

The Part 11 Toolkit makes your MS Access Databases compliant with 21 CFR Part 11 – Electronic Records and Signatures.

How does it work?

The Part 11 Toolkit is a set of tools that are applied to one of your existing Access programs to make it compliant. It adds all the technical requirements of 21 CFR Part 11 to secure and protect your data and allow Electronic Signatures to be implemented.

Step 1. Start with an existing MS Access database program.

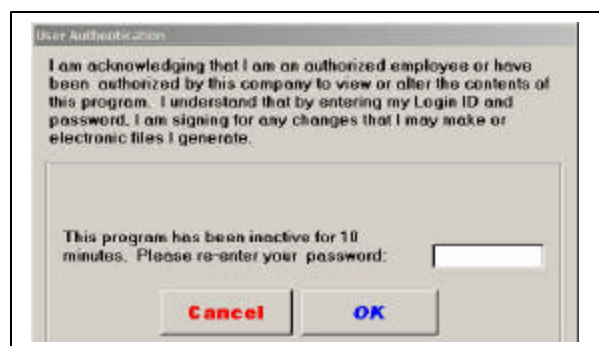
Step 2. Attach the Toolkit and add references within your own program for:

- ✓ Unique login ID's with passwords
- ✓ Audit trails and event logging
- ✓ Electronic signatures
- ✓ Search Engine with custom reports

Step 3. Use the Toolkit to secure the records and the program.

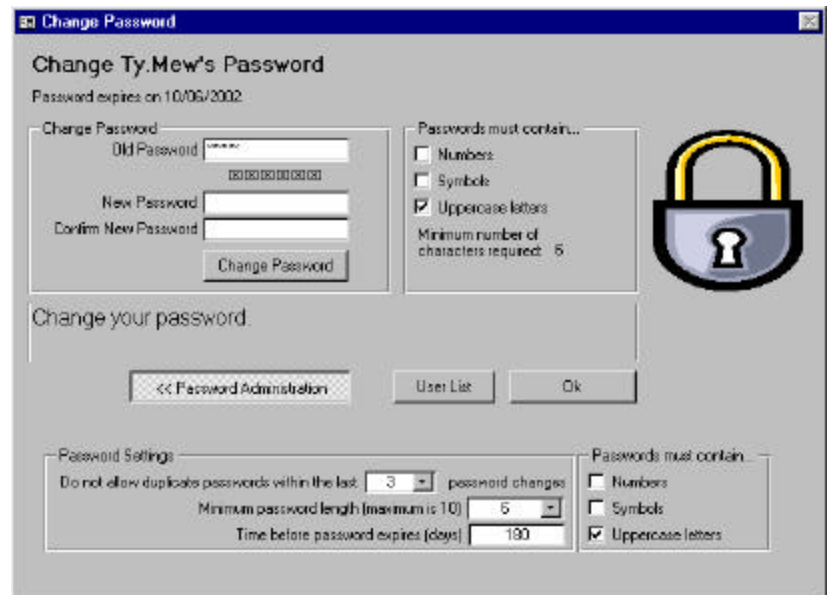
In less than a day, your Access programs can meet all of the technical requirements of 21 CFR Part 11.

***Your programs,
made compliant.***



SECURITY

- **Unique Login ID's and passwords** are assigned to all users and required for all logins.
- **Password requirements** for complexity and expirations can be set by Administrators.
- **Multiple Levels of Security** allows for different parts of your program to be seen or updated by users with the appropriate credentials.



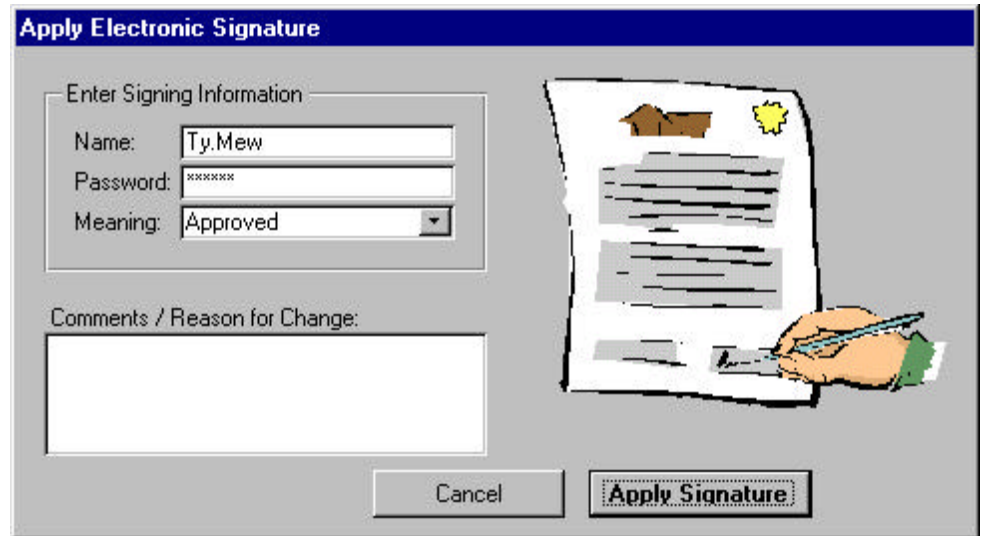
DATA INTEGRITY

- **Audit Trails** provide a complete change history for each record.
- **Event Logs** record any event that occurs within the program, including logins, logouts, error messages, or any other event specified by the program.



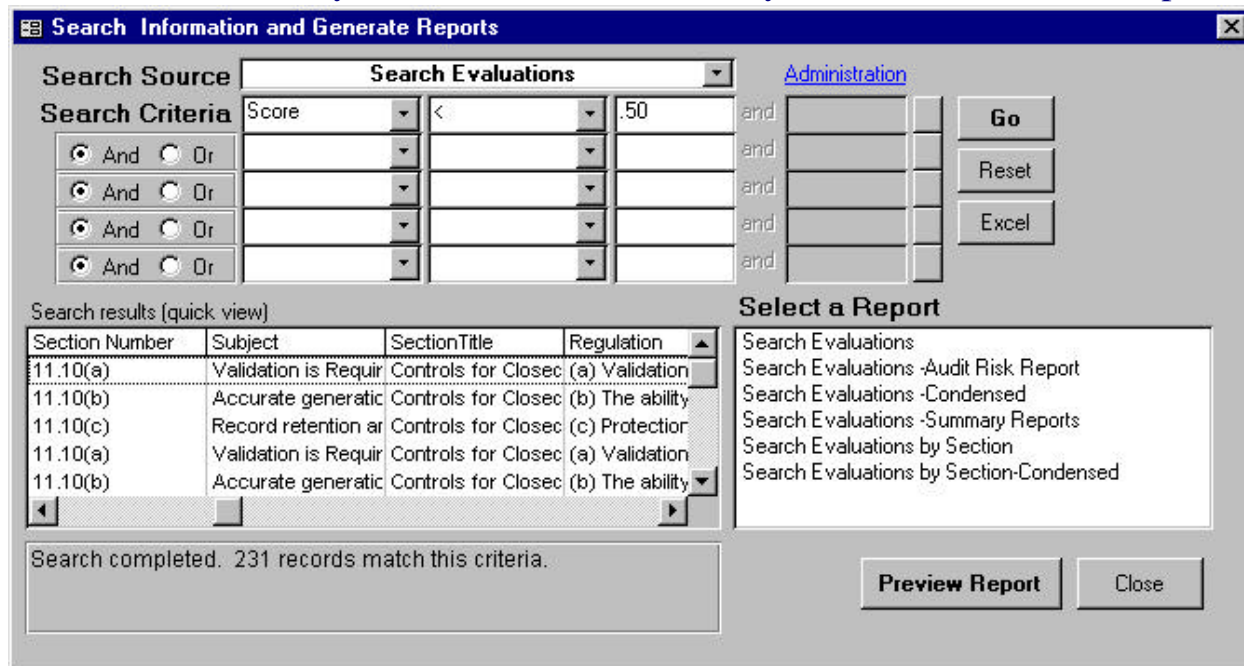
ELECTRONIC SIGNATURES

- **Add Electronic Signatures** to any form within your program.
- Records are locked from changes once signed.
- Developers may implement advanced features such as batch signing of records.



SEARCH ENGINE with CUSTOM REPORTS

A Search Engine is included that allows users the ability to search for any records contained within your program. The Search Engine is completely secure and includes the ability to view search results in any number of customized reports.



Frequently Asked Questions

Q: What version of Access is the Toolkit compatible with?

A: Access 97, 2000, XP and the new office system..

Q: How much does this program cost?

A: The license for the Part 11 Toolkit is \$2,495. The license entitles you to implement and use the toolkit on or within one MS Access program.

Q: How is it installed?

A: We can implement the Toolkit either remotely or on-site. The cost of installation, \$1000, is not included in the purchase price. Most installations will take less than 8 hours and include testing and the generation of a Part 11 compliance statement.

Q: Can I install it myself? Do you have training courses for how to implement the Toolkit?

A: Onsite training for the implementation of the Toolkit is available. Developer training is required for correct installation. Please contact us if you have any questions about training on your site.

Q: I have a large number of Access databases in my organization. Is there a discount available when purchasing multiple copies?

A: Yes. Given the likelihood of large numbers of databases within an organization, volume pricing applies. The greater the number of databases, the greater the discount.

Q: Are there restrictions on the number of users?

A: No. Licensing is done per database, not by user.

Q: What is your technical support policy?

A: Support plans are available with each copy of the software sold.

Q: Does the Toolkit provide functionality to do automatic backups and archiving?

A: This functionality is not a part of the Toolkit itself. However, we do offer a third party Access database backup utility that performs these functions.

Other questions? Please send an e-mail to Info@OfniSystems.com

We also provide help with evaluations and training on Part 11. For more information, call (919) 844-2494 or visit us online.

Contact: Ofni Systems Inc.
www.OfniSystems.com
Info@OfniSystems.com