CMC STRATEGY FORUM
ADVANCING BIOPHARMACEUTICAL DEVELOPMENT
LATIN AMERICA 2023

Overview

13:00 - 13:10

CASSS Welcome
Ana Padua, *Merck KGaA*

CMC Strategy Forum Latin America 2023 Introductory Comments
Daniela Manzoli Bravo, *AbbVie SA*

13:10 - 14:30

One Single Dossier for Global Submissions: The Role of Regulatory Convergence and Harmonization to Improve Efficiency and Reduce the Regulatory Burden of CMC Post-Approval Changes
Session Co-Chairs:
Daniela Manzoli Bravo, *AbbVie SA*
Ana Padua, *Merck KGaA*
Silmara Cristiane da Silveira Andreoli, *ANVISA*

Imagine a world where a single dossier can be used worldwide, reducing the regulatory burden for industry and regulators, and accelerating access to better quality therapeutical products to the patients. Although it seems a very long-term new world to prospect, lots of ongoing global initiatives are contributing to this result. The international convergence and harmonization on the regulatory requirements are the first steps that need to be achieved to reduce the global regulatory complexity and support this outcome, but they are still challenges to overcome.

The first and second editions of the CMC Strategy Forum Latin America explored how the CMC post-approval changes represents a significant and increasing workload for regulators and industry and approached some potential solutions for the much-needed regulatory agility and effectiveness, as the convergence with international standards and the implementation of best practices such as reliance and collaborative assessments.

The third edition of the CMC Strategy Forum Latin America will continue to explore the challenges for achieving the desirable convergence and harmonization for the CMC post-approval changes and the consequences of the diversity of requirements, as well as some ongoing initiatives that support the “one single dossier” to become a reality in the future.

Note: View the full list of speaker talk titles and abstracts below

14:30 - 14:40 **Break**

14:40 - 15:35 **Panel Discussion**
Moderators:
Daniela Manzoli Bravo, *AbbVie SA*
Silmara Cristiane da Silveira Andreoli, *ANVISA*

Panelists:
Hanane Abdellah, *Merck KGaA*
Evangelos Kotzagiorgis, *European Medicines Agency (EMA)*
Ingrid Markovic, *CBER, FDA*
João Tavares Neto, *ANVISA*

Additional Panelists:
José Crisostomo, *ISPCH (Chile)*

Emabelle Ramnarine, *Boehringer Ingelheim Fremont, Inc.*

15:35 - 15:45 **Session Summary & Closing Remarks**
Ana Padua, *Merck KGaA*

15:45 **Adjourn Session III**

Speaker Presentations

13:10 - 13:30 **Post Approval Change Management - Global Harmonization Perspectives**
Hanane Abdellah, *Merck KGaA*

Efficient post-approval change management is essential for health authorities and industry to achieve the common goal of ensuring timely and continuous supply of medicines to the patients worldwide while maintaining the quality efficacy and safety of the products. This presentation will share insights on some of the global challenges faced during life cycle management of biologics. It will also cover perspectives on areas where agencies and industry can foster their collaboration and work hand in hand to move toward regulatory convergence.

13:30 - 13:50 **The Revision of Brazilian Guidelines for Post-Approval Changes and Stability, and Its Impact on International Convergence in the Regulation of Biotechnological Products**
João Tavares Neto, *ANVISA*

In August 2020, Anvisa published revised standards for conducting stability studies and post-approval changes (PAC) to authorized biological products. The new regulations aimed at aligning with the WHO

and ICH, updating requirements that had been in place since 2011. The new regulatory landscape has enabled the receipt of dossiers more in line with manufacturers' best international practices and the implementation of projects in collaboration with the industry to reduce the queue for PAC approvals. This presentation is intended to identify the progress achieved and discuss opportunities for improvement.

13:50 - 14:10 **Genesis of ICH M4Q: From Inception to the Present Day**
Ingrid Markovic, *CBER, FDA*

The current ICH M4Q(R1), introduced in 2002, provides a harmonized structure and format for presenting the quality information for registration of pharmaceuticals for human use. This initial effort was a foundational initial step towards more harmonized regulatory communication benefiting industry, regulators, patients, and consumers. M4Q(R1) is now due for revision to further streamline registration efficiency, support new therapeutic modalities, leverage digital technologies, and accelerate patient and consumer access to pharmaceuticals. This presentation will describe the status of ICH’s effort and present the high-level design of M4Q(R2).

14:10 - 14:30 **EMA Perspectives on International Convergence and Collaboration for CMC Submissions**
Evangelos Kotzagiorgis, *European Medicines Agency (EMA)*

The presentation will be about how EMA assess post approval changes and will provide a very brief description of the European Centralised procedure.

The focus of the presentation will on the role of EMA in the global environment discussing mechanisms and opportunities for international collaboration. In this regard the EMA parallel Scientific Advice, Open and ICMRA Pharmaceutical Quality Knowledge Management System (PQKMS) will be elaborated.