

Biotechnology/Vaccines/Biologics

Tunnell Consulting—Solutions that Support the Future of Healthcare

The Challenging Biotechnology Market Demands Unusual Know-How.

Bringing new vaccines, 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 vaccines/biologics/biotechnology industry. With more than 50 years of technical, process, and organizational experience, we give you the knowledge you need – and focus on coaching and mentoring 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.

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

We Drive Your Products to Market

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

Tunnell Consulting Partners with You from Discovery to Commercialization

OPERATIONAL EXCELLENCE

- Organizational Excellence
- Lean/Six Sigma
- Cost Reduction
- Business Transformation, Operations Strategy
- Operations Organizational Design & Change Management
- Process Improvement

MANUFACTURING SCIENCE AND TECHNOLOGY

- Technology Transfer Strategy & Implementation
- Formulation Development
- Process Development
- Analytical Method Development
- Product Process Improvement
- QbD/PAT
- Process Characterization & Control
- Equipment Qualification
- Process & Analytical Method Validation
- Lab Operations Support
- Facilities Start-Up

QUALITY / REGULATORY / COMPLIANCE

- Quality Culture
- Quality Management Systems
 - Design & Development Support
 - Global QMS Management
 - SOP Authoring Support
 - QMS Optimization
 - Root Cause Analysis
 - CAPA Management
 - Quality Risk Management
 - Quality System Assessments
- cGMP/cGLP, cGCP, PAI
 - cGMP/cGLP/cGCP Assessments
 - cGMP Inspection Readiness
 - PAI Readiness
 - Equipment Design
 - PART II Compliance
 - Data Integrity & Due Diligence Assessments
- Remediation Support
- Regulatory Submission Support
 - CMC Authoring & Publishing
- Regulatory Strategy
- Product Development
 - QbD Application & Review
 - Question-Based Development
 - Continued Process Verification

Put Our Expertise to Work for You

Our consultants' vast and substantial expertise offers an integrated and holistic approach to solving your vaccines and biologics challenges, whether technical, organizational or quality/compliance related. They can design and implement the most advantageous solution for your specific problem and then transfer the necessary knowledge so that results are sustained and goals are achieved.



Founded in 1962 and serving many of the world's leading life sciences firms, Tunnell Consulting integrates strategic, technical, process, and organizational skills to design and implement sustainable solutions that exactly meet client needs. With deep industry knowledge, extensive scientific credentials, and superior measurable results, we consistently boost the operating performance of each unique client we serve.