Part 11 Toolkit™

Access compliance made simple.

Key Benefits of Part 11 Toolkit

- Simple to Use – Your Access program, with a few extra control buttons on the main menu and key data entry forms. You retain your data collection and workflow.

- Compliance – The Part 11 Toolkit provides full 21 CFR Part 11 compliance for MS Access, including Audit Trails, Electronic Signatures, Password Protection and User Level Security.

- Easy to Implement – Ofni Systems can implement the Part 11 Toolkit on most programs in less than a business day.

- Multi-User – No restrictions to the number of users who are granted access to the program.

Compliance Features

The Part 11 Toolkit provides all of the technological tools for MS Access programs to be compliant with 21 CFR Part 11, including:

- Audit Trails - All changes to data are recorded. The original audit trail is protected. Even deleted records are recorded.

- Password Protection - All programs require a password to access.

- User-Level Security – Part 11 Toolkit supports user level security. Specific groups can be allowed very specific rights on all Users can be designated with specific privileges to edit or alter spreadsheet data.

- Electronic Signatures - Electronic signatures can lock records, preventing accidental or intentional changes to the data.

- Event Logging – All key system events are logged to an Administrators only page.

Powerful Data Mining Tools

- Search Engine included for data mining of all system data.

- Export to MS Excel or to custom reports

Your Access program protected and the data secure. Users retain the familiar interface. Your regulatory requirements are fulfilled. The Part 11 Toolkit is Access compliance made simple.

Contact Ofni Systems for a free demonstration. Volume discounts and validation packages are available.