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应用纪要

Increasing Quality Control Testing Efficiency with Compliant-ready SOP Digital Forms

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这是一份应用简报，不包含详细的实验部分。

Abstract

This application brief describes an electronic SOP form designing utility called SDMS Form Designer, that provides a straightforward and standardized mechanism for creating compliant-ready SOP forms.

Introduction

Pharmaceutical Manufacturing magazine conducted a survey of pharmaceutical team leaders in 2005, and found that the three biggest challenges facing pharmaceutical manufacturing were Standard Operating Procedures (SOP’ s) and training, quality management and testing, and documentation.[1] All three of these challenges for pharmaceutical manufacturing revolve around adhering to government regulations to ensure the efficacy and safety of their pharmaceutical products. With the pharmaceutical industry’ s historically high profit margins, improving manufacturing efficiency hasn’ t been a primary

objective until recently. In the past 5 to 10 years, most pharmaceutical companies have begun utilizing some type of Lean Process Manufacturing or Six-Sigma strategy to improve manufacturing efficiency. Improving the efficiency in challenge areas such as quality testing, plus SOP, and quality documentation management, presents an important opportunity to improve overall manufacturing operational efficiency.

Migrating to an electronic documentation solution represents an important strategy for improving efficiency in labs utilizing SOP' s because it helps fulfill QC documentation requirements and reduces QC testing turnaround times. Although a number of vendors offer electronic SOP forms, the creation of those forms can be complex and time-consuming. Indeed, the primary challenge labs face when implementing digital SOP forms is not in their usage, but rather in form design and authoring.

Here we describe an electronic SOP form designing utility called SDMS Form Designer, that provides a straightforward and standardized mechanism for creating compliant-ready SOP forms.

Results and Discussion

QC Data and Test Result Management

Before creating and using electronic SOP' s, the QC data and test results need electronic organization. Scientific Data Management Systems, such as Waters® NuGenesis® SDMS solution, provides a convenient platform for standardizing the management of QC testing raw data and paper documentation into a centralized digital repository, as shown in Figure 1. The file capture capability of NuGenesis SDMS automatically captures and catalogs data originating from QC instruments into a searchable relational database, while its print-to-database capability automatically indexes printed test documents into the searchable database. Digitally storing QC test data and documents represents the keystone step towards implementing an electronic SOP documentation and workflow system because it provides the content necessary to implement the SOP forms, as shown in Figure 2.

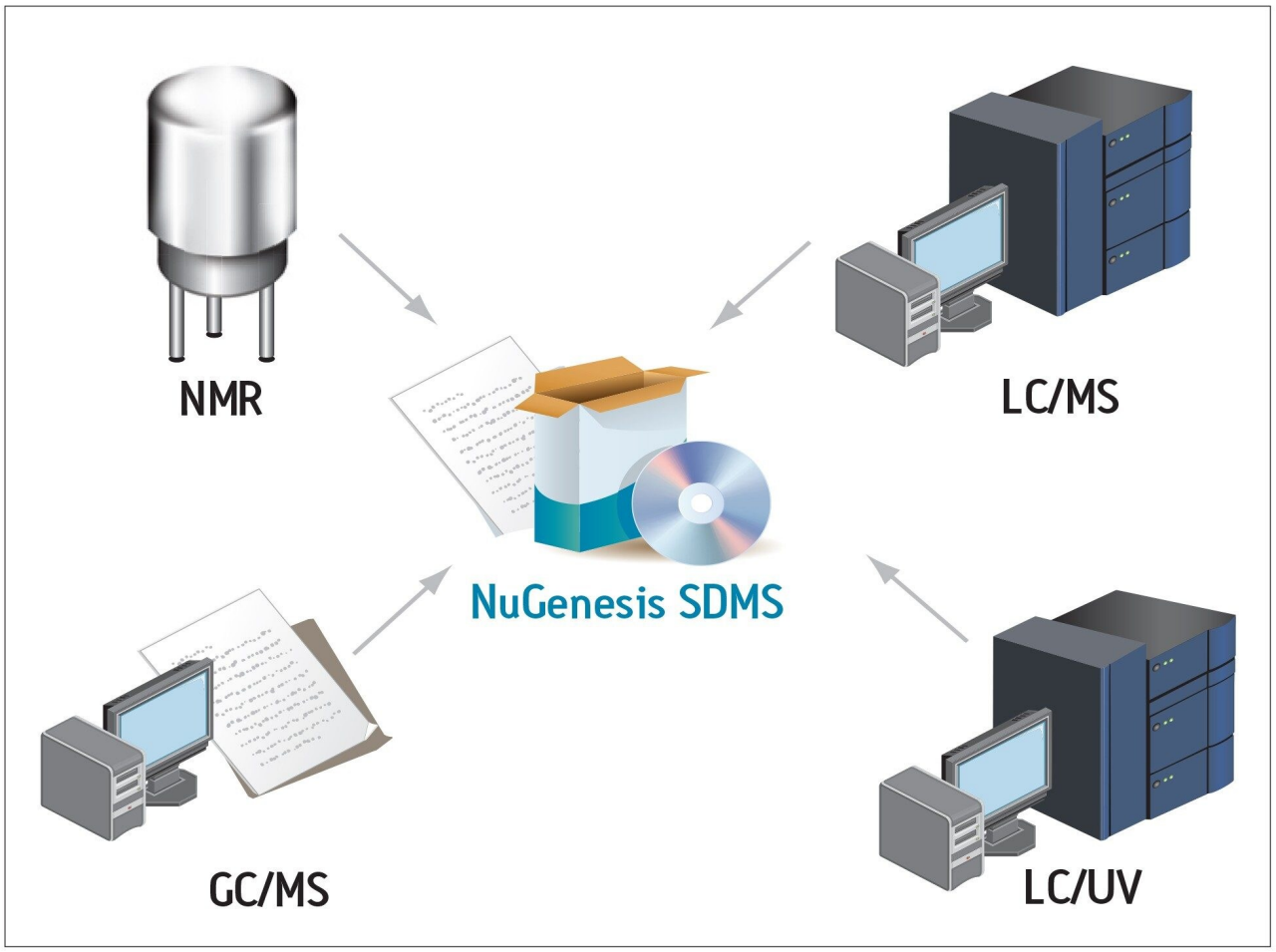

Figure 1. Capturing and cataloging QC data and test results within NuGenesis SDMS, a central QC data repository.

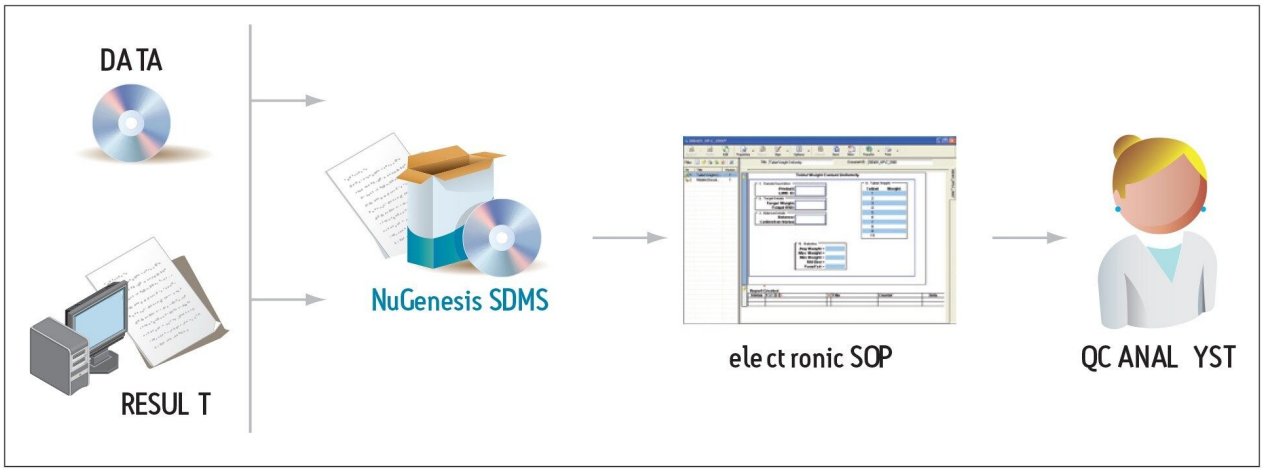

Figure 2. A QC analyst utilizes data contained within the NuGenesis SDMS data repository while completing electronic SOP forms.

Electronic SOP and Workflow System

Waters' SDMS Vision Publisher,™ the report and authoring tool for NuGenesis SDMS, is available with an electronic form and documentation workflow system, the SDMS Intelligent Procedure Manager, as shown in Figure 2. Intelligent Procedure Manager provides an electronic SOP creation utility called SDMS Form Designer, which is the focus of the remainder of this article. Figure 3 illustrates the steps involved to create a typical electronic SOP form.

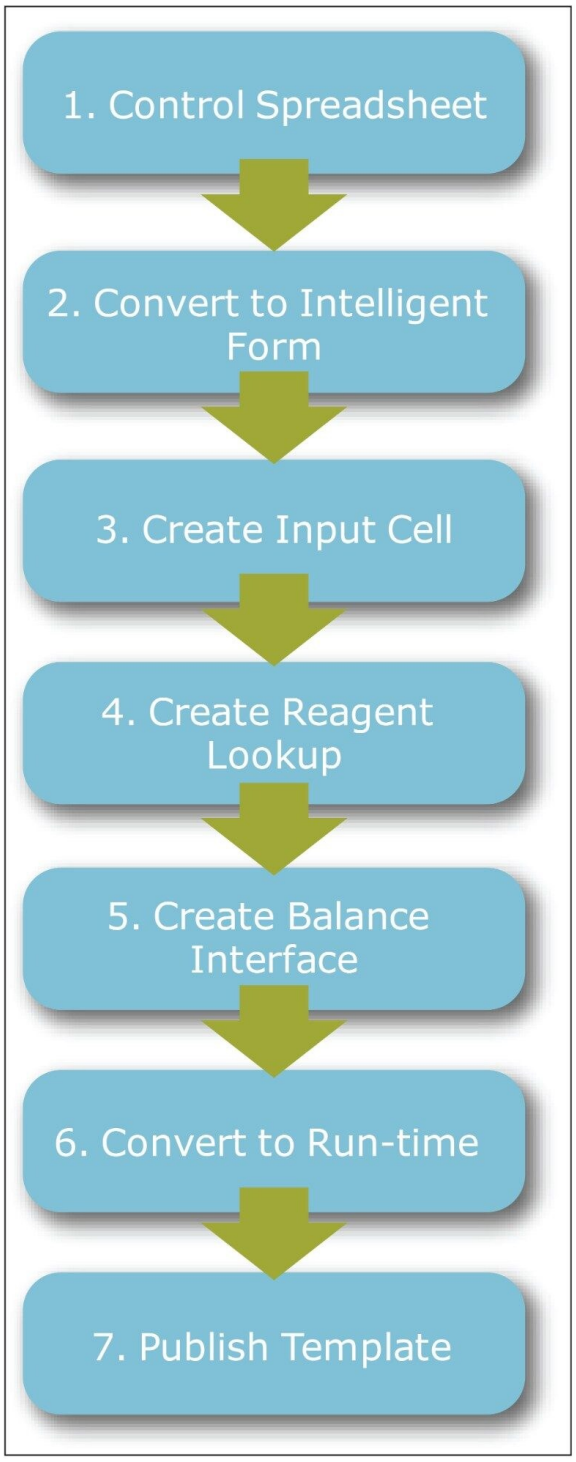

Figure 3. Seven-step workflow utilized to create a functioning, intelligent SOP form.

Controlling Electronic Forms

The first step for creating electronic SOP forms involves placing a form under software control in accordance with 21 CFR Part 11 (Step 1, Figure 3). Figure 4 demonstrates how an SOP worksheet created in Microsoft Excel is utilized within a compliant-ready solution, such as SDMS Vision Publisher.[2] Vision Publisher is a 21 CFR Part 11 compliant-ready report and authoring tool that is a standard extension of NuGenesis SDMS. Laboratory analysts can use a Microsoft Office application, such as Microsoft Excel directly within Vision Publisher with a minimal learning curve, and take advantage of Vision Publisher's document management capability at the same time.

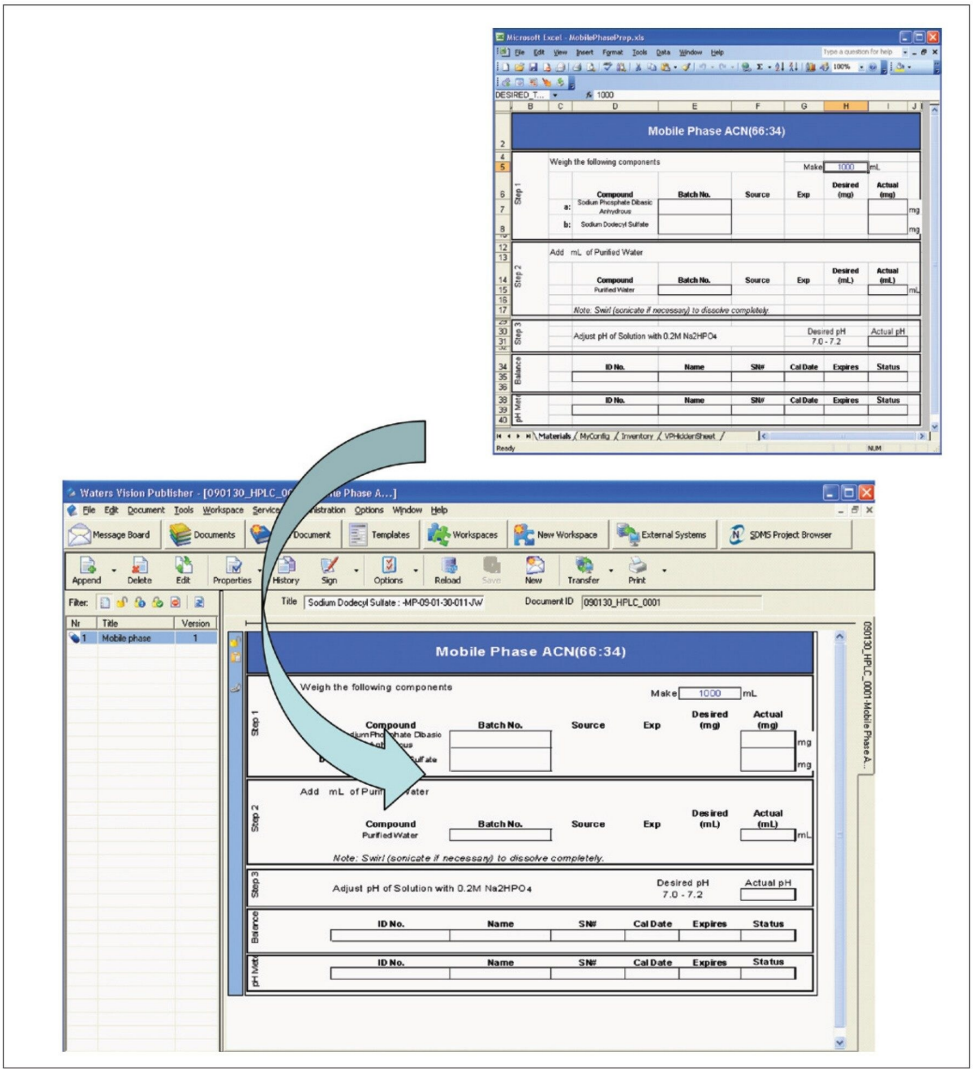

Figure 4. Adding a form layout designed by using Excel to the 21 CFR Part 11 compliant-ready SDMS Vision Publisher to provide document control.

Converting a Spreadsheet Into an Intelligent Form

The next step in creating an electronic SOP involves activating the Form Designer functionality of Intelligent Procedure Manager (Step 2, Figure 3). Converting the Excel worksheet into an intelligent form starts by clicking Convert to Form, as shown in Figure 5. The electronic form then switches on additional functionality such as the capability to interface directly with electronic balances and database tables.

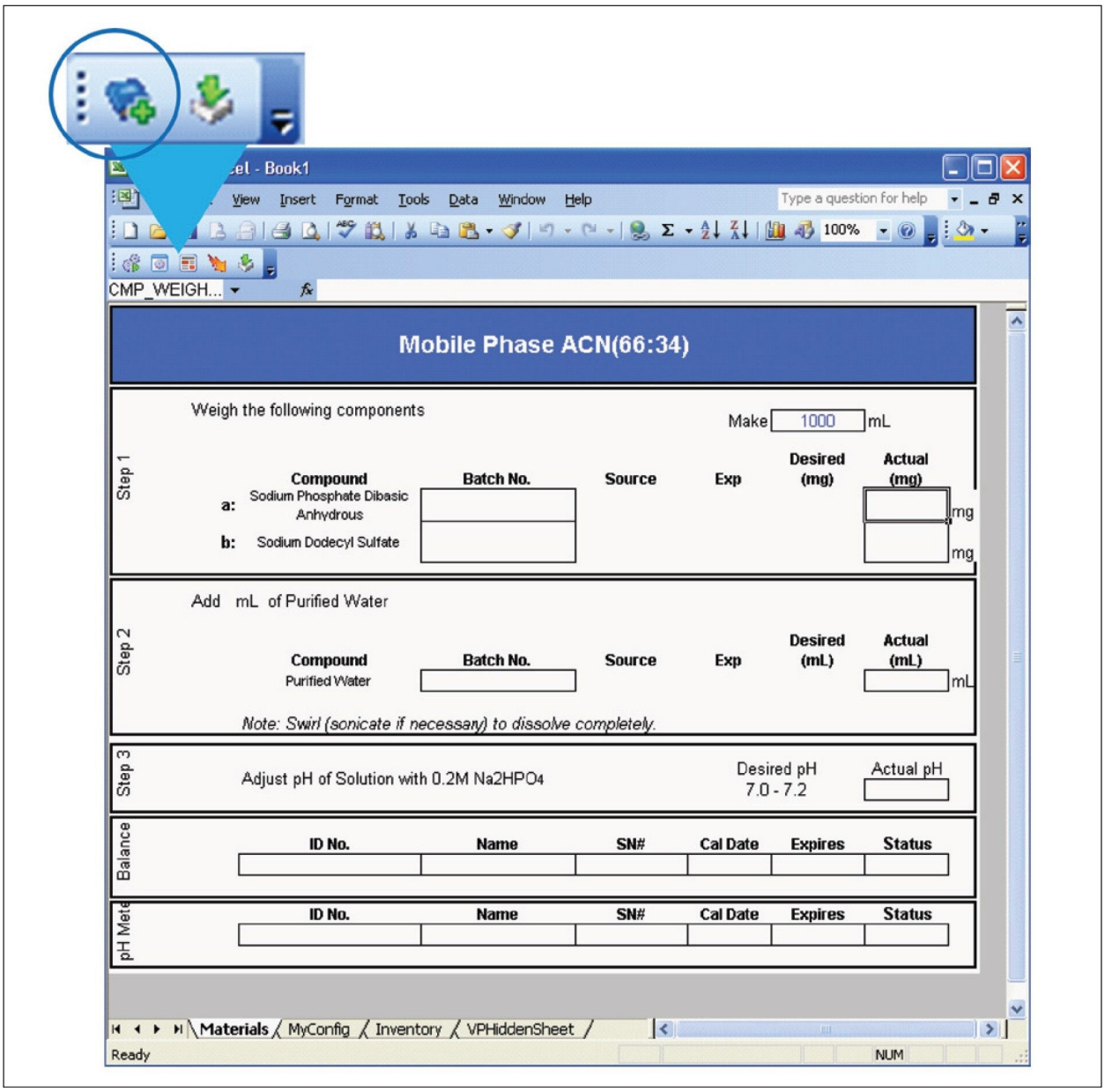

Figure 5. Converting an Excel form into an intelligent electronic SOP form by clicking the Convert-to-form button (item 1).

Adding Intelligence to a Form

Converting a spreadsheet into an intelligent form, as shown in Figure 5, protects the entire worksheet from unauthorized input/editing, and applies 21 CFR Part 11 safeguards such as audit trails. However, in order for the form to accept user input, individual spreadsheet cells are selectively made editable during design time (Step 3, Figure 3). Functionality, such as balance interfacing and input range validation, can be added by selecting appropriate functionality from the cell settings menu, as shown in Figure 6.

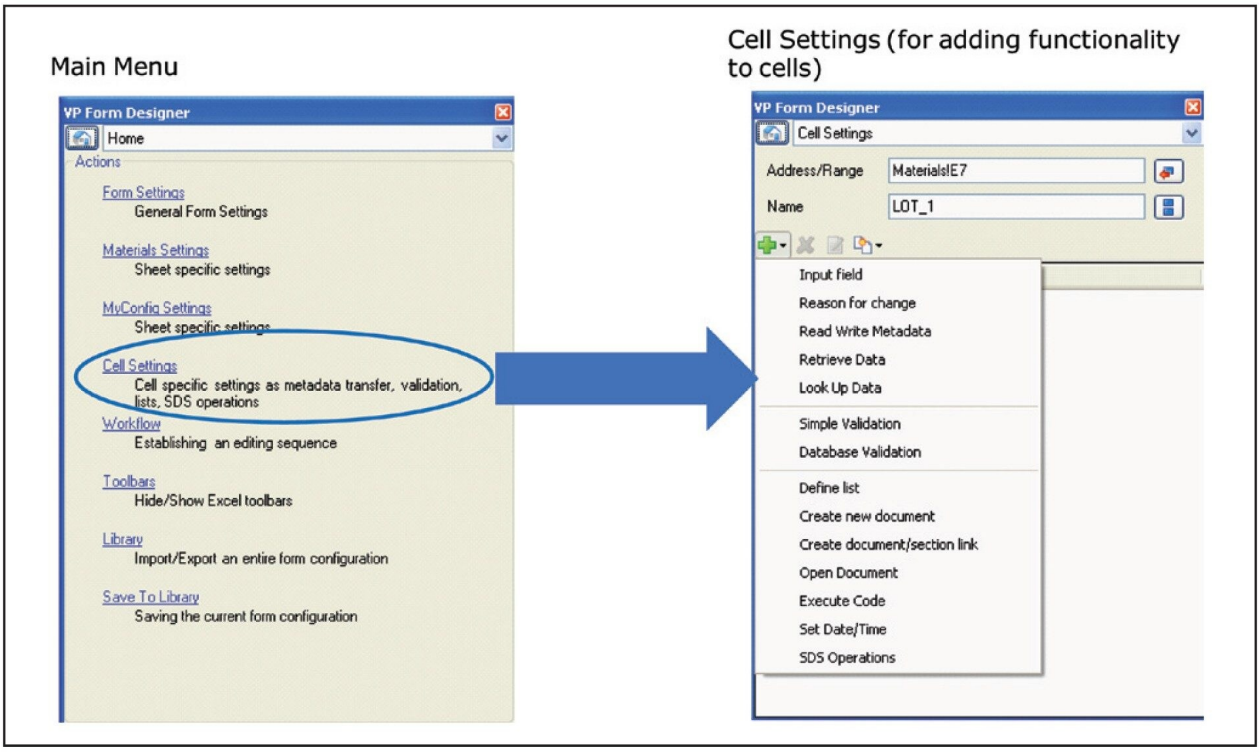

Figure 6. Form Designer's main menu (left) provides high-level functionality, such as overall form settings, workflow settings, etc. The Cell Settings submenu adds functionality, such as input fields to individual spreadsheet cells.

The most basic type of cell functionality to add to a form is called an Input Field. This functionality allows a user to manually type a value into a specified cell. For example, in Figure 7, an analyst may wish to prepare a 1000 mL solution. The analyst would key 1000 into the Input Field, and all subsequent calculations within the SOP form would automatically update based on 1000 mL. Next, during solution preparation, the analyst would select appropriate reagents to add to the solution, as shown in Figure 8.

In most organizations, a database table holds an inventory of available chemical reagents. The SDMS Form Designer allows a form to directly retrieve reagent information from a reagent database, as shown in Step 4, Figure 3.

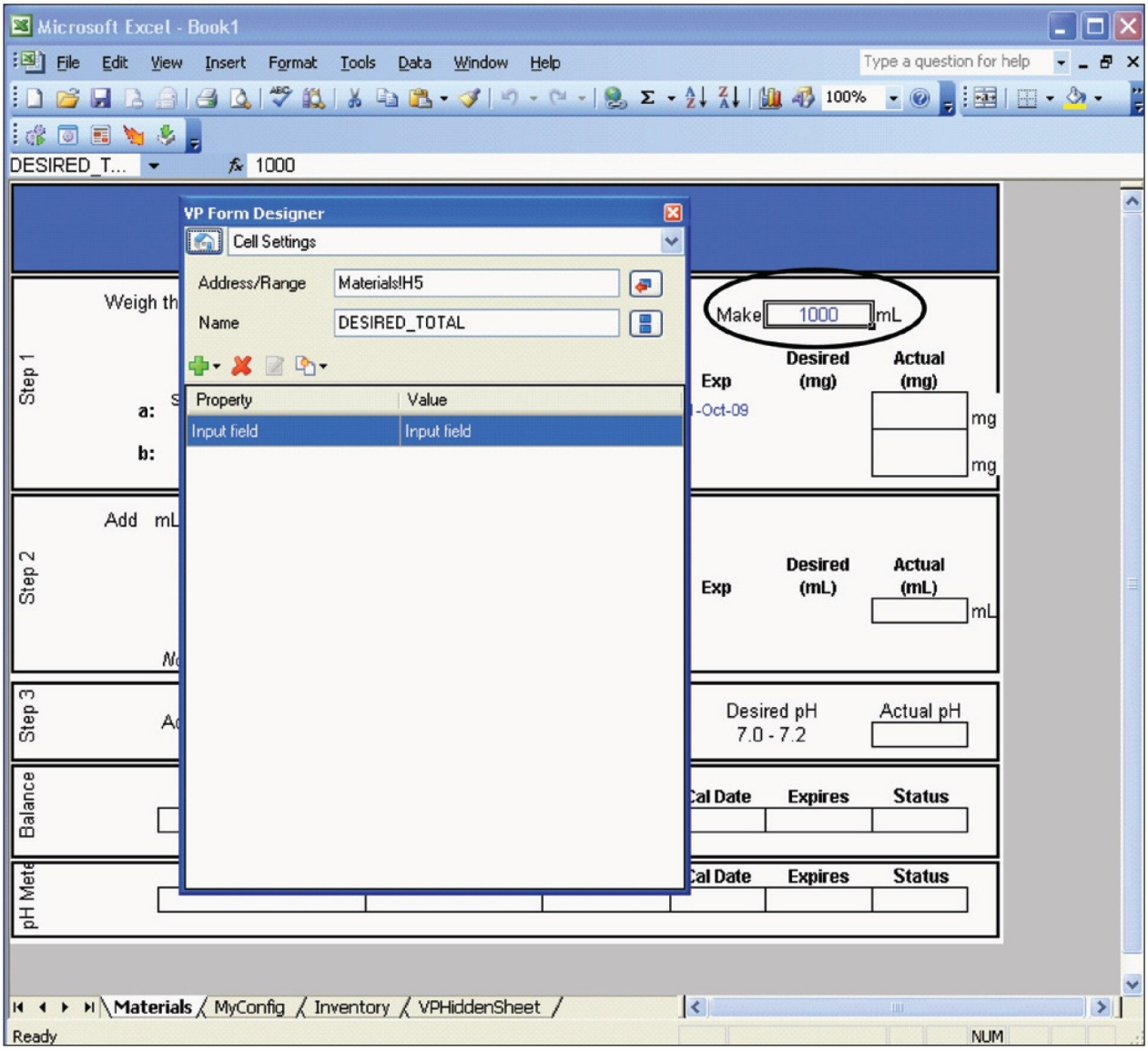

Figure 7. The entire Excel worksheet is protected and prevents unauthorized input, except for designated input cells or fields. This figure illustrates removing input protection from the volume field by creating an input field via the form designer.

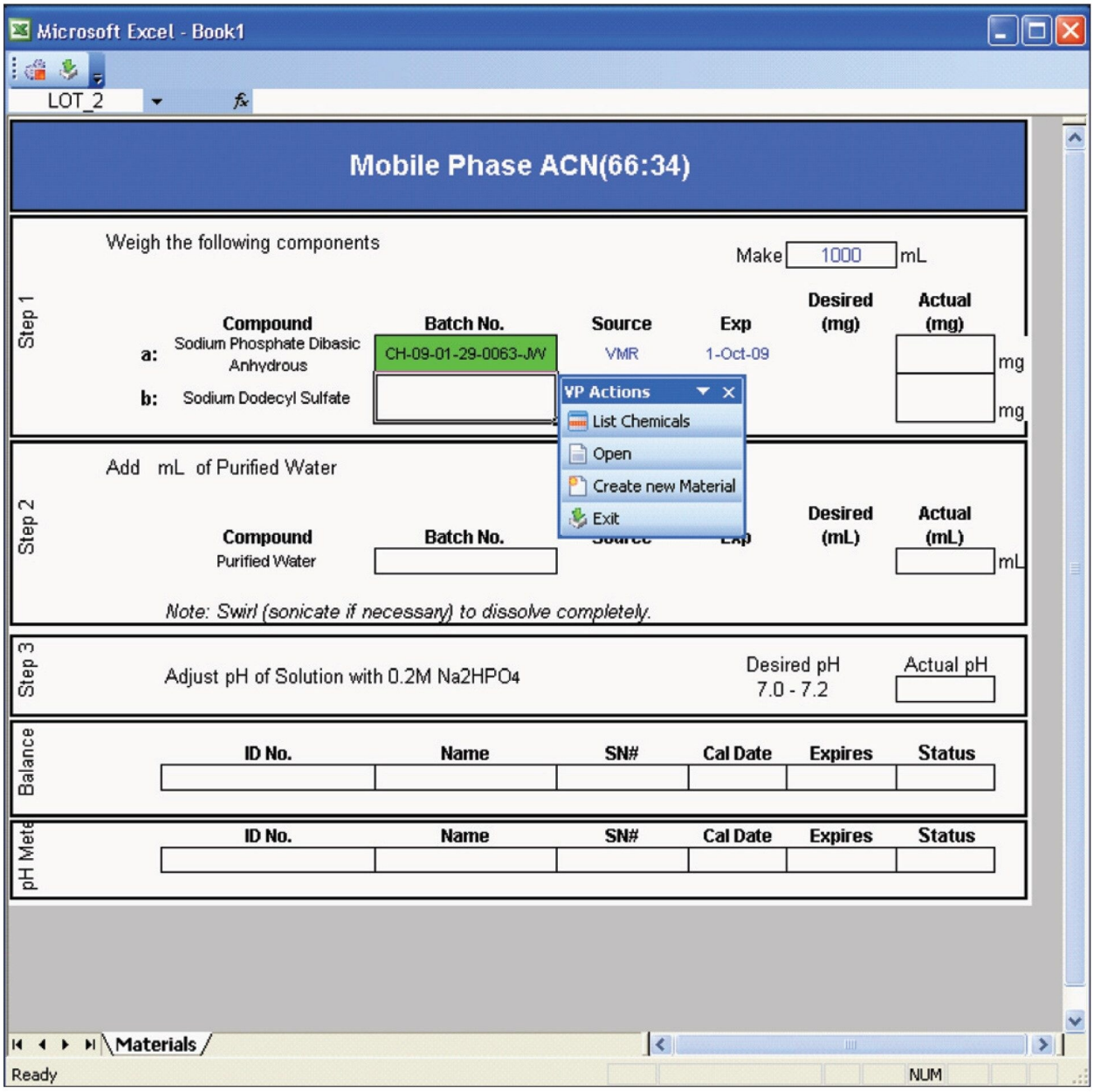

Figure 8. Access to a chemical reagent database table demonstrated from a laboratory analyst's point-of-view. When the analyst hovers the mouse below Batch No. heading,. a shortcut menu appears. The analyst can select List Chemicals results to retrieve a chemical reagent record as shown.

Accessing information from a reagent database is accomplished by using the Query Wizard in Form

Designer to walk the form author through the necessary record access steps by presenting a series of configurable tabs, while automatically creating the necessary SQL command in the background.

Direct Transfer of Balance Measurements to a Form

After specifying the solution volume and necessary reagents needed to prepare the solution, the analyst weighs the reagents on an analytical balance and records the results in a notebook. With Form Designer, it is possible to design a form that directly transfers reagent weights, as seen in Step 5, Figure 3, into the electronic form (Figure 9). The first step in designing a form that directly accepts weight information from an analytical balance is to establish an electronic connection between the form and the balance. This is accomplished by making use of the Waters Serial Device Support (SDS) application.[3] This application serves as a software intermediary that handles communication between the electronic form and the balance. To add the reagent weighing functionality to the form, the SDS application is associated with a worksheet form at the cell level by adding the SDS Operations. Recording the balance name, serial number, and location are important for maintaining complete records, while adhering to GMP and ISO regulations. To satisfy documentation requirements, invoking the SDS Operation can also transfer important identifying information to individual spreadsheet cells, as shown in Figure 9.

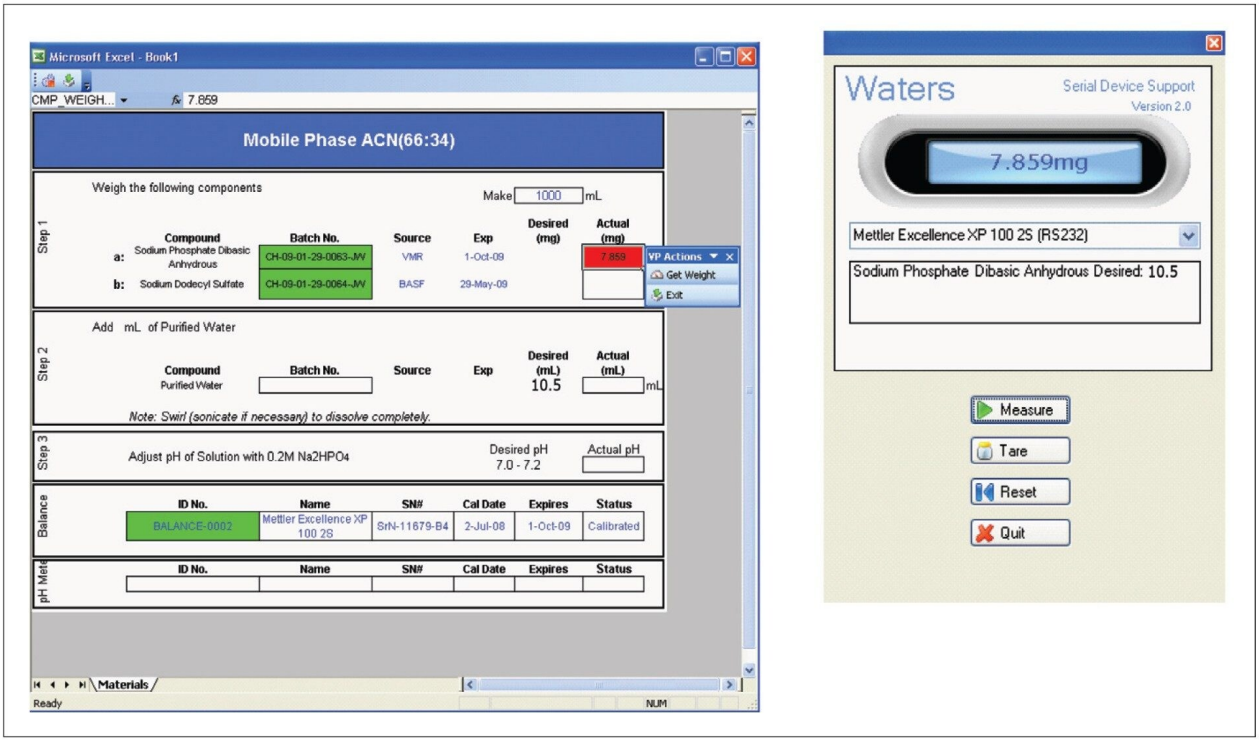

Figure 9. Weighting a reagent from the laboratory analyst's point-of-view. When the analyst mouses below the keyword Actual (mg), a shortcut menu appears. Selecting Get Weight generates the Waters Serial Device Support application that handles communication between an electronic balance and the SOP form.

Approving and Publishing the Form

Publishing the finalized form involves two steps: 1. convert the completed form to runtime mode, as shown in Figure 10 (Step 6, Figure 3); and 2. approve the form within the SDMS Vision Publisher Template Editor (Figure 11). A finalized and approved form then becomes accessible to laboratory analysts and is ready for use (Step 7, Figure 3).

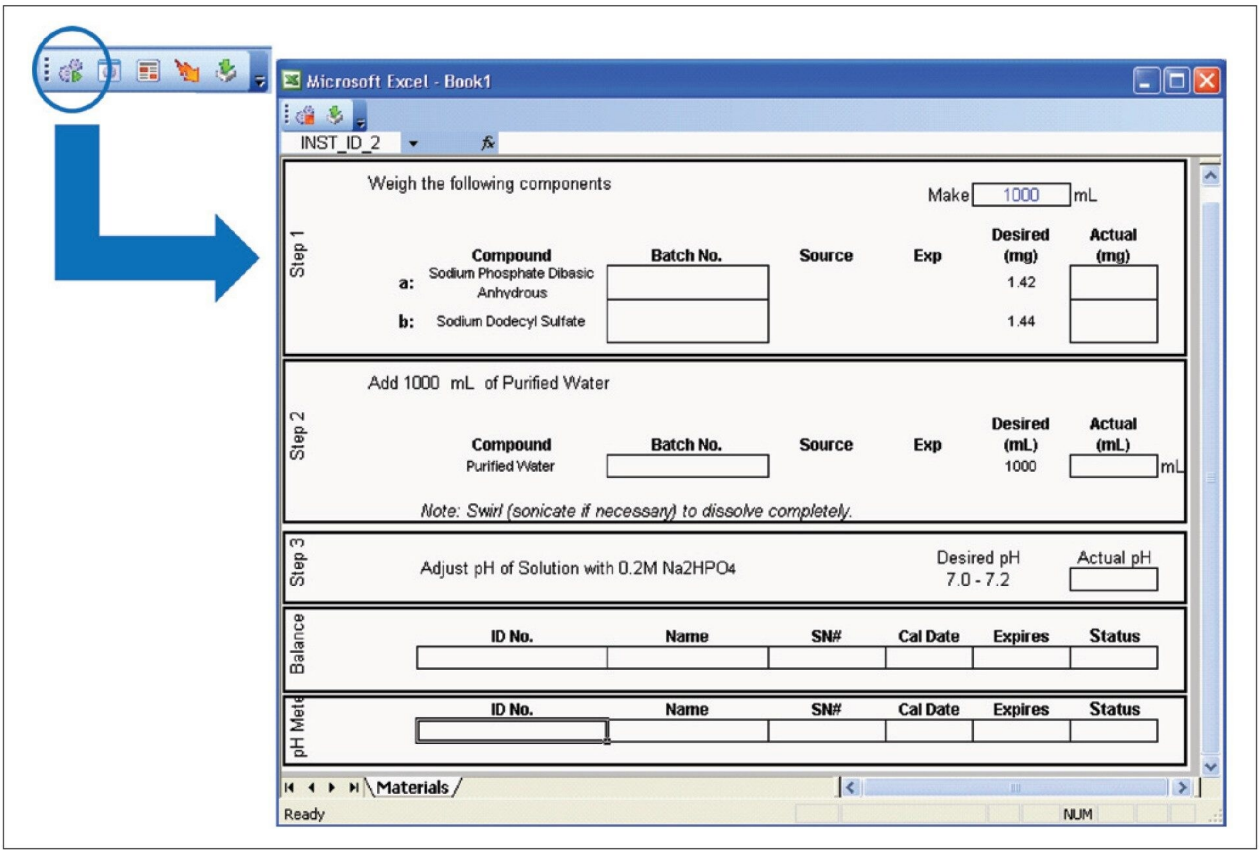

Figure 10. Pressing the form play button activates the form; hence, switching on functionality added by using the SDMS Form Designer.

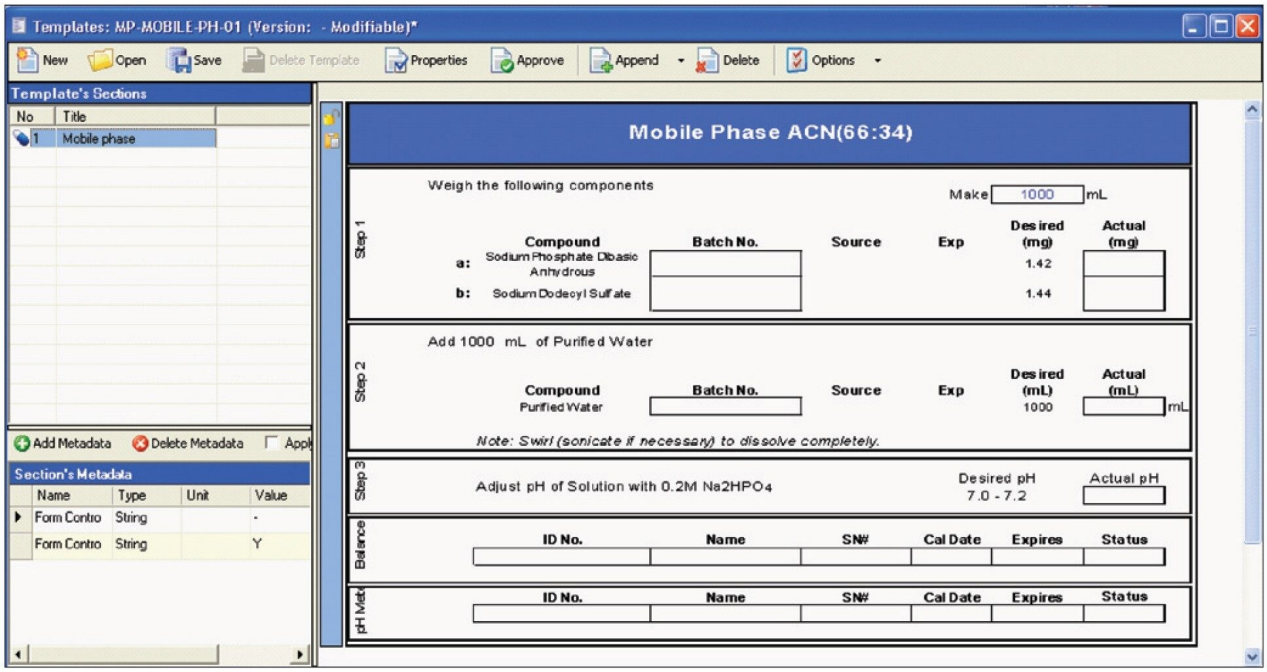

Figure 11. Approving the form template and publishing for use by laboratory staff represents the final step in SOP form creation.

Conclusion

Migrating QA/QC data and records from paper to a digital form offers the opportunity to improve overall operational efficiency in manufacturing environments that adhere to government regulations, such as GxP, ISO, *etc*.

QA/QC records consist of not only raw data, and printed test results, but also SOP documents. The SDMS Intelligent Procedure Manager is a compliant ready solution for managing raw data and printed test results, as well as using intelligent electronic SOP documents.

The SDMS Form Designer streamlines the creation of intelligent electronic SOP forms. The forms in turn allow QC laboratories to increase productivity by:

- Error-proofing the information input by analysts
- Reducing transcription errors via a direct interface with analytical balances (error rates near 0%)
- Saving analyst time via a direct interface with reagent and solution databases.
- Reducing review and sign-off time (average 50% improvement)

Finally, implementing the SDMS Intelligent Procedure Manager solution translates into a streamlined QA/QC operation meaning that products are released to the market faster with better quality.

References

1. Schmidt T., Fiege M., Yurach D., Kilby P., Stumpf C. GXP Spreadsheets Encapsulated in a Compliant-Ready Solution. Waters Application Note. 720002803. November 2008.
2. Schmidt T., Koblischke C., Lemmerz W., Stumpf C. Minimizing Errors Through Standardization of GxP and R&D Laboratory Measurement Processes. Waters Application Note. 720002888. January 2009.

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