



6th Annual U.S.  
CMO Consulting Summit  
Seattle, WA  
12-14 September, 2017  
AGENDA

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**TUESDAY, 12 SEPTEMBER – ARRIVE SEATTLE, WASHINGTON – [PAN PACIFIC HOTEL](#)**

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- 18:00— **Summit Welcome Reception—LakeFront Patio**  
21:00 Following your check-in at the hotel, please join CMC Biologics for an evening of wine and hors d'oeuvres in the Lakefront Patio (*located on 2nd floor*)

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**WEDNESDAY, 13 SEPTEMBER— LAKEFRONT ROOM – SECOND FLOOR – PAN PACIFIC HOTEL**

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- 6:30- 8:00 **Buffet Breakfast**
- 8:00 **Opening Remarks and Review of Meeting Agenda and Objectives / Introduce Chairperson (5min)**  
Bob Broeze, PhD., Chief Business Officer, CMC Biologics
- 8:05 **CMC Biologics Update / Introduction to AGC (20min)**  
Gustavo Mahler, PhD., President & Chief Executive Officer, CMC Biologics
- 8:25 **AGC Overview (20min)**  
Hideyuki Kurata, Chairman of the CMC Biologics Board & General Manager of Life Science General Division, Chemical Company, AGC Asahi Glass
- 8:45 **Biologics Trends and CDMO Market Overview (25min)**  
Speaker: Eric Langer, President & Managing Partner, BioPlan Associates, Inc.

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**MORNING SESSION: HOW DO I GET MY PRODUCT FROM PHASE 2 THROUGH COMMERCIALIZATION?**

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- 9:10 **Introduction to the Morning Session (10min)**  
Patti Seymour, Senior Consultant, BioProcess Technology Consultants, Inc. (BPTC), *CMO Summit Chair*
- 9:20 **What's involved as you take your late phase product to commercialization? What are the challenges that we are currently facing? What is required from a Quality and Regulatory perspective?**  
9:20 (35 min) U.S.& E.U.: Chris Watts, Principal, Volpal  
9:55 (25 min) Japan: Kazuo Sakamoto, Director, Pharmaceutical Group, Bioscience Division, AGC
- 10:20 **Coffee Break (15 min)**
- 10:35 **Strategies to Optimize Time to Submission and Prepare for Successful BLA/MAA (25 min)**  
Speaker: Sue Behrens, Principal, SB Executive Consulting, LLC & Sr. Director, Process Design at IPS
- 11:00 **A Regulator's Perspective on Commercializing Your Biotech Product (25min)**  
Speaker: Kirsten Vadheim, President, BioCompliance Consultant Inc.
- 11:25 **Moderated Speakers' Roundtable Discussion (60min)**  
Session Moderator: Patti Seymour & morning session speakers
- ~12:30 **Lunch Buffet and Networking (60min)**



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**AFTERNOON SESSION: WHAT'S TRENDING FOR THE DEVELOPMENT AND MANUFACTURE OF THE BIOLOGICS? (WHAT DOES THE MARKET LOOK LIKE? WHAT'S IN THE PRODUCT PIPELINE? WHAT TECHNOLOGIES ARE BEING USED? HOW DO YOU FAST-TRACK YOUR CLIENT'S PRODUCT TO THE MARKET?)**

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- 1:30 Introduction to the Afternoon Session (5min)**  
Patti Seymour, Senior Consultant, BioProcess Technology Consultants, Inc. (BPTC), *CMO Summit Chair*
- 1:35 Get Ready for Biopharmaceutical Process Characterization(25min)**  
Speaker: Patti Seymour, Senior Consultant, BPTC, Inc.
- 2:00 Practical Considerations for Analytical Requirements to go from Late Phase to Commercialized Product (25 min)**  
Speaker: Lauren Little, Quality Services, Principal Consultant
- 2:25  Continuous Processing Optimization with Smarter Tools (25min)**  
Speaker: Michael Benning, BioProcessing Division, Thermo Fisher Scientific
- 2:50 Afternoon Break (15min)**
- 3:05 Accelerating the Biotech Value Chain by Implementing High Through-Put Technologies (25min)**  
Speaker: John Moscariello, Vice President of Process Development, CMC Biologics, Seattle
- 3:30 Life Cycle Management for Your Biologics Product (25min)**  
Speaker: Gary Camlin, Senior Consultant, RMC Pharmaceutical Solutions, Inc.
- 3:55 Cell Therapy Overview and Update (25min)**  
Mark Backer, PhD, General Manager, Alava Biopharm Partners LLC
- 4:20 Moderated Speakers' Roundtable Discussion (60min)**  
**Session Moderator:** Patti Seymour & afternoon session speakers
- 5:20 Wrap-Ups by: (10min)**  
Patti Seymour, Senior Consultant, BioProcess Technology Consultants, Inc. (BPTC), *CMO Summit Chair*  
Gustavo Mahler, PhD., President & CEO, CMC Biologics
- 5:30 Close of Program**  
**Shuttle to Evening Event**
- 6:00-10:00 Museum Tour & Dinner:**  
**Chihuly Garden & Glass Museum**  
305 Harrison St.  
Seattle, WA 98109  
(206) 753-4940



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**THURSDAY, 14 SEPTEMBER – CMC SITE TOUR / WINERY TOUR/ LUNCHEON**

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- 6:30 – 7:30**     **Buffet Breakfast at Hotel**  
**BE NOTE THAT CHECK OUT TIME is at NOON**  
Luggage may be stored at Concierge or on Shuttle Bus for direct departures
- 7:30**             **Shuttle to CMC Biologics, Bothell Office**  
**22021 20<sup>th</sup> Avenue SE**  
**Bothell WA 98021**
- 8:30**             **CMC Overview/ Site Tour**  
Intro: Patricio Massera, COO, CMC Biologics  
PD Tour: Mark Rice & Team  
Manufacturing Tour Lead: Matt Selley & Team
- Coffee Break for groups not on tour
- 11:30**           **Shuttle to DeLille Winery**  
**14208 Woodinville-Redmond Rd NE**  
**Redmond WA 98052**
- 12:00**           **Wine Tasting in Gardens & Buffet Lunch**
- ~14:00**           **Closing remarks by Gustavo Mahler/ Bob Broeze**
- ~14:30**           **Shuttle bus back to Pan Pacific Hotel or Airport or other**