

UK Pharmaceutical Case Study

21 CFR PART 11 COMPLIANCE PROJECT

The Challenge

To upgrade an existing data entry application developed by a pharmaceutical company in order to be 21 CFR Part 11 compliant. The application is used to record data from different Case Report Forms and it needs minimal in-house expertise to maintain and develop new entry screens.

The Solution

A reformed data entry application was developed. The 21 CFR Part 11 compliance meant that the solution needed to include audit trails, password protection on both the datasets and the source code and user authentication methodology. The technologies used were SAS/AF, SAS Base, SAS Macro and SAS/FSP.

The Results

The customer now has an easy to use, flexible, data entry application, which can easily be configured to cover any data entry requirements with minimal implementation time. Thanks to the CFR Part 11 compliance, their data is now fully traceable and secure.

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