

Patient Advocate
FADEPOF, Argentina

Founder and President of the Association to Help Patients with Primary Immunodeficiency since 2005 due to her eldest daughter's primary immunodeficiency diagnosis. Roberta is also a board member of the International Patient Organisation for Primary Immunodeficiencies since 2007, responsible for the LATAM national members organisations. She is founder and currently Secretary of the Argentine Federation of Rare Diseases since 2024, Vice-chair from 2018 to 2020 and Chair from 2020 to 2024. She is a member of the Ibero-American Alliance for Rare Diseases & Rare Disease International. In 2014 she received an Honorary Diploma in “Recognition of her committed action in the defense of human rights” by the Honorable Senate of the Argentine Nation.

Orphan and Rare Disease Management: Are Patients in LatAm Getting the Therapies They Need?

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.

Regulation of Advanced Therapies in Argentina: Status, Experience, and Challenges of ANMAT

Gabriela Beatriz Bravo

Biologics Regulatory Reviewer
ANMAT Ministry of Health, Argentina

Gabriela Beatriz Bravo is a Biologics Regulatory Reviewer at the Directorate for the Evaluation and Control of Biological and Radiopharmaceutical Products, National Institute of Medicines (INAME), ANMAT, Argentina. She is a member of ANMAT's Advanced Therapies (ATMP) evaluation group and participates in the ICH Cell and Gene Therapy Discussion Group (CGT-DG), as well as biosimilar working groups. Her expertise covers both pre- and post-authorization quality assessment. She has been working at ANMAT since 2014 and is currently pursuing a master's degree in Pharmacopolitics

10:30 AM — 11:45 AM G. Leopardi

Session 5, Track B: Challenges, Opportunities, and Best Practices in Pharmacovigilance in the LATAM (Part I)

This session will offer participants insights into the key challenges affecting Pharmacovigilance practices in the LATAM region, informed by recent global updates. We will explore opportunities for enhancement based on global regulatory changes and review the best practices from successful global PV initiatives applicable to LATAM. Participants will engage with global experts and industry representatives to foster collaboration and drive improvements in Pharmacovigilance across the region.
Learning Objective :

- Identify key challenges in LATAM Pharmacovigilance activities based on recent global initiatives
- Explore opportunities for enhancing PV practices in LATAM, informed by global regulatory landscape changes
- Discuss best practices from global PV initiatives applicable to the LATAM context

Track: Pharmacovigilance

Session Chair(s)

Gislaine Villarta Capeleti Dib, PharmD

Operational Manager
PGA Farma, Brazil

Gislaine Capeleti is a licensed pharmacist and seasoned Operations Manager with over two decades of experience in the pharmaceutical industry, specializing in Patient Safety. Currently serving as Operational Manager at PGA Farma, she leads initiatives that support clinical trial and post-marketing safety activities for a diverse portfolio of pharmaceutical companies . Her mission is to help

organizations optimize internal processes with high performance and quality, in alignment with regulatory requirements from local and global health authorities. Throughout her career, Gislaine has built a strong reputation for excellence in pharmacovigilance and has expanded her expertise to include medical devices, cosmetovigilance, and nutrivigilance.

Maria Victoria Abdala, MHS, RPh, RAC

Director, Pharmacovigilance (PV) Cluster Lead - LA South
MSD, Argentina

Director, Pharmacovigilance Lead for the LATAM South Cluster at MSD. Pharmacist and biochemist from the University of Buenos Aires, Argentina, with over 12 years of experience in Pharmacovigilance. Background includes leading patient safety for South America at Boehringer Ingelheim and earlier roles in PV and Regulatory Affairs at Sanofi Genzyme. Holds a specialization in Drug Regulatory Affairs. Contributing author of the “Manual de Buenas Prácticas de Farmacovigilancia, Ed. Latinoamérica (2018)” and board member of the Argentine Society of Pharmacovigilance since 2019. Committed to improving patient well-being and driving a positive impact on public health.

Speaker(s)

CIOMS XII: Structured Benefit Risk Framework: A Strategic Lifecycle Approach

Carmit Strauss, PharmD

Executive Director, Head of Risk Management, Organ Toxicity and Benefit Risk
Takeda, United States

Carmit Strauss PharmD, is an Executive Director at Takeda overseeing the Risk Management, Organ Toxicity and Benefit Risk centers of excellence. She has an extensive experience in risk management working in various leadership roles within Safety, Pharmacovigilance and Medical Affairs. Carmit participants in BR and RM workshops and panels and is a member of CIOMS XII BR on Benefit-Risk Balance for Medicinal Products. Carmit has authored multiple scientific and benefit risk abstracts and publications as well as presented at different benefit risk related conferences on various topics. Carmit obtained her PharmD at the University of Southern California (USC) and holds a Bachelor of Science degree from University of California Los Angeles.

Modernizing ICSR Management: A Model for Meaningful Multi-Stakeholder Dialogue

Patrice Wright, PhD, PMP

Health Authority Engagement Director
TransCelerate BioPharma Inc., United States

Patrice is responsible for shaping and delivering on TransCelerate’ s Health Authority Engagement strategy enabling the overall mission of TransCelerate: to advance collaboration in driving efficient, effective, and high-quality delivery of new medicines through the convergence of clinical care and clinical research. Before joining TransCelerate, Patrice spent 13 years at Johnson and Johnson holding roles in Regulatory including Operations, Policy, and Affairs for both consumer and pharmaceutical products. Prior to J&J, Patrice held various scientific positions at the Nonprescription Drug Manufacturers Association in the US. Patrice has a PhD in pharmacology.

Pharmacovigilance in Latin America - Updates, Advances, and Challenges

Salvador Alvarado Lopez, MD, MPH, MSc

Regional Pharmacovigilance Manager
Uppsala Monitoring Centre, Sweden

Dr Alvarado has worked since 2018 at the Uppsala Monitoring Centre (Uppsala, Sweden),which is the World Health Organization-Collaborating Centre responsible for supporting the Program for International Drug Monitoring(WHO-PIDM), his current position is Regional Pharmacovigilance Manager. Dr Alvarado graduated as a medical doctor from the National Autonomous University of Mexico, has a Master´s degree in Public Health with a major in Health Economics and Policy, from the Karolinska Institute(Stockholm, Sweden), and Master´s degree in Pharmacovigilance and Pharmacoepidemiology from the University of Alcalá (Madrid, Spain). Dr Alvarado provides Pharmacovigilance support to Ministries of Health and Regulatory Authorities around the world.

11:45 AM — 1:00 PM Gaudi Foyer

Luncheon, Exhibits, and Networking Break

1:00 PM — 2:15 PM Gaudi

Session 6, Track A: Clinical Trials Operations and Management – Designing Quality into Innovative Clinical Trials

Clinical trials are evolving to better meet participant expectations by enhancing data collection methods, incorporating decentralized and pragmatic elements. The ICH E6(R3) Good Clinical Practice guidelines have adapted to reflect these advancements, highlighting the importance of quality by design (QbD), integrating quality management guidance, and actively promoting engaging key stakeholders to implement quality by design in protocol development.

Early identification of Critical to Quality (CtQ) factors during protocol design, along with understanding the associated risks and their mitigations, plays a vital role in shaping the protocol and the operational and quality plans that direct trial conduct. This proportionate, risk-based approach ultimately leads to clinical trials that are fit for purpose—ensuring that all important trial components effectively address the research question, support the generation of reliable results, and prioritize participant safety. This presentation will delve into how publicly available tools can aid companies in navigating the implementation of ICH E6(R3), providing examples that illustrate these concepts.

Learning Objective : At the conclusion of this session, participants should be able to:

- Recognize changes in regulations to address the evolution in clinical trial design
- Identify innovative clinical trial design and the challenges in their implementation
- Define the quality by design concept and the quality risk management process

Track: Regulatory/Clinical

Session Chair(s)

Monica Lizano, MD, MBA

Global Director, Clinical Quality Management
Merck Chile, Chile

Monica is the Global Director of Clinical Quality Management at Merck Chile. A physician with an MBA, Monica brings over 30 years of experience in clinical research. Her career began at the site level, where she managed operations for a Site Management Organization. She later founded her own Contract Research Organization (CRO), expanding its reach to five different countries in Central and South America before selling to Quintiles/IQVIA. While with IQVIA, she developed a partner site network and oversaw site identification operations. In her current role at Merck, Monica is responsible for overseeing early-phase oncology trials, in addition, she is the Business Process Owner for Quality Risk Management within Global Development Operations.

Speaker(s)

Clinical Trial Operations and Management: Quality Design for Innovative Clinical Trials

Cristina Elena Papayannis, DrMed

Medical Doctor
ANMAT Ministry of Health, Argentina

PhD in Medicine (University of Buenos Aires), specialist in Neurology and Clinical Pharmacology. Since 2011, she has worked as a medical evaluator at the Clinical Trials Department of ANMAT. Her main role involves reviewing clinical research protocols in phases I, II, and III, ensuring compliance with national and international Clinical Pharmacology regulations. Her responsibilities include the technical evaluation of study protocols and related documentation, the analysis of efficacy, safety, and quality data. She actively contributes to the ongoing revision of ethical and methodological procedures, as well as continuous training activities. Her work is carried out in coordination with other areas of the agency, such as the Safety and Ef

Patient Perspective

Florencia Braga Menendez

Directora de Proyectos
ALAPA Alianza Argentina de Pacientes, Argentina

Former intern at the Carolina Foundation of Spain and the U.S. Department of State (IVLP). Curator, specialist in international cultural management, and General Director of Museums of the Ministry of Culture of the City of Buenos Aires until 2012. After receiving the diagnosis of her son with Stargardt (a degenerative retinal disease with no treatment), her professional focus shifted to promoting precision medicine and applied science in health in Latin America and the Caribbean, a leadership activity for which she is internationally recognized. Currently, she is: Director of Projects at ALAPA, the Argentine Alliance of Patients and Founding member of ULAPA, the Latin American Union of Patients with Rare Diseases.

1:00 PM — 2:15 PM G. Leopardi

Session 6, Track B: Challenges, Opportunities, and Best Practices in Pharmacovigilance in the LATAM (Part II)

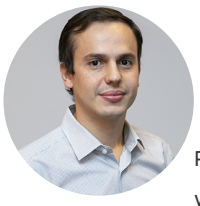
Continuing as Part II, this session focuses on strengthening pharmacovigilance in LATAM through Regional and local perspectives. Examine current challenges arising from diverse regulations, identify practical opportunities for regional collaboration (regulators, HCPs, industry), and learn from best practices showcased from successful LATAM initiatives to enhance local PV effectiveness.

Learning Objective :

- Identify key challenges due to diverse regulations and local operations
- Describe collaboration opportunities among stakeholders (regulatory bodies, HCPs, industry) within LATAM to strengthen PV systems
- Recognize successful best practices and strategies implemented within Latin America that have demonstrably enhanced local or regional pharmacovigilance effectiveness

Track: Pharmacovigilance

Session Chair(s)



Raphael Elmadjian Pareschi, PharmD, MBA

Patient Safety Lead/ Head of Pharmacovigilance Brazil
Roche, Brazil

Raphael has more than 20 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.

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. 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.

Speaker(s)

Challenges, Opportunities, and Best Practices in Pharmacovigilance in LATAM

Diana Gonzalez, MD, MBA

Colombia PSL & PV Policy Lead Latam
Roche, Colombia

Diana is a physician with an emphasis on public health, a Master's in Healthcare Business Administration, and a current Medical Law student. She is the Patient Safety Lead for Colombia and PV Policy Lead for Latin America at Roche, where she drives pharmacovigilance, patient safety, and risk management strategies. With over 13 years of experience in the pharmaceutical industry, she has expertise in medical affairs and pharmacovigilance systems. As the leader of FIFARMA's pharmacovigilance working group and a #SafetyTogether ambassador, Diana promotes PV as a key driver of regulatory harmonization across the region and as a trusted bridge between patients and the PV ecosystem.

Challenges, Opportunities, and Best Practices in Pharmacovigilance in Latin America

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.

Challenges, Opportunities, and Best Practices in Pharmacovigilance in Latin America

Fernanda Simioni Gasparotto, MPharm

Specialist Health Surveillance - Pharmacovigilance
ANVISA, Brazil

She is pharmaceutical-biochemical graduate from the Faculty of Pharmaceutical Sciences of Araraquara. She has a specialization in Sanitary Surveillance from the School of Public Health at USP and in Sanitary Surveillance in Public Health from FIOCRUZ. In 2005, she completed a Master's in Pharmaceutical Sciences in the area of technological development and quality control of pharmaceutical products by the Federal University of Rio Grande do Sul. She is part of the professional staff of the National Health Surveillance Agency (ANVISA) since March 2000 in the field of medicines, where she worked for two and a half years as a Generic Medicines Manager. Currently works in the Pharmacovigilance area of ANVISA since 2008.

2:15 PM — 3:00 PM Gaudi Foyer

Refreshments, Exhibits, and Networking Break

3:00 PM — 4:15 PM Gaudi

Session 7, Track A: Connecting PACs, Sustainability, and Cloud Solutions for Effective Life Cycle Management

This session will highlight the recent accomplishments of the ICMRA PQKM Collaborative Pilots, illustrating how the collaborative assessment process pilot has the potential to evolve into a global regulatory programme. Regulatory authorities will share experiences as full participants or observers on the collaborative pilots.

Additionally, the session will highlight the significance of sustainability in Pharmaceutical Lifecycle Management by examining the evolution of electronic product information practices.

Learning Objective : At the conclusion of this session, participants should be able to:

- Analyze ICMRA PQKM Pilot results and their impact on global collaborative assessment processes
- Apply insights gained from regulatory authorities to enhance future collaborative initiatives
- Recognize sustainability in Pharma Lifecycle Management and the shift to electronic product information and its industry impact

Track: Regulatory/Clinical

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.

Flavia Firmino Ribeiro, PharmD

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.

Speaker(s)

Connecting PACs, Sustainability, and Cloud Solutions for Effective Life Cycle Management

Brenda Gomes Valente, MPharm

Regulation Specialist
Brazilian Health Regulatory Agency (ANVISA), Brazil

Mrs. Brenda Gomes Valente holds a degree in Pharmacy and a Master's degree in Microbiology. She has been working at the Brazilian Health Regulatory Agency (ANVISA) since 2005, in the Department of Biological Products Assessment (GPBIO), as a Specialist in Regulation and Health Surveillance. In this role, she has served as a reviewer for marketing authorization applications and post-approval changes of biological products. She has also contributed to the development and revision of regulations and guidelines concerning biological products in Brazil.

ePI in Focus: Rethinking the Life Cycle Management of Labeling

María Lineth Perez Rodriguez, PharmD, MSc

Labeling Team Lead
Pfizer, Costa Rica

Maria Lineth Perez is a pharmaceutical professional with over 12 years of experience in labeling and pharmacovigilance. She currently serves as International Labeling Team Lead for LATAM at Pfizer, where she drives regulatory compliance, operational excellence, and cross-functional collaboration. She holds a master's in digital health management, and a specialization in business analytics. With more than four years dedicated to ePI implementation across LATAM, she brings critical expertise in advancing digital labeling solutions that support regulatory agility and patient access to medicinal product information. She has also contributed as a speaker at regional conferences and educational sessions with Health Authorities focused on ePI.

ICMRA Collaborative Assessment Pilot – Roche's Experience

Erika Hannibal, RPh

Senior Regulatory Group Director, PTR, International Regulatory
Roche International Ltd, Uruguay

A Registered Pharmacist with deep expertise in global CMC requirements, Erika has a proven track record of developing registration strategies that successfully secure renewal approvals and implementation of post-approval changes for a diverse range of molecules worldwide. Now as a Senior Regulatory Group Director at Roche, Erika leads a team of professionals building and overseeing the end-to-end CMC regulatory strategy for products across more than 120 international markets. Based in Montevideo, Uruguay, she specializes in navigating the complex and often unpredictable regulatory landscapes of Asia, Africa, Eastern Europe, the Middle East, and Latin America.

Connecting PACs, Sustainability, and Cloud Solutions for Effective Life Cycle Management: Swissmedic Perspective

Gabriela Zenhaeusern, PhD

Head Stakeholder Engagement
Swissmedic, Switzerland

Gabriela Zenhäusern, a pharmacist with a PhD in biomedical research, joined the Stakeholder Engagement Division at Swissmedic, Switzerland in 2019. In her current position, she is leading a team responsible for the coordination of national and international collaboration including development cooperation, acts as Vice-Chair of the Assembly of the International Council of Harmonisation (ICH) and represents Swissmedic at the International Pharmaceutical

Regulators Programme (IPRP) Management Committee and the Access Consortium. In addition, she is leading the patient organisation working party at Swissmedic. Gabriela Zenhäusern used to work in the sector authorization at Swissmedic from 2010 to 2015 before joining WHO from 2015 to 2019.

3:00 PM — 4:15 PM G. Leopardi

Session 7, Track B: Good Pharmacovigilance Practices - Inspections and Compliance within Pharmacovigilance in Latin America

This session will focus on the critical aspects of Good Pharmacovigilance Practice (GVP) inspections and compliance, with an emphasis on real-world case examples featuring regulatory experts. Understanding the requirements and best practices for GVP compliance is essential for Pharmacovigilance (PV) professionals to ensure the safety and efficacy of pharmaceuticals while maintaining regulatory adherence and compliance.
Learning Objective :

- Describe the landscape of pharmacovigilance inspections in LATAM from the perspectives of regulatory authorities
- Interpret the regulatory framework for pharmacovigilance inspections in LATAM by reviewing key regulations and guidelines governing inspections
- Identify opportunities best practices from regulatory authorities to enhance practices and processes

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.

Maria Victoria Abdala, MHS, RPh, RAC

Director, Pharmacovigilance (PV) Cluster Lead - LA South
MSD, Argentina

Director, Pharmacovigilance Lead for the LATAM South Cluster at MSD. Pharmacist and biochemist from the University of Buenos Aires, Argentina, with over 12 years of experience in Pharmacovigilance. Background includes leading patient safety for South America at Boehringer Ingelheim and earlier roles in PV and Regulatory Affairs at Sanofi Genzyme. Holds a specialization in Drug Regulatory Affairs. Contributing author of the “Manual de Buenas Prácticas de Farmacovigilancia, Ed. Latinoamérica (2018)” and

board member of the Argentine Society of Pharmacovigilance since 2019. Committed to improving patient well-being and driving a positive impact on public health.

Speaker(s)

Pharmacovigilance Good Practices - Pharmacovigilance Inspections and Compliance in Latin America

Fernanda Simioni Gasparotto, MPharm

Specialist Health Surveillance - Pharmacovigilance
ANVISA, Brazil

She is pharmaceutical-biochemical graduate from the Faculty of Pharmaceutical Sciences of Araraquara. She has a specialization in Sanitary Surveillance from the School of Public Health at USP and in Sanitary Surveillance in Public Health from FIOCRUZ. In 2005, she completed a Master's in Pharmaceutical Sciences in the area of technological development and quality control of pharmaceutical products by the Federal University of Rio Grande do Sul. She is part of the professional staff of the National Health Surveillance Agency (ANVISA) since March 2000 in the field of medicines, where she worked for two and a half years as a Generic Medicines Manager. Currently works in the Pharmacovigilance area of ANVISA since 2008.

Speaker

Edgar Dominguez

Head of the Pharmacovigilance Department of the National Directorate of Pharmacy
Ministry of Health of the Republic of Panama, Panama

Edgar holds a Master's in Pharmacoepidemiology and Pharmacovigilance (PV), specializes in Pharmacotherapy and Clinical Drug Management and Higher Education. He has over 18 years of experience in drug regulation, PV and the promotion of rational drug use. He has contributed to strengthening regulatory and health surveillance processes in the country, with special emphasis on the safety, efficacy and quality of medicines and other human health products. He is Head of the Pharmacovigilance and Other Human Health Products Department at the National Directorate of Pharmacy and Drugs, leading programs and strategies aimed at monitoring drug safety and strengthening the national pharmacovigilance system for the benefit of public health in Panama.

Good Pharmacovigilance Practices - Inspections and Compliance within Pharmacovigilance in Latin America

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.

Day 3 Oct 01, 2025

8:00 AM — 12:00 PM Gaudi Foyer

Registration

8:30 AM — 9:45 AM Gaudi

Session 8, Track A: Advancing Global Health through Regulatory Convergence and International Collaboration

This session will explore the importance and benefits of participating in international harmonization and convergence initiatives, such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), the International Medical Device Regulators Forum (IMDRF) and the Pharmaceutical Inspection Co-operation Scheme (PIC/S). Attendees will hear firsthand from LATAM regulators about their experiences and impacts on their regulatory processes when participating in these initiatives and gain invaluable insights into how the regulators and industry can work for building capacity towards regulatory harmonization.
Learning Objective :

- Understand the key benefits of ICH membership and engagement in this important platform for both regulators and industry
- Hear firsthand from LATAM regulators on their experiences in participating in international harmonization and convergence initiatives and the impact on their regulatory processes
- Recognize the importance of accelerating international convergence through IMDRF for medical devices and PIC/S for Regulatory Inspections

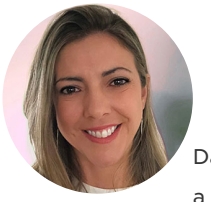
Track: Regulatory/Clinical

Session Chair(s)

Carolina Sian, PharmD, RAC

Regulatory Affairs Director
CAEME, Argentina

Carolina is Regulatory Affairs Director at CAEME (Argentine Chamber of Innovative Medicines) with over 20 years of experience in the pharmaceutical and biopharmaceutical industry, locally and internationally. She is Academic Director of the International Diploma in Regulatory Affairs, member of the Regulatory Affairs Expert Committee of SAFYBI and active in FIFARMA's Regulatory and PV Working Group. She also serves on the Board of AsAF, is a founding member of Pharmacovigilance en español, and represents the Argentine pharmaceutical industry at ICH through IFPMA. Carolina holds degrees in Pharmacy and Biochemistry with a focus in Biotechnology from UBA, as well as national and international postgraduate qualifications in Regulatory Affairs.



Daniela Bravo, DrSc, MBA, MSc

Regulatory Policy and Intelligence Latam Associate Director
AbbVie, Brazil

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

Speaker(s)

Advancing Global Health through Regulatory Convergence and International Collaboration

Geraldine Lissalde-Bonnet

Secretary General
International Council for Harmonisation (ICH), Switzerland

Géraldine Lissalde-Bonnet is the Secretary General of the ICH Secretariat based in Geneva, Switzerland. As Secretary General, Géraldine is responsible for setting and executing the strategic direction and priorities of the ICH Secretariat, for driving internal and external partnerships across the world, ensuring the ICH Secretariat's agility in responding to the evolving needs of the organisation. Géraldine brings over 20 years' experience in global health, public affairs and international healthcare supply chain management. Before joining ICH, Géraldine was Vice-President for Healthcare at GS1 Global Office. A lawyer by training, Géraldine started her career in the private sector, complemented by several years in the European Commission

Regulatory Convergence: ANMAT's Experience in International Forums

Yesica Anastasio

Licenciada en Relaciones Públicas
ANMAT Ministry of Health, Argentina

Yesica Anastasio is the Coordinator of the International Relations Program at the National Administration of Drugs, Food and Medical Devices (ANMAT). Over the last thirteen years, she has collaborated with institutional development policies and, since 2018, she has been involved in the International Relations field. She is a public relations specialist and holds a Master´s Degree in Organizational Communication Management. Her expertise in the international regulatory arena includes involvement and coordination on behalf of ANMAT in harmonization and convergence mechanisms such as MERCOSUR, Red EAMI, PAHO/WHO, ICH, PIC/S, ICMRA, and IMDRF. Also, she is actively involved in bilateral cooperation with regulatory agencies around the world.

Boosting Global Health through Regulatory Convergence and International Collaboration

William Oswaldo Cortez Mendoza

Head of International Affairs, General Directorate of Medicines, Supplies, and D
DIGEMID, Peru

William Cortez is Pharmacist specialist in Clinical Pharmacy. Graduated from the master's degree in Biotechnology and specialist in Health Regulation who has worked at DIGEMID since 2013. Brings over 10 years of experience in regulation of preclinical and clinical research of medicines. Since 2023, he is head of international affairs of the General Directorate of Medicines, Supplies and Drugs of Peru, and his experience in the international regulatory field

includes participation and collaboration in regulatory projects of DIGEMID related to harmonization and regulatory convergence.

8:30 AM — 9:45 AM G. Leopardi

Session 8, Track B: Next-Gen Pharmacovigilance: AI, NLP and Beyond

Learn how the AI and NLP are revolutionizing pharmacovigilance, enhancing drug safety monitoring, streamline case processing and enable predictive analytics or more accurate adverse event detection and signal management. Gain insights into the future of PV as we push beyond the traditional methods not next generation safety surveillance.
Learning Objective :

- Describe how AI and NLP enhance adverse event detection, signal management, and risk assessment in pharmacovigilance
- Assess the potential of advanced technologies (machine learning, real world data analytics and automations) in transforming traditional pharmacovigilance processes
- Identify practical use cases where Ai and NLP can streamline case processing, improve data accuracy, enable predictive safety analytics in PV operations

Track: Pharmacovigilance

Session Chair(s)

Betty Duarte, PharmD, MBA

Pharmacovigilance Director CAN & LATAM
Pfizer, Costa Rica

Pharmacist with 14+ years of experience in the pharmaceutical industry, specializing in Pharmacovigilance across Latin America and Canada. Currently Sr Director at Pfizer, leading regional safety operations and supporting global services. I hold a Master's and Business Analytics (Machine Learning & AI). Passionate about team leadership, regulatory compliance, and academic mentorship—having taught at Universidad de Iberoamérica and led collaborative projects with health authorities and international groups.

Lina Valero, MD, MBA, MSc

Regional PV Head LATAM
Opella Healthcare, Colombia

Dr. Lina Valero is a multinational leader with over 9 years of experience in the pharma industry. A medical doctor with a focus on Public Health, Master's in Epidemiology and Business Management. Passionate about Pharmacovigilance, Clinical Research, Medical Engagement, and People Development, Dr. Valero currently serves as PV Head for the LATAM region at Opella Healthcare, formerly part of Sanofi. Her expertise spans clinical trials and post-marketing surveillance across biologicals, general medicines, vaccines, and beyond. As an international speaker in Europe, North America, and LATAM, Dr. Valero is recognized for her strategic, patient-centered approach and her commitment to advancing global collaboration in healthcare.

Speaker(s)

Innovation In Pharmacovigilance: Strategies for Personalized Safety

Felix Arellano, MD, PhD, FISPE

Global Head Safety Risk Management
Hoffmann-La Roche Limited, Switzerland

A graduate in medicine from Universidad Autonóma de Madrid, Spain, postgraduate studies in pharmacoepidemiology at Macgill University, Montreal, Canada and in pharmaceutical medicine (combined Strasbourg, Basel and Freiburg universities) Dr Arellano has more than 20 years of experience in the safety and pharmacovigilance (PV) field in the pharmaceutical industry. A senior executive having worked in global roles for top 10 pharma in PV of medicines, consumer products, devices and vaccines Dr Arellano is Global Head of Safety Risk Management at F Hoffmann La Roche, Switzerland. With a career spanning all elements of PV Dr Arellano is committed to excellence in medical compliance and innovation in safety science to create value for society.

Artificial Intelligence for Pharmacovigilance

Flávia Moreira Cruz, PharmD

Specialist at Pharmacovigilance Officer (GFARM)
ANVISA, Brazil

Flávia Moreira Cruz is a Pharmacist and Specialist in Health Surveillance and Regulation who has worked at ANVISA since 2005. Her experience spans marketing authorization, traceability/anti-counterfeiting, and package inserts and labeling. Since 2016, she has focused on pharmacovigilance, supporting the national ICSR management system and leading Brazil's implementation of VigiFlow (VigiMed) in partnership with the Uppsala Monitoring Centre (UMC), while advancing the use of PV databases and analytics. She represents ANVISA in international fora, including the ICH E2B(R3) and ICH E2D(R1) Working Groups, and the CIOMS Working Group XIV on Artificial Intelligence in Pharmacovigilance.

9:45 AM — 10:30 AM Gaudi Foyer

Refreshments, Exhibits, and Networking Break

10:30 AM — 11:45 AM Gaudi

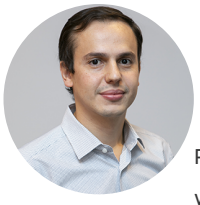
Session 9 Plenary: How Advancements in AI are Revolutionizing the Pharmaceutical World

This session will present how advancements in AI are revolutionizing the regulatory submissions to streamline processes, reduce costs and time, and the crucial role of the electronic Common Technical Document (eCTD) in facilitating these advancements, ensuring that regulatory submissions are standardized and efficient. The session will also explore perspectives on AI applied for pharmacovigilance processes and the current landscape of AI regulations.
Learning Objective : At the conclusion of this session, participants should be able to:

- Discuss recent advancements in AI for regulatory submissions
- Recognize the challenges and opportunities for eCTD implementation in Latin America and identify existing opportunities
- Explore the current landscape of AI regulations and identify the latest trends in AI for pharmacovigilance processes

Track: General Session

Session Chair(s)



Raphael Elmadjian Pareschi, PharmD, MBA

Patient Safety Lead/ Head of Pharmacovigilance Brazil
Roche, Brazil

Raphael has more than 20 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.

Flavia Firmino Ribeiro, PharmD

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.

Speaker(s)

eCTD in LATAM: Turning Regulatory Challenges into Innovation Opportunities

Ana Mak

Associate Director - Lifecycle Department Regulatory & Access
Parexel, Argentina

Over 20+ years of pharmaceutical regulatory affairs expertise including Lifecycle management for regulatory submissions (INDs, NDAs, MAAs, BLAs, DMFs, ANDAs, CTAs) , Regulatory project management across multiple applications and Cross-functional experience in commercial and import/export operations. Key expertise: Technical consulting for global regulatory bodies (FDA, Health Canada, EMA, Swissmedic, Gulf Region, LATAM) • Project leadership: contract/budget management, status analysis, kick-off meetings, submission reports • eCTD consulting and global resource management • Comprehensive project oversight ensuring sponsor-team collaboration within timelines/budgets • Custom business solutions leveraging industry best practices.

Pioneering the Future: CMC Post-approval Change (PAC) Dossier Automation and Delivery to Global Regulators Simultaneously

Nina S. Cauchon, PhD

Director Regulatory Affairs CMC
Amgen, United States

Nina S. Cauchon, PhD, leads external engagement and advocacy for RA-CMC at Amgen Inc. She has experience leading both early phase & commercial programs, including small molecules and biologics. Her areas of interest are regulatory harmonization including collaboration, regulatory challenges for innovative modalities and emerging technologies, and science and risk-based approaches to regulations. Nina is active in several external organizations which provide a strong network and knowledge base, including being a speaker/committee member for ISPE (PQLI co-lead), CASSS WCBP (2026 co-chair), AAPS, IQ, and DIA. She is a member of the PhRMA Global Quality and Manufacturing group, and the ICH Q2(R2)/Q14 IWG.

Innovation In Pharmacovigilance: Strategies for Personalized Safety

Felix Arellano, MD, PhD, FISPE

Global Head Safety Risk Management
Hoffmann-La Roche Limited, Switzerland

A graduate in medicine from Universidad Autonóma de Madrid, Spain, postgraduate studies in pharmacoepidemiology at Macgill University, Montreal, Canada and in pharmaceutical medicine (combined Strasbourg, Basel and Freiburg universities) Dr Arellano has more than 20 years of experience in the safety and pharmacovigilance (PV) field in the pharmaceutical industry. A senior executive having worked in global roles for top 10 pharma in PV of medicines, consumer products, devices and vaccines Dr Arellano is Global Head of Safety Risk Management at F Hoffmann La Roche, Switzerland. With a career spanning all elements of PV Dr Arellano is committed to excellence in medical compliance and innovation in safety science to create value for society.

Regulatory Perspectives on the Use of AI in the Development of Drug and Biologic Products

Jason Cober, MPA

Director Regulatory Review, AI, Digital Transformation
ProPharma Group, United States

Jason Cober is the Director - Regulatory Review, AI, and Digital Transformation at ProPharma Group. He previously led FDA/OPDP's eCTD implementation and has 17 years' experience with the Agency's eCTD specification and guidance development process.

11:45 AM — 12:00 PM Gaudi

Closing Remarks