Providing confidence in databases to satisfy regulatory auditors.

Regulated companies use access databases for data storage, analysis, and reporting. The flexibility and familiarity of Microsoft Access is unsurpassed as a database tool for end users. However, many companies have not validated their use of access to the standards required to meet current regulations. Companies need to demonstrate to their auditors that their databases are secure and that data reporting is accurate.

**What we offer**
Access is the universal database standard for end user data storage and data reporting, and the majority of companies use access for handling and storing regulatory data.

Demonstrating that databases are securely maintained and reporting correctly is critical not only for internal business processes, but also for satisfying regulatory auditors. If companies cannot show with documented test evidence that their databases are generating the correct data, then the auditors can stop the use of their Access databases or worse still stop your operations until the situation is resolved.

ABB offer a complete service to validate databases and provide documented evidence of their correct functionality.

The process is designed to maximise efficiency and focuses on repeatability for a total inventory of databases.

- Detailed user requirements and specifications ensure that databases are designed to meet their needs
- Comprehensive qualification testing to demonstrate correct functionality and reporting coupled with evidence that the operation is maintained within a secure and recorded environment
- Analyse and process data in Access with full audit trails, and report data with validated queries and searches

**Access database validation process**
The ABB access validation solution has been developed from the highly successful spreadsheet validation process used to deal with 1000’s of spreadsheets from most of the worlds top pharmaceutical companies.

- Experienced consultancy to review user requirements and ensure databases meet expectations and comply with required regulations
- Database development to add ABB good practice features such as version control and security features
- Documented user and functional specifications to define the input and output functionality
- Comprehensive yet risk based installation, operational and performance qualification testing to ensure accurate usage in a controlled environment
- Validation planning, reporting and experienced project management

**Access database validation tools**
- Database analysis provided by a combination of software technology and pragmatic consultancy experience
- Fully developed and proven document set covering the whole of the project lifecycle, from concept to retirement
- Best in field 3rd party software tools to provide secure environments and database analysis
- Ofni systems (www.ofnisystems.com)
- Spirit computing (www.spiritcomputing.net)
- ‘One stop’ supplier to analyse, supply and train organisations on the whole database validation process
Benefits
- Continue the use of Access, with the current databases and trained users and satisfy the regulatory auditors
- Complete confidence in database outputs both for regulatory compliance and operational accuracy
- An ‘off the shelf’ documentation set, configurable for in-house quality systems and already proven in the top pharmaceutical companies worldwide
- Receive a turn key solution from the world leaders in spreadsheet and database validation

Why ABB
ABB are the world leaders in spreadsheet and database validation. Use our experience to ensure a successful, efficient and scalable validation project.

- Use ABB’s pre-developed process, or adapt our proven process for in-house quality systems and validation practices
- Why risk such a critical and resource intensive project to validation teams with little or no experience of validating access?
- ABB and our Access technology partners are the industries key speakers on access validation at conferences. ABB present joint sessions with the FDA and Allergan as case studies
- A scalable process, suitable for individual databases through to departmental or whole company inventories
- A scalable consultancy service that can provide a complete turn-key solution with minimal end user input or ABB can provide training on the whole process and leave companies to undertake their own project

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