VERISTA

Top 100 Pharma Company Reduces Total Cost of Laboratory Validation Services

CASE STUDY

OVERVIEW

✓ **Client Situation:** A top 100 pharmaceutical client built three new laboratories for testing and release of a new medication which contained over 48 new laboratory instruments (HPLCs, GCs, AAs, FTIRs, TOCs, etc.)

✓ **Regulatory Demand:** To meet FDA regulations the client needed to validate the systems used in the testing and release of the products.

✓ **Client Challenge:** The client did not have expert resources available to complete the project in the desired time frame.

SOLUTION

✓ **Proven Expertise and Program Management Framework:** A team of 9 skilled CSV resources, including 1 lead and 8 specialists, were assigned to develop and execute the following deliverables for all 48 systems:

- System Requirements
- Risk Assessment
- System Configuration Specification
- Installation Qualification
- Operational Qualification
- Performance Qualification
- Traceability Matrix
- Validation Summary Report

Our experts team up with some of the world's most recognizable brands in the life science industry, solving critical and complex business challenges from research to manufacturing to post-marketing with clarity and confidence. Verista is about making sure that your business, operations and products are optimized, compliant, and consistently high-quality.

✓ **Trusted Partnership:** Ongoing support for upgrades and validation of new software versions

  • 5 team members extended to complete CSV on additional laboratories

CLIENT **BENEFIT**

✓ **Efficiency:** Managing the compliance of the lab to Verista allowed for the client's lab staff to focus on the making and testing of life saving drugs

✓ **Company ROI:** Verista's resources are more cost effective than our client having to hire, train and maintain full-time employees; Cost of validation services for the lab is capitalized

ABOUT **VERISTA**

Verista is a leading business and technology consultancy firm that provides systems, compliance, validation and quality solutions to life science companies enabling them to improve health and improve lives. We help clients solve their most critical and complex challenges across the GxP lifecycle, from preclinical and clinical to commercialization, manufacturing and distribution – bringing together decades of knowledge, the most advanced engagement platforms and transformative technologies. This allows clients to benefit from the ease, efficiency and trust that results from working with one partner who excels across specialties. Verista's clients trust the company's 500+ experts to deliver consistent, safe, and high-quality results across the product development lifecycle.

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