IN VITRO DIAGNOSTICS
PRODUCT DEVELOPMENT

Learn the requirements for moving an IVD product — from concept to regulatory approval and market launch.

As biotech and In Vitro Diagnostics (IVD) companies mature, the need for professionals with a broad understanding of the skills required to be effective in a biological product development environment will increase.

APRIL 13–29, 2021
Tuesdays and Thursdays
4PM–7PM PST
Live Online using Zoom Conference Technology

INFORMATION
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TOPICS WILL INCLUDE
• Planning for success by setting product requirements and specifications to meet customer needs
• Resource planning
• Principles of assay development
• Instrumentation
• Role and composition of the product development team
• Risk analysis
• IVD clinical and regulatory issues including compliance and complaint handling
• Specific product development cases will be discussed

“As a VP of Engineering in the Medical Devices industry, the quality of my decisions is enhanced by the extent of my understanding of the Product Development Life Cycle. This course covers the most critical aspects of that process, including requirements engineering, risk analysis, design control and resource planning.”

— Shane Dultz, Ph.D. VP Engineering

REGISTER TODAY
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WHO SHOULD ATTEND
This course is geared towards managers, entrepreneurs, investors and scientists seeking an overview of the regulatory, clinical, scientific and business aspects of In Vitro Diagnostic product development.

SESSION SCHEDULE

SESSION 1 – APRIL 13
• Introduction to the IVD World
• Package Insert – Begin with end in mind
• Product Development Process
• Resource Planning

SESSION 2 – APRIL 15
• Design Control
• Customer Input, PRD
• Product Risk Analysis
• Case Study 1 - DNA Sequencing

SESSION 3 – APRIL 20
• Group Assignment and Breakout
• Business Case (NPV, IRR, Standard Costs)
• Case Study 2 – COVID

SESSION 4 – APRIL 22
• Principles of Assay Development
• Companion Diagnostics

SESSION 5 – APRIL 27
• Group Assignment and Breakout – Companion Diagnostics
• Instrumentation/ Software in IVD

SESSION 6 – APRIL 29
• Design and Conduct of Preclinical and Clinical Trials
• Regulatory Overview
• Exam Review

INSTRUCTORS

Larry Mimms, Ph.D.
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