

## MCTM 5361 : Idea to Clinic I: Pre-clinical

This course will cover: 1) Financing strategies for basic and translational research in academe and the start-up companies (biotech models). 2) Financial dynamics of research (indirect costs, "subsidies", matching funds). 3) Intellectual property management at the academic-industry interface: Bayh-Dole, IP revenue cycle, the strategic chokepoints. 4) Differentials between research and medical product development. 5) Preparing for regulatory admission to clinical trials; current Good Manufacturing Practices (cGMP) and Good Laboratory Practices (GLP) en route to submission of Investigational New Drug (IND) and Investigational Device Exemption (IDE) for Premarket Approval (PMA). 6) Special regulatory classes: Cell therapy; Nanomedicine; Biomaterials. 7) Funding strategies to cross the preclinical Valley of Death.

**Credits** 3

**Course ID**

008046