CMC STRATEGY FORUM
ADVANCING BIOPHARMACEUTICAL DEVELOPMENT
LATIN AMERICA 2023

12:45 – 13:00 **Sign-in to Zoom**

13:00 – 13:10 **CASSS Welcome and Introductory Comments**
Cammilla Horta Gomes, *Produtos Roche Químicos e Farmacêuticos S.A.*

13:20 – 14:20 **Why optimize the submission and review of CMC post-approval changes? Global trends and challenges for Latin America**

Session Co-Chairs: Cammilla Horta Gomes, *Produtos Roche Químicos e Farmacêuticos S.A.*, Karina Cuadra, *Ministerio de Salud Publica de Uruguay*

Post-approval changes (PAC) to the registered information of authorized medicinal products are routinely introduced worldwide, and their review represents a significant and increasing workload for regulators. Moreover, handling many different types of dossiers for the same product and managing change implementation worldwide is burdensome for industry. In Latin America, the diversity of CMC requirements and reporting change categories, regulatory gaps, and distinct procedures for PAC continue to represent a challenge, with potential impact on the availability of medicinal products in the region.

The first edition of the 2023 CMC Conversations in Latin America will be a virtual interactive session, gathering regulators and industry - from the region and beyond - to explore solutions in optimizing the submission, review, and implementation process of CMC variations, focusing on convergence with international standards and adoption of best practices.

13:20 – 13:40 **Global Trends in Lifecycle Management**
Hugo Hamel, *Health Canada*

Manufacturing processes are often altered after regulatory approval and medicines can undergo changes during their product lifecycle. Changes are essential for the continual improvement of the manufacturing process and for maintaining state-of-the-art controls of medicinal products, and often need to be implemented after the product has been approved. With the approval of new products every year, the number of post-approval changes requiring regulatory approval keep increasing and can delay access to important drugs to patients. This presentation will highlight the importance to have a regulatory framework in place which use a risk-based approach for lifecycle management. It will also highlight different tools that are available to help manage the post-approval changes.

13:40 – 14:00 **Reliance for Post-Approval Changes: An Industry Perspective**

Maria Antonieta Román, *Latin American Federation of the Pharmaceutical Industry – FIFARMA*

Currently, pharmaceutical innovation in the development and continuous improvement of drug products generates many applications that exceed the capacities of human and material resources of most regulatory authorities to respond in the shortest possible time and through evaluations that guarantee the quality, safety and efficacy of the products involved. Given the above, regulatory reliance is a mechanism that is becoming increasingly relevant among most regulatory agencies in the world and is endorsed by the World Health Organization as a key item in the strengthening of regulatory systems.

While having expedited processes for the approval of new medicines is crucial for health systems, so is effective management during the life cycle of products and an important part of this is the assessment and authorization of post-approval changes. During this lecture the perspective of the industry will be presented, based on the position paper recently published by the Latin American Federation of the Pharmaceutical Industry (FIFARMA for its acronym in Spanish): “Recommendations to apply regulatory reliance for the evaluation of post-approval changes”, which describes the main challenges facing the Latin American and Caribbean region regarding post-

registration changes, the importance of the implementation of ICH Q12 guide, and recommendations for the regulated industry and for regulators, including the selection of trusted authorities and a decision tree for post-approval change management.

14:00 – 14:20 **Accelerating CMC Review in PAC: ANVISA's Online Optimized Assessment Project**
Carolina Blades, *Brazilian Health Regulatory Agency – ANVISA*

During the COVID pandemic, almost all efforts of the Office of Biological Products were focused on the assessment of COVID applications. Therefore, the backlog of non-COVID applications waiting for review increased a lot. Beginning in 2022, after the worst period of the pandemic, the management team of the Office of Biological Products thought of a different way of doing the assessments, keeping the quality but in a faster speed. The Online Optimized Assessment Project was born, putting together online tools (virtual meetings) and a previous strategy of accelerated assessment, which grouped different applications of some companies to speed up the assessments.

The Project was initially thought for CMC Post approval changes applications, since they were the most demanding backlog in terms of numbers. Then we selected the top 5 companies in terms of numbers of CMC applications, which corresponded to 50% of the backlog of this type of request. The assessments were done during virtual meetings with each company, one by one, for 2 weeks. During this period, if the reviewers needed any clarification, they could ask the applicants in real time, and if it was needed the presence of an expert to clarify a specific technical issue, it was also done, avoiding the emission of deficiency letters, and saving time. After this period, if any doubts still remained, then a deficiency letter was sent and the ordinary assessment pathway was followed.

Since only 2 or 3 senior reviewers were fully dedicated to the project, the remaining companies also benefit since the total backlog reduced, and the rest of the team continue to

review the applications ordinarily. The project generated excellent results and we intend to have a new round in the future, with other companies. However, we don't believe that this way of assessment can be permanent, since it requires a lot of planning and energy, but can be applied sporadically to reduce the backlog.

14:20 – 14:30 **Break**

14:30 – 15:30 **Panel Discussion**
Chat Moderator: Cammilla Horta Gomes, *Produtos Roche Químicos e Farmacêuticos S.A.*
Question Moderator: Karina Cuadra, *Ministry of Public Health of Uruguay*

Panelists:
Carolina Blades, *Brazilian Health Regulatory Agency – ANVISA*
Andrew Deavin, *EFPIA*
Beatriz Fernandes, *AbbVie*
Hugo Hamel, *Health Canada*
Irene Esther Grados Miguel, *DIGEMID Perú*
Maria Antonieta Román, *Latin American Federation of the Pharmaceutical Industry – FIFARMA*

15:30 – 15:45 **Closing Remarks and Topic Voting**
Cammilla Horta Gomes, *Produtos Roche Químicos e Farmacêuticos S.A.*

15:45 **Adjourn Session 1**