UNIVERSITY OF THE

PACIFICJie Du Center for Innovation and
Excellence for Drug Development

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	Discovery & Development: Research is conducted in laboratories with the purpose of discovering promising compounds.	Preclinical Research: Basic safety questions for compounds are answered via laboratory and animal testing.	Clinical Research: Compound is tested on humans in clinical trials to ensure its safety and effectiveness.	Government Review: Compound is submitted for government review / approval. A thorough examination of data is conducted.	Post-Market Safety Monitoring: Safety and efficacy of the drug is closely monitored once made available for use by the public.
Clinical Pharmacology in Drug Development	 Discovery of a Drug candidate: Evaluating its Safety, Efficacy, and Manufacturability 	 Pharmacokinetics (PK) and Pharmacodynamics (PD) models & simulations. Biomarkers and Endpoints Toxicology Studies 	 Evaluation of Drug Candidate: DMPK (Drug Metabolism & Pharmacokinetics), PD (Pharmacodynamic Studies) 	 Regulatory Compliance Statements. Assessment of Risk/Benefits: Regulatory decision-making, Real-World Data. 	 Post-Marketing Surveillance. Pharmacovigilance: monitoring for adverse effects.
Design Thinking for Entrepreneurs	 Introduction to the Healthcare and Pharmaceutical Industry, Finding Opportunities and Market Segments in Healthcare. 	 Concept Development, Implementation and Planning. Understanding types of companies / partnerships. Analyzing Financials. 	 Key business decisions during clinical trials. Filing an Investigational New Drug (IND), Investigational Device Exemption (IDE), New Drug Application (NDA). 	 Maneuvering Regulatory Landscape. Building social capital. Patenting Life Science Inventions and Intellectual Property due Diligence. 	 Commercial Activity in each stage of the drug development process. Mergers, Acquisitions and IPO process.
Regulatory Science or Drug Development Scientists	 The role of a regulatory professional. Differences between US and EU regulatory agencies and impact on companies. 	Drug Substance Process Dev.: understand and differentiate the drug substance and drug product, and the regulations for each.	 Describe and differentiate the regulatory guidance on setting specifications for Immediate Release and Modified Release Drug Products 	• Formulation & Process Development: understand the guidance for formulation, process, scale-up, and post approval changes.	Life cycle management: understand the regulatory considerations related to life cycle management of a drug product.
Market Principles and Applications for harma Entrepreneurs	The Marketing Research Process: from defining problems and research objectives to decision making.	Technology Assessment: Evaluation of early-stage technology and value assessment during the product development process.	 Forecast and Modeling with case studies and exercises. Cost analysis and Budget. How to build marketing into product development process. 	 Conducting market research and simple techniques for gathering information and understanding pharmaceutical data sources (audits). 	 Assessing the market- size of patient population Competitors, analysis of their strengths and weaknesses.