



Clinical Pharmacology in Drug Development	<ul style="list-style-type: none"> Discovery of a Drug candidate: Evaluating its Safety, Efficacy, and Manufacturability 	<ul style="list-style-type: none"> Pharmacokinetics (PK) and Pharmacodynamics (PD) models & simulations. Biomarkers and Endpoints Toxicology Studies 	<ul style="list-style-type: none"> Evaluation of Drug Candidate: DMPK (Drug Metabolism & Pharmacokinetics), PD (Pharmacodynamic Studies) 	<ul style="list-style-type: none"> Regulatory Compliance Statements. Assessment of Risk/Benefits: Regulatory decision-making, Real-World Data. 	<ul style="list-style-type: none"> Post-Marketing Surveillance. Pharmacovigilance: monitoring for adverse effects.
Design Thinking for Entrepreneurs	<ul style="list-style-type: none"> Introduction to the Healthcare and Pharmaceutical Industry, Finding Opportunities and Market Segments in Healthcare. 	<ul style="list-style-type: none"> Concept Development, Implementation and Planning. Understanding types of companies / partnerships. Analyzing Financials. 	<ul style="list-style-type: none"> Key business decisions during clinical trials. Filing an Investigational New Drug (IND), Investigational Device Exemption (IDE), New Drug Application (NDA). 	<ul style="list-style-type: none"> Maneuvering Regulatory Landscape. Building social capital. Patenting Life Science Inventions and Intellectual Property due Diligence. 	<ul style="list-style-type: none"> Commercial Activity in each stage of the drug development process. Mergers, Acquisitions and IPO process.
Regulatory Science for Drug Development Scientists	<ul style="list-style-type: none"> The role of a regulatory professional. Differences between US and EU regulatory agencies and impact on companies. 	<ul style="list-style-type: none"> Drug Substance Process Dev.: understand and differentiate the drug substance and drug product, and the regulations for each. 	<ul style="list-style-type: none"> Describe and differentiate the regulatory guidance on setting specifications for Immediate Release and Modified Release Drug Products 	<ul style="list-style-type: none"> Formulation & Process Development: understand the guidance for formulation, process, scale-up, and post approval changes. 	<ul style="list-style-type: none"> Life cycle management: understand the regulatory considerations related to life cycle management of a drug product.
Market Principles and Applications for Pharma Entrepreneurs	<ul style="list-style-type: none"> The Marketing Research Process: from defining problems and research objectives to decision making. 	<ul style="list-style-type: none"> Technology Assessment: Evaluation of early-stage technology and value assessment during the product development process. 	<ul style="list-style-type: none"> Forecast and Modeling with case studies and exercises. Cost analysis and Budget. How to build marketing into product development process. 	<ul style="list-style-type: none"> Conducting market research and simple techniques for gathering information and understanding pharmaceutical data sources (audits). 	<ul style="list-style-type: none"> Assessing the market- size of patient population Competitors, analysis of their strengths and weaknesses.