



Regulatory Compliance and Validation Services

Regulated companies use Access databases for data storage, analysis, and reporting. The flexibility and familiarity of 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. You need to demonstrate to your auditors that your databases are secure and that data reporting is accurate.

ABB Database Compliance

Access Validation Service

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

ABB offer a complete service to validate your databases and provide documented evidence of their correct functionality. The process is designed to maximise efficiency and focuses on repeatability for your whole inventory of databases.

- Detailed user requirements and specifications ensure that your 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 your data with validated queries and searches.

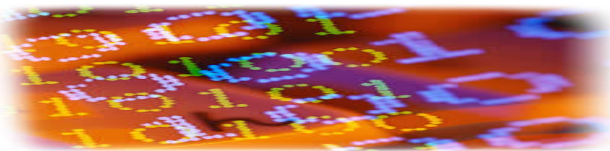
Validation Service Benefits

- Continue the use of Access, with your current databases and trained users and satisfy your regulatory auditors.
- Complete confidence in your database outputs 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 spreadsheet and database validation.

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 your databases meet expectations and comply with your regulations.
- Database development to add ABB good practice features such as version control and security features.
- Documented user and functional specifications to define your 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 (<http://www.ofnisystems.com>)
 - Spirit Computing (<http://www.spiritcomputing.net>)
- "One stop" supplier to analyse, supply and train your company on the whole database validation process.

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ABB Access Validation Experience

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

- Use ABB's pre-developed process, or adapt their proven process into your own 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 their 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 you to undertake your own project.



ABB Services

ABB provide a full range of consultancy services for database validation, including database development, 3rd party software tools, training and testing services.

For more information visit.


www.accessvalidation.com

ABB is a leader in power and automation technologies that enable utility and industry customers to improve performance while lowering environmental impact. The ABB Group of companies operates in around 100 countries and employs about 115,000 people.

