

Molecular Diagnostics Development Course Agenda

Molecular Diagnostics Development is a one-day course that explores how diagnostics are developed, approved and reimbursed. The course introduces concepts such as sensitivity, specificity, false positives, false negatives, and ROC curves, which are used to determine how well the diagnostic performs. Once the strength of a diagnostic is determined participants learn how the diagnostic is evaluated by the FDA and the various pathways to approval a company can pursue. The course ends with a look at how diagnostics are reimbursed once in the marketplace.

Five takeaways:

1. An improved ability to communicate with scientists, regulators and clients
2. Fluency in the essential terminology used in the diagnostics sector
3. Statistics background needed to understand basic diagnostic measurements
4. An understanding of how to interpret diagnostic measurements
5. The ability to predict if a diagnostic would be approved by the FDA based on statistical analysis of sensitivity and specificity results

Course Agenda

Diagnostics' Role in Medicine Today 9:00-10:00

What is a molecular diagnostic?

Uses of diagnostic tests

Types of diagnostic tests

Break 10:00-10:15

Statistical Features of Diagnostics 10:15-11:00

Diagnostic need for gold standard

Measures

Standard curve

Measurement and distribution

Statistical Measures of Tests 11:00-12:00

False positive and false negative

Sensitivity and specificity

True positive

Activity: sensitivity and specificity

Lunch 12:00-1:00

Measuring the Strength of a Test 1:00-1:45

RADAR sensitivity and specificity

Receiver operator curves (ROC curves)

ROC curves reclassification analysis

Risk of Diagnostics Tests 1:45-2:30

Low Prevalence

Mammography

Invasive Procedures

Break 2:30-2:45

Diagnostic Development & Approval 2:45-3:30

Testing Against the Gold Standard

Development of Clinical Tests

Pathways to Approval

Class I

Class II

Class III

How Diagnostic Tests Are Reimbursed 3:30-4:15

Center for Medicare and Medicaid Services (CMS)

Reimbursement in-hospital and out-patient

Methods of economic evaluation

Q&A | Review 4:15-4:30