



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

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

- 17:00— **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*)

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

- 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 (15min)**
Mr. Kurata-san, to be confirmed, Chairman of the Board, Life Science General Division, AGC
- 8:40 **Biologics Trends and CDMO Market Overview (25min)**
Speaker: Eric Langer, President & Managing Partner, BioPlan Associates, Inc.

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

- 9:05 **Introduction to the Morning Session (10m)**
Patti Seymour, Senior Consultant, BioProcess Technology Consultants, Inc. (BPTC), *CMO Summit Chair*
- 9:15 **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?**
9:15 (25 min) U.S.: Chris Watts, Principal, Volpal
9:40 (25 min) E.U.: To be confirmed
10:05 (25 min) Japan: Kazuo Sakamoto, Director, Pharmaceutical Group, Bioscience Division, AGC
- 10:30 **Coffee Break (15 min)**
- 10:55 **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
- 11:10 **A Regulator's Perspective on Commercializing Your Biotech Product (25min)**
Speaker: Kirsten Vadheim, President, BioCompliance Consultant Inc.
- 11:35 **Moderated Speakers' Roundtable Discussion (45min)**
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?)

- 1:30** **Introduction to the Afternoon Session (5min)**
Patti Seymour, Senior Consultant, BioProcess Technology Consultants, Inc. (BPTC), *CMO Summit Chair*
- 1:35** **How Do You Design your Process for a Process Characterization Study?**
Patti Seymour, Senior Consultant, BPTC, Inc.
- 2:00** **Practical Considerations for Analytical Requirements to go from Late Phase to Commercialized Product**
Speaker: Lauren Little, Quality Services, Principal Consultant
- 2:25** **A Pharmaceutical Company's Perspective on Commercializing a Late-phase Product (25min)**
Speaker: Michael Rooney, Senior Director of Bioanalytical Development, Jazz Pharmaceuticals
- 2:50** **Life Cycle Management for Your Biologics Product (25min)**
Speaker: Gary Camlin, Senior Consultant, RMC Pharmaceutical Solutions, Inc.
- 3:15** **Afternoon Break (15min)**
- 3:30** **Thermo Fisher Scientific Continuous Processing Optimization with Smarter Tools (25min)**
Speaker: Michael Benning, BioProcessing Division, Thermo Fisher Scientific
- 3:55** **Accelerating the Biotech Value Chain by Implementing High Through-Put Technologies (25min)**
Speaker: John Moscariello, Vice President of Process Development, CMC Biologics, Seattle
- 4:20** **Cell Therapy Overview/Update**
Speaker: (to be confirmed)
- 4:45** **Moderated Speakers' Roundtable Discussion (45min)**
Session Moderator: Patti Seymour & afternoon session speakers
- 5:30** **Wrap-Ups by: (10min)**
Patti Seymour, Senior Consultant, BioProcess Technology Consultants, Inc. (BPTC), *CMO Summit Chair*
Gustavo Mahler, PhD., President & CEO, CMC Biologics
- 5:40** **Close of Program – Shuttle to Evening Event**



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6:00 - 10:00 **Museum Tour & Dinner:**
Chihuly Garden & Glass Museum
305 Harrison St.
Seattle, WA 98109
(206) 753-4940

THURSDAY, 14 SEPTEMBER – CMC SITE TOUR / WINERY TOUR/ LUNCH

7:00 – 8:30 **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

8:30 **Shuttle to CMC Biologics, Bothell Office**
22021 20th Avenue SE
Bothell WA 98021

9:15 **CMC Overview/ Site Tour**
PD Tour Lead: Matt Selley
Manufacturing Tour Lead: Mark Rice

Coffee Break for groups not on tour

11:00 **Shuttle to DeLille Winery**
14208 Woodinville-Redmond Rd NE
Redmond WA 98052

11:30 **Wine Tasting in Gardens & Buffet Lunch**

~14:00 **Closing remarks by Gustavo Mahler/ Bob Broeze**

~14:30 **Shuttle back to Pan Pacific Hotel or Airport**