

## **BD ProbeTec ET System**

### **Semi-Automated Molecular Diagnostic Platform**

#### **Key Goals and Accomplishments**

Company First Molecular Platform  
Competitive Performance – High Sensitivity and Specificity Performance  
World Class Reliability and Confidence in Results  
Compact Instrument  
Simplified Workflow

#### **Approach and Tools**

Business Requirements Analysis & Mapping  
Competitive Benchmarking Research & Analysis  
Concept Selection & Decision Process Facilitation  
Requirements Capture & Documentation  
System Specification Development & Documentation (Database)  
Module Specifications & Requirements Traceability Analysis & Documentation  
Overall Project Planning & Management  
Risk Management & Failure Modes & Effects Analysis  
Test Planning, Protocols, Execution and Reports  
User & Clinical Validations  
Production ( Drawings, Assembly Procedures, DMRs, DHF)

#### **Results and Recognition**

BD ProbeTec™ ET Core Team Award, 2000.  
BD ProbeTec™ ET Individual Superstar Award, 2000.  
Demonstrated on-time project delivery and credibility.  
BD's first molecular diagnostic assays (CT/GC).  
FDA clearance for two new assays 25% below average industry clearance time.  
Displaced market leader within 2-3 years of commercialization.

