Quality Solutions &

VIGILANT BIOSERVICES™

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

VIGILANT BIOSERVICES™

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

VIGILANT BIOSERVICES

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
- Yokogowa, 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°C)
- Ultra Low Storage (-70°C to -90°C)
- Frozen Storage (-15°C to -25°C)
- Refrigerated Storage (2°C to 8°C)
- Ambient Storage (20°C to 25°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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Quality Solutions

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