VALSOURCE

Consulting Services

Why ValSource for Consulting?

ValSource consultants help organizations strengthen quality systems, optimize operations, and navigate complex regulatory requirements. Whether supporting product development, manufacturing, validation, supplier quality, or regulatory readiness, our consulting team members are uniquely equipped to deliver tailored solutions that align with each organization's goals while promoting efficiency, quality, and long-term success.







As recognized authorities in the life sciences industry, ValSource consultants are sought-after subject matter experts well-known for their scientific knowledge, regulatory awareness, and unmatched practical experience. Our experts are an essential part of proactive process development and issue resolution, providing valuable solutions for a variety of project needs.

Quality Risk Management (QRM)

- Benchmarking/Maturity Assessments/Auditing
- QRM Program Development
- Training
- Facilitation
- QRM Master Plan Development and Implementation
- Tools and Templates (Standard and Customized)
- QRM Lifecycle Management and Risk Review

Microbiology

- Airflow Visualization Study Design & Remediation
- Aseptic Processing Simulations (Media Fills)
- Environmental Monitoring Program Development/ Improvement Including EMPQ Design & Execution
- Contamination Control Strategy Development & Implementation
- Quality Control Laboratory Design
- Gowning & Aseptic Processing Behavior(s)
- EM Risk Assessment Facilitation and SME Support
- Microbiology Training and Education
- Cleaning & Disinfection Program Support
- Microbiology Deviation Root Cause Analysis & Investigation Support
- EM & Utilities Data Trending Support
- Alternative & Rapid Microbiological Method Implementation & Validation Support

Regulatory Strategy

- Regulatory Strategy & Submissions
  - IND, BLA, NDA, DMF, PMA
  - Marketing Authorization
  - Lifecycle Management
- Remediation & Compliance Recovery
  - 483/Warning Letter Response
  - Remediation Roadmap
  - Effectiveness Checks
- Validation Design & Execution
  - Validation Strategy
  - Aseptic/Sterile Readiness
  - Post-Approval Changes
- Inspection Readiness & Correspondence
  - Mock Audits
  - Validation Package Review
  - Deviation and CAPA Review
  - SME Coaching and Interview Prep
  - Written Gap Assessment Report
  - Prioritized Remediation Roadmap
  - Inspection Readiness Action Plan
  - Effectiveness Check Strategy
  - Executive Summary/Decision Support

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Manufacturing Science & Technology (MSAT)

- Process Validation Lifecycle
- Technology Transfer
- Process and Operational Control Strategies
- Process Characterization and Optimization
- Operational Strategy
- Capacity Planning
- Failure Investigations, Root Cause Analysis, and CAPA
- Process Efficiency Improvement
- Process Transfer Expertise and Mentoring
- Fast Track/Light Speed Project Realization
- Sampling Plan Optimization and Development
- Cleaning Process Development and Validation
- Shipping Validation
- Process Change Management and Comparability Studies
- Process Commercialization and Lifecycle Management
- Chemistry, Manufacturing and Controls (CMC)
- Process Engineering

About ValSource

- Since 1996, ValSource has worked with hundreds of pharma, biopharma, and medical device organizations around the world.
- Our 350-strong talent force has proudly served our clients as advisors, trusted consultants, and highly experienced program managers.
- We offer a complete line of services to ensure client projects speed-to-market and success.

Learn More

ValSource.com

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Specialty Consulting

- Microneedle & Transdermal Delivery Product Development and Regulatory Support
  - Identifying Appropriate Microbial Control Specifications (CDER/CBER/CDRH)
  - Pre-IND Communications
  - EOP2 Meetings and Planning for Commercialization
  - Negotiating Specifications/Release Testing
  - Document Preparation
  - Generating Product-Specific Microbial Data
  - Applying USP Methods/Suitability Studies
  - Method Development/Validation
  - Marketing Submissions
- GMP Consulting for Advanced Therapy & Medicinal Products (ATMPs)
  - CDMO Support
  - Quality Risk Management
  - CMC/Regulatory
  - Manufacturing Science & Technology
  - Facility & Equipment
  - Contamination Control Strategy
  - Quality Systems & Inspections
- Radiopharmaceutical Manufacturing Solutions
  - Facility Design & Manufacturing Support
  - Commissioning, Qualification, & Validation (CQV)
  - Quality Risk Management & Decision Support
  - Quality Systems & GMP Readiness
  - Sterility Assurance & Microbiology
  - Quality Control & Laboratory Support
- Process Engineering