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. Topics include planning for success by setting product requirements & specifications to meet customer needs, critical path management, resource planning, principles of assay development, instrumentation, role and composition of the product development team, risk analysis, and IVD clinical and regulatory issues including compliance and complaint handling. Specific product development cases will be discussed.

Instructors

Tammy Brach, MBA  
Vice President  
Hologic

Larry Mimms, Ph.D.  
Chief Scientific Officer  
Prometheus Labs

Al Maderazo,  
VP, Quality Assurance and Regulatory Affairs  
GenMark Diagnostics

Damon Getman, Ph.D.  
Director  
Hologic

Valerie Day, MBA  
Consultant  
Prometheus Labs

Course Details

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.

Date & Time
Friday and Saturday, 8am-5pm  
November 3-4, 2017 (2 mtgs.)

Location
Room 316  
UCSD Extension University City Center  
6256 Greenwich Dr., San Diego

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extension.ucsd.edu/ivdworkshop
Workshop Agenda

Day 1:
- Introduction to IVDs
- Drafting of a Package Insert
- Product Development Process
- Product/Customer Requirements
- Design Control
- Risk Analysis and Failure Mode and Effects Analysis (FMEA)

Day 2:
- Principles of assay development
- Instrumentation and software for IVDs - home testing/ physicians' office testing and central labs.
- Preclinical and Clinical Trial design
- Companion Diagnostics
- Case study in Cancer
- IVD Regulatory Issues
- Exam
- Q&A Panel Discussion

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