CMC Strategy Forum Latin America 2024

Schedule

Tuesday, 6 August, 2024

13:00-13:10

CASSS Welcome & CMC Strategy Forum Latin America 2024 Introduction

Cammilla Horta Gomes, Susan Zavala Coloma

Session Chairs: Cammilia Horta Gomes, *Produtos Roche Quimicos e Farmaceuticos S.A.* and Susan Zavala Coloma, *DIGEMID - General Directorate of Medicines, Supplies and Drugs*

Opening Remarks presented by Cammilla Horta Gomes, *Produtos Roche Quimicos e Farmaceuticos S.A.*

13:10-14:30

Session 1 - Convergence of Regulatory Variation Category Assignment and Defined Health Authority Review Timelines through Risk-based Assessment of Post Approval Changes

Cammilla Horta Gomes, Susan Zavala Coloma

Session Chairs: Cammilia Horta Gomes, *Produtos Roche Quimicos e Farmaceuticos S.A.* and Susan Zavala Coloma, *DIGEMID - General Directorate of Medicines, Supplies and Drugs*

Simplification of the regulatory processes and adhering to common fundamentals for managing post-approval changes would enable international collaboration and cooperation towards regulatory convergence and consequentially speed to market of quality medicines. This can be achieved by harmonized change classifications, leveraging scientific risk-based principles for regulatory evaluations and decision making, adherence to defined and predictable review timelines, collaboration and open dialogues between Industry and Regulators as well as the use of novel regulatory, and scientific tools and practices.

The upcoming 2024 CASSS CMC LATAM Session 1 will continue conversations for understanding barriers enabling Risk-based classification of PACs, promoting convergence of regulatory variation reporting category assignment and defined HA review timelines and partner with HAs in the regions to identify pragmatic solutions like Reliance enabling regulatory efficiencies.

Session Speakers:

Approaches to Design an Efficient, Predictable Global Post-approval Change Management System that Facilitates Continual Improvement and Product Availability
Emabelle Ramnarine, *Boehringer Ingelheim International GmbH.*

Regulatory Advances in Post Approval Changes of Biological Products in Peru
Cinthia Noemi Torres Huari, *General Directorate of Medicines, Supplies and Drugs, Peru (DIGEMID)*

Regulatory Convergence in Latin America: Overcoming Challenges in Post-Registration
Patricia Almeida, *Eurofarma Laboratórios*

14:30-14:40

Break

14:40-15:45

Session 1 Panel Discussion

Cammilla Horta Gomes, Susan Zavala Coloma

Session Chairs: Cammilia Horta Gomes, *Produtos Roche Quimicos e Farmaceuticos S.A.* and Susan Zavala Coloma, *DIGEMID - General Directorate of Medicines, Supplies and Drugs*

Additional Panel Members:

Flavia Firmino, *Pfizer Inc.*

Sairah O'campo, *National Association of Pharmaceutical Laboratories (ALAFARPE)*

15:45-15:55

Session 1 Summary & Concluding Remarks

Cammilla Horta Gomes, Susan Zavala Coloma

Session Chairs: Cammilia Horta Gomes, *Produtos Roche Quimicos e Farmaceuticos S.A.* and Susan Zavala Coloma, *DIGEMID - General Directorate of Medicines, Supplies and Drugs*

Closing Remarks presented by Cammilla Horta Gomes, *Produtos Roche Quimicos e Farmaceuticos S.A.*

Tuesday, 13 August, 2024

13:00-13:10

CASSS Welcome & CMC Strategy Forum Latin America 2024 Introduction

Kavita Aiyer, Claudia Saidman

Session Chairs: Kavita Aiyer, *Global Regulatory Affairs Professional* and Claudia Saidman, *ANMAT - National Administration of Drugs, Food and Medical Devices*

Opening Remarks presented by Kavita Aiyer, *Global Regulatory Affairs Professional*

13:10-14:30

Session 2 - Streamline Management of Product Life Cycle Changes and Build Regulatory Efficiencies Leveraging Reliance

Kavita Aiyer, Claudia Saidman

Session Chairs: Kavita Aiyer, *Global Regulatory Affairs Professional* and Claudia Saidman, *ANMAT - National Administration of Drugs, Food and Medical Devices*

Post-approval changes (PACs) are an essential part of product lifecycle management. Bringing CMC changes through global health authority (regulatory) systems can be a complex, lengthy process taking several years and their timely approval is critical to maintaining and ensuring continuous supply of quality medicinal products. On the face of regulatory diversity amongst National Regulatory Authorities (NRAs), WHO strongly encourages abridged regulatory pathway like “Reliance” as an effective solution fostering more equitable and timely access to quality-assured medical products. Relying on the assessment performed by a reference regulatory authority will build regulatory efficiencies for both health agencies and industry by optimizing use of effort and resources and eliminating redundancies.

The upcoming 2024 CASSS CMC LATAM Session 2 aims to understand opportunities and challenges of implementing Reliance in the region, how can industry partner with the HAs to move this along, are there other regulatory mechanisms that might be beneficial to consider?

Session Speaker:

ICMRA efforts to achieve Regulatory Convergence and Reliance Through a Pharmaceutical Quality Knowledge Management Capability
Evangelos Kotzagiorgis, *European Medicines Agency (EMA)* and
Stelios C. Tsinontides, *CDER, FDA*

Ignite the Future - Our Exciting PAC Reliance Journey with 48 NRAs
Francesca Mangia, *F. Hoffmann-La Roche Ltd*

ICMRA PACMP – Biologic DS Process Change – Experience and Learnings
Lisa Little-Tranter, *Merck & Co., Inc.*

14:30-14:40

Networking Break

14:40-15:45

Session 2 Panel Discussion

Kavita Aiyer, Claudia Saidman

Session Chairs: Kavita Aiyer, *Global Regulatory Affairs Professional* and Claudia Saidman, *ANMAT - National Administration of Drugs, Food and Medical Devices*

Additional Panelist:

José Crisóstomo, *ISP Chile*

Elkiane Macedo Rama, *ANVISA - Brazilian Health Regulatory Agency*

15:45-15:55

Session 2 Summary & Concluding Remarks

Kavita Aiyer, Claudia Saidman

Session Chairs: Claudia Saidman, *ANMAT - National Administration of Drugs, Food and Medical Devices* and Kavita Aiyer, *Global Regulatory Affairs Professional*

Closing Remarks presented by Kavita Aiyer, *Global Regulatory Affairs Professional*