



Experience that Matters....

***in vitro* Diagnostic and Laboratory Products**

The staff at Quest Product Development has worked on a number of Class II *in vitro* diagnostic (IVD) products and non-medical laboratory products. These products ranged from point-of-care (POC) systems to the floor model diagnostic and microbiology systems. Critical elements in the design and development process include:



- Understanding the diagnostic laboratory environments
- Understanding the automation demands that may vary depending on the assay type
 - ♦ Immunoassays
 - FIA
 - EIA
 - ELISA
 - Luminescence
 - ♦ Molecular diagnostics
 - ♦ Microarrays
 - ♦ Cytology
- Specific automation areas to consider include:
 - ♦ Sample tube handling robotics
 - ♦ Fluid handling, pipetting, etc.
 - ♦ Cuvette design and handling
 - ♦ Detection systems
 - PMT
 - CCD Arrays/Cameras
 - ♦ Disposable design
 - POC
 - Floor model systems
 - ♦ Industrial Design
 - Floor models
 - POC
 - ♦ Software Architecture
 - Embedded
 - User Interface
 - Laboratory information system interface (HL7)
 - ♦ Cellular imaging





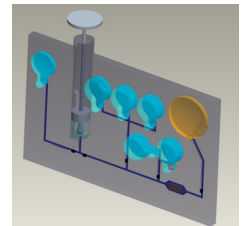
- Review of specific IVD industry standards
 - ♦ CLSI standards (formerly NCCLS)
 - ♦ IVD Directive (Directive 98/79/EC)
 - ♦ Others (61010-1)
- Following appropriate procedures to comply with FDA regulations
 - ♦ 21 CFR 820
 - ♦ 21 CFR 809



Technical Experience

Key technical experience in the IVD and laboratory market place includes:

- Nucleic acid analysis system for the research market
 - ♦ Disposables
 - ♦ Instruments
- Several high throughput floor model random access systems
 - ♦ Coagulation
 - ♦ Immunoassay
 - ♦ Molecular
- POC Instrumentation
 - ♦ Coagulation
 - ♦ Cytology
- Imaging systems
 - ♦ Cellular POC
 - ♦ Cellular bench-top
 - ♦ Microarray



Quest focuses on developing long-term relationships with their clients providing value at critical junctures and pointing out where efficiencies and savings can be found. They have saved us hundreds of thousands of dollars on projects, literally. At the same time they have provided valuable deliverables on-time and under budget. A very hands on value-adding team for any project in the contract engineering / med-device space.

Howard Merry
President, Lexicor Medical Technologies

