Welcome to the CMC Strategy Forum Europe 2018

The 12th annual CMC Strategy Forum Europe, organized by CASSS, will explore many critical topics focused on improving the quality in development and manufacturing of biopharmaceutical products. A series of plenary sessions and workshops led by experts from global regulatory agencies, academia and industry seek to explore emerging aspects of CMC technology and regulation in areas where existing modalities and systems are undergoing change. Topics will include: Regulatory Update from Around the World; Adding to the Complexity – Combining Drugs and Devices; Clinical Relevance of Specifications; Current and Future Approaches to Enhance Development, QbD and Design Spaces; and Prior Knowledge.

The EBE session will present updates on the following concept papers: Drug Device Combination Products / A Biopharmaceutical Industry Perspective on the Control of Visible Particles in Biotechnology-derived Injectable Drug Products; Quality Aspects of Antibody Drug Conjugates; EMA Guideline – Reflection Paper on Statistical Methodology for the Comparative Assessment of Quality Attributes in Drug Development; as well as the workshop topic: CAR-T Cell Therapy.

The CMC Strategy Forum is designed to maximize dialog between participants. Presentations are relatively short and focused and set the agenda for the panel discussions to engage all the participants who have experience and expertise to share. It should be important for you to attend this event as we come together to discuss important issues on how to ensure product safety and efficacy for the patients we serve.

We would like to thank the speakers and panel members who are giving generously of their time and resources, and to you, for your attendance. We acknowledge the generosity of our program partners: Amgen Inc.; Biogen, Bristol-Myers Squibb Company; Eli Lilly and Company; F. Hoffmann-La Roche Ltd.; MedImmune, A member of the AstraZeneca Group; MSD; Novo Nordisk A/S and Pfizer, Inc. We are grateful for the expert management from CASSS and the audio-visual expertise of Michael Johnston 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 program partners for their generous support of the CMC Strategy Forum Europe 2018.

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The Scientific Organizing Committee gratefully acknowledges the following media for their promotional consideration of the CMC Strategy Forum Europe series.

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Monday, 14 May 2018

EBE-European Biopharmaceutical Enterprises Satellite Session

06:30 – 10:30  Breakfast in Oriento Restaurant
(Breakfast is included in the CMC Strategy Forum group sleeping room rate; other attendees / guests can pay individually for breakfast if they are not included in the group room rate)

07:30 – 12:00  Registration in the Wintertuin Foyer

08:30 – 08:45  Welcome and Introduction to the European Biopharmaceutical Enterprises (EBE) Ongoing Activities and Initiatives in Wintertuin
Markus Goese, F. Hoffmann-La Roche Ltd.

Concept Paper 2018 Updates
In Wintertuin
Session Chairs: Fionnuala O’Driscoll, Eli Lilly Kinsale Limited and Saroj Ramdas, GlaxoSmithKline

08:45 – 09:00  EBE’s Approach to Development of Concept / Position Papers
Saroj Ramdas, GlaxoSmithKline, USA

09:00 – 09:10  Drug Device Combination Products: A Biopharmaceutical Industry Perspective on the Control of Visible Particles in Biotechnology-derived Injectable Drug Products
Serge Mathonet, Sanofi R&D, France

09:10 – 09:20  Quality Aspects of Antibody Drug Conjugates
Karoline Bechtold Peters, Novartis Pharma AG, Switzerland

09:20 – 09:30  EMA Guideline – Reflection Paper on Statistical Methodology for the Comparative Assessment of Quality Attributes in Drug Development
Richard Keane, Biogen Idec Limited, United Kingdom

09:30 – 10:00  Panel Discussion – Questions and Answers

10:00 – 10:30  Networking Break in the Wintertuin Foyer
Monday, 14 May continued…

**CAR-T Cell Therapy Workshop**
**In Wintertuin**

**Session Chairs:** Fionnuala O’Driscoll, *Eli Lilly Kinsale Limited* and Karoline Bechtold Peters, *Novartis Pharma AG*

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<tr>
<th>Time</th>
<th>Session Title</th>
<th>Speakers</th>
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<tr>
<td>10:30 – 10:45</td>
<td>Regulatory Aspects of CAR-T Cell Therapy</td>
<td>Marcel Hoefnagel, <em>CBG-MEB, Netherlands</em></td>
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<tr>
<td>10:45 – 11:00</td>
<td>Case Study – Success Story of Kymriah™</td>
<td>Erik Rutjens, <em>Novartis Pharmaceuticals Corporation, USA</em></td>
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<tr>
<td>11:00 – 11:15</td>
<td>Manufacturing Challenge of CAR-T</td>
<td>Andrea Schilz, <em>BioNTech Innovative Manufacturing Services, Germany</em></td>
</tr>
<tr>
<td>11:15 – 11:30</td>
<td>Mechanism of Action of CAR-T and the Current Medication in Development</td>
<td>Sam Yaghmour, <em>Amgen Inc., USA</em></td>
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</table>
| 11:30 – 12:00 | Panel Discussion – Questions and Answers                | Marcel Hoefnagel, *CBG-MEB, Netherlands*       
|               |                                                         | Erik Rutjens, *Novartis Pharmaceutical Corporation, USA* 
|               |                                                         | Andrea Schilz, *BioNTech Pharmaceutical Corporation, USA* 
|               |                                                         | Heli Suila, *Finnish Medicines Agency, Finland* 
|               |                                                         | Sam Yaghmour, *Amgen Inc., USA* |
| 12:00 – 12:15 | Concluding Remarks                                      | Barbara Freischem, *EBE-European Biopharmaceutical Enterprises, Belgium* |
Monday, 14 May continued…

CMC Strategy Forum Europe 2018
Scientific Program Summary

12:15 – 13:45 Buffet Lunch in Oriento Restaurant

13:15 – 17:00 Registration in the Wintertuin Foyer

13:45 – 14:00 CASSS Welcome and Introductory Comments in Wintertuin
Nadine Ritter, Global Biotech Experts LLC

Introduction / Welcome to the 12th European CMC Strategy Forum
Kowid Ho, F. Hoffmann-La Roche Ltd., Switzerland

14:00 – 14:15 TBD
Martijn van der Plas, CBG-MEB, Netherlands

Regulatory Updates from the Around the World: Part One
Plenary Session in Wintertuin
Session Chairs: Niklas Ekman, Finnish Medicines Agency and Kowid Ho, F. Hoffmann-La Roche Ltd.

14:15 – 14:30 TBD
Eric Karikari-Boateng, Food and Drugs Authority, Ghana

14:30 – 14:45 An Overview of the Regulation of Biotechnological and Biosimilar Products in Peru
Ana Maria Chura Tito, DIGEMID-General Directorate of Medicines, Supplies and Drugs, Peru

14:45 – 15:00 The Highest Priorities for ANVISA in 2018
Kalinka de Melo Carrijo, ANVISA-Brazilian Health Regulatory Agency, Brazil

15:00 – 15:45 Panel Discussion – Questions and Answers
Kalinka de Melo Carrijo, ANVISA-Brazilian Health Regulatory Agency, Brazil
Ana Maria Chura Tito, DIGEMID-General Directorate of Medicines, Supplies and Drugs, Peru
Chana Fuchs, CDER, FDA, USA
Eric Karikari-Boateng, Food and Drugs Authority, Ghana
Patrick Owusu-Danso, Food and Drugs Authority, Ghana
Martijn van der Plas, CBG-MEB, Netherlands

15:45 – 16:15 Networking Break in the Wintertuin Foyer
### Monday, 14 May continued…

**Regulatory Updates from the Around the World: Part Two**

**Plenary Session** in Wintertuin


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<tr>
<th>Time</th>
<th>Speaker</th>
<th>Organization</th>
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<tr>
<td>16:15 – 16:30</td>
<td>TBD</td>
<td>Veronika Jekerle, <em>European Medicines Agency (EMA), United Kingdom</em></td>
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<td>16:30 – 16:45</td>
<td>TBD</td>
<td>Takahiro Nakamura, <em>PMDA-Pharmaceuticals and Medical Devices Agency, Japan</em></td>
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<tr>
<td>16:45 – 17:00</td>
<td>TBD</td>
<td>Robin Levis, <em>CBER, FDA, USA</em></td>
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| 17:00 – 18:00 | Panel Discussion – Questions and Answers | Kalinka de Melo Carrijo, *ANVISA-Brazilian Health Regulatory Agency, Brazil*  
                        | Veronika Jekerle, *European Medicines Agency (EMA), United Kingdom*         
                        | Robin Levis, *CBER, FDA, USA*                                               
                        | Takahiro Nakamura, *PMDA-Pharmaceuticals and Medical Devices Agency, Japan* |
| 18:00 – 19:00 | Networking Reception            | in the Wintertuin Foyer                                                     |
| 19:00       | Adjourn Day One                 |                                                                              |
Tuesday, 15 May 2018

06:30 – 10:30  
**Breakfast** in Oriento Restaurant  
(*Breakfast is included in the CMC Strategy Forum group sleeping room rate; other attendees / guests can pay individually for breakfast if they are not included in the group room rate*)

08:00 – 17:00  
**Registration** in the Wintertuin Foyer

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<td>Adding to the Complexity – Combining Drugs and Devices</td>
<td>Workshop Session One in Wintertuin</td>
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<td><strong>Session Chairs:</strong></td>
<td>Chana Fuchs, CDER, FDA and Ilona Reischl, AGES-Austrian Agency for Health and Food Safety</td>
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09:00 – 09:10  
**Introduction**

09:10 – 09:35  
**TBD**  
Janine Jamieson, *JCombinations AB, Sweden*

09:35 – 10:00  
**TBD**  
Mark Chipperfield, *Corvus Device Limited, United Kingdom*

10:00 – 10:25  
**TBD**  
Paul Jansen, *Board Member & Senior Advisor, Haselmeier; Board Member, Subcutject; and Chair Elect ISO TC84, USA*

10:25 – 10:50  
**TBD**  
Tine Juul Zachariasen, *Novo Nordisk A/S, Denmark*

10:50 – 11:20  
**Networking Break** in the Wintertuin Foyer

11:20 – 12:20  
**Panel Discussion – Questions and Answers**  
Elizabeth Baker, *MHRA-Medicines and Healthcare Products Regulatory Agency, United Kingdom*  
Mark Chipperfield, *Corvus Device Limited, United Kingdom*  
Janine Jamieson, *JCombinations AB, Sweden*  
Ann Jans, *FAMPS-Federal Agency for Medicines and Health Products, Belgium*  
Paul Jansen, *Board Member & Senior Advisor, Haselmeier; Board Member, Subcutject; and Chair Elect ISO TC84, USA*  
Peter Jongen, *CBG-MEB, Netherlands*  
Tine Juul Zachariasen, *Novo Nordisk A/S, Denmark*

12:20 – 13:50  
**Buffet Lunch** in Oriento Restaurant
**Tuesday, 15 May continued…**

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<tr>
<td>13:50 – 14:00</td>
<td><strong>Introduction</strong></td>
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| 14:00 – 14:25 | **TBD**  
Mats Welin, *Medical Products Agency, Sweden*                               |
| 14:25 – 14:50 | **TBD**  
Campbell Bunce, *Abzena, United Kingdom*                                     |
| 14:50 – 15:15 | **TBD**  
Wim Jiskoot, *Leiden University, Netherlands*                                 |
| 15:15 – 15:45 | **Networking Break** in the Wintertuin Foyer                             |
| 15:45 – 16:45 | **Panel Discussion – Questions and Answers**  
Brigitte Brake, *BfArM- Federal Institute for Drugs and Medical Devices, Germany*  
Campbell Bunce, *Abzena, United Kingdom*  
Wim Jiskoot, *Leiden University, Netherlands*  
Robin Levis, *CBER, FDA, USA*  
Anthony Mire-Sluis, *AstraZeneca, USA*  
Linda Narhi, *Amgen Inc., USA*  
Mats Welin, *Medical Products Agency, Sweden*                                   |
| 16:45       | **Adjourn Day Two**                                                     |
| 18:00 – 21:00 | **Off Property Networking Reception and Dinner**                         |
Wednesday, 16 May 2018

06:30 – 08:45  Breakfast in Oriento Restaurant
(Breakfast is included in the CMC Strategy Forum group sleeping room rate; other attendees / guests can pay individually for breakfast if they are not included in the group room rate)

08:30 – 17:00  Registration in the Wintertuin Foyer

| Current and Future Approaches to Enhance Development, QbD and Design Spaces |
| Workshops Session Three in Wintertuin |
| **Session Chairs:** Brendan Hughes, *Bristol-Myers Squibb Company* and Martijn van der Plas, *CBG-MEB* |

09:00 – 09:10  Introduction

09:10 – 09:35  Integrating Product and Process Knowledge and Control in Developing Vaccine Products
Marta Germano, *Janssen Vaccines, Netherlands*

09:35 – 10:00  TDB
Kowid Ho, *F. Hoffmann-La Roche Ltd., Switzerland*

10:00 – 10:25  From QbD to Control Strategy
Mairead Looby, *Bristol-Myers Squibb Company, Ireland*

10:30 – 11:00  Networking Break in the Wintertuin Foyer

11:00 – 12:00  Panel Discussion – Questions and Answers
Koen Brusselmans, *Scientific Institute of Public Health, Belgium*
Marta Germano, *Janssen Vaccines, Netherlands*
Steffen Gross, *Paul-Ehrlich-Institut, Germany*
Kowid Ho, *F. Hoffmann-La Roche Ltd., Switzerland*
Veronika Jekerle, *European Medicines Agency (EMA), United Kingdom*
Mairead Looby, *Bristol-Myers Squibb Company, Ireland*

12:00 – 13:30  Buffet Lunch in Beachclub O Restaurant
**Wednesday, 16 May continued…**

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<td>13:30 – 13:40</td>
<td><strong>Introduction</strong></td>
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| 13:40 – 14:20 | **Summary of the 2017 EMA Workshop on Prior Knowledge and Its Use in Regulatory Applications**  
Markus Goese, *F. Hoffmann-La Roche Ltd., Switzerland*  
Mats Welin, *Medical Products Agency, Sweden*          |
| 14:20 – 14:45 | **Modular Retrovirus Clearance in Support of Clinical Development**  
Marie Murphy, *Eli Lilly Kinsale Limited, Ireland*     |
| 14:45 – 15:10 | **Use of Prior Knowledge in Shelf-life Setting for Vaccines in Clinical Development**  
Jolanta Zamelczyk, *Janssen Vaccines, Netherlands*     |
| 15:15 – 15:45 | **Networking Break** in the Wintertuin Foyer                           |
| 15:45 – 16:45 | **Panel Discussion – Questions and Answers**                            
Emmanuelle Charton, *EDQM-Council of Europe, France*  
Chana Fuchs, *CDER, FDA, USA*  
Markus Goese, *F. Hoffmann-La Roche Ltd., Switzerland*  
Marie Murphy, *Eli Lilly Kinsale Limited, Ireland*  
Mats Welin, *Medical Products Agency, Sweden*  
Jolanta Zamelczyk, *Janssen Vaccines, Netherlands*   |
| 16:45 – 17:15 | **Forum Summary**                                                       
Nadine Ritter, *Global Biotech Experts, LLC, USA*     |
| 17:15 – 17:30 | **Closing Remarks and Invitation to CMC Strategy Forum Europe 2019**    
Ronald Imhoff, *Janssen Biologics BV*                 |
| 17:30        | **Adjournment**                                                        |
Session Chairs: Ronald Imhoff, Janssen Biologics BV and Fionnuala O’Driscoll, Eli Lilly Kinsale Limited

NOTES:
Presenter’s Abstracts