

CSS Informatics Company Overview

Our Qualifications

CSS Informatics, a division of PPD, Inc., has a rich, 17-year history of providing software and related services to the pharmaceutical and biotech industry. Since 1990, we have served more than 150 companies on five continents, migrated 160 clinical and drug safety systems, and trained more than 4,000 software users. Our detailed understanding of how clinical and safety systems work provides our people with an unparalleled depth that allows us to offer creative, sophisticated and successful solutions. In fact, no independent pharmaceutical software consulting firm today has the breadth of experience and time-tested history of CSS Informatics.

CSS Informatics has solid experience implementing, customizing and validating every major, commercial clinical database management and drug safety software system – Oracle® Clinical / TMS / RDC, Oracle AERS, Clintrace™, Clintrial™, ARISg™ and Argus Safety™. Additionally, through development relationships with pharmaceutical software vendors, we have also created a market-leading adverse event reporting system, introduced the first commercial E2B software and produced sophisticated applications for loading, cleaning and coding clinical data. We are also Oracle's preferred provider for Oracle Life Science (OLS) hosting.

Our Expertise

CSS Informatics supports pharmaceutical software systems in four core areas: implementation and consulting, validation, training and proprietary software solutions.

Implementation and Consulting

- Software evaluation and selection guidance
- Installation, configuration and customization
- Functional consulting and staff augmentation
- Remote and on-site support
- Process development and efficiency analysis
- Project management

Software Validation

- Development of validation documents
- Ready-to-go validation packages
- Custom test case development
- Test script execution and support
- Independent audits and reviews
- SOP templates and development

Software Training

- Oracle Clinical, TMS, RDC and AERS
- User, administrator and workshop classes
- On-site training available globally
- Training facility in Blue Bell, PA
- Extensive presentation and practice materials
- Trainers with practical industry experience

Proprietary Software Solutions

- eLoader™ - Load any data onto OC and TMS
- PPD® Patient Profiles – Graphical data reporting
- E2B ICSR Browser™ – Electronic ICSR reporting
- MedDRA Browser and Query Manager
- MVAU - MedDRA version analysis and upgrade
- TableTrans® - Data migration / verbatim analysis

Our Value

There are different ways of solving the same problem. Consulting firms without our range of experience offer limited perspectives. Why risk your projects with less-experienced firms or low-priced commodity consultants? There are always better ways to do things and CSS Informatics is leading the way with our Experience + Innovation.

Contact: Sheldon S. Wong • +619 665 4097 • swong@csscomp.com • www.cssinformatics.com