



# Biologics/Biotechnology

*Tunnell Consulting Solutions that Support the Future of Healthcare*

## *The Challenging Biotechnology Market Demands Unusual Know-How.*

Bringing new biological and biotech products to market is a challenging and time-consuming process. These revolutionary new products often take longer to manufacture and may be more difficult to control than standard pharmaceuticals. To enhance commercialization, manage stiff competition, and confidently give consumers the powerful products they are anxiously awaiting – every step from R&D to Technology Transfer to Manufacturing to Distribution demands extraordinary levels of efficiency, compliance and speed. Robust processes and sustainable systems are crucial to success.

## *Great Ideas Are Only the Beginning.*

To solve complicated biotechnology problems "right first time" demands more than a company's great ideas, talent and technology. To be successful, the essential components of science, technology, business, quality and regulatory must be carefully integrated. "Right first time" success calls for each of these crucial components to be supported by sound processes and a cohesive infrastructure that maximize potential, meet competitive and business realities head-on, and quickly and consistently deliver quality products to market.

## *Tunnell is Your Knowledge Partner.*

Tunnell Consulting actively partners with you to lay a sustainable infrastructure for success in the aggressive biologics / biotechnology industry. With more than 40 years of technical, process and organizational experience, we give you the knowledge you need – and focus on coaching your staff to self-sufficiency – so you can boost quality, compliance, capability and cost effectiveness now and in the future. Tunnell Consulting provides an exceptional team of partners who can skillfully shepherd your brightest new products to successful commercialization.

## **We Drive Your Products to Market**

- BIOLOGICS
- BIOTECHNOLOGY
- VACCINES
- DIAGNOSTICS
- BLOOD PRODUCTS
- MONOCLONAL ANTIBODIES
- PEPTIDES
- OLIGONUCLEOTIDES
- PROTEINS



# Tunnell Consulting Partners With You From Discovery to Commercialization



## RESEARCH and DEVELOPMENT (R&D)

We boost the success of R&D by supplying direct hands-on support and training throughout the product development cycle. Our services include formulation development, excipient/ingredient selection, analytical methods development, analytical testing, product development, and technical writing. Our comprehensive technology transfer methodology begins at the R&D level and effectively transitions onto the manufacturing floor.

## MANUFACTURING SUPPORT

We deliver professional services in manufacturing plant start-up, necessary plant shutdown, and turnkey plant transformation. Specific areas of expertise include troubleshooting, process improvement, cycle time reduction, manufacturing and laboratory investigations (IR optimization), critical path management, barrier/isolation systems design, sterilization cycle development, aseptic manufacturing systems design, cleaning validation, filling and packaging process design and validation, documentation systems assessment and remediation, and technology transfer.

## QUALITY SYSTEMS/ REGULATORY COMPLIANCE

Tunnell's quality and regulatory experts guide you step-by-step through cGMP/quality systems auditing, PAI readiness, quality systems design and management, stability program design/implementation, regulatory strategy design, regulatory submissions preparation (IND, CTD, ANDA, IDE, PMA, BLA, and 510k), vendor certification process design and implementation, policies and procedures (SOP) development, training and training documentation, vendor audits, and remediation/intervention.

## PROCESS REDESIGN and IMPROVEMENT

Tunnell has decades of experience in process optimization tools and techniques including process capability and control (PC&C) approaches, six sigma methodologies, design of experiments (DOE), and statistical process control (SPC), and uses analytical problem solving to investigate and improve manufacturing process development, scale-up and validation, manufacturing cycle time, and equipment qualification.

## BUSINESS STRATEGY/OPERATIONAL VALUE

We unlock hidden value and increase financial outcomes by applying a unique predictive business model that identifies and prioritizes key opportunities for improvement in strategy, operations and organization. We then help you devise specific guidelines for closing the gap between where your company is today and where it wants to be tomorrow, combining technical, process and organizational skills to help you achieve your goals.

## SUPPLY CHAIN OPTIMIZATION

We optimize connections from suppliers to manufacturing to distribution to customer delivery by enhancing supply chain strategy, strategic sourcing/purchasing, distribution network effectiveness, inventory effectiveness, RFID practice solutions, and facility operations and design.

## ORGANIZATIONAL DEVELOPMENT

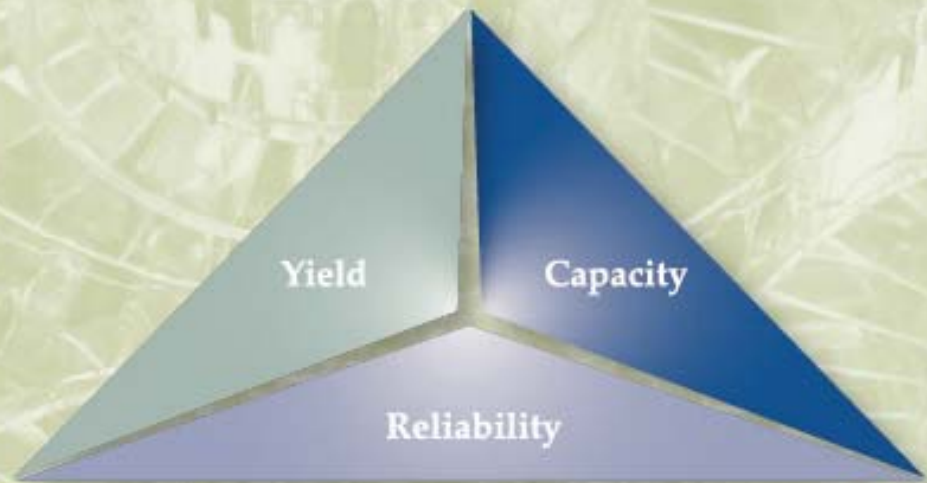
Tunnell merges technical, process and business solutions with organizational design and development services such as core competency determination, metrics identification and deployment, and performance management system alignment to achieve total organizational improvement that leads to sustainable compliance cultures, boosts time to market, and delivers solid bottom-line results.

*It is Always Our Goal  
to Transfer Our Knowledge*



# We Maximize Manufacturing Performance

*Manufacturing capability depends on the interaction of three components – capacity, yield and reliability. Tunnell Consulting helps clients understand the current relationship between these factors, prioritizes opportunities for improvement, and then applies a variety of tools and techniques to effect maximum manufacturing performance.*



- ▲ Increase Yield
- ▲ Boost Capacity
- ▲ Improve Consistency
- ▲ Enhance Reliability
- ▲ Reduce Batch Failures
- ▲ Satisfy Demand

## *Tunnell Improves Your Regulatory Success*

- ◆ We Evaluate All Regulatory Activities
- ◆ We Devise Specific Regulatory Strategy
- ◆ We Prepare Regulatory Submissions
- ◆ We Act as Your Liaison to Regulatory Authorities

## Our Results Are Proven

### ORGANIZATIONAL TRANSFORMATION

Effectively transformed the biopharm division of a global manufacturer by doubling production capacity, increasing yield 10-20%, reducing batch record review cycle time 50%, instituting a multi-level metrics program, and delivering a 10-fold ROI.

### DEVIATION MANAGEMENT SYSTEM REDESIGN

Redesigned the Deviation Management System of a major life sciences company, ensuring the system attained the highest degree of confidence to prevent critical compliance issues for the entire product line.

### PAI READINESS

Quickly prepared an emerging biopharm company for pre-approval inspection (PAI) – and achieved 100% of stated goals – by identifying and remediating gaps and establishing a new foundation for ongoing Quality Systems excellence.

### PROCESS VALIDATION

Defined and implemented a comprehensive validation strategy for a “top ten” firm, providing subject matter expertise, technical writing, protocol execution, data analysis, and report generation to fully address FDA compliance demands.

## Our Skilled Experts Help You:

- Make Financially-Sound Business Decisions
- Achieve Process Capability and Control
- Boost Comprehensive Quality Systems Compliance
- Ensure Accurate, Timely Regulatory Submissions
- Manage Technology Transfer
- Optimize Investigative Reports
- Implement Six Sigma Approaches
- Boost Capability
- Increase Speed to Market
- Optimize Supply Chain/Transportation
- Enhance Organizational Development
- Cut Costs from Discovery to Commercialization

*Our professional consulting staff includes skilled Ph.D. scientists, experienced technical consultants, and proven organizational experts with extensive industry knowledge, top academic credentials, and broad management and executive leadership backgrounds. We combine the expertise of a large in-house staff with the knowledge of key industry specialists to ensure projects are managed with a state-of-the-art team.*

## Our Consulting Clients Include:



### **About Tunnell Consulting**

*Tunnell Consulting integrates technical, process and organizational skills to boost the operating performance of manufacturing and service firms with a focus in the pharmaceutical/ life sciences industries. We implement value-added, cost-effective solutions that fit the unique needs of each client we serve.*



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