

CRITICAL CAPABILITIES FOR BIOLOGIC PRODUCTION
VIRTUAL EDITION
AUGUST 9–11, 2021

Contaminant Control

Chaired By:
Raymond Nims, PhD
RMC Pharmaceutical Solutions, Inc.
S. Steve Zhou, PhD
Microbac Laboratories, Inc.

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

Raw Materials Science & Control

Chaired By:
Lisa M. Dixon, DVM
USDA APHIS
Ron Kelly, PharmD, PhD
Amgen Inc.
Gaurav Chauhan
Merck & Co., Inc.
Aaron C. Mack
Biogen

MONDAY - AUGUST 9, 2021

9:00 am – 9:15 am	Intro/Overview		
9:15 am – 9:30 am	Break		
	Contaminant Control	Cell Banking & Characterization	Raw Materials Science & Control
9:30 am – 10:10 am	<i>Updates on Using NGS for Adventitious Virus Detection in Biologics</i> Arifa S. Khan, PhD FDA CBER	<i>Biobanking — from Primary Cells to Clinical Trial Samples</i> Karin Gedda AstraZeneca AB	<i>Structuring your Raw Material Shortages Risks for Understanding and Control</i> Mark F. Witcher, PhD Exyte
10:10 am – 10:25 am	Break		
10:25 am – 11:05 am	<i>Ensuring That APHIS Licensed Equine Plasma or Serum Veterinary Biologic Products are Negative for Equine Parvovirus-Hepatitis</i> Amy F. Gill, DVM, PhD USDA APHIS	<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>Rapid Identification of Raw Materials for Release in GMP Manufacturing</i> Christine Elizabeth Coffman Biogen

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

11:05 am – 11:20 am	Break		
11:20 am – 11:50 am	Technology Workshop <i>Controlling Raw Material Variability in Cell Culture Media</i> FUJIFILM Irvine Scientific, Inc.		
11:50 am – 12:40 pm	Lunch		
	Contaminant Control	Cell Banking & Characterization	Raw Materials Science & Control
12:40 pm – 1:20 pm	<i>Evaluation of the Survivability of SARS-CoV-2 on Cardboard and Plastic Surfaces and the Transferability of Virus from Surface to Skin</i> Giffe Johnson, PhD National Council for Air and Stream Improvement, Inc.	<i>Next-Generation DMSO-Free & Serum-Free Cryopreservation for Cell Therapy Manufacturing and Processing</i> Xiaoxi Wei, PhD X-Therma Inc.	<i>Implementation of Raman Spectroscopy for Identification of Raw Materials Used in Biopharmaceutical Manufacturing</i> Robert Soto, PhD Amgen Inc.
1:20 pm – 1:35 pm	Break		
1:35 pm – 2:15 pm	<i>Viral Quantification in Wastewater-Based Epidemiology for Covid-19 Surveillance</i> Aaron D. Peacock, PhD Microbac Laboratories, Inc.	<i>Sand-Based Serum-Free, Low-Cryoprotectant Cryopreservation of Human-Induced Pluripotent Stem Cells</i> Xiaoming He, PhD University of Maryland	<i>Zero Defect: A Continuous Improvement Journey</i> Snehal Parikh Genentech, a Member of the Roche Group

TUESDAY • AUGUST 10, 2021

9:00 am – 9:15 am	Intro/Overview		
9:15 am – 9:30 am	Break		
	Contaminant Control	Cell Banking & Characterization	Raw Materials Science & Control
9:30 am – 10:10 am	<i>Understanding and Controlling TSE Risk: The Value of TSE Clearance Studies</i> Andy Bailey, PhD ViruSure GmbH	<i>Quality Control Challenges for Large Pluripotent Stem Cell Biobanks</i> Glyn N. Stacey International Stem Cell Banking Initiative	<i>Animal Byproducts and the Import of Kits and Reagents for Human Testing (Including COVID-19 Testing)</i> David J. Pasnik, DVM USDA APHIS
10:10 am – 10:25 am	Break		
10:25 am – 11:05 am	<i>Crouching T1, Hidden DE3 — How Lysogeny, Pseudolysogeny, and Hibernation May Camouflage Phages in the Process</i> Marcin Łoś, PhD, DSc Phage Consultants	<i>Enhancing Cryopreservation Outcome through Molecular and Device-Based Strategies</i> John M. Baust, PhD CPSI Biotech	<i>Raw Materials: Considerations of Risk (from Development to Commercial) and Forays Into the Digital Age</i> Ewelina Flamm Merck & Co., Inc.
11:05 am – 11:20 am	Break		
11:20 am – 12:00 noon	<i>Container Closure Integrity Testing Using Laser-Based Gas Headspace Analysis for Biologic Products</i> Tom Millner Lighthouse Instruments	<i>Biobanking During the COVID-19 Pandemic</i> Jim Vaught, PhD Biopreservation and Biobanking	<i>Raw Material Characterization: A Phased-Based Approach to Quality by Design</i> Nathaniel Golden bluebird bio Inc.
12:00 noon – 12:50 pm	Lunch		

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	Contaminant Control	Cell Banking & Characterization	Raw Materials Science & Control
12:50 pm – 1:30 pm	<p><i>Characterization and Safety Testing Considerations for Viral Vectors</i> Marian L. McKee, PhD Eurofins BioPharma Product Testing</p>	<p><i>Imposter Cell Lines — A Continuing Threat to the Validity of Biomedical Research</i> Christopher Korch, PhD University of Colorado School of Medicine</p>	<p><i>Application of Data Analytics to Enhance Raw Material Understanding and Control — Framework, Progress, and Lessons Learned</i> Ting Wang, PhD Amgen Inc.</p>

WEDNESDAY • AUGUST 11, 2021

9:30 am – 10:00 am	Intro/Overview		
10:00 am – 10:15 am	Break		
	Contaminant Control	Cell Banking & Characterization	Raw Materials Science & Control
10:15 am – 10:55 am	<p><i>A Novel Particulate Database for Foreign Particulate Matter Investigations</i> Antonio J. Scatena Gateway Analytical, an Aptar Pharma company</p>	<p><i>Developing Novel Viral Production Cell Lines — From Characterization to Cell Banking</i> Fang Tian, PhD American Type Culture Collection (ATCC)</p>	<p><i>Data Management Initiative for a Better Perspective on Cell Culture Raw Materials</i> Harika Vemula, PhD Thermo Fisher Scientific</p>
10:55 am – 11:10 am	Break		
11:10 am – 11:50 am	<p><i>Application of Rapid Molecular Methods for Monitoring Manufacturing Cell Culture Processes</i> Michael Brewer Thermo Fisher Scientific</p>	<p><i>Enhancing Product Quality Through CHO Cell Engineering</i> Nathan E. Lewis, PhD University of California, San Diego</p>	<p><i>Enhancing the Visible Particle Control Strategy through Raw Material Understanding and Controls</i> Stefan Yohe, PhD Genentech, a Member of the Roche Group</p>
11:50 am – 12:40 pm	Lunch		
12:40 pm – 1:20 pm	<p><i>A Rapid Multiplex Degenerate PCR Approach for Detection of Adventitious Viruses in Raw Materials</i> Afshin Sohrabi, PhD MilliporeSigma BioReliance® Services</p>	<p><i>Characterization of Human Pluripotent Stem Cells: Standards vs. Practices</i> Tenneille Ludwig, PhD WiCell Research Institute</p>	<p><i>So You Want to Import an Organism or Vector? The In's and Out's</i> Troy T. Bigelow, DVM USDA APHIS</p>
1:20 pm – 1:35 pm	Break		
1:35 pm – 2:35 pm	Roundtable	Roundtable	Roundtable

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Due to circumstances beyond the control of meeting organizers, this program is subject to change without notice.