DIA

Latin America Regulatory Conference

February 22-24 | Virtual

PROGRAM COMMITTEE

Patricia Aprea, MD
Director, Evaluation and Control of Biológicals
ANMAT, Argentina

Cammilla Horta Gomes, MA
LATAM Regulatory Policy Lead
Roche, Brazil

Maria Guazzaroni Jacobs, PhD
Director Quality and Regulatory Policy (QRP)
Global Supply Pfizer Inc

Fernanda Lessa, MBA, MPH
Regulatory Affairs Specialist - Health Systems and Services/ Medicines & Health Tech
Pan American Health Organization PAHO/WHO

Livia Lopes
LatAm Regulatory Affairs Policy Manager
Novartis

Roberta Mele Mazza, RPh, RAC
Q&RA Manager, División Diagnóstica
Productos Roche, Argentina

Maria Cristina Mota Pina, MBA
Director, Regulatory Policy and Intelligence -Japan Emerging Markets and Australia AbbVie, Inc.

Carlos Pinoargote
Chief Operating Officer
BRCR Global

Ana Padua, MSc, RPh
Associate Director GRA CMC Regulatory Intelligence Biopharam Global Regulatory
EMD Serono, Switzerland

Leonardo Semprún, RPh
Director, Global Regulatory Policy - Latin America
MSD, Panama

Renata De Lima Soares
Regulation and Health Surveillance Specialist
Anvisa, Brazil

Sonia Viejobueno, LLM
Latin America Lead, Global Regulatory Policy and Intelligence
The Janssen Pharmaceutical Companies of Johnson & Johnson, Argentina

Overview

Join global regulators, industry, and academia to engage in a series of strategic discussions on current regulatory landscape, globalization, and harmonization initiatives in Latin America.

DIA brings you a symposium with interactive dynamics, where you will be engaged in discussions with key stakeholders influencing the advancement and implementation of regulatory convergence initiatives in Latin America.

Join us to discuss multi-regional cooperation, global harmonization, and best practices related to Latin America's regulatory landscape. Sessions will highlight regulatory approaches and good practices to ensure reliance in Latin American and strategic initiatives to improve collaboration and cooperation.

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

Who Should Attend?

Professionals involved in:

- Drug regulation
- Clinical Research and Development
- Medical and Scientific Affairs
- Quality Assurance
- Research and Development
- Strategic Sourcing/Planning
- Regulatory Affairs

Schedule At-A-Glance

DAY ONE | MONDAY, FEBRUARY 22

9:45AM-12:00PM	**Welcome and Session 1:** Regional and Global Updates Part 1
12:00-12:45PM	Networking Break
12:45-1:45PM	**Session 2:** Reliance and Regulatory System Strengthening
1:45-2:15PM	Networking Break
2:15-3:15PM	**Session 3:** Lifecycle Management

DAY TWO | TUESDAY, FEBRUARY 23

10:00-11:00AM	**Session 4:** Evolution in Manufacturing / Advanced Therapies
11:00-11:30AM	Networking Break
11:30AM-12:45PM	**Session 5:** Regulatory Pathways for IO Drugs and How to Select the Right Endpoint(s)
12:45-1:15PM	Networking Break
1:15-2:15PM	**Session 6:** eLabeling in Latin America is This Concept a Possible Reality?

DAY THREE | TUESDAY, FEBRUARY 24

10:00-11:30AM	**Session 7:** How Can Clinical Trial Innovative Designs Accelerate Medical Innovation for Patients?
11:30AM-12:00PM	Networking Break
12:00-1:00PM	**Session 8:** Regulatory Convergence in Pandemic Situations
1:00-1:30PM	Networking Break
1:30-3:30PM	**Session 9:** Regulator Panel – Regional and Global Updates Part 2

Learning Objectives

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

- Identify the current regulatory landscape across Latin America including updates on harmonization and convergence efforts, and individual regional priorities from various National Regulatory Authorities
- Discuss how emerging regulatory trends and new technologies impact the development and lifecycle of medical products
- Establish various approaches and best practices to promote regulatory reliance in Latin America

TO ACCESS MY TRANSCRIPT

- Visit DIAglobal.org
- **Sign In** with your DIA User ID and Password
- Select the Welcome Menu in the upper right hand corner (where your name appears)
- Select **My Account** from the menu
- Select **My Transcripts** then **Manage My Transcripts**

ACCESS PRESENTATIONS

- Visit DIAglobal.org
- **Sign In** with your DIA User ID and Password
- Select the Welcome Menu in the upper right hand corner (where your name appears)
- Select **My Account** from the menu
- Choose **My Presentation**

Please Note: DIA User ID and Password are needed to access presentations. If you have forgotten your DIA User ID and Password, or this is your first time logging into the DIA website, please use our Login Reminder. **Presentations will be available for six months post conference.*

DAY ONE | MONDAY, FEBRUARY 22

9:45AM-12:00PM

Welcome and Session 1: Regional and Global Updates Part 1

Session Chair
Renata De Lima Soares, Regulation and Health Surveillance Specialist, Anvisa, Brazil

This session is intended for each National Regulatory Authority (NRA) to provide a summary of the progress made on their regulatory projects as well as their priorities for 2021. Each NRA will have approximately 15-20 minutes to provide an update on progress made on several local, regional, and global projects as well as their priorities for the year that affect regulators and manufacturers/regulated sector in Latin America. A Q&A panel discussion will be held at the end of this session to provide any clarification where necessary.

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

- Be familiar with the most up-to-date resources that support regulatory systems strengthening and the adoption of good reliance practices
- Value the benefits of reliance approaches in regulatory decision making, including in the context of public health emergencies
- Understand the current regional landscape and identify opportunities to improve regulatory efficiencies

Speakers
Ana Patricia Pineda, MSc, International Regulatory Analyst, OIP, OGROP, OC, FDA, Mexico

Carlos Junio Falconí Borja, Director Técnico de Elaboración, Evaluación y Mejora Continua de Normativa Protocolos y Procedimiento, Argencia Nacional de Regulacion, Control Y Vigilancia Sanitaria (ARCSA), Ecuador

Doris María García Moreno, Coordinadora General Técnico de Regulación para la Vigilancia y Control Sanitario (ARCSA), Ecuador

Role of the National Agency of Reference in the Combat to COVID-19 Pandemic
Olga Sofía Ponce Quiñonez, Coordinadora General Técnico de Certificaciones, Control Sanitario (ARCSA), Ecuador

Heriberto García, Director, Instituto de Salud Pública de Chile, Chile

Eliana Caballero, Directora General Ejecutiva, AGEMED

Leonardo Sánchez, Agencia de Regulación Sanitaria (ARSA), Honduras

12:00-12:45PM **Networking Break**

12:45-1:45PM **Session 2:** Reliance and Regulatory System Strengthening

Session Chairs
Cammilla Horta Gomes, MA, LATAM Regulatory Policy Lead Roche, Brazil

Roberta Mele Mazza, RPh, RAC, Q&RA Manager, División Diagnóstica Productos Roche, Argentina

As an approach that supports the best use of available resources and expertise, reliance plays an important role in facilitating timely access to safe, effective and quality-assured medicines and medical devices, as well as in helping regulatory preparedness and response, particularly in context of public health emergencies.

This session will focus on discussing the role of good reliance practices in regulatory decision-making, as well as other tools for regulatory systems strengthening that increase the efficiency of regulators, producing better public health outcomes. It will present the most recent global developments and resources to support regulators, as well as updated information about the global and regional regulatory scenario and practical considerations that can lead to more consistent regulatory processes.

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

- Be familiar with the most up-to-date resources that support regulatory systems strengthening and the adoption of good reliance practices
- Value the benefits of reliance approaches in regulatory decision making, including in the context of public health emergencies
- Understand the current regional landscape and identify opportunities to improve regulatory efficiencies

Regulatory Systems Strengthening – Global Update
Samvel Azatyan, **MD, PhD**, Team Lead, Regulatory Convergence and Networks (RCN/REG), World Health Organization (WHO), Switzerland

Results of CIRS Reliance Study for Latin America
Lawrence Liberti, **PhD, PMP**, Adjunct Assistant Professor, Temple University School of Pharmacy, Regulatory Affairs and Quality Assurance Graduate Program

Strengthening Regulatory Systems: a consolidated industry perspective
Sandra Ligia González, Executive Secretary, Inter-American Coalition for Regulatory Convergence, Medical Technology Sector

Panelists
Steven Bipes, Vice President - Global Strategy & Analysis Advanced Medical Technology Association (AdvaMed)

Rebecca Lumsden, PhD, Director, Regulatory Policy, Pfizer, Inc, United Kingdom

1:45-2:15PM **Networking Break**

2:15-3:30PM **Session 3:** Lifecycle Management

Session Chairs
Ana Padua, MSc, RPh, Associate Director GRA CMC Regulatory Intelligence Biopharam Global Regulatory EMD Serono, Switzerland

Leonardo Semprún, **RPh** Director, Global Regulatory Policy - Latin America, MSD, Panama

This session will discuss 2 aspect related to the lifecycle management of pharmaceutical products.

1. The concept Effective Management of Post-Approval Changes in the Pharmaceutical Quality System (PQS) - Through Enhanced Science and Risk-Based Approaches Industry (1VQ concept paper). How is possible to achieve a transformational shift with faster implementation of new knowledge, continual improvement, and innovation through post-approval changes
2. Applicability of Post-Approval Change Management Protocols (PACMPs). Current adoption and implementation status worldwide, and benefits

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

- Understand the concept of Post-Approval Change Management Protocols (PACMPs)
- Understand Effective Management of Post-Approval Changes in the Pharmaceutical Quality System (PQS) - Through Enhanced Science and Risk-Based Approaches Industry
- Discuss the opportunities that this initiative could bring to the region

1VQ Concept Paper- Effective Management of Post-Approval Changes in the Pharmaceutical Quality System (PQS) - Through Enhanced Science and Risk-Based Approaches Industry
Anders Vinther, Site Head & VP Global Quality, Intarcia Therapeutics, Inc.

Post-Approval Change Management Protocols (PACMPs)
Sylvie Meillerais, MSc, Director Global CMC Policy, MSD, Europe, Belgium

Recent Advances in the Development of PAC Guidelines
Raphael Sanches Pereira, Health Regulation Expert, Brazilian Health and Surveillance Agency, Brazil

DAY TWO | TUESDAY, FEBRUARY 23

10:00-11:00AM

Session 4: Evolution in Manufacturing / Advanced Therapies

Session Chair
Maria Guazzaroni Jacobs, PhD, Director Quality and Regulatory Policy (QRP), Pfizer Global Supply Pfizer Inc

Due to the pandemic, 2020 has seen new technologies being advanced, many in search for vaccines for COVID-19. In this session, participants will hear from industry on experience and lessons learned advancing vaccine manufacturing, as well as the considerations from a quality perspective, including alliances with other companies, quality agreements and qualification of suppliers.

The session will continue with a second industry presentation focused on quality considerations for ATMPs and a representative from ANVISA on the regulatory model for ATMPs including risk/benefit assessment and challenges in application of GMPs.

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

- Discuss quality considerations in manufacturing of ATMPs
- Learn from regulators on ATMP's GMP standards and the regulatory model for Advance Therapies

COVID Vaccine – Development and Current Status
Pamela Siwik, MBA, Vice President, Pfizer Global Supply Rare Diseases and New Modalities and New Product Leader, Pfizer Inc

COVID-19 Vaccine Quality and Compliance Summary
Jennifer Sloan, MS, Director PSQA BTx Portfolio, Pfizer Global Supply, Pfizer Inc

Quality Considerations of ATMPs
Joerg Garbe, PhD, Global Quality Manager & Policy Lead F. Hoffmann-La Roche Ltd, Switzerland

Anvisa´s Regulatory Model in ATMP-GMP
Joao Batista Silva Junior, MHS, RAC, Manager of Blood, Tissues, Cells and Organs Office, ANVISA, Brazil

11:00-11:30AM **Networking Break**

11:30AM-12:45PM **Session 5:** Regulatory Pathways for IO Drugs and How to Select the Right Endpoint(s)

Session Chairs
Carlos Pinoargote, Chief Operating Officer, BRCR Global

Leonardo Semprún, RPh, Director, Global Regulatory Policy - Latin America, MSD, Panama

From a medical and clinical point of view, it is important to point out that, when a disease is found in different stages, clinical studies to determine the safety and efficacy of the treatment are designed accordingly and regarding the disease to be treated /stage in which it is found.

The intend of this session will be to discuss primary endpoints criteria of the clinical studies of IO drugs.

In this session, we could bring with SME´s some of the most used valuation criteria. Guidance documents from the European Medicines Agency (EMEA) and the United States Food and Drug Administration (FDA) include endpoints that demonstrate clinical benefit and therefore can be used as primary endpoints in clinical trials seeking regulatory approval.

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

- Understand surrogate endpoints that FDA/EMA accepts to support an accelerated approval of IO drugs
- Understand factors associated with regulatory success in the approval of Immune oncology (IO) drugs based on primary end points

Surrogate Endpoints that FDA Accepts to Support an Accelerated Approval of IO Drugs
Amy McKee, MD, Vice President, Regulatory Consulting Services, Parexel

Understand Surrogate Endpoints that EMA Accepts to Support an Accelerated Approval of IO Drugs
Sacha Wissink, PhD, Executive Director, Regulatory Affairs Europe, MSD, Netherlands

Observation of Endpoint Properties and their Relationship to the Regulatory Success in the Approval of Oncology Drugs
Lawrence Liberti, PhD, PMP, Adjunct Assistant Professor, Temple University School of Pharmacy, Regulatory Affairs and Quality Assurance Graduate Program

12:45-1:15PM **Networking Break**

1:15-2:15PM **Session 6:** eLabeling in Latin America is This Concept a Possible Reality?

Session Chair
Maria Cristina Mota Pina, MBA, Director, Regulatory Policy and Intelligence -Japan, Emerging Markets and Australia AbbVie, Inc.

This session will discuss the concept of eLabelling, the potential benefits that the initiative could provide to different stakeholders (patient, industry, regulators, health care professionals) How different regulators globally are implementing this concept and the opportunities for the Latin America Region.

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

- Understand the concept of e labeling and potential benefits
- Initiatives that are currently ongoing in the region
- Discuss the opportunities that this initiative could bring to the region

eLabelling as a Tool for Enhancing Patient Care
Aimad Torqui, BSc, MSc, Executive Director Global Regulatory Policy, MSD, the Netherlands, Netherlands

Labeling Considerations
Márcia Gonçalves de Oliveira, e-labeling para a America Latina, Agência Nacional De Vigilância Sanitária, Brazil

eLabeling as Digital Transformation in Brazil
Erika Rufino, BsC, MBA, Regulatory Affairs Senior Manager, Janssen Pharmaceuticals, Brazil

10:00-11:30AM

Session 7: How Can Clinical Trial Innovative Designs Accelerate Medical Innovation for Patients?

Session Chairs

Sonia Viejobueno, LLM, Latin America Lead, Global Regulatory Policy and Intelligence, The Janssen Pharmaceutical Companies of Johnson & Johnson, Argentina

Renata De Lima Soares, Regulation and Health Surveillance Specialist, Anvisa, Brazil

In contrast to traditional trial designs, where a single drug is tested in a single disease population in one clinical trial, designs such as master protocols use a single infrastructure, trial design, and protocol to simultaneously evaluate multiple drugs and/or disease populations in multiple sub-studies, that may contain an adaptive design.

We will discuss Innovative Clinical Trials design, including Basket, Umbrella, Platform and Adaptive Clinical Trials and how they are contributing to accelerate patient access to new medicines and improve the efficiency and the success rate of clinical trials.

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

- Understand basic concepts of Innovative Clinical Trials Design and their importance for current drug development
- Obtain greater understanding of Innovative Clinical Trials Design and how can industry and regulators across Latin America collaborate to support their implementation in the region

Speakers

John Scott, MA, PhD, Director, Division of Biostatistics, OBE, CBER, FDA

Clinical Trial Innovative designs: Regulatory Agency Perspective

Laura Traversi, MD, Head of Clinical Trials Department, ANMAT, Argentina

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

Telba Irony, PhD, MS, MSc, Senior Scientific Director, Quantitative Sciences, Janssen R&D

11:30AM-12:00PM

Networking Break

12:00-1:00PM

Session 8: Regulatory Convergence in Pandemic Situations

Session Chairs

Roberta Mele Mazza, RPh, RAC, Q&RA Manager PRODUCTOS ROCHE, División Diagnóstica, Argentina

Maria Cristina Mota Pina, MBA, Director, Regulatory Policy and Intelligence -Japan, Emerging Markets and Australia AbbVie, Inc.

"Regulatory convergence," represents a process whereby the regulatory requirements across countries or regions become more similar or "aligned" over time. This session aims to provide an overview of "lessons learned" during a pandemic situation and share examples of good regulatory practices for medical devices and medicines in the Latin America the region.

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

- Raise the awareness on different Convergence initiatives already existing and new initiatives for medical devices and medicines
- Understand how Regulators are working towards regulatory convergence in pandemic situations for medical devices and medicines
- Provide an industry perspective in how regulatory convergence initiatives supports availability of medical devices and medicines in pandemic situations

Speakers
Agnès Saint-Raymond, DrMed, Head of International Affairs Division, European Medicines Agency, Netherlands

Regulatory Convergence in Pandemic Situations an Industry perspective
Rebecca Lumsden, PhD, Director, Regulatory Policy, Pfizer, Inc, United Kingdom

Regulatory Convergence in Pandemic Situations
Sandra González, Executive Secretary,Inter-American Coalition for Regulatory Convergence, Advanced Medical Technology Association (AdvaMed)

Panelist
Steven Bipes, Vice President - Global Strategy & Analysis, Advanced Medical Technology Association (AdvaMed)

1:00-1:30PM **Networking Break**

1:30-3:30PM **Session 9:** Regulator Panel – Regional and Global Updates Part 2

Session Chair
Renata De Lima Soares, Regulation and Health Surveillance Specialist, Anvisa, Brazil

This session is intended for each National Regulatory Authority (NRA) to provide a summary of the progress made on their regulatory projects as well as their priorities for 2021. Each NRA will have approximately 15-20 minutes to provide an update on progress made on several local, regional, and global projects as well as their priorities for the year that affect regulators and manufacturers/regulated sector in Latin America. A Q&A panel discussion will be held at the end of this session to provide any clarification where necessary.

Upon completion of this session, the participant should be able to

1. Understand the progress made by NRAs in their projects
2. Identify NRAs priorities for 2021
3. Understand the impact of projects and priorities for regulators and manufacturers

Speaker
María Antonieta Gamarra, Pharm., General Director of the Dirección Nacional de Vigilancia Sanitaria Paraguay

Regulation of Medicines and Biological Products in Peru
Susan Katherin Zavala Coloma, General Directorate of Medicines, Supplies and Drugs (DIGEMID)

Speakers
Rian Extavour, PhD, MSc, RPh, RAC, Carribean Public Health Agency (CARPHA), Trinidad And Tobago

Nicole Ennis, MSc, Head Medicines Quality Control and Surveillance Department, Caribbean Public Health Agency (CARPHA), Jamaica

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