

## TXCL 5545 - An Introduction to Regulatory Affairs

<b>Day</b>	<b>Lecture</b>	<b>Category</b>	<b>Topic</b>	<b>Speaker</b>
Tuesday	1	Overview	An Overview of Course, Grading, Drugs, Devices, Biologics, and Food	Mike Murphy & Betsy Wattenberg
Tuesday	2	Overview	The Importance of Patents in Medical Product Development	Jim Ciapetta, Patent Counsel, Boston Scientific
Wednesday	1	Overview	FDA Organization & 483 Letters	Tim Phillips: FDA Compliance Officer, Minneapolis, MN
Wednesday	2	Overview	FDA Organization & 483 Letters	Tim Phillips: FDA Compliance Officer, Minneapolis, MN
Thursday	1	Overview	IACUC & IRB	Dick Bianco; Director of Regulatory Affairs University of Minnesota
Thursday	2	Overview	IDE's, IND's GLP audits	Dick Bianco; Director of Regulatory Affairs University of Minnesota
Friday	1	Consumer Products	Federal Hazardous Substances Act/Consumer Product Safety Commission	Cathrine Jacobson, 3M Corporate Toxicology
Friday	2	Consumer Products	Proposition 65	Cathrine Jacobson, 3M Corporate Toxicology
Monday	1	Biologic	Animal Biologics	Dr. Gustafson, Ft. Dodge Animal Health
Monday	2	Drugs	The Impact of Genomics on Drug Development and Marketing	Jonathon Kahn, Hamline University School of Law
Tuesday	1	Device	Combination Products: Drug Eluting Stents	Mike Duvall, Senior Research Toxicologist, Abbott Labs
Tuesday	2	Device	Combination Products: Drug Eluting Stents	Mike Duvall, Senior Research Toxicologist, Abbott Labs
Wednesday	1	Drugs	Human Drug Development: Preclinical Considerations	Herve Lebrech, Manager 3M Pharmaceuticals
Wednesday	2	Drugs	Developmental and Reproductive Toxicology	Elaine Daniels, Research Specialist, 3M Pharmaceuticals
Thursday	1	Drugs	Food Animal Drug Development	Scott Brown, Director, Metabolism & Safety, Pfizer Animal Health
Thursday	2	Drugs	Food Animal Drug Development	Scott Brown, Director, Metabolism & Safety, Pfizer Animal Health
Friday	1	Drugs	Neutraceuticals	Joy Frestedt, Research Director, Minnesota Applied Research Center
Friday	2	All Medical Products	Post market surveillance	Joy Frestedt, Research Director, Minnesota Applied Research Center