VALSOURCE

Innovative Solutions. Sustainable Results.

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ValSource provides a wide range of consulting, commissioning, and validation services that make your organization even more successful.

How can we contribute to your success?

Depth of expertise.

Since 1995, ValSource and its consultants have worked with hundreds of pharma, biopharma, and medical device organizations around the world, helping them successfully achieve their process control goals. Whether getting a new site commissioned, qualified, validated, and ready to pass a stringent regulatory inspection, or helping a pharmaceutical, biotech, medical device company, or compounding pharmacy company streamline its development activities by emphasizing an integrated quality risk management effort, ValSource has experts who have the knowledge, skills, experience, and curiosity to help you achieve what is important.

ValSource personnel have contributed to the knowledge and skill-base of the pharmaceutical industry worldwide, writing books and articles, leading the development of regulatory guidelines and pharmacopeial monographs, heading professional organizations and task groups, and training regulatory inspectors from both developed and developing countries.

By intention, ValSource doesn't claim to do everything. What we focus on – areas described here – utilizes a depth of expertise you will find nowhere else.

Commissioning & Validation Solutions

ValSource technical teams, located in key regions of North America, provide experience and resources to assist clients in the planning, management, execution, and analysis of commissioning, qualification, and validation studies - all in a consistent, compliant, and timely manner. Highly skilled in project leadership, we utilize advanced program management tools and methods to help develop risk based approaches, so you can focus on the other critical tasks you must do.

Services include:

- Program and inspection readiness audit, review, and remediation
- System commissioning, qualification, validation (CQV) protocols, execution, and reporting Commissioning & Validation Solutions
- Process validation (PV) and continued process verification (CPV) programs
- Statistical approaches for sample sizes and batches
- DOE development, performance, and analysis
- CQA and CPP determination and evaluation
- Control strategy development
- Program management and critical system procurement utilizing powerful PIMSSM and MarkTimeSM project database systems
- Computer system, serialization, cleaning, and sterilization validation
- Advanced, conventional, and barrier system aseptic process validation
- EM-REMSM Clean room classification and monitoring program development

Cv
COMMISSIONING, QUALIFICATION & VALIDATION

Lt

LEARNING & TRAINING

Learning Solutions

Developing, producing, and controlling pharma and biopharma products is challenging. It demands people who have the knowledge and skills to perform complicated tasks and make complex decisions. ValSource has a team of experts who have developed and delivered creative, engaging learning solutions for companies, non-governmental organizations and national regulatory authorities throughout the world. Our training uses evidence-based, innovative learning approaches combined with current, quality content.

Frequently requested workshops include:

- Quality Risk Management
- Investigations, Corrective Actions, and Report Writing
- Basic and Advanced GMPs
- Contamination Control
- GMP Refresher and Updates for operations personnel and leadership
- Risk and Statistics in the Process Validation Lifecyle

Whether you have a few or thousands of people needing critical GMP information and training using face-to-face instructors or customized e-learning, ValSource can deliver a learning solution that meets your needs.

Pc
Pharmacy Compounding

Pharmacy Compounding

A growing emphasis in clinical pharmacy practice is providing parenteral and high potency products prepared for a specific patient's need. As pharmacy compounding grows, it is also receiving more attention from Federal regulators (US FDA) and state pharmacy boards. ValSource has a unique combination of people with both clinical/ retail pharmacy, regulatory, and manufacturing experiences that can tailor risk based approaches to hospital pharmacies and compounding centers. ValSource has established a team to assist compounders seeking compliance with new requirements of USP <797> and <800>, and also expectations of FD&C Act 503B.

Services include:

- USP <800> Guidance, facility/operational review, and design
- USP <797> Guidance, facility/operational review and design
- Project management
- Quality system development
- Compliance remediation

What Do You Need Delivered?

- Are you just starting a project and need to clarify what is happening and where it might go?
- Have you run into some unexpected challenges?
- Are you looking for another set of creative eyes that might recommend a different approach?
- Do you require an integrated risk management system?
- Are your contract labs and suppliers causing some challenges that ValSource experts could provide industry-expert support?
- Are you in need of a systematic approach to training, learning, and development?
- Do you need CGMP training or training on specialized CGMP topics like an annual GMP Update?

Quality Risk Management (QRM)

While the pharma and biopharma industry has long thought about risks and protecting patients, the approach has been rather informal. Now, however, regulators are expecting that we use a more structured, consistent approach to risk-based thinking. We see growing expectations that risk-based thinking be integrated into Quality Risk Management (QRM) Quality Management Systems. The ICH Q9 Quality Risk Management guidance document provides a starting point, it doesn't cover the practical issues like where do you start? What scales should we use? Or, what tools are there besides FMEA?

Rm

QUALITY RISK MANAGEMENT

Our QRM Experts Will:

- Design integrated risk-based thinking and QRM approaches into your Quality Management System (including Quality SOPs, training, and specialized tools)
- Facilitate risk assessments
- Apply QRM to drug-biologic-device combination products
- Develop QRM competencies that are self-sustaining within your organization
- Deliver QRM learning events for team members, facilitators, and leadership
- Help create an organizational culture that supports risk-based thinking
- Building processes to support integration of QRM methods into the Quality Management System

Md
MANAGEMENT
SYSTEM DESIGN

Quality Management Systems

Effective and efficient Quality Management Systems, not only meet the compliance requirements, but should drive continuous improvement activities and contribute to the success of the business. With the increasing complexity of the Regulatory landscape, many companies are challenged with having the resources to focus on continuous improvement. Proactive work is the cornerstone of a strong Quality Management System and is necessary to have an efficient business. Within ValSource there is a strong Quality Management Systems acumen. Let ValSource focus resources on building a QMS program that can find that balance of proactive versus reactive quality work. Our experts will assess your processes, provide feedback, and assist in remediation plans.

Product Lifecycle

The emphasis will be in the following areas within the product lifecycle:

- Quality Manual and Governance
- Process performance and product quality monitoring system
- Deviation Management
- Change Management
- CAPA system development and implementation
- Audits/Self-Inspections
- Management Review
- A Culture of Quality

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