

Hartington Case Study

MAINTAINING 21 CFR PART 11 COMPLIANCE WITH HARTINGTON STATISTICS AND DATA MANAGEMENT

The Challenge

Hartington are a Contract Research Organisation specialising in the management and analysis of clinical trials data for the Pharmaceutical Industry. Hartington has developed its own clinical data management system using SAS technology.

This system required updating with new functionality whilst maintaining compliance with industry regulatory requirements. *"Amadeus were a natural choice to help us with this project. They have substantial SAS expertise as well as a solid background within the pharmaceutical industry. They worked closely with us from initial design through to final validation testing to deliver exactly what was required."* Cynthia Haliburn, Hartington Managing Director.

The Solution

The pharmaceutical industry has been steadily addressing the requirements outlined in the FDA ruling 21 CFR Part 11, for the capturing and processing of electronic records and signatures. Amadeus were elected to provide an independent assessment of the current clinical data management system maintained by Hartington and the change control processes for the systems maintenance. The following items were addressed:

- Review of software infrastructure and configuration
- Usage and purpose of the system with respect to compliance for 21 CFR part 11
- Review of security
- Review of migration and validation process
- Implementation of a formal development lifecycle

Amadeus senior consultants were able to quickly evaluate the existing system and processes before providing a detailed report to Hartington's managers.

The Results

Hartington commissioned Amadeus Software to implement a selection of the recommended features suggested in the report.

- Functionality such as network user authentication for regulating access to screens was quickly implemented.
- Data access was further secured by protecting SAS data sets.
- Automatic tracing facilities were extended throughout the data entry and editing areas of the application

Hartington and Amadeus worked closely together ensuring the requirements were satisfied and enabling seamless project delivery. Hartington's own data management team are now able to maintain the new features using the comprehensive documentation. Personal handover of the system contributed to the seamless delivery. Amadeus provided the consultancy services that resulted in a robust application that is fully 21 CFR Part 11 compliant.

ABOUT AMADEUS – The SAS Specialists Amadeus Software Limited, formed in 1989, provides Business Intelligence Solutions. We are a SAS9 Preferred Implementation Partner for delivery of SAS projects across all industries. We have earned our outstanding reputation by providing first-class solutions, unrivalled technical support and clear, practical training. We achieve this by remaining at the forefront of Business Intelligence technology and providing solutions that meet customer objectives. Our Project Management is structured to provide pragmatic quality assurance ensuring successful delivery.



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