# HMX Pro Pharmacology - Drug Discovery and Development

With all the advances in science and with closer collaboration between different scientific disciplines, a multifaceted approach is now being applied to drug discovery and development. Therefore, learning about the process of drug discovery and development has important implications for anyone working in health care and related sectors. This advanced course offers a unique way for professionals to learn from leading Harvard Medical School faculty and industry veterans about how drugs are developed and about the advances happening in this field that are ultimately helping to improve the treatment and prevention of disease. Participants will:

- Learn about project selection and initiation and how the indication and unmet need are identified
- Learn about drug discovery and how this occurs for different drug modalities
- Gain an understanding of the various stages of nonclinical drug development and how the therapeutic profile is established for a new compound with emphasis on drug toxicity
- Get an insight into clinical drug development and how an investigational therapeutic is assessed for safety and efficacy in humans

### **Topics Covered**

## Overview of Drug Discovery and Development

- Introduction to Drug Discovery and Development
- The Promise of Drug Discovery and Development

#### **Project Initiation and Selection**

- Introduction to Drug Research and Development
- Understanding the Disease/Indication Being Targeted
- Understanding the Drug Being Developed
- Understanding the Mechanism of Action of the Drug
- Understanding the Effect of the Drug on the Disease/Indication
- Having a Clear Plan for Drug Development
- Genetics in Drug Discovery

#### **Drug Discovery**

- Pharmacological Principles
- · Biochemical Models and Cell Models
- Disease Models
- · Small Molecules
- Protein Therapeutics
- RNA Therapeutics
- · Clinical Linkage: Cystic Fibrosis

#### **Nonclinical Drug Development**

- · Goals of Nonclinical Drug Development
- · Animal Pharmacology
- Good Laboratory Practice (GLP)
- Toxicology and Safety Pharmacology
- Toxicology Testing
- Genotoxicity, Carcinogenicity, and Reproductive Toxicity
- Early Clinical Studies

#### **Clinical Drug Development**

- Establishing a Causal Pathway
- · Chance and Bias
- Confounding and Effect Modification
- Basic Epidemiologic Considerations
- Surrogate Endpoints
- Fundamentals of Randomized Trial Design
- · Anatomy of a Randomized Trial
- · Clinical Linkage: PCSK9 Inhibitors

#### Wrap-up

• The Future of Drug Discovery and Development

The HMX Pro Series offers a new online learning experience designed to get busy professionals up to speed on the latest advances in medicine. Concepts are taught using whiteboard-style videos and animations and reinforced by interactive elements, true-to life scenarios, and real patient cases to enhance learning.

