

Innovative Solutions Sustainable Results

ValSource provides a wide range of consulting, commissioning and validation services that make your organization even more successful. We are experts in navigating regulated industries and the rigorous requirements that accompany them.

How can we contribute to your success?

001
Pd

PROJECT DELIVERY

002
Cv

COMMISSIONING,
QUALIFICATION, VALIDATION

003
Rm

QUALITY RISK
MANAGEMENT

004
Mi

MICROBIOLOGY

005
Co

SPECIALITY CONSULTING

006
Ms

MANUFACTURING SCIENCE
AND TECHNOLOGY (MSAT)

007
Rc

REGULATORY
COMPLIANCE & SUPPORT

008
Lt

LEARNING & TRAINING

009
Mc

METROLOGY &
CALIBRATION

010
Ss

SAFETY SOLUTIONS



Depth of Expertise.

Since 1996, ValSource has worked with hundreds of pharmaceutical, biopharma, and medical device organizations around the world. Our subject matter experts have made significant contributions to the knowledge and skill-base of these highly regulated industries by writing books, publishing articles, leading the development of regulatory guidelines and pharmacopeial monographs, heading professional organizations, and training health authorities.

Whether getting a new site commissioned, qualified, validated, and ready to pass a stringent inspection, or helping a pharmaceutical company streamline its development activities by emphasizing an integrated quality risk management effort, ValSource has the knowledge, skills, and experience to help your organization successfully achieve its goals.

What we focus on - the core service areas described here - utilizes a depth of expertise you will find nowhere else.





Project Delivery

We communicate and establish all appropriate project deliverables and processes up front to deliver the most effective, compliant outcome. Reach a qualified and validated state, with ValSource as your guide.

By harnessing our full complement of expertise and streamlined practices, ValSource enhances total project delivery. We pride ourselves on executing projects with precision and efficiency, which not only eliminates rework but also maximizes overall project efficiency. Our strong track record of successful delivery of capital projects demonstrates our commitment to excellence and delivering optimal results for our clients.

- PROGRAM MANAGEMENT
- PROCESS ENGINEERING
- PROCUREMENT/EXPEDITING
- CONSTRUCTION SAFETY
- HAZOP
- CALIBRATIONS / METROLOGY
- COMMISSIONING, QUALIFICATION AND VALIDATION (CQV)
- COMPUTERIZED SYSTEM VALIDATION



Commissioning, Qualification and Validation (CQV)

ValSource technical teams, located in strategic locations across North America, provide experienced resources to assist clients in the planning, management, execution, and analysis of commissioning, qualification, and validation projects - in a safe, consistent, compliant, and timely manner.

- CAPITAL PROJECT SUPPORT AND STAFF AUGMENTATION
- PROJECT PLANNING: SCHEDULING, BUDGETING, REPORTING
- PROJECT MANAGEMENT
- COMMISSIONING, QUALIFICATION & VALIDATION (CQV) MASTER PLANNING
- COMMISSIONING AND DECOMMISSIONING GENERATION AND EXECUTION
- REQUALIFICATION STRATEGY, PLANNING AND EXECUTION
- DESIGN REVIEW AND QUALIFICATION



- FAT/SAT PLANNING AND EXECUTION AND DECOMMISSIONING GENERATION AND EXECUTION
- IQ/OQ/PQ GENERATION AND EXECUTION
- FACILITY, EQUIPMENT, AND UTILITY QUALIFICATION
- LAB EQUIPMENT VALIDATION
- STERILIZATION (SIP) & VHP VALIDATION
- CYCLE DEVELOPMENT CONTAINER CLOSURE VALIDATION
- COMPUTER SYSTEM ASSURANCE (CSA)
- COMPUTER SYSTEM VALIDATION (CSV)
- DATA INTEGRITY ASSESSMENTS
- CONTROLLED TEMPERATURE UNIT MAPPING
- AIRFLOW VISUALIZATION STUDIES
- AUTOCLAVE CYCLE DEVELOPMENT AND QUALIFICATION
- SHIPPING VALIDATION
- PROFICIENT WITH MULTIPLE PAPERLESS VALIDATION PLATFORMS
- TECHNICAL WRITER(S) FOR VALIDATION, MANUFACTURING, ENGINEERING AND FACILITIES



Quality Risk Management (QRM)

QRM has evolved to be the cornerstone of all activities in product, process, and facility design, development, qualification, and operation. Our QRM team is comprised of best-in-class consultants who can develop novel approaches and fit-for-purpose strategies to comply with ICH Q9 (R1) and all of the associated regulations that require the use of QRM and risk-based decision making. Our approaches help your organization drive efficiency and appropriate resource utilization, reducing costs and improving product quality.

- 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

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

- AIRFLOW VISUALIZATION
- ASEPTIC PROCESSING SIMULATION
- CONTAMINATION CONTROL
- DEVIATION INVESTIGATIONS
- ENVIRONMENTAL MONITORING
- FACILITY CLEANING & DISINFECTION
- INSPECTION READINESS
- QUALITY ASSURANCE/CONTROL AND COMPLIANCE
- PROCESS OPTIMIZATION
- RISK ANALYSIS
- RISK ASSESSMENT AND MITIGATION
- TRAINING AND EDUCATION
- TROUBLESHOOTING, ROOT CAUSE ANALYSIS (RCA), AND INVESTIGATION SUPPORT
- PROCESS DEVELOPMENT
- PRODUCT SAFETY
- REGULATORY SUPPORT
- CLEANROOM BEHAVIOR



Specialty Consulting

ValSource is available to help solve the complex issues surrounding regulatory expectations for control strategies and assist with regulatory communications beginning with initial developmental stages through commercialization.

ValSource consultants have unparalleled expertise to help navigate the complex regulatory environment of emerging therapeutics and delivery systems. We provide full services for key challenges including employing a science driven, risk-based approach to ensure success. Our consultants are widely known as thought leaders on ATMP and transdermal product development and manufacturing.

- MICRONEEDLE & TRANSDERMAL DELIVERY PRODUCT DEVELOPMENT AND REGULATORY SUPPORT
- GMP CONSULTING FOR ADVANCED THERAPY & MEDICINAL PRODUCTS (ATMPs)
- PROCESS ENGINEERING
- RADIOPHARMACEUTICAL MANUFACTURING SOLUTIONS



Manufacturing Science and Technology (MSAT)

Our comprehensive suite of technical and scientific services is designed to streamline your operations and empower your business for success. With expertise spanning a wide array of disciplines, our consultants are equipped to tackle any challenge and have a proven track record of delivering innovative solutions and unparalleled support. Let us help you solve your challenges and drive your business forward with optimized performance and reliability.

- 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
- PROCESS PERFORMANCE QUALIFICATION (PPQ)
- CONTINUED/CONTINUOUS PROCESS VERIFICATION (CPV)
- CHEMISTRY, MANUFACTURING, AND CONTROLS (CMC)



Regulatory Compliance & Support

Our regulatory compliance strategy & support consulting services include:

- INSPECTION PREPAREDNESS
- INSPECTION RESPONSES
- SYSTEM ASSESSMENTS, ASEPTIC SET-UP, STERILE FILL-FINISH, ASEPTIC PROCESSING BEHAVIOR
- DRUG SUBSTANCE, DRUG PRODUCT PRE-LICENSE, AND POST-APPROVAL CHANGES AND MANUFACTURING PREPAREDNESS
- MARKETING SUBMISSION STRATEGY
- PRE-MARKETING SUBMISSIONS (E.G., EUA'S, INDS, IDES)
- MARKETING AUTHORIZATION APPLICATION DEVELOPMENT
- POST-MARKETING CHANGE MANAGEMENT, VALIDATION APPROACHES, AND SUBMISSIONS
- ASSISTANCE WITH REGULATORY CORRESPONDENCE (E.G., DEVIATIONS, REGULATORY DEFICIENCY RESPONSES, POST-INSPECTION COMMUNICATIONS)
- PROCESS VALIDATION APPROACHES



Learning & Training

As processes and systems become more complicated, having a workforce that can perform and respond appropriately when problems arise is essential. That means not only knowing the how-to, but also the what and the why. Risk-based-, quality-, and critical-thinking skills are more important today than ever before. ValSource Learning Solutions understands this and has a comprehensive set of innovative solutions to help your organization reach its goals.

ValSource Learning Solutions provides high-quality, customized courses including:

- ASEPTIC TECHNIQUE TRAINING AND COACHING
- GOWNING TRAINING AND COACHING
- INSPECTION READINESS
- ROOT CAUSE INVESTIGATIONS / CAPA
- QUALITY RISK MANAGEMENT (QRM)
- QRM FACILITATOR TRAINING
- BASIC AND ADVANCED GMP TRAINING
- CUSTOM E-LEARNING SOLUTIONS



Metrology & Calibration

ValSource calibration and validation teams work together – solving overlaps in process and eliminating scheduling challenges between the project and a third party. Our expert teams perform instrument calibrations, investigate OOTs, develop entire calibration programs (including personnel training), and improve processes through onsite consulting. Calibrations occur at the same time IQ checks or instrument receipt verifications take place, with instant certificate access through PIMSHQ innovative software.

ValSource is ISO 9001 Accredited for Calibration and Calibration Related Consulting Services for Pharmaceutical, Biotechnology, Medical Device, and Other Tech Companies. ISO 9001 Accreditation ensures our defined process and procedures are high quality, effective and consistently meet client expectations.

- TEMPERATURE CAPABILITIES
- SPEED
- MASS
- PRESSURE
- PH/CONDUCTIVITY
- PIPETTES
- GASES
- LIGHT
- STAFFING AND CONSULTING



Safety Solutions

Proactive planning matters. ValSource Safety Solutions can swiftly plan, direct, and implement an effective safety program to ensure a safe, healthy, and accident-free project and work environment. We are skilled in corporate safety and risk management, guaranteeing compliance with all applicable federal, state, county and local safety-related regulations. ValSource Safety Solutions combines expert consulting and safety services with PIMSHQ - a pioneer in the field of safety management software. This comprehensive solution provides clients with tailor-made strategies that help create a more proactive and effective safety culture among their employees.

- SITE SPECIFIC SAFETY PLAN (SSSP)
- AUDIT
- RISK MANAGEMENT
- COMPLIANCE

A unique partnership for total project delivery.

Our integrated approach is unlike any other in the industry -
providing an end-to-end, total project delivery solution to our clients.



VALSOURCE

Together - we help clients manage and deliver compliant-ready, safe projects and products.

EPREX

PIMSHQ

EPREX, our woman-owned, WBENC-certified equipment and service procurement partner provides a seamless, integrated process for procurement and expediting that includes CQV strategy at every stage of your project.

PIMSHQ, our software solution partner enables on-location, real-time project management and documentation access with a suite of mobile tools.

VALSOURCE



info@valsource.com



www.valsource.com



610.269.2808



@valsource-inc

