

# Validating Oracle® AERS

## Company Background

CSS Informatics is the most established drug safety software consulting practice in the industry with sixteen years of continuous innovation and support. Our team of industry-proven experts has a consultant average of ten years of pharmaceutical technology experience and offers solid experience with every major drug safety application – Oracle AERS, ARISg™, Argus Safety™ and Clintrace™.

We began consulting with Oracle AERS shortly after Oracle acquired EventNet in 2002. Since then, CSS Informatics has provided Oracle AERS implementation, training, data migration, validation, and hosting services to dozens of clients in the U.S. and Europe. Today, while others promote their past role in developing Oracle AERS, CSS Informatics is proud that we're making it better!

## What Can We Offer?

CSS Informatics has participated in numerous validation engagements for Oracle AERS and has developed their own package of comprehensive validation documents and test scripts.

Our Oracle AERS Validation Package can be customized to your needs and includes:

- Validation Plan and Summary Report
- Detailed Requirements Specification including Part 11 requirements
- Requirements-to-Tests Traceability Matrix
- IQ Plan, Checklist, and Summary Report
- OQ/PQ Test Plan and Summary Report
- Full functional testing with 21 CFR Part 11 coverage
- Detailed testing of standard reports logic
- Full testing of edit check logic
- Assistance during test execution
- Customization of documents and tests for non-standard installation
- Consultation on system configuration and use
- Vendor audit support
- Departmental SOP review and development

## Why choose CSS Informatics for your Oracle AERS validation?

- Software vendor independence - no conflict of interest
- Our validation specialists also have practical application experience
- Flexibility – our package and consulting services can be customized to your needs
- Proven track record – our validations have passed numerous audits and inspections
- Experience – Almost two decades of drug safety, software testing, and validation experience

With CSS Informatics, you're not just getting our Oracle AERS expertise. You're benefiting from sixteen years of experience with every major drug safety system in the world! There are different ways of solving the same problem and consulting firms without our range of experience offer limited perspectives. Sure, we've developed a major drug safety application too. But we've moved on. There are better ways to do things now and CSS Informatics is leading the way.