

# Quality Solutions &



## UM BioPark January 25, 2012



# Two Companies – Shared Vision



- Commitment to Quality
- Value Added Turn-Key Services
- Protocol Driven
- Long-Term Partnerships
- Ensure a Return on the Cost of Quality

# Quality Solutions Company History

- Started in 2002 as a validation services provider, Quality Solutions has developed a portfolio of services to provide a high-quality, cost-effective solution to the Biotech/ Pharma industry.
- This portfolio of service offerings can be tailored to any client project, regardless of size or scope.
- Our offices in Maryland and Utah have allowed us to execute projects both nationally and internationally.

# Quality Solutions Core Services

- Facility Design
- Qualification/Validation
- Project Management
- GMP Compliance/Regulatory
- GMP Training
- Cleanroom Support Services
- Calibration



# Quality Solutions Validation

## Master Plan Development

- Facility Design and Development
- Facility Validation Master Plan
- Computer/Software/Automation Validation Master Plan
- Cleaning Validation Master Plan
- Calibration Master Plan
- Preventive Maintenance Master Plan

# Quality Solutions Validation

## Process Equipment

- Bioreactors
- Autoclaves
- Custom Equipment Design
- Glassware Washers
- Chromatography Systems
- Clean in Place Systems
- Ultra and Micro Filtration Equipment
- Cleaning Validation Approaches for Process Equipment
- Various Controlled Temperature Units

## Utility Validation

- Cleanroom Design
- Cleanroom Validation to Harmonized ISO Regulations
- Clean/Plant Steam Systems
- RO/WFI Water Systems
- Compressed Air Systems
- Facility Waste Neutralization/Decon Systems

## Process Validation

- Steam in Place (SIP) Development
- Cleaning Validation Methodologies and Implementation
- Cell Culture
- Fermentation

# Quality Solutions Validation

## Computer/Software Validation

- Electronic Signature Requirements, 21 CFR Part 11
- Building Monitoring System Design and Validation
- Building Control System Design and Validation (inclusive of HVAC and Cleanroom)
- SCADA Systems
- Programmable Logic Controllers
- Chromatography Software
- Custom Software Packages

# Quality Solutions Cleanroom

- HEPA & Hood Certification
- Room Certification
  - HEPA Testing
  - Airflow Velocity and Volume Testing
  - Differential Pressure
  - Temp/RH Testing
  - Viable and Non-Viable Air Sampling
- Environmental Monitoring Program Design and Execution
- Personnel and Cleanroom SOP Development
- USP<797>



# Turn-Key Approach

- Quality by Design
- Project Management
- GMP Compliance/Regulatory
- GMP Training
- Ongoing technical support services

**EU  
GMP  
GLP  
GTP  
ICH  
ISO**

# Company Differentiators

- Assist clients during the drug discovery/development stage to streamline supporting quality activities; resulting in faster time to market with reduced risk during the product life cycle
- Reduce redundancies and identifying efficiencies
- Provide up-front pricing with NO hidden costs
- Build long-term professional relationships with clients through qualified staff who evolve with the industry and its compliance guidelines
- Supply the necessary expertise to develop, implement and support Quality Assurance Programs/Quality Systems

# Projects

- MedImmune, Frederick, MD
- Osiris Therapeutics, Columbia, MD
- Lentigen, Rockville, MD
- Western MD Regional Medical Center, Cumberland, MD
- Watson Pharmaceuticals, Salt Lake City, UT
- Yokogawa, Tokyo, Japan

# Vigilant Bioservices Company History

- Vigilant was founded in 2009 by biotech and tissue banking professionals who understand the importance of efficiency and compliance in product storage and distribution, and unlike biorepository "freezer farms," can leverage that experience to customize services that provide the best returns for our clients.
- From the ground up, our facilities and quality systems have been designed to the highest standards, featuring multiple redundancy infrastructure, and a validation approach that meets or exceeds regulatory guidelines and industry standards.

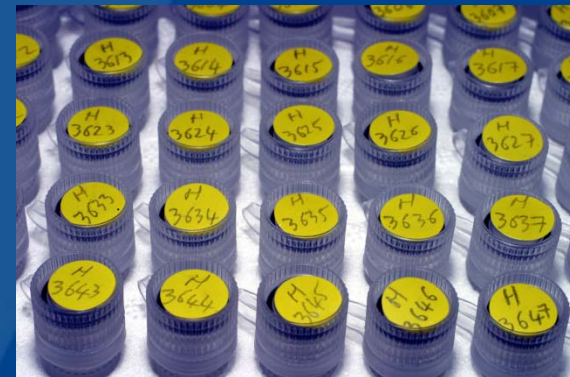
# Vigilant Core Services

- Biomaterials Storage
- Sample Management
- Cold Chain Logistics
- Tissue Banking
- Cell Banking
- Shipping/Packaging Validation



# Vigilant Storage Conditions

- Vapor Phase Liquid Nitrogen Storage (below  $-135^{\circ}\text{C}$ )
- Ultra Low Storage ( $-70^{\circ}\text{C}$  to  $-90^{\circ}\text{C}$ )
- Frozen Storage ( $-15^{\circ}\text{C}$  to  $-25^{\circ}\text{C}$ )
- Refrigerated Storage ( $2^{\circ}\text{C}$  to  $8^{\circ}\text{C}$ )
- Ambient Storage ( $20^{\circ}\text{C}$  to  $25^{\circ}\text{C}$ )
- Stability Storage Meeting ICH Guidelines (all ranges)



# Vigilant Storage Materials

- Clinical research materials
- Patient Samples
- Legal Retains
- Reference Standards
- Human cell and tissue based products
- Biological raw materials, intermediates, and finished goods inventories
- Contingency Storage

# Vigilant Healthcare Solutions

- Serve as a partner to take on technological and compliance burdens of handling and storing temperature-critical implants and medical products
- Offer tissue banking and cell therapy expertise to manage:
  - Vendor qualification
  - Cell and tissue traceability
  - Overall compliance expectation of JCAHO, FDA and other regulatory authorities



# Vigilant's Facility

- FDA-compliant Quality Systems
- Critical systems validated to the highest industry standards
- Building/Equipment Monitoring System with 24-hour alarm coverage
- HVAC and power systems redundancy
- Rapid retrieval of real-time and trend data
- Close proximity to commercial shipping hubs
- Relationships with custom courier services



# Complete Support for New Facilities

- Facility Design
- Facility/Equip Qualification
- Staff Training
- Distribution and cold chain support
- Ongoing compliance and regulatory support
- Ongoing calibration, validation and environmental monitoring support



# Quality Solutions & Vigilant Bioservices

*Ensuring a Return on the Cost of  
Quality*

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