# CMC Strategy Forum Latin America 2025

Schedule

## Wednesday, 13 August, 2025

09:00-09:10

### CASSS Welcome & CMC Strategy Forum Latin America 2025 Introduction

José Crisóstomo, Rosana Mastellaro, Liliane Saadi
Presentation type: V - Virtual

Session Chairs: José Crisóstomo, *ISPCH - Public Health Institute of Chile*, Rosana Mastellaro, *Sindusfarma*, and Liliane Saadi, *Sindusfarma*

09:10-10:15

### Session I – From Marketing Authorizations to PAC's: Reliance Across the Life Cycle of a Product

José Crisóstomo, Rosana Mastellaro, Liliane Saadi
Presentation type: V - Virtual

Session Chairs: José Crisóstomo, *ISPCH - Public Health Institute of Chile*, Rosana Mastellaro, *Sindusfarma*, and Liliane Saadi, *Sindusfarma*

WHO supports reliance on the work of other regulators as a general principle to make the best use of available resources and expertise. This principle allows leveraging the output of others whenever possible while placing a greater focus at national level on value-added regulatory activities that cannot be undertaken by other authorities, such as, but not limited to vigilance, market surveillance, and oversight of local manufacturing and distribution (1). In this session, we will tackle the concept of "sameness of product", which is fundamental for the adoption of reliance. How can we demonstrate the similarity between products in a dossier that is submitted to different Regulatory Authorities?

The adoption of reliance is more common during the marketing authorization process, however, it is important to consider Post Approval Changes (PACs), because products are constantly changing, and a high number of these procedures, could be a huge challenge for the NRAs. Furthermore, the level of detail in technical information should not prejudice the adoption of analysis rationalization and optimization tools. Finally, industry usually requests marketing authorization to different NRAs at different times, and this could significate that the product that was authorized by the reference NRA, is already different, because the product experimented with different PACs. That is why lifecycle management practices to maintain the quality attributes of the products and secure the current reliance practices are important for industry.

The Session 1 of CASSS CMC LATAM 2025 will explore the fundamental principles of product sameness and regulatory reliance, analyzing their understanding and application by some regulatory authorities. Additionally, the session will discuss how the pharmaceutical industry has incorporated these concepts into regulatory submissions to ensure compliance and facilitate global market access.

(1) - WHO: Annex 10 Good reliance practices in the regulation of medical products: high level principles and considerations

Session Speakers:

Navigating Complexity: PGMP Implementation for Sterile Medicines During the Pandemic
Fernanda Batista and Beatriz Pompeu, *EMS S.A.*

Biologic Product Review Through Reliance: A Chilean Pilot
Francisco Bori, *Public Health Institute of Chile (ISPCH)*

International Cooperation and Reliance in Practice
Martin Harvey, *European Medicines Agency (EMA)*

10:15-10:45

### Break

Presentation type: V - Virtual

10:45-12:35

Session I Panel Discussion

José Crisóstomo, Rosana Mastellaro, Liliane Saadi
Presentation type: V - Virtual

Session Chairs: José Crisóstomo, *ISPCH - Public Health Institute of Chile*, Rosana Mastellaro, *Sindusfarma*, and Liliane Saadi, *Sindusfarma*

Additional Panelists:

Victoria Espinola, *Roche International Ltd.*

Raphael Sanches Pereira, *Brazilian Health Regulatory Agency (ANVISA)*

Cinthia Torres Huari, *General Directorate of Medicines, Supplies, and Drugs (DIGEMID) - Peru*

12:35-12:45

Session I Summary & Concluding Remarks

José Crisóstomo, Rosana Mastellaro, Liliane Saadi
Presentation type: V - Virtual

Session Chairs: José Crisóstomo, *ISPCH - Public Health Institute of Chile*, Rosana Mastellaro, *Sindusfarma*, and Liliane Saadi, *Sindusfarma*

Wednesday, 20 August, 2025

09:00-09:10

CASSS Welcome & CMC Strategy Forum Latin America 2025 Introduction

Daniela Bravo, Maria Cristina Mota Pina, Cinthia Torres Huari, Susan Zavala Coloma
Presentation type: V - Virtual

Session Chairs: Daniela Bravo, *AbbVie Inc.,* Maria Cristina Mota Pina, *AbbVie Inc.,* Cinthia Torres Huari, *DIGEMID - General Directorate of Medicines,* Supplies and Drugs, and Susan Zavala Coloma, *DIGEMID - General Directorate of Medicines, Supplies and Drugs*

09:10-10:30

## Session II – Regulatory Innovation: Building Capacity for Convergence and Digitalization in a Globalized World

Daniela Bravo, Maria Cristina Mota Pina, Cinthia Torres Huari, Susan Zavala Coloma
Presentation type: V - Virtual

Session Chairs: Daniela Bravo, *AbbVie Inc.,* Maria Cristina Mota Pina, *AbbVie Inc.,* Cinthia Torres Huari, *DIGEMID - General Directorate of Medicines,* Supplies and Drugs, and Susan Zavala Coloma, *DIGEMID - General Directorate of Medicines, Supplies and Drugs*

The future of regulatory submissions is approaching rapidly. Ongoing initiatives may completely transform how submissions are currently conducted, such as establishing a single dossier for global submission, where regulatory convergence plays a significant role to reach this outcome.

The CMC landscape is evolving, including changes in CMC submission requirements, the implementation of structured data, a focus on cloud computing, and the use of collaborative review. To promote international convergence and increase efficiency for the application of regulatory reliance and data sharing, regulators and the industry will need to transform the current quality assessment of an application from unstructured narrative information in PDF files to a core dossier that utilizes structured data and modern IT tools and platforms.

To fully capitalize on all the benefits this new regulatory landscape can offer, regulators, industry and academia should collaborate in building capacity and implementing harmonized requirements.

The upcoming 2025 CASSS CMC LATAM Session 2 aims to explore the global initiatives that will shape the future of regulatory requirements and practices, and how regulators and the industry in Latin America and the Caribbean can be better prepared.

Session Speakers:

Reliance as an Essential Tool to Promote Efficient and Robust Global Regulatory Oversight
Marie Valentin, *World Health Organization*

Development of ICH M4Q(R2) Common Technical Document on Quality - Guideline Update
Hugo Hamel, *Health Canada*

Bridging Innovation and Access: Advancing Regulatory Capacity and AI-Driven Drug Development
Jared Auclair, *Northeastern University*

Innovative Digital Regulatory Transformation: The First Cloud-based Submission
Michael Abernathy, *Amgen Inc.*

10:30-11:00

## Break

Presentation type: V - Virtual

11:00-12:35

## Session II Panel Discussion

Daniela Bravo, Maria Cristina Mota Pina, Cinthia Torres Huari, Susan Zavala Coloma
Presentation type: V - Virtual

Session Chairs: Daniela Bravo, *AbbVie Inc.,* Maria Cristina Mota Pina, *AbbVie Inc.,* Cinthia Torres Huari, *DIGEMID - General Directorate of Medicines,* Supplies and Drugs, and Susan Zavala Coloma, *DIGEMID - General Directorate of Medicines, Supplies and Drugs*

Additional Panelists:

Francis Reisdorfer, *International Vaccines Institute*
María del Pilar Hernández Svendblad, *Superintendencia de Regulación Sanitaria*

12:35-12:45

## Session II Summary & Concluding Remarks

Daniela Bravo, Maria Cristina Mota Pina, Cinthia Torres Huari, Susan Zavala Coloma
Presentation type: V - Virtual

Session Chairs: Daniela Bravo, *AbbVie Inc.,* Maria Cristina Mota Pina, *AbbVie Inc.,* Cinthia Torres Huari, *DIGEMID - General Directorate of Medicines,* Supplies and Drugs, and Susan Zavala Coloma, *DIGEMID - General Directorate of Medicines, Supplies and Drugs*