



## Overview

- 13:00 - 13:15      **CASSS & CMC Strategy Forum Latin America 2023**  
**Welcome and Introductory Comments**  
*Kavita Aiyer, Seagen Inc.*
- 13:15 - 14:20      **Pathway to Optimizing Submission and Review of**  
**CMC Post-Approval Changes: Employing Scientific**  
**Risk-Based Principles, Reliance Pathways,**  
**Adoption of WHO Post-Approval Guidelines, and**  
**Collaborative Assessments**  
Session Co-Chairs:  
*Kavita Aiyer, Seagen Inc.*  
*Susan Zavala Coloma, DIGEMID-General Directorate*  
*of Medicines, Supplies and Drugs*

Post-approval changes (PAC) to the registered information of authorized medicinal products are inevitable and often present significant regulatory burden for global submission and approval. Acknowledging the regulatory complexity within Latin America presented by diversity of CMC requirements and reporting change categories, regulatory gaps, and distinct procedures for PAC, a strategic, scientific risk-based and nimble management of data package required for submissions and subsequent review by the health agencies is foundational to speedy access of quality medicines to patients.

There is growing support for pursuing a practical approach to better leverage resources and information among regulators to reduce regulatory complexity. Ultimately, this approach would require that regulators in all participating regions adopt standardized requirements for the formats and data expectations in regulatory submissions and apply the similar standards in regulatory review, assessment, and inspection. Importantly, this would also require that sponsors submit the aligned quality dossier for the same product in all regions (i.e., same formulation, facilities, etc.).

Thus, the second session of the 2023 CMC Conversations in Latin America will focus on potential solutions for the much-needed regulatory agility and effectiveness. Considerations would be given to discussing the framework of WHO PAC guidance and the benefits. This would largely encourage adaptation of this guidance by LATAM Health agencies and thus promote standardization in management of PAC for biologics. The session will also focus on opportunities and case studies for collaborative assessments pilots, reliance pathways and industry approach towards assimilation of data packages corroborating with the risk level associated with the PACs.

## **Presentations**

13:15 - 13:35

**Post Approval Change Management  
Collaboration, Creativity and Commitment in a  
Complex Global Environment**

Sarah Miksinski, *Gilead Sciences, Inc.*

13:35 - 14:00

**Accelerate CMC Post Approval Changes: The Story  
of a Regulatory Reliance Pilot**

Heraclio Rodriguez, *Sanofi*  
Ana Luisa Silva, *Sanofi*

After a marketing authorization is granted, a substantial number of Post-Approval Changes (PACs) are managed throughout lifecycle of product to ensure a continuous supply. Over the last decade, the number of requirements for CMC PACs has increased due to the development of National Regulatory Authorities capabilities. However, the overall duration of the review and approval processes has not significantly improved. This triggers an increased risk of supply disruptions or discontinuations of products, and in particular, vaccines. PACs associated with vaccines can be one of the most complex to manage due to manufacturing process perse, as well as combination vaccines use different antigens. The different timing in PACs approval affects product supplies and can lead to shortages. In this context reliance between national regulatory authorities is key to enhance availability of vaccines for the populations.

With the support of Health Canada, WHO, Pan American Health Organization, and the Paul-Ehrlich-Institute, Sanofi has launched a regulatory pilot on a CMC PACs of a WHO pre-qualified vaccine marketed in 40 countries, regarding the transfer of the filling and packaging activities of a single-dose vial presentation, from a Sanofi manufacturing site in Canada to another Sanofi manufacturing site in France.

Out of the 40 countries, 19 countries & WHO accepted to join the pilot in addition to the reference authority Health Canada.

The pilot was set-up to test convergence in assessments, timing, and reliance principles, with

the overall objective of having the PAC reviewed and approved in all participating countries within 6 months after submission;

The overall approach consisted of 2 main steps:

- Step 1: Submit a dossier and receive approval from Health Canada as reference authority for the vaccine.
- Step 2: Submit the same dossier approved. To encourage NRAs and WHO to apply reliance, the company shared the unredacted assessment report from BRDD.

14:00 - 14:20

**Changes Post Approval of Biological Products in Perú: Regulation and Challenges**

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

This presentation will focus on Peruvian Regulation and changes post-approval submissions presented in DIGEMID, challenges about adopting WHO guidelines, and future perspectives.

14:20 - 14:30

**Break**

14:30 - 15:35

**Panel Discussion**

Moderator:

Kavita Aiyer, *Seagen Inc.*

Question Moderator:

Susan Zavala Coloma, *DIGEMID-General Directorate of Medicines, Supplies and Drugs*

Panelists:

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

Sarah Miksinski, *Gilead Sciences, Inc.*

Heraclio Rodriguez, *Sanofi*  
Ana Luisa Silva, *Sanofi*

15:35 - 15:45

**Closing Remarks**

Susan Zavala Coloma, *DIGEMID-General Directorate  
of Medicines, Supplies and Drugs*

15:45

**Adjourn Session II**