

Certificate Program in Pharmaceutical Research & Development

Course Director: Kunwar Shailubhai, Ph.D., MBA.

Description on topics to be covered

- *Week 1: Introduction to pharmaceutical drug discovery and development processes*
 - Types of therapeutics
 - Types of dosing regimen
 - Types of routes of administration
- *Week 2 Biochemical pathways and human diseases*
 - Metabolic dysregulation
 - Immunological dysregulation
 - Genetic mutations
 - Loss or Gain of function
- *Week 3 Identification of a translatable concept*
 - Etiology of disease
 - Deficiency or Overexpression
 - Targeting the causes of disease
- *Week 4 Validation of a product concept in animal studies*
 - Mechanism of action studies
 - Animal studies for POC and safety
- *Week 5 Chemistry, Manufacturing, and Controls (CMC) and druggability*
 - Synthesis, stability, and identification of impurities
 - Pharmacokinetics
 - Drug product formulation
- *Week 6 Safety and Toxicology*
 - IND-enabling safety and toxicology studies in rodents and primates
 - Safety of metabolites of drug substance
 - Specific route of administration
- *Week 7 Phases of clinical development*
 - Phase 1 to phase 3 clinical development
 - post-marketing clinical studies
- *Week 8 Regulatory affairs in pharmaceutical development*
 - Regulatory affairs related to IND submission
 - Alternative approaches for FDA submissions
- *Week 9 Financial planning*
 - Seed money financing
 - Valley of death in financing
 - Venture capitalists
 - Listing on public markets
- *Week 10 Guest lecture (Case study Bench to Market): TBD*
- *Week 11 Guest lecture (Case study Repurposing of drugs) TBD*
- *Week 12 Guest lecture (Case study Nanomedicine): TBD*