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應用手冊

GxP Spreadsheets Encapsulated in a Compliant-Ready Solution

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Abstract

This application note will demonstrate how a Microsoft Excel spreadsheet document functions in a GxP

Laboratory by implementing NuGenesis SDMS.

Introduction

The first commercially available electronic spreadsheet was released in 1979.[1] During the 1980s, the financial and accounting industries rapidly implemented electronic spreadsheets and adoption quickly spread to other arenas, including the sciences. Today, electronic spreadsheets are widely used in scientific laboratories to provide experimental result interpretations, such as plotting data into charts, performing simple-to-complex calculations, and serving as simple databases.

Laboratories adhering to regulations such as 21 CFR Part 11, Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP) in compliance with 21 CFR Parts 58 and 211, seek to ensure that electronic records, including electronic spreadsheets are trustworthy, reliable, and equivalent to paper records. Built-in safeguards that ensure data authenticity such as electronic signatures, audit trails, and date and time stamps are not provided with electronic spreadsheets such as Microsoft Excel. U.S. regulators have issued warning letters citing insufficient controls for spreadsheets that are used in regulated environments.[2,3,4] In order to utilize electronic spreadsheets in the GxP environment, spreadsheets such as Excel need additional controls. Electronic Laboratory Notebooks (ELN), and Scientific Data Management Systems (SDMS) are software applications that provide a mechanism to increase spreadsheet control.

Waters NuGenesis SDMS acts as a data repository for file data and printed electronic records as a core feature. Added functionality of NuGenesis SDMS includes SDMS Vision Publisher, a report and authoring tool, and SDMS Intelligent Procedure Manager, a GxP workflow documentation tool. Both Vision Publisher and Intelligent Procedure Manager can serve as a compliant ready shell for maintaining the authenticity of Microsoft Excel electronic documents (Figure 1). This compliant-ready functionality makes the functionality of Microsoft Excel spreadsheets accessible to analysts working in GxP laboratories by providing the necessary safeguards for using electronic documents in GxP environments.

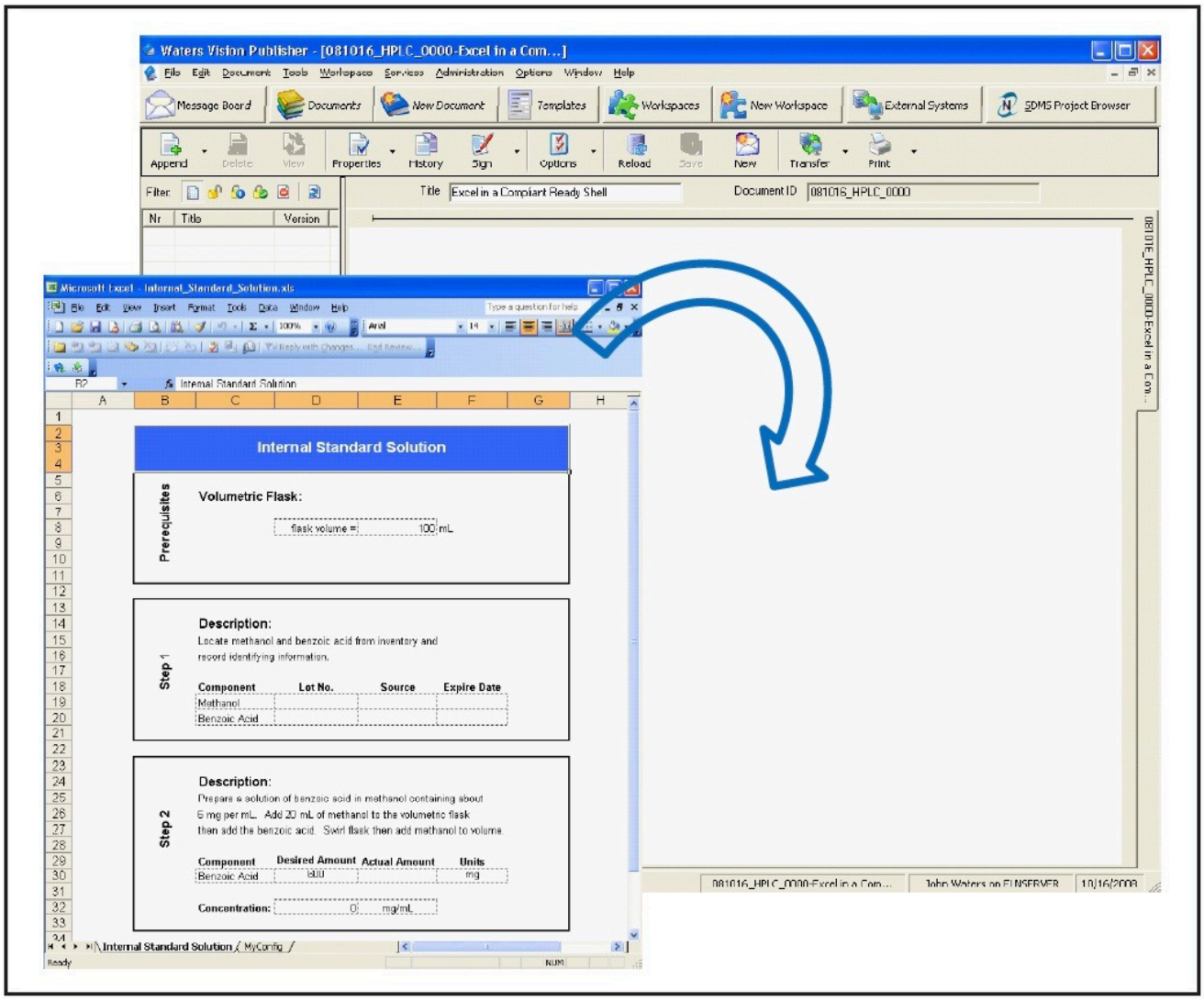

Figure 1. Microsoft Excel embedded within the compliant-ready shell of SDMS Vision Publisher.

This application note will demonstrate how a Microsoft Excel spreadsheet document functions in a GxP Laboratory by implementing NuGenesis SDMS.

Results and Discussion

Preparing an Excel Worksheet

Extensive practice of Standard Operation Procedures (SOPs) ensures quality and consistency during laboratory procedures in the regulated laboratory. Figure 2 illustrates an electronic form implemented by using Microsoft Excel. The form contains data input fields and a formula for determining solution concentration. Formula

accuracy for the calculation may be verified manually or by comparison with a validated mathematical software package.

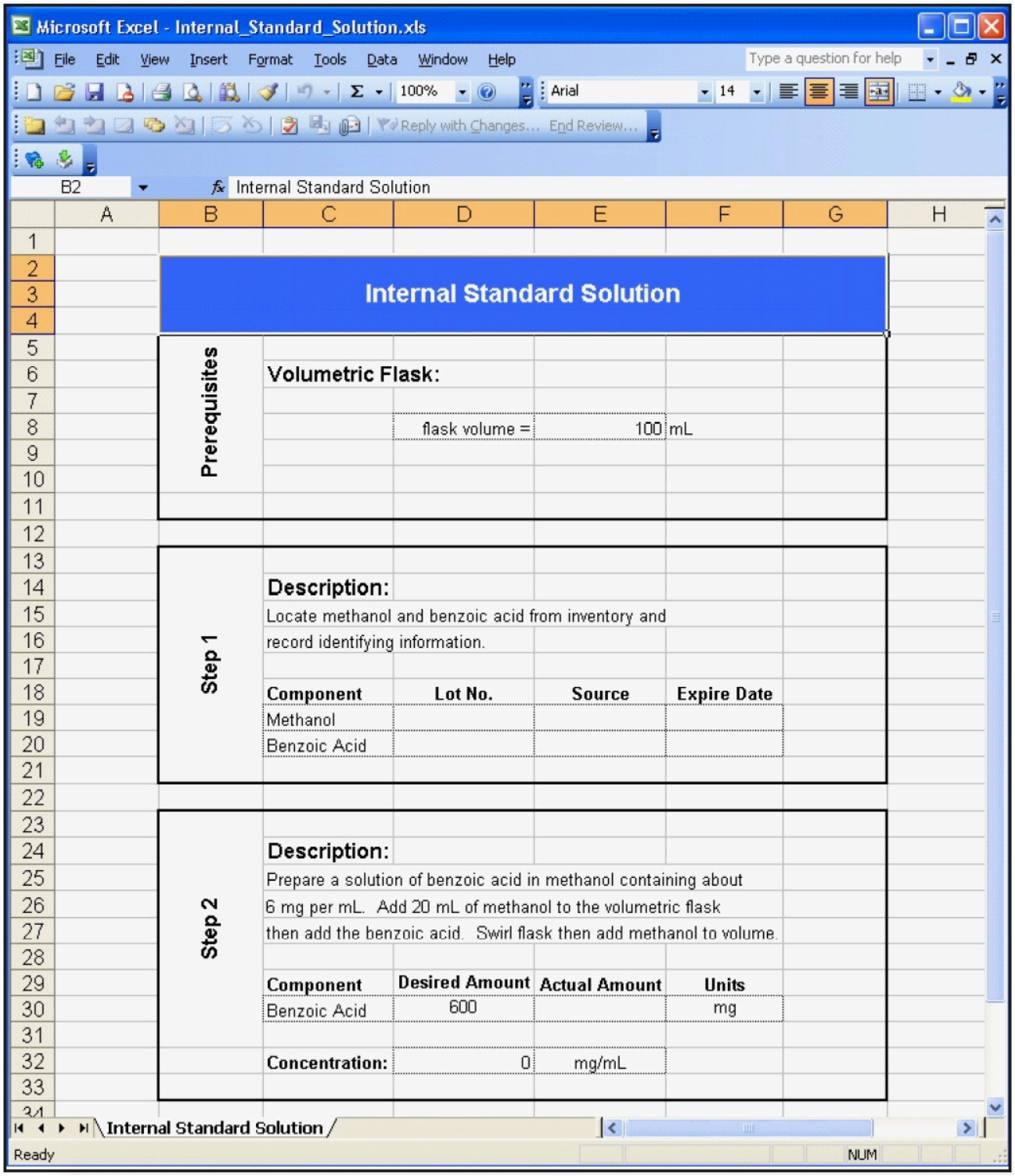

Figure 2. Form created in Microsoft Excel including a concentration calculation utilizing a verified equation.

Embedding and Using Excel

Once the spreadsheet calculations have been qualified, the spreadsheet still lacks version control and unauthorized modifications may compromise confidence in experimental results. Incorporating an Excel form into the compliant-ready framework of the Vision Publisher tool enables the integration of 21 CFR Part 11 requirements such as audit trails and version control. A relational database such as Oracle provides data traceability to support the implementation of 21 CFR Part 11 requirements. Embedding a spreadsheet within Vision Publisher begins with the system login (Figure 3). Adding an Excel form requires a user to login with administrative privileges. Object Linking and Embedding (OLE) technology[5,6] provide the connectivity to incorporate an Excel form into Vision Publisher. The file browser dialog window allows the administrator to locate the Excel form on the system (Figure 4) and assign it to SDMS Vision Publisher (Figure 5). Once the form resides within SDMS Vision Publisher, the administrator can assign access levels to the document. Verified formulae and input fields can be password protected and finally SDMS Vision Publisher tracks, via an audit trail (Figure 6), input made by the user.

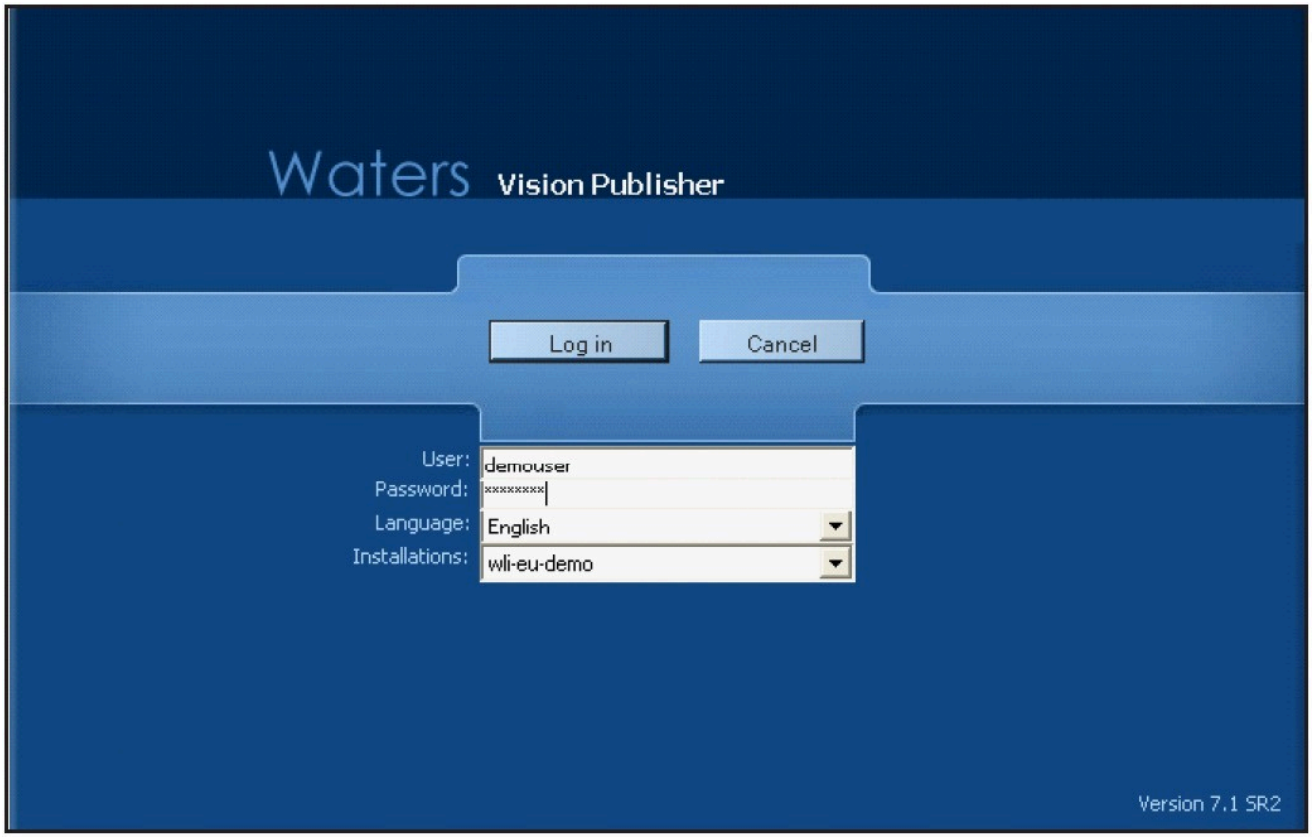

Figure 3. Electronic login to SMDS Vision Publisher. Analyst supplies unique user name and password.

Figure 4. Microsoft Excel form inserted into SDMS Vision Publisher as an OLE object. Form selected for inclusion with a file browser dialog window.

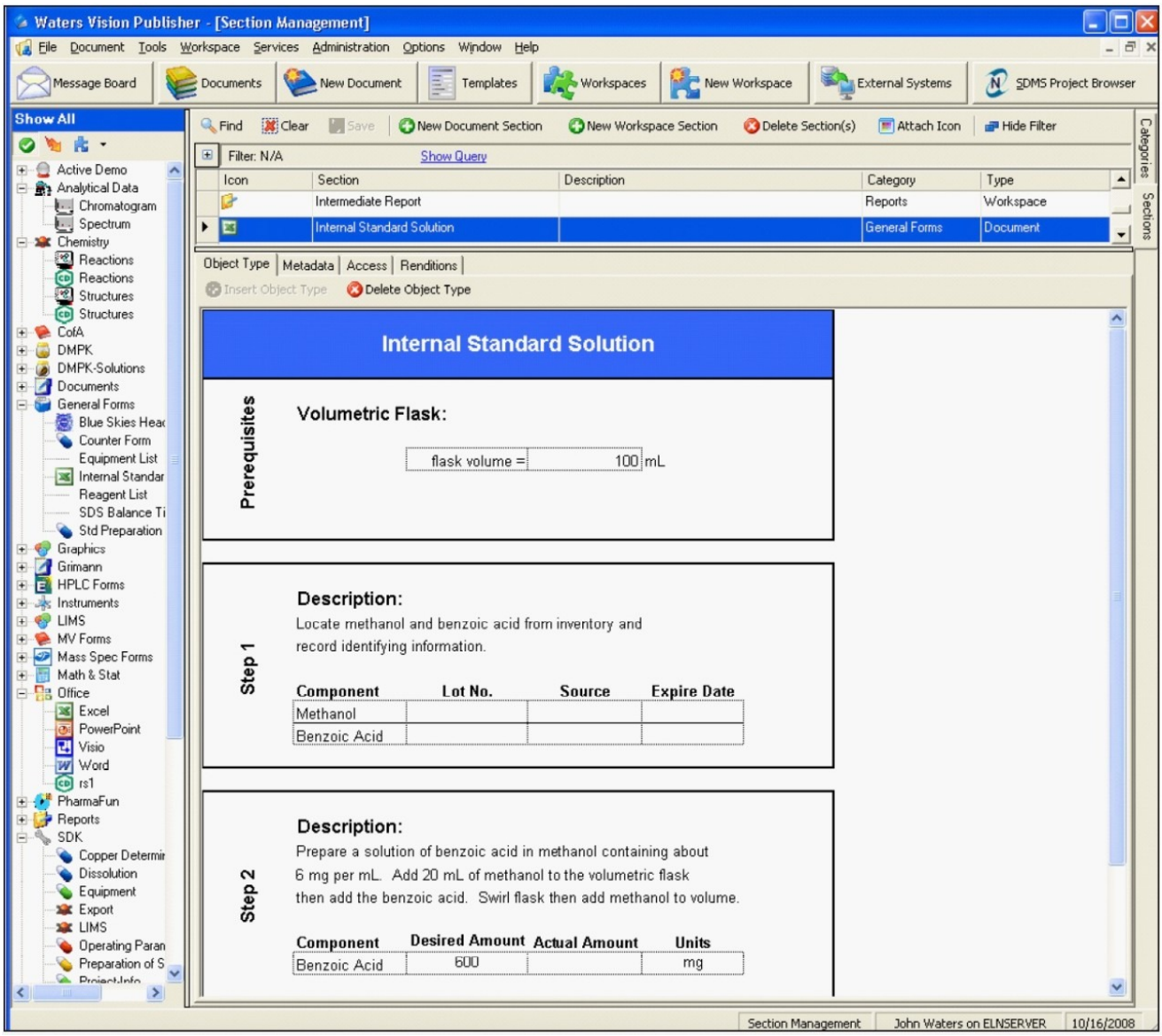

Figure 5. Microsoft Excel form added to SDMS Vision Publisher and available as a section in a SDMS Vision Publisher electronic document.

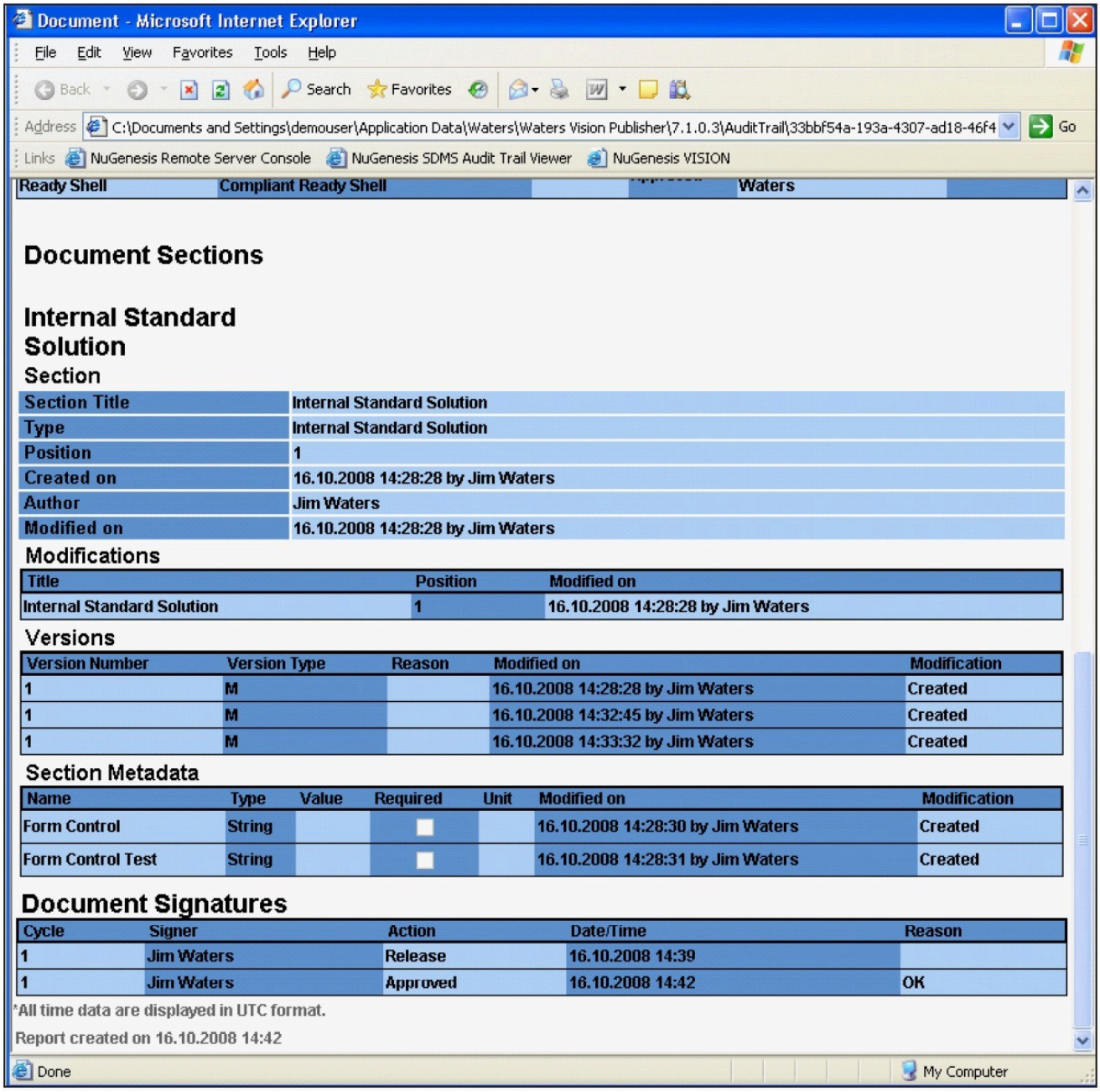

Figure 6. Modifications and signatures applied to Excel form tracked in the Audit Trail.

For the analyst, the spreadsheet functions normally with the exception that they can only provide input into designated fields and cannot modify the form or equations. Electronic signatures are available to the analyst and are initiated by releasing the document for review. The signature process requires a unique login and password combination as well as a signature reason (Figure 7). After the analyst applies their electronic signature, a notification for review and signature is automatically routed to a manager or supervisor. Up to 3 signatories may be configured for review and signoff.

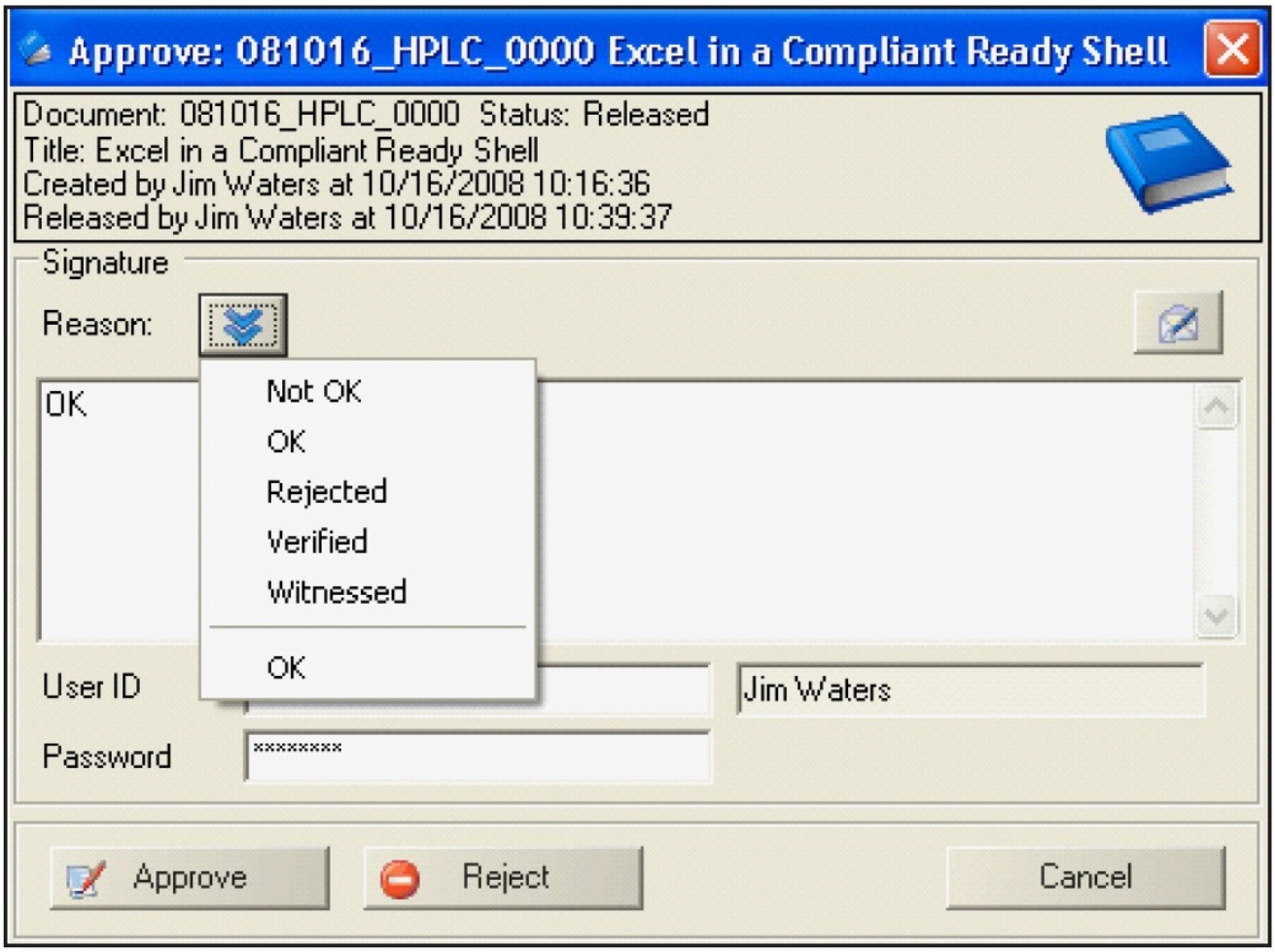

Figure 7. Electronic signature applied to the completed document including reason for signature. Request for additional review and approval routed via electronic signature functionality.

Conclusion

Microsoft Excel is a versatile and powerful tool for performing laboratory calculations and plotting data, but does not provide a mechanism to adhere to regulations and guidances, such as 21 CFR Part 11 and Annex 11, for authentic and secure records. Incorporating Excel spreadsheets inside a compliant-ready shell like SDMS Vision Publisher enables regulated laboratories to utilize Excel while adhering to GxP regulations for authentic and traceable records.

Storing Excel content inside a compliant-ready shell like SDMS Vision Publisher can improve data record quality and reduce the quality operation cycle times for returning QC results. Quality assurance efforts benefit due to decreased record review times since records are housed centrally with complete audit trails. Greater efficiency

and productivity result in shipping products faster and maximizing available resources.

References

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720002803, November 2008

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