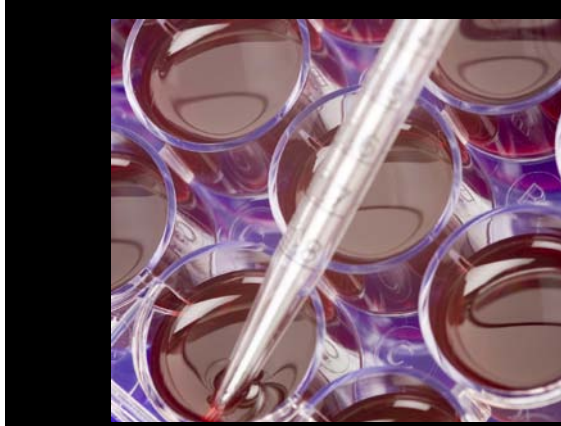


In Vitro Diagnostics Product Development

November 6 & 7, 2009



As San Diego's biotech and In Vitro Diagnostics (IVD) companies mature, the need for professionals with a broad understanding of the multiple skills required to be effective in a biological product development environment blending biological development, with hardware and software innovations will increase. The course will focus on issues in moving an IVD product from concept to regulatory approval and market launch. Although the focus is on IVD product development much of the material is applicable to product development in other areas of biotechnology and pharmaceuticals.

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 in for IVDs – home testing/physicians' office testing and central labs.
- Preclinical and Clinical Trial design
- Case study1: Blood screening
- Case study 2: Cancer
- IVD Regulatory issues
- Exam
- Q&A Panel Discussion

Coarse Goals

- Understand the IVD product development process- beginning to end
- Learn the "language" of IVD
- Think like an IVD product developer

Who Should Attend?

This course provides managers, entrepreneurs, investors and scientists an overview of regulatory, clinical, scientific and business aspects of In Vitro Diagnostic product development.

Course Details

Date & Time

November 6 & 7, 2009
Friday & Saturday, 8:00 a.m. – 5:00 p.m.

Location

Room 106
UC San Diego, Extension – Sorrento Mesa Center
6925 Lusk Blvd., San Diego, CA 92121

Fee

\$395

Instructors

This two day course will be team taught by experienced professionals in the field of IVD product development.

Larry Mimms, Ph.D.

20+ years in IVD Product Development, Strategic Planning and Business Development; Abbott Labs, Gen-Probe, VDX

Valerie Day, M.S., MBA

Abbott, Gen-Probe, Dexcom

Damon Getman, Ph.D.

Gen-Probe, R&D and Product Development

Glen Freiberg, M.A., RAC

Regulatory and Clinical Affairs, B-M, Bard, FDA, Gen-Probe

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