Regulatory Compliance and Validation Services

DaCS™ is well recognised as the leading spreadsheet compliance environment, CSV offer a complete validation service to ensure that your DaCS™ installation is validated to meet the most stringent of regulatory expectations.

Vendor documentation and testing is combined with specification, configuration and thorough qualification in your unique environment.

Spreadsheet Compliance
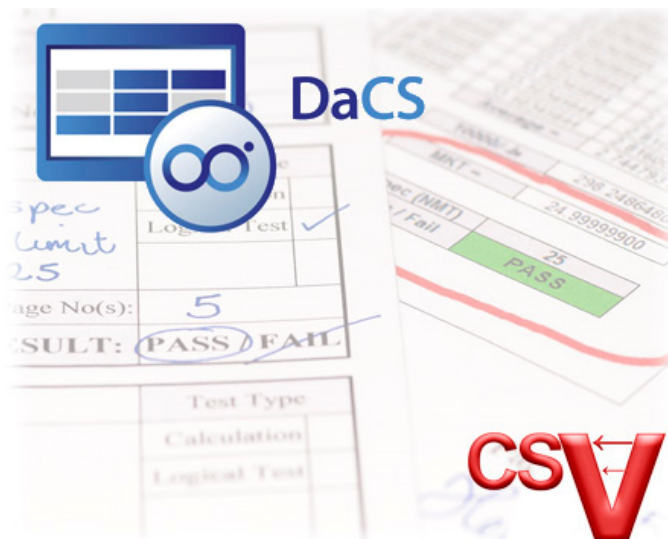
DaCS™ Validation Service

Excel is the universal standard for data handling and data processing and Finsbury Solutions DaCS™ is the software of choice for Excel compliance with FDA 21 CFR Part 11.

Demonstrating that your spreadsheets are functioning correctly needs to be combined with demonstrating a secure Excel environment. DaCS™ provides that environment but you also need to have validation of the system in place to satisfy your regulatory auditors. If you cannot show with documented test evidence that the environment is secure and that users actions are audit trailed then your auditors can stop the use of your Excel spreadsheets or worse still stop your operations until the situation is resolved.

CSV offer a complete service to validate DaCS™ and provide documented evidence of the correct operation of your environment. Maximising use of vendor documentation yet still verifying and qualifying your unique environment strikes the perfect balance between validation efficiency and satisfying regulatory needs.

Validation Service Benefits

- Continue the use of Excel in a 100% secure environment and satisfy your regulatory auditors.

- Complete confidence in your spreadsheet environment both for regulatory compliance and operational accuracy.

- An "off the shelf" documentation set, configurable for your own quality system and already proven in the top pharmaceutical companies worldwide.

- Receive a turn key solution from the world leaders in DaCS™ services.

DaCS™ Validation Process

The CSV DaCS™ Validation Service has been provided by a dedicated spreadsheet team since 2003. The process has been rolled out on 100's of installations around the world and within most of the worlds top pharmaceutical companies.
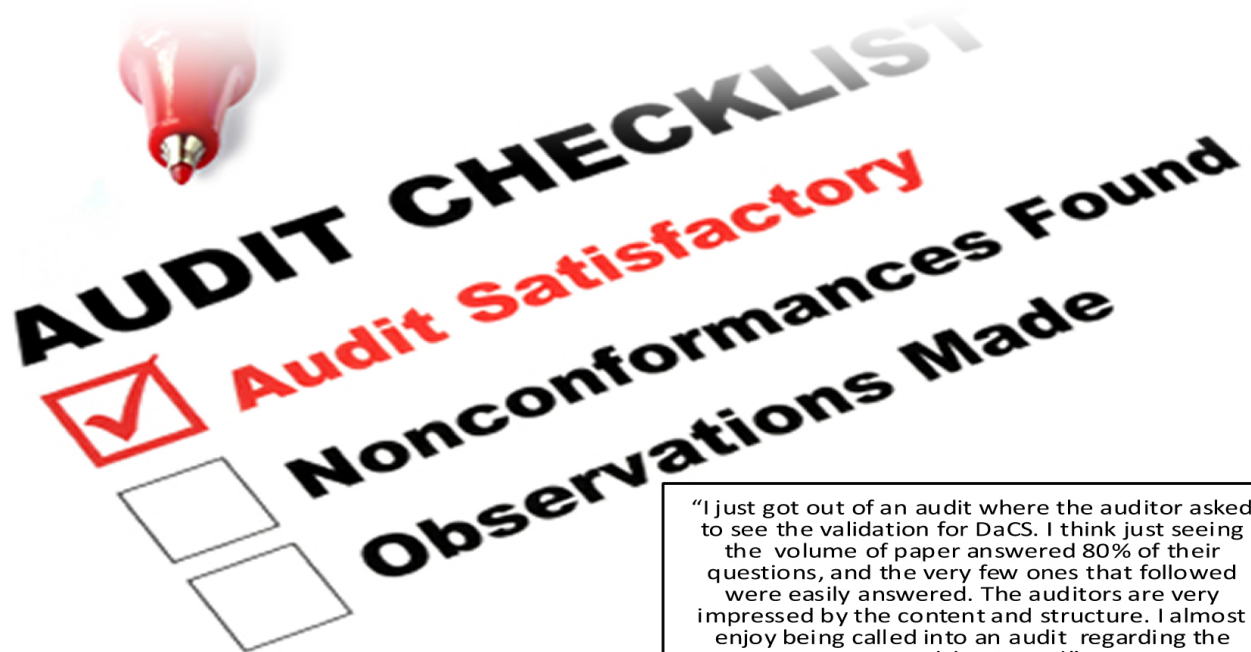
- Vendor supplied specifications and functional testing undertaken within our own quality system.

- Client specific validation documents generated by our proven GAMP based validation templates.

- Comprehensive yet risk based installation and operational qualification testing to ensure accurate configuration and functionality of the controlled environment.

- Options for validation planning, reporting and experienced project management.

- Fully developed and proven document set covering the whole of the project lifecycle, from planning to reporting.

- Use our pre-developed process, or adapt our proven process into your own quality systems and validation practices.

spreadsheetvalidation.com

CSV Validation Experience

CSV are the world leaders in spreadsheet validation and their computer system validation experience and standing is second to none in the industry. Use their experience to ensure a successful, efficient and compliant validation project.

- Why risk such a critical project to validation teams with little or no experience of validating DaCS™ ? If DaCS™ is not secure and correctly validated then neither are all of your spreadsheets.

- CSV are the industries key speakers on spreadsheet validation at conferences and providing white papers for journals. We have presented joint sessions with the FDA, Pfizer and Allergan to show how the DaCS™ validation process fits into your spreadsheet project.

AUDIT CHECKLIST
Audit Satisfactory
Nonconformances Found
Observations Made

> "I just got out of an audit where the auditor asked to see the validation for DaCS. I think just seeing the volume of paper answered 80% of their questions, and the very few ones that followed were easily answered. The auditors are very impressed by the content and structure. I almost enjoy being called into an audit regarding the spreadsheet now!"

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CSV Compliance is the global leader in spreadsheet validation services for the Life Sciences and regulated industries. The CSV Compliance team supply spreadsheet validation and compliance services worldwide.