

MBI 406: BIOMANUFACTURING

TEAM-BMTD

Classroom: TBD

Schedule Fall: 2019 9:40 – 10:55 AM

Registration: tracy_pezzimenti@urmc.rochester.edu

Instructor and information: luisa_caetanodavies@urmc.rochester.edu

TEAM-BMTD Course Director: Tracey_Baas@URMC.Rochester.edu

Date	Lecture #	Section	Topic	Presenter
Aug 29 (Thu)	1	Intro to Biomanufacturing and Good Manufacturing Practices (GMP)	What is Biomanufacturing and GMP?	Luisa Davies, PhD Director of the Upstate Stem Cell cGMP facility (USCGF)
Sep 3 (Tues)	2	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 of the Good Manufacturing Practice (GMP) laboratory at UC Davis Institute for Regenerative Cures
Sep 5 (Thu)	3	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 10 (Tues)	4	USCGF 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, PhD Director, USCGF
Sep 12 (Thu)	5	USCGF GMP tour	GMP Facility tour; Learning proper gown in procedures and gowning SOP writing practice	Luisa Davies, PhD Director, USCGF
Sep 17 (Tues)	6	Stem Cell Introduction	ESC and iPSC-based cell therapy in regenerative medicine	Luisa Davies, PhD Director, USCGF
Sep 19 (Thu)	7	Drug and Cell-based Therapies Overview	Bringing Bench science to the bedside	Steve Dewhurst, PhD Vice Dean for research, University of Rochester Medical Center (URMC)
Sep 24 (Tues)	8	Clinical development of a Therapeutic Monoclonal Antibody	Clinical Development of a Passive Immunization for MRSA Infection of Total Joint Replacements	Edward Schwarz, PhD Co-Founder and Chief Science Advisor Telephus Biosciences
Sep 26 (Thu)	9	GMP Quality Management System	Intro to quality system elements (document control, change control, CAPA, supplier qualification, raw materials management, product release, auditing, personnel training)	Sharyl Zaccaglino, MSc Director, Quality & Compliance URMC
Oct 1 (Tues)	10	The Real World: Vaccine Development	Live attenuated influenza vaccines	Luis Martinez-Sobrido Associate Professor URMC
Oct 3 (Thu)	11	Manufacturing and Bioprocess Engineering	Aspects of Bioprocess Engineering (downstream processing)	Jason Condon, MSc Senior Project Manager Vaccinex
Oct 8 (Tues)	12	Intro to Upstream Process	Fermentation, cell culture, bioreactors, process control	Charles Rutter Senior Scientist BTEC at NC State University

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Oct 10 (Thu)	13	Intro to Upstream Process	Process development, scale-up, process validation	Charles Rutter BTEC
Fall Break				
Oct 22 (Tue)	14	Disease Modeling	Stem cell-based organoids for disease modeling and therapy	Ben Cosgrove, PhD Biomedical Engineering Cornell University
Oct 24 (Thu)	15	Disease Modeling	In vitro disease modeling of neuropsychological diseases	Bryan Vought Principal Research Scientist Alkermes
Oct 29 (Tue)	16	The Real world: Cancer Immunotherapy	Deep™ IL-15 Primed multi-targeted T cells demonstrate potent antigen-specific cytotoxic activity against human cancer cells	Eden Fucci Vice-President of Biologics Manufacturing Torque Therapeutics
Oct 31 (Thu)	17	The Real world: Cancer Immunotherapy	Tethering IL-12 to the surface of T cells induces broad immune activation and potent anti-tumor activity in mice without inducing systemic toxicities	Eden Fucci Vice-President of Biologics Manufacturing Torque Therapeutics
Nov 5 (Tue)	18	The Real world: Cancer Immunotherapy	Discovery, development and commercialization of novel therapies for the treatment of cancer	James Clements Director of Project Management Athenex
Nov 7 (Thu)	19	The Real world: Cell therapy, Engineering and Automation	TBD	Fabio Fachin Head, Cell therapy and Automation Takeda
Nov 12 (Tue)	20	Class Presentation	Current Topics in Biomanufacturing/Case Studies	
Nov 14 (Tue)	21			
Nov 19 (Thu)	22			
Nov 21 (Thu)	23			
Thanksgiving recess				
Dec 3 (Tues)	24	Revisions	Gowning SOP revision	Luisa Davies, PhD USCGF
Dec 05 (Thu)	25	Revisions	Review on topics learnt	Luisa Davies, PhD USCGF
Dec 9 (Tues)	26	Revisions	Review on topics learnt	Luisa Davies, PhD USCGF
Dec 11 (Tues)	27	Final evaluation	Delivery of a 2-page review paper	Luisa Davies, PhD USCGF