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Spreadsheet Validation

Technical And Business Justifications For The Wimmer Systems DaCS™ Approach To Validating Spreadsheets.

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The following information provides you with some technical and business justifications for why you should choose the Wimmer Systems DaCS™ software approach to validating spreadsheets within your regulated environment.

This information is based upon our experience of validating spreadsheets for a wide variety of clients. It presents some facts and figures as to why the Wimmer Systems DaCS™ software approach is the most efficient and cost effective way of keeping your spreadsheets under compliance control and allowing their use in a regulated environment.

There are several inherent compliance gaps in “native” Microsoft ® Excel, particularly regarding audit trail and security functions. The Wimmer Systems DaCS™ software addresses these gaps. The DaCS™ software is an enhancement to Excel that allows it to operate in a 21 CFR Part 11 compliant manner.

Due to the compliance gaps in native Excel, validation of spreadsheets is a lengthy and resource consuming process, that inevitably never provides you with an adequate level of compliance against modern computer validation practices. The DaCS™ software will allow you to foster a streamlined approach to the validation of your spreadsheets, which is both efficient and compliant with your validation needs.

This document is divided into two sections, one to address the technical factors, and one to address the business justifications. Please feel free to study whichever section is most valuable to you, but remember that this solution provides substantial benefits in both areas, and the combined effect goes above and beyond the sum of each part.

Technical Justification

What are the compliance and business concerns?

When considering the need to improve the compliance status of your Excel spreadsheets there are various approaches and software vendors offering solutions. However some of these may not suit your functionality or practicality requirements for your current environment.

There are five main areas of concern for spreadsheet validation:

1. Threat to the business.
2. Lack of validation and resulting validation effort required to remediate.
3. Limitation of security controls for each potential method.
4. Limitation of traceability, internal and external to the Excel environment.
5. The number of spreadsheets in use, and the number requiring validation.

Based on these areas of concern, there are a number of potential remediation costs involved in validating your spreadsheets:

1. Development of a spreadsheet validation approach.
2. Roll-out of a spreadsheet validation approach.
3. Any software used in the process.
4. Any hardware used in the process.
5. Installation and validation of any software used in the process.
6. Validation of the spreadsheet inventory.
7. Maintenance of hardware, software and spreadsheets.

Faced with these concerns, and with the potential remediation costs, spreadsheet validation is a crucial compliance driven project that must be faced. Failure to address spreadsheet validation issues is likely to result in one or more of the following threats to your business:

1. Increased need for data processing resources
2. Loss of GxP records and the subsequent recovery effort to regenerate data
3. Prolonged FDA audit
4. Possible FDA 483 or warning letter

These threats can easily turn into ever-increasing costs due to the forced need for:

1. More local resources for remediation activities
2. Logistical restrictions
3. Shutdown or fines

Any of these would result in a decrease in your customer confidence or bottom line (and probably both).

What is the regulatory status?

A search of the FDA.gov web site shows that within computer systems validation, the FDA are actively pursuing 483's against spreadsheet violations and it is known that FDA inspectors are aware that the Wimmer Systems DaCS™ software solution is available in the compliance marketplace (see http://www.fda.gov/ohrms/dockets/dockets/00d1540/m00009_01.PDF).

FDA 21CFR Part 11 requires certain controls on electronic records, even when adopting guidelines on the new "risk-based approach" to validation. The Excel spreadsheets used in many regulatory environments constitute electronic records or they process and generate regulatory data. These spreadsheets often lack the required FDA controls. Procedures can be developed that place certain controls on Excel for security and audit trails, but these controls will also prohibit certain actions and are not independent from the operator. The only way to re-enable the flexible use of Excel and to remove the inherent security concerns is to use the DaCS™ software.

What about other similar products?

The DaCS™ software was the first commercial solution for Excel spreadsheet compliance and many vendors have attempted to imitate its features and functionality. It is our view that all have failed to reach an adequate level of technical control, and many have attempted to minimise these product quality deficiencies by attempting to compete on considerably reduced price or by "bundling" other software (or services) that are required for operation of the product.

Will the Quality of the “imitator” products improve?

Most probably the other products in the market place will improve, but because they are already selling to the market, it is unlikely that they will make fundamental changes to their products due to complaints from their current customers over excessive revalidation cost. As a result, changes are likely to be incremental and non-innovative.

Wimmer Systems had the foresight to innovate out the major technical concerns. These innovations include features such as the DaCS™ digital signature verification process and the inclusion of the audit trail and security within the workbook. These crucial features provide a level of control, flexibility and portability that imitators will not match without substantial re-engineering.

What are the benefits of using DaCS™ rather than another product?

Due to these innovations the DaCS™ software is very simple to use and can deal with the vast majority of your spreadsheets quickly and without any need for modification.

In addition, the DaCS™ software can, if required, go above and beyond the simple spreadsheets, and deal with all of your more complex spreadsheets as well. This is something that imitator products **cannot truthfully** claim.

One of the main reasons you should choose DaCS™ is because nearly every client will have a number of difficult spreadsheets in their inventory (usually 5-10% of the total which include complex macros, external linking, or the need for multiple workbooks being open at one time). DaCS™ is scalable to deal with these spreadsheets whilst imitator products will avoid these

spreadsheets. This will leave you with a number of uncontrolled spreadsheets that still have to be dealt with. Therefore you may need to withdraw the spreadsheets (and the business benefit they provide), or purchase and develop another approach for dealing with them, in which case you repeat your effort for no additional gain. The one thing that DaCS™ does not supply is “restrictions”, imitators do.

DaCS™ is the leading 21 CFR Part 11 compliant solution for Excel spreadsheets, and unlike other products is not an after thought, or a part of a larger system. As mentioned previously many other products attempt to add benefit by “bundling” in other types of software solutions (such as converting to Microsoft® Access). As a result, when such a product attempts to provide multiple complex solutions, it often fails to live up to your requirements on both. An analogy might be *if you try to sit on two chairs at once, you often end up falling down between them.*

If you require a solution for other files types please feel free to contact us and we will guide you to solutions that will meet your needs†.

If you need to assess DaCS™ against its competitor products, please feel free to contact us and we will provide you with a list of features and benefits solved by DaCS™ that have not yet been imitated.

† Example:
<http://www.ofnisystems.com> for MS Access files.

What about validating “native” Excel?

Returning to DaCS™ vs. “native” Excel the following items are of particular relevance and have been provided as bullets points for direct comparison. Throughout each of the sections, remember to ask yourself “**how will I validate my spreadsheet based on this fact**”. The honest answer for the native Excel issues is generally that you can’t.

Security Issues

“Native” Excel

- Password and protection easily broken (for example see www.elcomsoft.com/prs.html or multiple others)
- Utilizes a shared password to open or modify the spreadsheet.
- No login controls on the spreadsheets resulting in issues such as:
 - No password aging. Passwords must be manually reset and must be tracked procedurally.
 - No minimum password length required.
 - Passwords can be reused immediately.
 - No limit on the number of unauthorized access attempts.

Wimmer DaCS™ Software

- Requires a unique user I.D. and password to open the spreadsheet.
- Allows password aging and passwords cannot be re-used (configurable based on date since use, or number of replicates of the same password).
- Minimum password length required (configurable).
- Limits unauthorized access attempts (configurable number of attempts).
- Prevents renaming and moving of sheets where the user has defined that the workbook structure is protected.
- Provides for Electronic Signature Management providing functionality for Electronic signature notification to appear on the worksheet itself, as well as the audit trail. This allows for more transparent process in a business flow.
- Wimmer DaCS™ uses digital signatures to ensure the authenticity of the workbook between saving and reopen. This is a feature that imitator products do not use, and we consider is crucial for Excel files. It is an important check that prevents spreadsheets being tampered with outside of the application software. The DaCS™ feature holds the check within the spreadsheet rather than within a central server file.
- Wimmer DaCS™ uses randomly generated passwords to additionally protect workbooks changed every time it saves or closes. Again this is an important feature that has not yet been imitated. Using password recovery software (for example www.elcomsoft.com/prs.html) will provide you with worksheet and workbook passwords in a matter of seconds. DaCS™ guards against this security concern. This is an interesting check to perform on imitator products, after all, your files are only as secure as the passwords (or password) used to protect them.

Audit Trail

“Native” Excel

- Track changes features don’t work as required, are easily bypassed. In addition they can cause file size bloat and sharing collisions, as well as preventing access to macros (change histories are lost if macros are accessed).
- Procedural audit trails are not automatic and not acceptable.
- No reason is required for making a change.
- User identification can be modified on the local machine prior to making a change.

Wimmer DaCS™ Software

- Audit trail is kept in the same workbook so the history remains with file, even if you want to send it between locations, sites, or customers. This coupled with the digital signature security allows you to securely send files between locations and you can be sure of the authenticity on arrival.
- Reasons for change can be picked from pre-defined reasons or user may type in a new reason.
- Audit trail functions can be customized.

Flexibility

“Native” Excel

- If you attempt to use any degree of security, you have to set-up in such a way that gives very limited ability to customize the workbook once the spreadsheet is set up and protected.

Wimmer DaCS™ Software

- User can work in Excel without any restriction, with DaCS™ monitoring changes to data.
- DaCS™ saves files as standard Excel workbooks. Any person with Excel can open the workbook or import data from it, but cannot make changes to it without using DaCS™.
- DaCS™ can be configured to run over a network or a stand-alone PC.
- All the flexibility that you have in Excel for macros and programming in spreadsheets still exists in DaCS™. DaCS™ has its own object model, which is very comprehensive and allows you to program pretty much anything that you can do in normal Excel (as long as it is not inherently insecure). Imitator products do not have this.

Who developed the validation approach for spreadsheets and validation of DaCS™?

ABB Process Solutions (formally Eutech), as a professional validation consultancy company and one of the founder members of GAMP has extensive experience of working with regulatory guidelines and under appropriate validation guidelines. All supplied documentation is developed and/or approved by ABB Process Solutions. This is critical in providing assurance that the installed system and spreadsheets can meet regulatory expectations and satisfy subsequent inspections and approvals.

Business Justification.

This information provides some guidance on return on investment for the Wimmer Systems DaCS™ Software approach. It provides you with comments, metrics, and views on why the ABB Process Solutions and DaCS™ Software approach is the most suitable approach to validating spreadsheets from a financial as well as a technical point of view.

The first point to note is that a spreadsheet validation project is normally divided into 2 aspects, Spreadsheet Validation and the DaCS™ validation.

Spreadsheet Validation

This component of the project needs to be performed for every GxP critical spreadsheet whether you decide to use DaCS™ or not. You may have a range of spreadsheets in your inventory that require validation.

Throughout this justification we will use an example of 20 spreadsheets, which is often representative of a small site.

If you try validating “native” Excel, you still have to invest effort into validating each spreadsheet. It is the spreadsheet validation component of the project that is the most time-consuming. We estimate 80% of resource effort will be on spreadsheet validation rather than on validating a 3rd party package (DaCS™ in this situation).

Spreadsheet Validation - Resource and Time considerations.

The effort to develop a spreadsheet validation approach from scratch is likely to take in excess of 20 days to develop, and then having developed it you will have limited experience of its use. You will be unsure of how well it will work, or how it will compare to other companies’ approaches. For this reason it would be prudent to follow a pre-developed approach such as the ABB Process Solutions and DaCS™ software approach.

There would be a requirement to undertake training on the ABB process, but even if you produce your own process, you would have to train your people on it (and develop a training session to do so), so undertaking a single pre-developed training course would be no more time consuming than training yourselves.

The following represents an example.

Once the process is in place, it is likely that each spreadsheet will require 10 days** to validate in “native” Excel, and one day to write a validation plan to cover the project.

***N.B. Some of the following figures are based on our experience of client-developed approaches; we have seen approaches that are 25% of these figures, but also others that are 200% of these figures. The figures provided represent a mean value. Please feel free to contact us to discuss how your approach measures up. We are always open for new ideas. Please remember the example figures given are for a straightforward spreadsheet, with approximately 4 worksheets, and 100 formulas. Clearly every spreadsheet is different and you will have to bear that in mind as you read. Please also remember the figures given are for total workload, including full completion of all deliverables. The basic process would be*

- Spreadsheet reformat,
- Spreadsheet informal test,
- Spreadsheet specification,
- Spreadsheet protocol,
- Install Spreadsheet,
- Test Spreadsheet,
- SOP for Spreadsheet.

DaCS™ removes many of the difficult validation concerns (security, audit trail etc) you would have with most spreadsheets, and as a result when you validate a spreadsheet in DaCS™, each spreadsheet takes less effort than one that is in “native” excel. As an estimate it is likely that each DaCS™ spreadsheet will take 40% less time to validate than a spreadsheet in “native” Excel (using the ABB process and deliverables). This extra effort is obviously multiplied by however many spreadsheet you may have (20 in our example).

Therefore the estimated total effort for running your “home grown” spreadsheet validation process with “native” Excel is 220 days.

The estimated total effort for running the ABB validation approach on 20 spreadsheets is 121 days.

Therefore, the ABB approach yields a saving of 101 days.

Spreadsheet Validation - Compliance considerations

When validating with “native” Excel you can never be fully compliant with 21 CFR Part 11, or with common computer validation practices due to the inherent problems within Excel. As a result you would probably only get to around 80% compliance. It is impossible to put a financial price on this shortfall, but it clearly represents a significant compliance risk, and also a well-known and common compliance risk in the eyes of an inspector. This risk is increasingly visible now that the DaCS™ spreadsheet solution is so well known in the market place (and by the FDA). In an effort to mitigate some of these risks you could build additional procedural and manual checks into your spreadsheet review process, perhaps adding 30 minutes of review time to **each use** of a spreadsheet. From a compliance view point there is no comparison between “native” Excel and DaCS™. You either chose full compliance with DaCS™ or you choose the risk of failing compliance aspects of your next audit.

DaCS™ Validation

If you choose DaCS™ you will need to run a separate project to install and validate it. The return on investment for adding the extra software solution is primarily from a compliance point of view and reduces your inspection risk. You have to budget for installation, training, and validation of the DaCS™ solution. This can be done by you or by ABB.

The DaCS™ install and validate project only needs to be done once for the site, and ABB can normally do the DaCS™ install and validation within 3 days (total of about 6 man days effort).

The DaCS™ solution may require some spreadsheet reformatting effort for more complicated macro-based spreadsheets. Normally these only make up 5% of your total inventory, (remember that imitator products will often restrict the use of these in their product).

There are a number of other areas where the DaCS™ product adds value when compared to a “do-it-yourself” approach, and as a result can be viewed as a long term investment and additional business security.

- Best-known solution in the industry.
- Being adopted by many of the major pharmaceutical companies.
- Being increasing adopted by instrument vendors to output in DaCS™ controlled Excel format.
- Adopted and supported by ABB in 100 countries worldwide.
- It is a standalone solution and not integrated into the success of a larger software package.
- DaCS™ files are viewable from “standard” Excel in read-only format even if you change from DaCS™ in the future.
- ABB Process Solutions are a professional validation consultancy company and therefore have backed the product based not only on its technical capability, but its suitability for providing validation of a very high standard for both the DaCS™ software and the spreadsheets that are inserted into it.

Project Summary

To summarize from a financial and resource point of view please see below. We have used an internal cost estimate of \$50/hr or \$400 per day.

The comparison figures show the most cost effective roll-out of the DaCS™ solution, with installation, training and validation of DaCS™ performed by ABB, and spreadsheet validation performed internally by yourselves following the ABB process.

In our estimate of 20 spreadsheets you would require an investment of around \$10,000 for the software (assumes around 20 users) and a further \$10,000 in getting installed, trained and validated. After this time you can add as many additional spreadsheets at no extra software cost.

Development of a spreadsheet validation approach could cost you 20 days internally (\$8000); you can instead use the proven ABB approach that provides the process, training and all required documentation for \$7,600.

The cost of validation of 20 spreadsheets internally using “native” excel would cost \$80,000 (20 x 10 days @ \$400/day).



The cost of validation of 20 spreadsheets internally using the ABB process would cost \$48,000 (20 x 6 days @ \$400/day).

We estimate that the overall project cost of running with DaCS™ as opposed to running “native” Excel for 20 spreadsheets would save you time and money,

in this example a **total saving of 101 days and a saving of \$12,400.**

When running with DaCS™ you would also **have a fully secure and validated spreadsheet validation process.** Any future implementation of spreadsheets could occur at a significantly reduced cost.

If you invest in validating spreadsheets without DaCS™ you run the risk of spending more money and still having identifiable compliance issues.

Comparison Table

Based on internal cost of \$400 per day, 20 spreadsheets (SS), and 20 users.

Activity	“Native” Excel Approach	ABB DaCS™ Process	Comments
Develop SS validation process	\$8,000 20 days	\$7,600	Will your developed approach work?
DaCS™ Installation and validation services	0	\$10,000	This assumes all services performed by ABB. If these activities are done internally the cost can be reduced.
Software	0	\$10,000	DaCS™ allows unlimited number of spreadsheets.
Validation Planning	\$1,900 (or more) 1 day	\$1,900	Assumes comparable effort, but ABB have predefined document set.
SS validation-internal	\$80,000 200 days	\$48,000 120 days	Assumes internal resources used based cost of \$400 per day and 20 spreadsheets (SS).
TOTALS	\$89,900 221 days	\$77,500 120 days	

Summary of Savings for 20 spreadsheets (using ABB and DaCS™)		
Total Cost Saving	\$12,400	14% cost saving (see figure 1).
Total number of internal man days saved	101 days	46% internal resource saving (see figure 2).
Cost Saving per spreadsheet	\$620 / SS	See figure 3.

The diagram below extends the example to show the comparative costs of validating various numbers of spreadsheets. It shows that after the initial investment in the introduction of DaCS™ there are considerable cost savings to be made for larger numbers of spreadsheets.

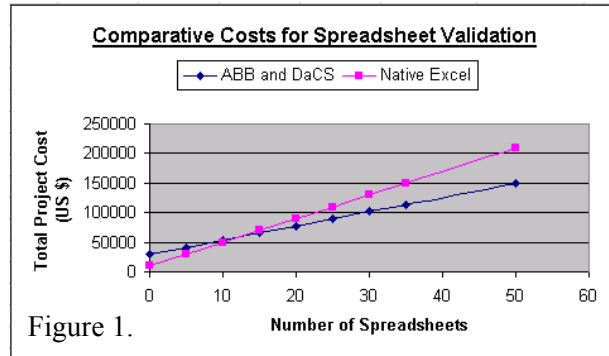
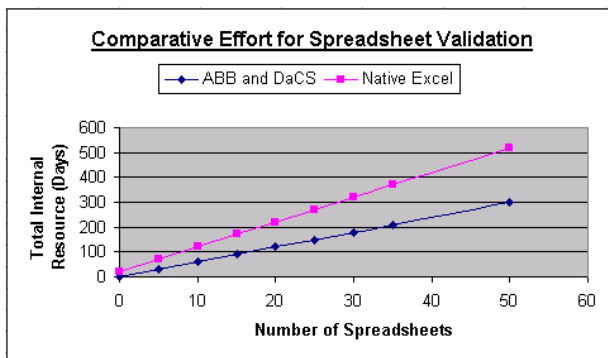


Figure 1.

Figure 2.



The diagram to the left shows the comparative internal resource effort involved in validating spreadsheets. It shows that the adoption of the ABB and DaCS™ approach provides significant resource savings coupled with the use of a proven process.

The diagram below shows the comparative costs of validating an individual spreadsheet. It shows that the ABB and DaCS™ approach pays for itself quickly and all future spreadsheets can be validated at a considerable saving.

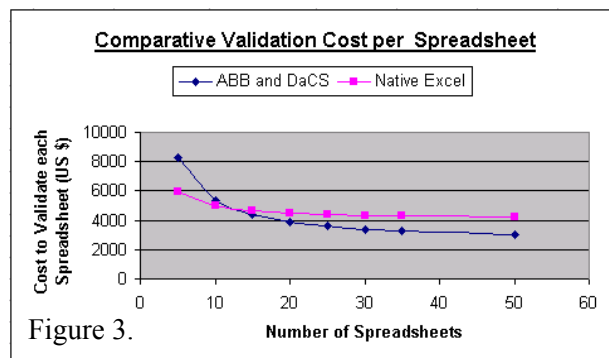


Figure 3.

These comparative costs don't highlight the fact that DaCS™ and the ABB process will provide compliance for 21 CFR Part 11 and good validation practices. The native Excel approach leaves considerable compliance risks.



Conclusion

The “native” Excel validation approach is not Part 11 compliant and does not allow you to validate to an acceptable level.

Therefore there are 3 options:

- (1) to utilize a third party solution (of which DaCS™ is the industry leader and the only one to offer full technical controls),
- (2) continue to operate out of compliance with the regulations and with unvalidated spreadsheets,
- (3) discontinue the use of the spreadsheets and the business benefits that spreadsheets provide you.

The Wimmer DaCS™ solution coupled with ABB Process Solution services will provide a 21CFR Part 11 compliant solution for the spreadsheets, and allow a streamlined validation approach, at a relatively low cost.

The DaCS™ software is user friendly and it allows the user to continue to work within the familiarity of Excel, with all security and auditing actions operating in the background.

Why ABB and Wimmer DaCS™

- No additional hardware required.
- No additional software required other than DaCS™.
- No dedicated server required.
- No expensive database system required.
- No expensive file/document management system required.
- No file conversion license or other hidden cost required.
- No customization required, although customized can be performed to meet specific requirements.
- No increase in validation overhead.
- Affordable cost for User License with maintenance included.
- Technical compliance with 21 CFR Part 11.
- Comprehensive Security and Audit Trail.
- The user can work in Excel without any restrictions
- Best known solution in the market place (references available on request).
- Fully proven validation process, documentation and resources.
- ABB supplies worldwide sales, support, training and consultancy; Wimmer Systems continue to innovate and lead the software market.

For further information please contact the ABB Process Solutions Sales and Support team:

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