

MBI 406: BIOMANUFACTURING

TEAM-BMTD

Schedule Fall: 2020 9:40 – 10:55 AM

Registration: tracy_pezzimenti@urmc.rochester.edu

Instructor and information: luisa_caetanodavies@urmc.rochester.edu

Date	Classroom	Section	Topic	Presenter
Aug 27 (Thu)		Intro to Biomanufacturing and Good Manufacturing Practices (GMP)	What is Biomanufacturing and GMP?	Luisa Davies Executive Director UR-CTMF
Sep 1 (Tues)		The Real world: Cell-based therapies for clinical trials	GMP manufacturing of cell and gene therapy products for clinical trials and beyond (Part 1)	Gerhard Bauer Director UC Davis Institute for Regenerative Cures
Sep 3 (Thu)		The Real world: Cell-based therapies for clinical trials	GMP manufacturing of cell and gene therapy products for clinical trials and beyond (Part 2)	Gerhard Bauer Director UC Davis Institute for Regenerative Cures
Sep 8 (Tues)		UR-CMTF GMP lab	Intro to USCGF Facility, Qualification concepts, facility design and flow, environmental control, Batch records, Compounding records, In-process tests, QC Release testing	Luisa Davies Executive Director UR-CTMF
Sep 10 (Thu)		UR-CMTF GMP tour	GMP Facility tour; Learning proper gown in procedures and gowning SOP writing practice	
Sep 15 (Tues)	"	Drug and Cell-based Therapies Overview	Bringing Bench science to the bedside	Steve Dewhurst Vice Dean for research, URMC
Sep 17 (Tues)	"	Drug Discovery	The use of Next Generation Sequencing in Drug Discovery	Bryan Vought Principal Scientist Alkermes
Sep 22 (Thu)		GMP Quality Management System	Intro to quality system elements (document control, change control, CAPA, supplier qualification, raw materials management, product release, auditing, personnel training)	Carrie Bowman Assistant Director, Quality UR-CTMF
Sep 24 (Thu)		The Real world: Cancer Immunotherapy	Connecting the dots: Practical considerations for early stage clinical evaluation of an advanced cell therapy	James Clements Director of Project Management Athenex

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Sep 29 (Tues)		The Real world: Cancer Immunotherapy	Clinical manufacturing of T cells for adoptive therapy for cancer and others	Jin Moonsoo Co-founder and inventor of the technology Afflymune Therapeutics, Inc
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Oct 1 (Thu)		Industry Job Interviews	How to Interview for Jobs in the Industry?	Paul Dunman Associate Professor URMC
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Oct 6 (Tues)		Intro to Upstream Process	Fermentation, cell culture, bioreactors, process control	Charles Rutter Senior Scientist BTEC at NC State University
Oct 8 (Thu)			Process development, scale-up, process validation	

Fall Break				
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Oct 20 (Tue)		Intro to Downstream Process	Downstream Process Development of Monoclonal Antibodies (Part 1)	Brian O'Mara Associate Director of Downstream Process Development Ambrex, Inc
Oct 22 (Tue)			Downstream Process Development of Monoclonal Antibodies (Part 2)	

Oct 27 (Tue)		Cell Therapy Clinical Trials	Considerations for manufacturing antigen-specific T cells in phase 1 clinical trials	Pat Hanley Director, GMP for Immunotherapy and Assistant Prof. Children's National & GWU
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Oct 29 (Thu)		Disease Modeling	Stem cell-based organoids for disease modeling and therapy	Ben Cosgrove Assistant Professor Biomedical Engineering Cornell University
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Nov 3 (Tue)		Class Presentation	Current Topics in Biomanufacturing/Case Studies	Luisa Davies Executive Director UR-CTMF
Nov 5 (Thu)				
Nov 10 (Tue)				
Nov 12 (Thu)				
Nov 17 (Tue)				
Nov 19 (Thu)				

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Thanksgiving recess

Dec 1 (Tues)		Revisions	Gowning SOP revision	<i>Luisa Davies</i> Executive Director UR-CTMF
Dec 3 (Thu)		Revisions	Review on topics learnt	
Dec 8 (Tues)		Revisions	Review on topics learnt	
Dec 15-17	E-mail	Final evaluation	Delivery of a 2-page review paper	