Welcome to CMC Strategy Forum Latin America 2016

On behalf of the CASSS Board of Directors and the CMC Strategy Forum Global Steering Committee, we would like to extend to you a warm welcome to the third meeting of the CMC Strategy Forum Latin America 2016.

We are very pleased to have the strong support from COFEPRIS-Federal Commission for the Protection against Sanitary Risk Regulatory Agency in Mexico, as well as AMIIF, CANIFARMA and several other Latin America regulatory agencies (Brasil, Ecuador and Peru), as well as the continued support by CASSS and the United States Food and Drug Administration.

The Forum will follow the established model of the CMC Forum series with focus on topics and regulatory updates relevant for Latin America and will feature an opening regulatory session that will include presentations from COFEPRIS, ANMAT, ANVISA, ARCSA, DIGEMID, as well as the FDA and EMA. In addition, FIFARMA is planning a half-day session to discuss transparency, as well as retesting, quality surveillance and pharmacopeia. The technical sessions will include discussion on lifecycle management control strategies and setting specifications, as well as risk management and established conditions.

The success of the CMC Strategy Forum Latin America will depend on your active participation in discussing and raising issues pertaining to the development of biologics. We encourage you to participate whole-heartedly in the panel discussions that have been designed to stimulate exchange of ideas and information.

We would like to thank the speakers and the panel members who are giving generously of their time and resources and to you for your attendance. We would also like to acknowledge the generosity of our strategic program partners for the continued support of the Forum series: AbbVie, Inc., Biogen, F. Hoffmann-La Roche Ltd. and MedImmune, A member of the AstraZeneca Group. We are grateful for the expert management from CASSS and the audio-visual expertise of Michael Johnstone from MJ Audio-Visual Productions. Their experience and guidance in the preparation of this Forum has been invaluable.
ACKNOWLEDGEMENTS

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The Scientific Organizing Committee gratefully acknowledges the pharmaceutical and biotechnology industry for their generous support of the CMC Strategy Forum Latin America 2016.

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CMC Strategy Forum Latin America 2016
Scientific Program Summary

Monday, 5 September 2016

07:30 – 17:00  Registration in the Regency Ballroom Foyer, 2nd Floor
07:30 – 09:00  Continental Breakfast Service in the Regency Room F, 1st Floor
08:30 – 08:45  CASSS Welcome and Introductory Comments in the Regency A Ballroom
               Wassim Nashabeh, F. Hoffmann-La Roche Ltd., Switzerland
08:45 – 09:15  CMC Strategy Forum Latin America 2016 Welcome and Introductory
               Comments in the Regency Ballroom A
               Mr. Julio Sanchez, Comisionado Federal, COFEPRIS, Federal Commission for
               the Protection from Sanitary Risks, Mexico

Regulatory Convergence: Recent Trends in the Regulations of Biotherapeutic Products in Latin
America
Plenary Session in the Regency Ballroom A
Session Chairs:

09:15 – 09:40  Regulatory Framework for Biotherapeutic Products in Mexico: An Overview
               Adriana Hernández Trejo, COFEPRIS, Federal Commission for the Protection
               from Sanitary Risks, Mexico
09:40 – 10:05  Brazilian Regulation of Biopharmaceuticals
               Bernardo Luiz Moraes Moreira, ANVISA, Brazilian Health Surveillance Agency,
               Brasil
10:05 – 10:35  AM Break in the Regency Ballroom Foyer, 2nd Floor
10:35 – 11:00  Recent Trends in the Regulation of Biotechnological Products in Peru
               Edith Roxana Vásquez Alaya, DIGEMID, General Directorate of Medicines,
               Supplies and Drugs, Peru
11:00 – 11:25  ANMAT Perspective: Recent Trends in the Regulation of
               Biopharmaceuticals
               Carlos Alberto Chiale, ANMAT, National Administration of Drugs, Foods and
               Medical Devices, Argentina
Monday, 5 September continued…

11:25 – 11:50  **Ecuadorian Biologic Products Regulation**  
Cesar Moncayo, ARCSA, National Agency for Regulation and Control Health Surveillance, Ecuador

11:50 – 12:15  **Regulatory Update from Europe**  
Margarida Menezes Ferreira, INFARMED, National Authority of Medicines and Health Products, Portugal

12:15 – 12:40  **Recent Trends in the Regulation of Biotherapeutic Products: US FDA Perspective**  
Leslie Rivera Rosado, CDER, FDA, USA

12:45 – 14:00  **Buffet Lunch** in the Regency Room F, 1st Floor

14:00 – 15:15  **Panel Discussion – Questions and Answers**  
Carlos Alberto Chiale, ANMAT, National Administration of Drugs, Foods and Medical Devices, Argentina  
Adriana Hernández Trejo, COFEPRIS, Federal Commission for the Protection from Sanitary Risks, Mexico  
Margarida Menezes Ferreira, INFARMED, National Authority of Medicines and Health Products, Portugal  
Cesar Moncayo, ARCSA, National Agency for Regulation and Control Health Surveillance, Ecuador  
Bernardo Luiz Moraes Moreira, ANVISA, Brazilian Health Surveillance Agency, Brasil  
Leslie Rivera Rosado, CDER, FDA, USA  
Edith Roxana Vásquez Alayo, DIGEMID, General Directorate of Medicines, Supplies and Drugs, Peru

15:15 – 15:45  **PM Break** in the Regency Ballroom Foyer, 2nd Floor

| Latin American Federation of Pharmaceutical Industry (FIFARMA) |  |
| Transparency of Regulatory Decision Making |  |
| Workshop Session in the Regency Ballroom A |  |

15:45 – 15:50  **Introduction**  
Thomas Schreitmüller, *F. Hoffmann-La Roche Ltd.*, Switzerland (on behalf of FIFARMA)

15:50 – 16:05  **Transparency in Regulatory Decision Making – The Brazilian Way**  
Bernardo Luiz Moraes Moreira, ANVISA, Brazilian Health Surveillance Agency, Brasil
Monday, 5 September continued…

16:05 – 16:20  
**Transparency Policies in the EU from Clinical Trials to Pharmacovigilance**  
Margarida Menezes Ferreira, INFARMED, National Authority of Medicines and Health Products, Portugal

16:20 – 16:35  
**Transparency in Regulatory Decision Making on the Approval for Biosimilar Products – The FIFARMA Position**  
Thomas Schreitmüller, F. Hoffmann-La Roche Ltd., Switzerland (on behalf of FIFARMA)

16:35 – 17:00  
**Panel Discussion – Questions and Answers**  
Adriana Hernández Trejo, COFEPRIS, Federal Commission for the Protection from Sanitary Risks, Mexico  
Margarida Menezes Ferreira, INFARMED, National Authority of Medicines and Health Products, Portugal  
Bernardo Luiz Moraes Moreira, ANVISA, Brazilian Health Surveillance Agency, Brasil  
Thomas Schreitmüller, F. Hoffmann-La Roche Ltd., Switzerland (on behalf of FIFARMA)  
Alexis Serlin, CANIFARMA, Mexico

17:00 – 17:10  
**Mini-break**

### Latin American Federation of Pharmaceutical Industry (FIFARMA)

**Public Quality Control Testing of Pharmaceutical Products**  
Workshop Session in the Regency Ballroom A  
Session Chairs: Gustavo Grampp, Amgen Inc. and Janett Mugaburu-Richards, Pfizer, Inc.

17:10 – 17:25  
**Local Re-testing – The Regulator’s Perspective**  
Iván Valentin Cruz Barrera, COFEPRIS, Federal Commission for the Protection from Sanitary Risks, Mexico

17:25 – 17:40  
**Import Testing – Opportunities for Improved Access to Safe and Efficient Medicines**  
Maria Guazzaroni Jacobs, Pfizer, Inc., USA (on behalf of IFPMA)

17:40 – 17:55  
**Import Testing – Opportunities for Improved Access to Safe and Efficient Medicines**  
Rafael Hernández Medina, Pharmacopeia of the United Mexican States, Mexico

17:55 – 18:25  
**Panel Discussion – Questions and Answers**  
Iván Valentin Cruz Barrera, COFEPRIS, Federal Commission for the Protection from Sanitary Risks, Mexico  
Maria Guazzaroni Jacobs, Pfizer, Inc., USA (on behalf of IFPMA)  
Rafael Hernández Medina, Pharmacopeia of the United Mexican States, Mexico  
Teresa Rosales Olivo, Eli Lilly y Compañía de Mexico S.A. de C.V., Mexico  
Sonia Mayra Pérez Tapia, UDIMEB, Mexico
Monday, 5 September continued…

18:25 – 18:40  FIFARMA Session Summary and Conclusion
Thomas Schreitmüller, *F. Hoffmann-La Roche Ltd., Switzerland (on behalf of FIFARMA)*

18:45 – 20:15  Networking Reception in the Regency Room D1, 2nd Floor

20:15       Adjourn Day One
Tuesday, 6 September 2016

07:30 – 17:00  **Registration** in the Regency Ballroom Foyer, 2\textsuperscript{nd} Floor

07:30 – 09:00  **Continental Breakfast Service** in the Regency Room F, 1\textsuperscript{st} Floor

| **Lifecycle Management Part One: Control Strategy and Setting Specifications** |
| Workshop Session in the Regency Ballroom A |
| Session Chairs: Carmilia Jimenez Ramirez, *Gilead Sciences* and Jaime Uribe, *Probiomed S.A. de C.V.* |

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<tr>
<th>Time</th>
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<tr>
<td>09:00 – 09:10</td>
<td><strong>Introduction</strong></td>
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| 09:10 – 09:35 | **Title TBD – Control Strategies**  
Lazaro Morales Reyes, *COFEPRIS, Federal Commission for the Protection from Sanitary Risks, Mexico* |
| 09:35 – 10:00 | **The Role of Analytics in the Development of Advanced Process Controls**  
Patrick Swann, *Biogen, USA* |
| 10:00 – 10:25 | **Points to Consider in Establishing Biologics Specifications**  
Athena Nagi, *Merck & Co., Inc., USA* |
| 10:25 – 10:50 | **Setting Specifications: From QbD to Continuous Validation**  
Nestor Octavio Pérez Ramírez, *Probiomed S.A. de C.V., Mexico* |
| 11:00 – 11:30 | **AM Break** in the Regency Ballroom Foyer, 2\textsuperscript{nd} Floor |
| 11:30 – 12:45 | **Panel Discussion - Questions and Answers**  
Francisco Kuri Breña, *Landsteiner Scientific, Mexico*  
Lazaro Morales Reyes, *COFEPRIS, Federal Commission for the Protection from Sanitary Risks, Mexico*  
Athena Nagi, *Merck & Co., Inc., USA*  
Nestor Octavio Pérez Ramírez, *Probiomed S.A. de C.V., Mexico*  
Patrick Swann, *Biogen, USA*  
Mauricio Trujillo Roldán, *Universidad Nacional Autónoma de Mexico, Mexico*  
Cecilia Tami, *CDER, FDA, USA* |
| 12:45 – 14:00 | **Buffet Lunch** in the Regency Room F, 1\textsuperscript{st} Floor |
Tuesday, 6 September continued…

Lifecycle Management Part Two: Risk Management and Established Conditions
Workshop Session in the Regency Ballroom A
Session Chairs: Pablo Martin Herrera Mondragon, Probiomed S.A. de C.V. and Joseph Kutza, MedImmune, A member of the AstraZeneca Group

14:00 – 14:25
Introduction

14:25 – 14:50
Reducing the Complexity and Impact of Regulatory Changes in Latin America
Janett Mugaburu-Richards, Pfizer, Inc., USA (on behalf of the BioPhorum Operations Group (BPOG), United Kingdom)
Kavita Ramalingam Iyer, Merck & Co., Inc., USA (on behalf of the BioPhorum Operations Group (BPOG),

14:50 – 15:15
Reduction of Post Approval Change Reporting Categories or Data Provided through Use of Risk Assessment
Mic McGoldrick, Merck Sharp & Dohme, USA

15:15 – 15:40
TBD
Renan Araujo Gois, ANVISA, Brazilian Health Surveillance Agency, Brasil

15:40 – 16:05
ICH Q12 on Life Cycle Management: Opportunities and Challenges
Wassim Nashabeh, F. Hoffmann-La Roche Ltd., Switzerland

16:15 – 16:45
PM Break in the Regency Ballroom Foyer, 2nd Floor

16:45 – 18:00
Panel Discussion – Questions and Answers
Ricardo Castro Acosta, Universidad Nacional Autónoma de Mexico, Mexico
Mic McGoldrick, Merck Sharp & Dohme, USA
Janett Mugaburu-Richards, Pfizer, Inc., USA (on behalf of the BioPhorum Operations Group (BPOG), United Kingdom)
Wassim Nashabeh, F. Hoffmann-La Roche Ltd., Switzerland
Kavita Ramalingam Iyer, Merck & Co., Inc., USA (on behalf of the BioPhorum Operations Group (BPOG), United Kingdom)
Leslie Rivera Rosado, CDER, FDA, USA

18:00 – 18:30
Recap of Program
Summary Slide Presentation
Carmilia Jimenez Ramirez, Gilead Sciences, USA

18:30 – 18:45
Closing Remarks
Thomas Schreitmüller, F. Hoffmann-La Roche Ltd., Switzerland

18:45
Adjournment