

THE WATERSIDE CONFERENCE™ : VIRTUAL

CRITICAL CAPABILITIES FOR BIOLOGIC PRODUCTION

NOVEMBER 16–18, 2020

Cell Banking & Characterization

Chaired By:

Fang Tian, PhD

American Type Culture Collection (ATCC)

Linda Fröderberg Roth, PhD

AstraZeneca R&D

Jean Qiu, PhD

Nexcelom Bioscience LLC

Contaminant Control

Chaired By:

Raymond Nims, PhD

RMC Pharmaceutical Solutions, Inc.

S. Steve Zhou, PhD

Microbac Laboratories, Inc.

Raw Materials Science & Control

Chaired By:

Lisa M. Dixon, DVM

USDA APHIS

Aaron C. Mack

Biogen

Ron Kelly, PharmD, PhD

Amgen Inc.

Gaurav Chauhan

Merck & Co., Inc.

Stefan Yohe, PhD

Genentech, a Member of the Roche Group

MONDAY • NOVEMBER 16, 2020

9:00 am – 9:20 am

Overview / Intro

9:20 am – 9:30 am

Break

Cell Banking & Characterization

Contaminant Control

Raw Materials Science & Control

9:30 am – 10:10 am

Quality Control in Large Induced Pluripotent Stem Cell Biobanks
Glyn N. Stacey
International Stem Cell Banking Initiative (ISCB)

Characterization and Safety Testing Considerations for Viral Vectors
Marian L. McKee, PhD
Eurofins Lancaster Laboratories, Inc.

Animal Byproducts and the Import of Kits and Reagents for Human Testing (Including COVID-19 Testing)
David J. Pasnik, PhD
USDA APHIS

10:10 am – 10:20 am

Break

10:20 am – 11:00 am

Biobanking — from Primary Cells to Clinical Trial Samples
Karin Gedda
AstraZeneca AB

Updates on Using NGS for Adventitious Virus Detection in Biologics
Arifa S. Khan, PhD
FDA CBER

Application of Data Analytics to Enhance Raw Material Understanding and Control — Framework, Progress, and Lessons Learned
Ting Wang, PhD
Amgen Inc.

All of the presentations shown in the program are included with your registration fee. Times are Eastern Standard Time (EST).

The Waterside Conference (continued): MONDAY • NOVEMBER 16, 2020

11:00 am – 11:10 am	Break		
11:10 am – 11:40 am	Technology Workshop		
11:40 am – 12:30 pm	Lunch		
12:30 pm – 1:10 pm	<i>Enhancing Cryopreservation Outcome through Molecular and Device-Based Strategies</i> John M. Baust, PhD CPSI Biotech	<i>SARS-CoV-2 Comparison to Other Viruses on the WHO List</i> Raymond Nims, PhD RMC Pharmaceutical Solutions, Inc.	<i>Data Management Initiative for a Better Perspective on Cell Culture Raw Materials</i> Harika Vemula, PhD Thermo Fisher Scientific
1:10 pm – 1:20 pm	Break		
1:20 pm – 2:20 pm	Daily Recap and Program Chair Synopsis	Panel Discussion: <i>Impact of SARS-CoV-2 on Jobs and Careers</i>	Daily Recap and Program Chair Synopsis

TUESDAY • NOVEMBER 17, 2020

9:00 am – 9:20 am	Overview / Intro		
9:20 am – 9:30 am	Break		
	Cell Banking & Characterization	Contaminant Control	Raw Materials Science & Control
9:30 am – 10:10 am	<i>Bioresource Center Biobanking</i> Alissa M. Resch, PhD Coriell Institute for Medical Research	<i>Ingredients of Animal Origin: What is Expected to Ensure Purity for Use in Biologics</i> Geetha B. Srinivas, DVM, PhD USDA APHIS	<i>Zero Defect: A Continuous Improvement Journey</i> Snehal Parikh Genentech, a Member of the Roche Group
10:10 am – 10:20 am	Break		
10:20 am – 11:00 am	<i>Ice-Free Cryopreservation of Large Tissue Samples with Retention of Cell Viability and Biomechanics Functions</i> Kelvin G.M. Brockbank, PhD Tissue Testing Technologies LLC	<i>Application of Rapid Molecular Methods for Monitoring Manufacturing Cell Culture Processes</i> Michael Brewer Thermo Fisher Scientific	Nathaniel Golden bluebird bio Inc.
11:00 am – 11:10 am	Break		
11:10 am – 11:40 am	Technology Workshop		
11:40 am – 12:30 pm	Lunch		
12:30 pm – 1:10 pm	<i>Enhancing Product Quality Through CHO Cell Engineering</i> Nathan E. Lewis, PhD University of California, San Diego	<i>Assay Development to Assay Validation: A Contract Testing Organization Perspective</i> Afshin Sohrabi, PhD MilliporeSigma BioReliance® Services	<i>Enhancing the Visible Particle Control Strategy through Raw Material Understanding and Controls</i> Stefan Yohe, PhD Genentech, a Member of the Roche Group
1:10 pm – 1:20 pm	Break		
1:20 pm – 2:00 pm	<i>Minimizing DMSO for the Cryopreservation of Induced Pluripotent Stem Cells</i> Xiaoming “Shawn” He, PhD University of Maryland	<i>Crouching T1, Hidden DE3 — How Lysogeny, Pseudolysogeny, and Hibernation May Camouflage Phages in the Process</i> Marcin Łoś, PhD, DSc Phage Consultants	<i>Raw Materials: Considerations of Risk (from Development to Commercial) and Forays Into the Digital Revolution</i> Ewelina Flamm Merck & Co., Inc.

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The Waterside Conference (continued): TUESDAY • NOVEMBER 17, 2020

2:00 pm – 2:10 pm

Break

2:10 pm – 3:10 pm

Daily Recap and Program Chair Synopsis

Panel Discussion:
New List of Viruses of Concern, and Their Impact on Non-CFR Testing

Daily Recap and Program Chair Synopsis

WEDNESDAY • NOVEMBER 18, 2020

9:00 am – 9:20 am

Overview / Intro

9:20 am – 9:30 am

Break

Cell Banking & Characterization

Contaminant Control

Raw Materials Science & Control

9:30 am – 10:10 am

Characterization of Human Pluripotent Stem Cells: Standards vs. Practices
Tenneille Ludwig, PhD
WiCell Research Institute

Understanding and Controlling TSE Risk: The Value of TSE Clearance Studies
Andy Bailey, PhD
Virusure GmbH

Rapid Identification of Raw Materials for Release in GMP Manufacturing
Christine Elizabeth Coffman
Biogen

10:10 am – 10:20 am

Break

10:20 am – 11:00 am

Biobanking During the COVID-19 Pandemic
Jim Vaught, PhD
Biopreservation and Biobanking

Release of Gene-Modified Cellular Products — Ensuring Safety and Quality
Philip J. Cross
Philip J. Cross & Associates, Inc.

So You Want to Import an Organism or Vector? The In's and Out's
Troy Bigelow, DVM
USDA APHIS

11:00 am – 11:10 am

Break

11:10 am – 11:40 am

Technology Workshop

11:40 am – 12:30 pm

Lunch

12:30 pm – 1:10 pm

Imposter Cell Lines — A Continuing Threat to the Validity of Biomedical Research
Christopher Korch, PhD
University of Colorado School of Medicine

Antonio J. Scatena
Gateway Analytical LLC

Implementation of Handheld Raman Spectroscopy for Raw Materials
Stephanie Moore, PhD
Amgen Inc.

1:10 pm – 1:20 pm

Break

1:20 pm – 2:00 pm

Magic on Ice: Next-Generation DMSO-Free Biopreservation
Xiaoxi Wei, PhD
X-Therma Inc.

Beyond LAL: The Monocyte Activation Test and Non-Endotoxin Pyrogens
Allen L. Burgenson, PhD
Lonza Walkersville, Inc.

Controlling Raw Material Variability in Cell Culture Media
Chandana Sharma, PhD
FUJIFILM Irvine Scientific, Inc.

2:00 pm – 2:10 pm

Break

2:10 pm – 3:10 pm

Daily Recap and Program Chair Synopsis

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Due to circumstances beyond the control of meeting organizers, this program is subject to change without notice. REV 09/29/2020