



TECHNOLOGY BRIEF

How to Achieve 50% More Capacity and 10 Times Less Compliance Risk in HPLC/UHPLC

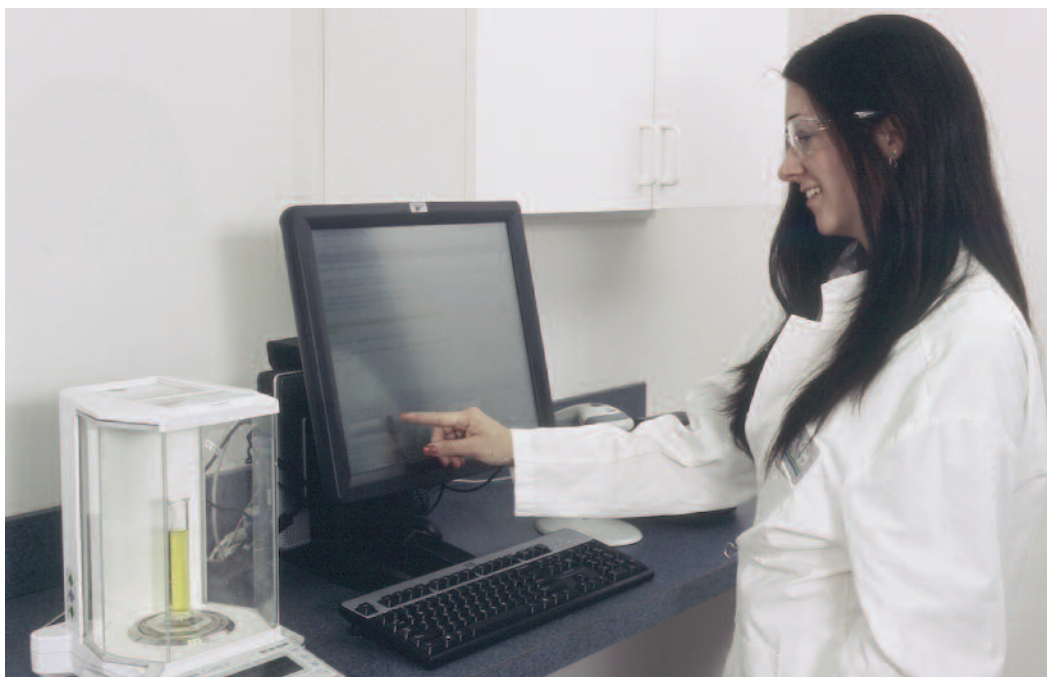
Free up hours/day of analyst time.

Automate all paper-based activity and electronically document all HPLC/CDS preparation tasks.

- Sample and sequence set preparation
- Mobile phase preparation
- HPLC column management
- Management of all lab materials inventory

By John P. Helfrich





INTRODUCTION

In all analytical laboratories, a common and routine task is the preparation of samples, reagents, and mobile phases used for HPLC analyses. In addition, all labs purchase, prepare, store, and control chemical reagents, solvents, standards, HPLC columns, and working reagents. In a regulated environment (such as the life science industry), the documentation of important metadata concerning the solutions and materials is critical for proper control of the preparation process and assurance of proper procedural completeness, accuracy, and documentation. In today's paper-based lab notebook environment, when samples and mobile phases are ready, all of the data must be manually keyed into the CDS sequence set for analysis. For all of the reagents, chemicals, HPLC columns, and other lab consumables, metadata such as manufacturer, purchase date, quantity, expiration date, usage by analyst, and minimum inventory needs are required to effectively manage the operations and provide the context link of these samples and consumables to the analytical data.

Today, the traditional process for both the HPLC prep and lab consumables inventory tracking is "paper-based" using notebooks and forms that often require reviews and approvals by peers or supervisors. In a paper-based environment, chemical reagents, HPLC columns, mobile phases, and materials management are subject to resource training and compliance with standard operating procedures that are often difficult to monitor and control.

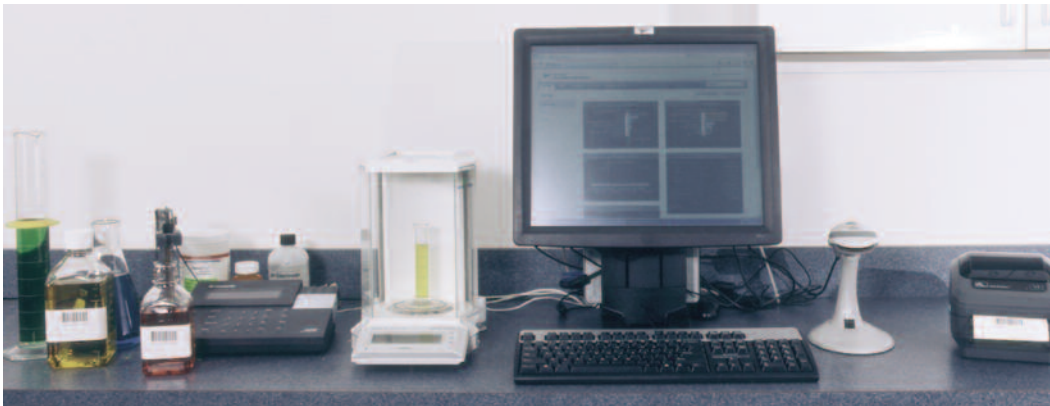
SmartLab™ HPLC Prep Workstation automates the checking in and out of critical chemicals, standards, and mobile phase components as well as all of the sample preparation data using electronic-based capture of all relevant information with full audit trails and management reporting. In addition to a comprehensive "track and trace" capability, the workstation provides a set of work instructions for preparation of solutions/mobile phases and samples to authorized analysts

via a PC workstation located in close proximity to the lab. It offers a fully electronic means of executing the instructions and capturing and cataloging all of the data and metadata as the materials are added to the lab inventory and used by analysts — in real time.

In addition, the system connects to existing balances, pH meters, and CDS systems. It captures the data direct to database and forwards the data to the CDS system in compliance with lab documentation “best practices.” Since all the data and metadata are captured in a database, reports are easily prepared for supervisory review and to offer management insight into areas such as consumables pedigree, inventory turns, lab investigations, usage logs, and a host of other lab procedures.

Typical materials requiring management include:

- Standards and controls
- Matrix standards
- Buffers
- Blanks
- HPLC mobile phases
- HPLC mobile phase solvents
- HPLC columns
- HPLC spare parts
- Dissolution bath media
- Radio-labeled materials
- Internal standard reagents
- And many more (any user-defined “consumable” can be added to the system)



HOW THE SMARTLAB HPLC PREP WORKSTATION WORKS

The SmartLab HPLC Prep Workstation is a standalone system that combines the power of VelQuest's SmartLab GMP Lab Execution System and ELN, the first method-centric automated compliance system that automates standard test methods (STM) or standard operating procedures (SOP) with data capture directly from analytical instruments and within the context of the procedure. This configurable platform is now defined for specific lab applications where often repetitive workflow tasks require compliant and comprehensive documentation and cataloging, such as HPLC preparation of mobile phases and samples as well as lab-based chemical/consumable inventories and reagent management.

The workstation is comprised of a touch-screen PC that can stand on its own or be networked within lab operations. Analysts and operators interact with the system that monitors user authentication and manages the preparation, addition, and real-time disposition of the inventory contents, HPLC sequence set samples, and columns and mobile phases. The workstation incorporates the direct integration of the pH meter, balance, and CDS. As analysts check in and check out materials, solutions, and HPLC columns, the workstation captures the content changes over time. At the end of the process, all of the data is aggregated in a user-defined report dashboard. Access to the workstation is controlled via a secure and granular privilege grid with full audit trails and electronic signature capabilities. This key feature eliminates the need for paper-based log books stationed throughout the lab, each of which requires management control and reporting. Now, all of that is done in real time electronically. The path to the paperless lab is here.

All sample preparation details and sequence set configurations are automatically pushed into the chromatography data system (CDS). This capability exists for all of the major CDS vendors (i.e. Agilent, Dionex, and Waters). Data such as sample weights, dilution factors, average tablet weights, etc. that are required for the CDS operation is electronically forwarded to the CDS template. Eliminating the manual keying of information can save hours per day in analyst time.

Each HPLC-related inventory item has its own workflow for creation, use, and disposition. The workflow is created using an innovative "drag-and-drop" icon process, so the setup requires no programming-based coding. Any lab analyst or technician with access rights can manage and use the system. Customized dashboards and written/printed reports can be quickly created and approved.

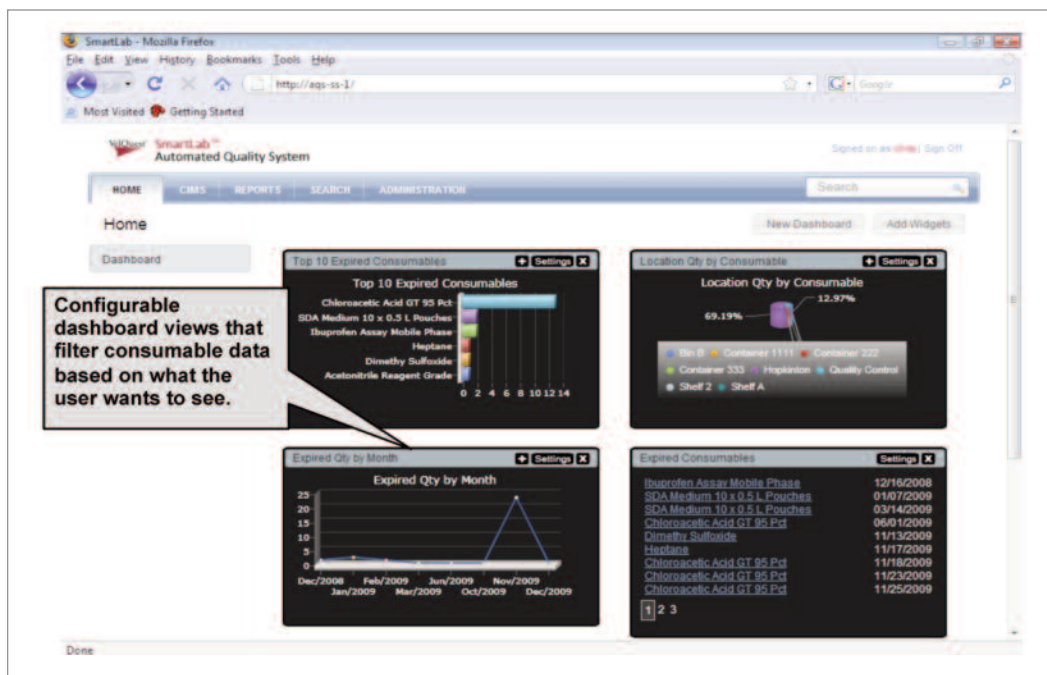
LABEL AND BAR CODE COMPATIBILITY

By using the SmartLab HPLC Prep Workstation, information/metadata is communicated via a bar code labeler and reader for proper tagging of the containers (or items) for use by the analysts during their routine testing processes. Through the bar-code reading, the entire pedigree of the consumable is known and documented, all with the touch of a button. Similar processes are used for tracking and tracing HPLC samples and sequence sets.

A DAY IN THE LIFE OF AN HPLC MOBILE PHASE

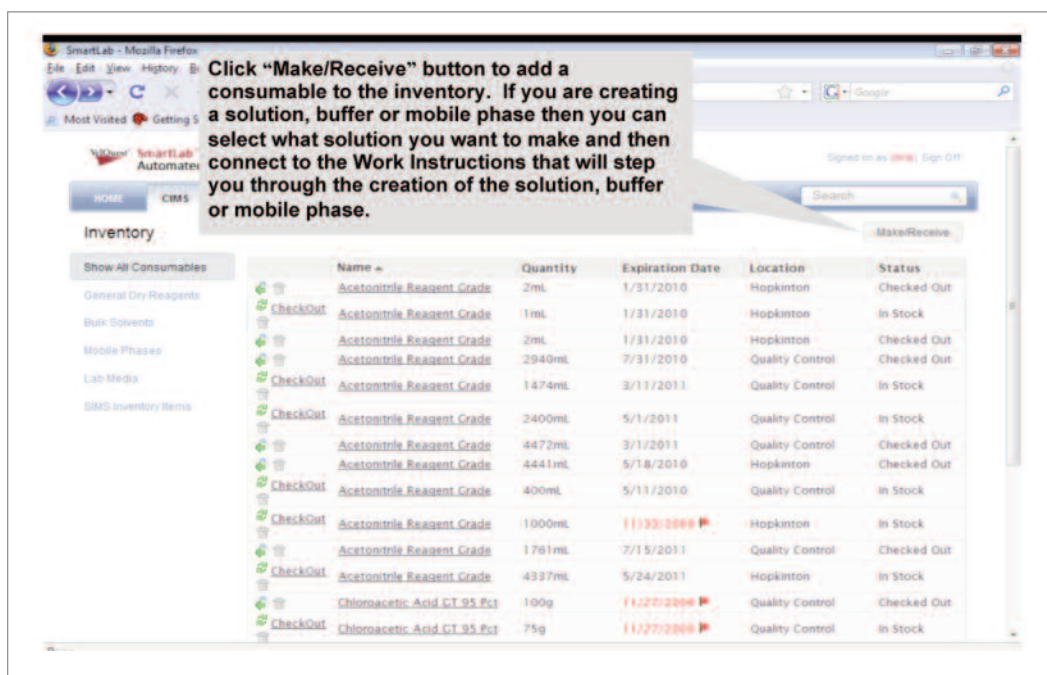
To provide a perspective on the capability of the SmartLab HPLC Prep Workstation, the following HPLC mobile phase preparation, addition to inventory, and use are outlined:

Dashboard view of Consumable Inventory Management System



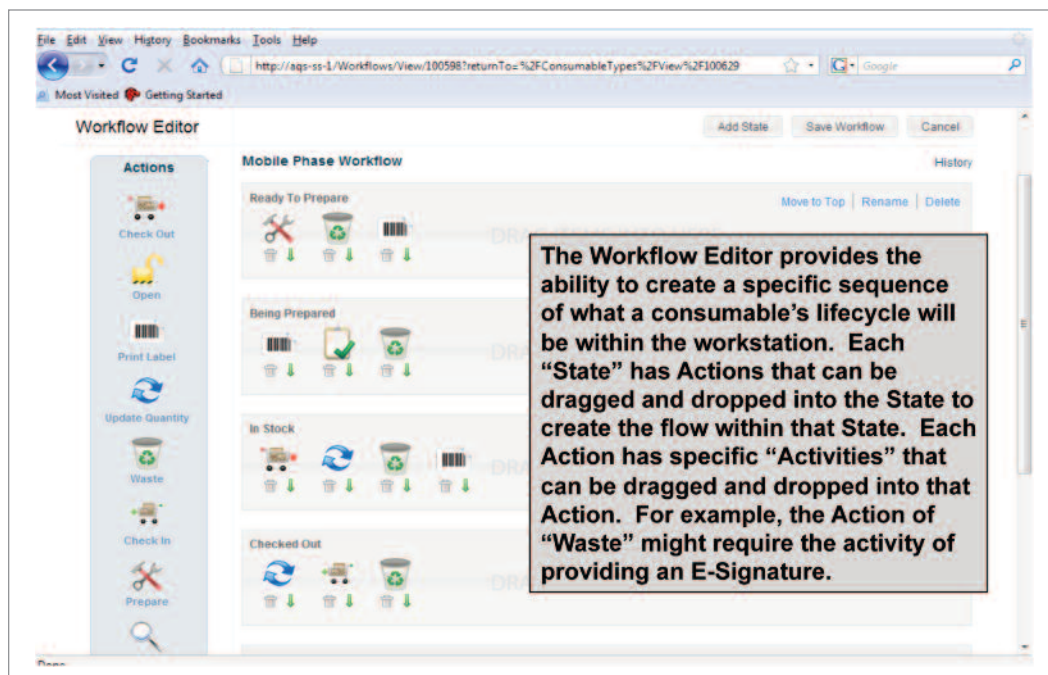
Step 1 — Analyst or Manager Dashboard view of real-time lab inventory status. Each item/graphic view is user-configurable, based on individual requirements. Number of units in stock, location, reagents needing preparation, usage by analyst, etc. can all be displayed for quick view of information.

Make/receive a new material



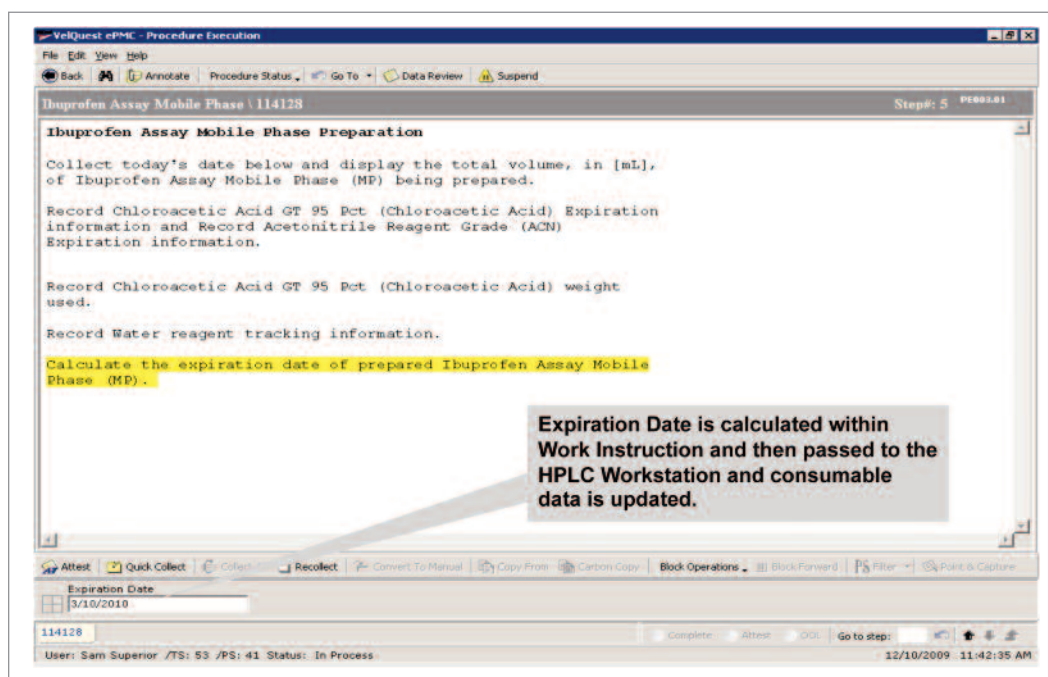
Step 2 — Addition of a new solution to the SmartLab HPLC Prep Workstation is done by answering a few questions with individualized workflows for each type of consumable (eg. HPLC mobile phase).

Lifecycle workflow editor for consumable types

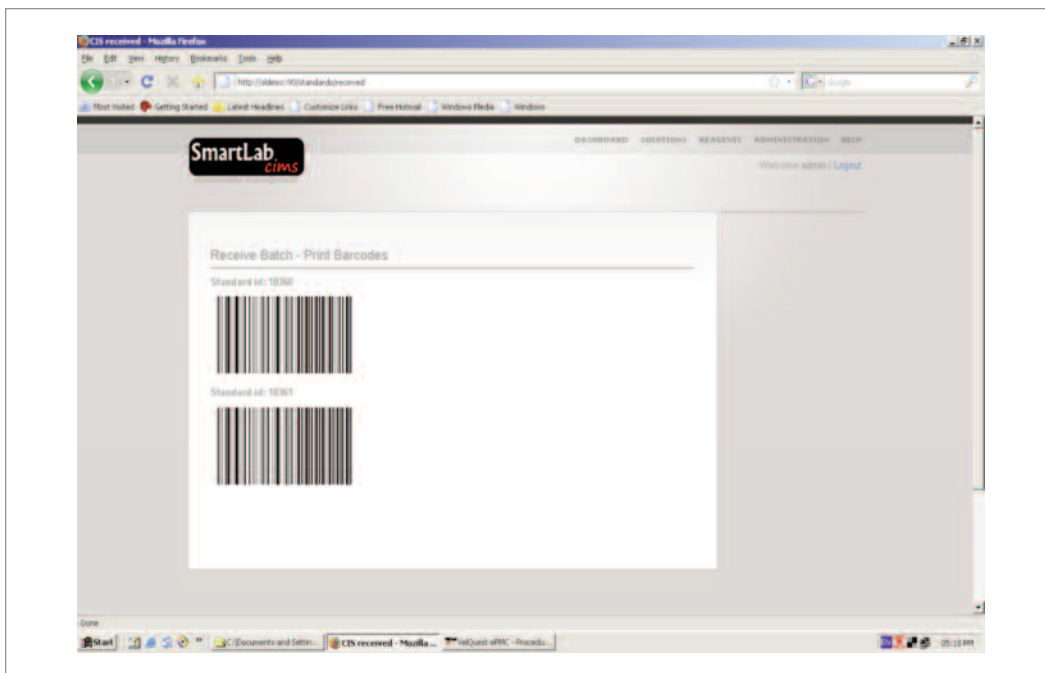


Step 3 — Each "consumable" item has its own workflow scheme (via drag-and-drop icon editor) for each "state" that the material is in. This enables individualized life cycle workflows for all inventory management items, HPLC solution, reagent, or sample preparations.

Expiration date calculated in work instructions



Step 4 — Work instructions are presented to the analyst to walk through the preparation with automated data capture from balances and pH meters. Actual real-time instrument data automatically populates appropriate fields in the SmartLab HPLC Prep Workstation database (in this case the mobile phase expiration date) along with all metadata on this preparation.



Step 5 — The bar code associated with this mobile phase prep is printed out for disposition on the container. All relevant “pedigree” metadata from the SmartLab HPLC Prep Workstation database is captured and is then available during usage of this reagent in the lab.

KEY BENEFITS OF ELECTRONIC CONTROL OF LAB CONSUMABLES INVENTORY AND HPLC PREP MANAGEMENT

The path to the paperless lab traditionally involved the custom coding of IT systems to provide a listing of materials. However, today’s modern labs require comprehensive control and electronic capture of all metadata associated with the addition, preparation, use, and disposal of consumables. By creating a fully preconfigured workstation, the system is up and running in a day, and in validated environments (pharmaceutical labs), the system is running and validated in 2 to 3 days. Key benefits include:

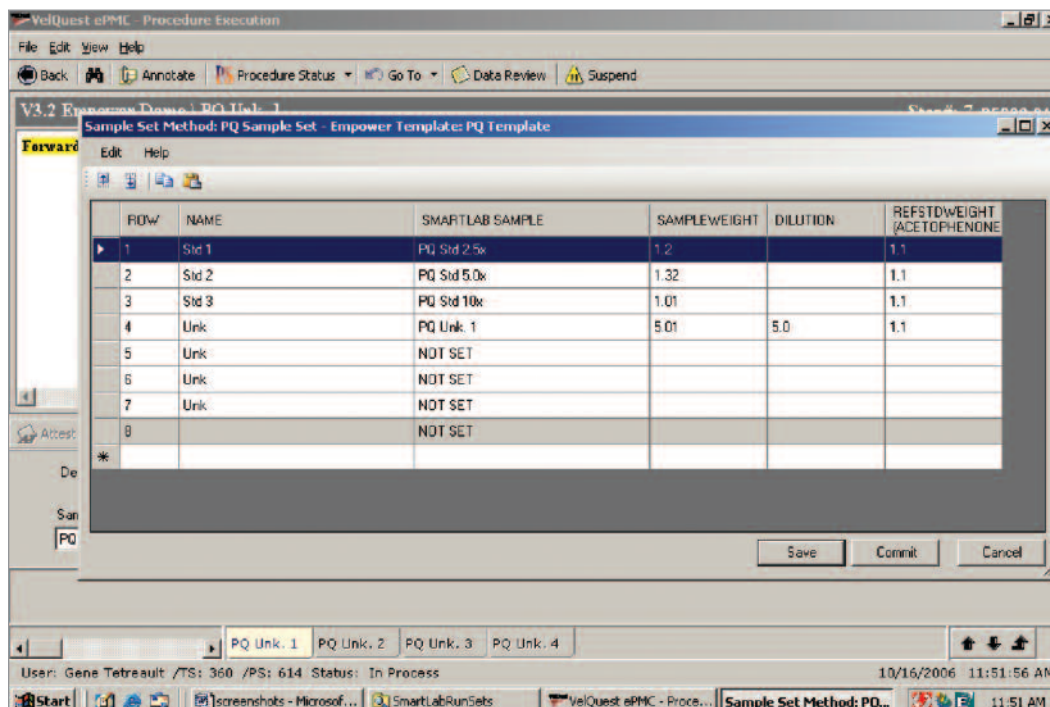
- Improved productivity of documentation and review processes for the creation, use, inventory, and storage of all lab consumables
- Comprehensive pedigree of lab consumables (who, what, when, and where) for compliant control and documentation
- Workflow instructions and ELN capture of information with direct instrument connectivity to a balance and pH meter for the creation of new solutions, reagents, mobile phases, etc.
- Elimination of paper-based logbooks and their management in both regulated and non-regulated lab operations
- Full electronic management of sample preparation and integration with CDS operations (sequence sets)
- Bar-code printing and scanning for ease of information management on the creation, use, and disposition of all lab materials

- Eliminates paper-based transcription and calculation errors during preparation of solutions
- Because the SmartLab HPLC Prep Workstation is powered by the SmartLab Lab Execution System/ELN, it is extensible to a full enterprise method execution system at any time
- User access control and viewable audit history provide technical controls for any regulatory compliance requirements for user-definable consumables.

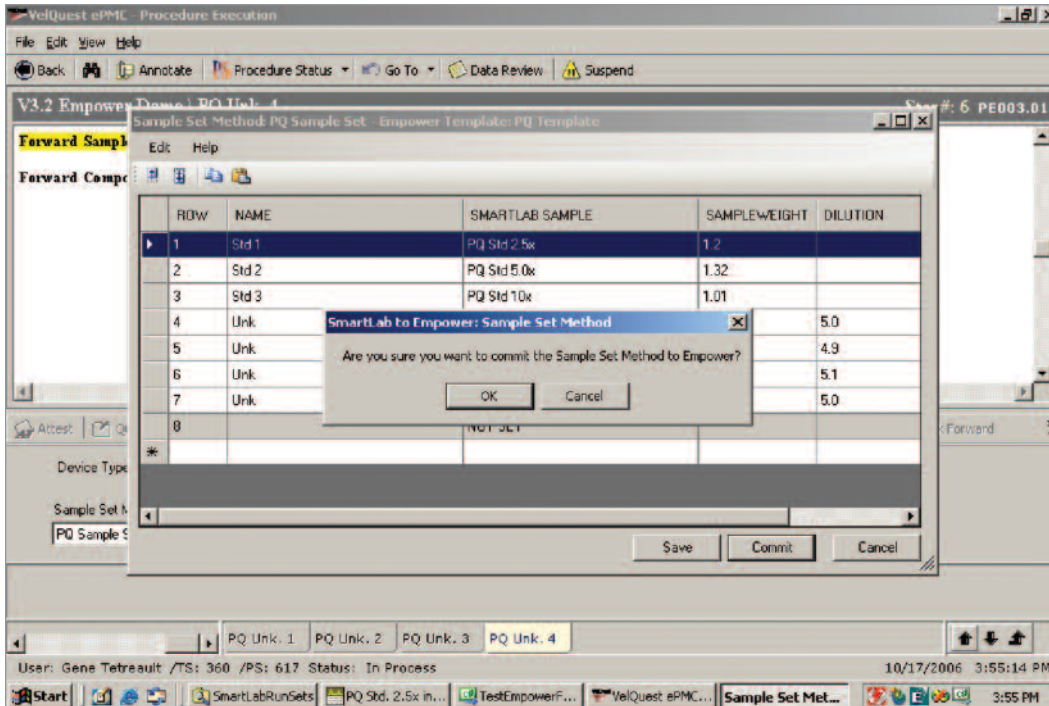
The SmartLab HPLC Prep Workstation is available today and comes with the following components:

- LCD monitor with touch-screen user interface, software, and keyboard
- Bar-code label printer and reader
- Integration with existing CDS, balance, and pH meter for full electronic data capture during preparation and use
- Step-by-step Work Instruction execution via electronic notebook (ELN) for compliant documentation of materials and sample preparation
- Connection to your network or completely independent with our lab-based server
- Installation and training — completed in a day!

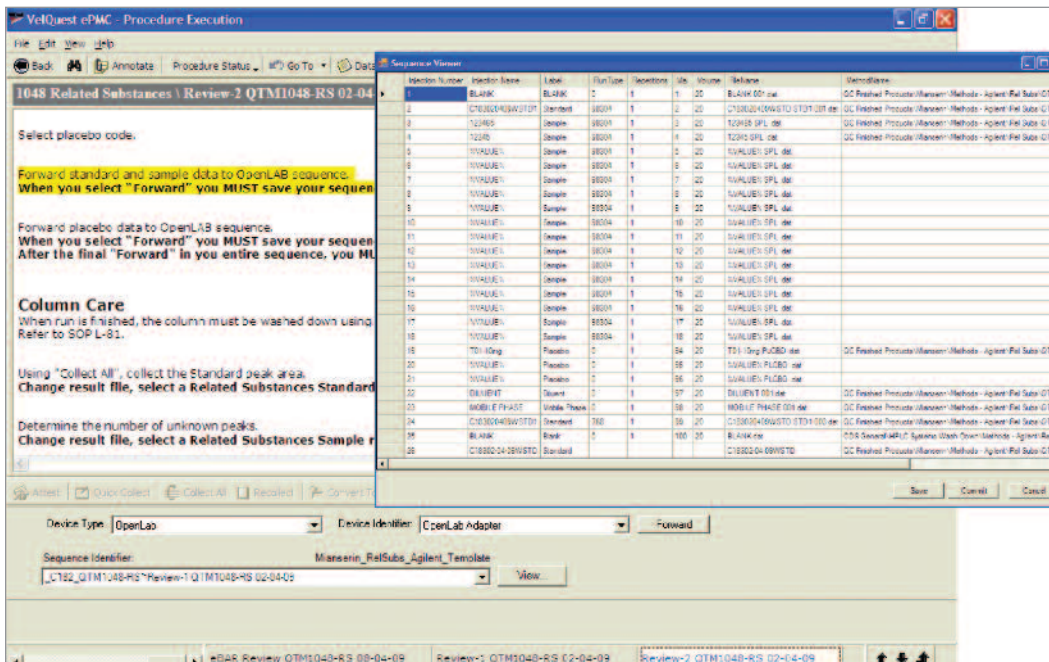
For less than the cost of an HPLC system, you can free up your valuable laboratory and management resources, eliminate all paper log books and their management tasks, and compliantly prepare, track, and trace your lab consumables and automatically send sample prep data directly to your CDS sequence set today.



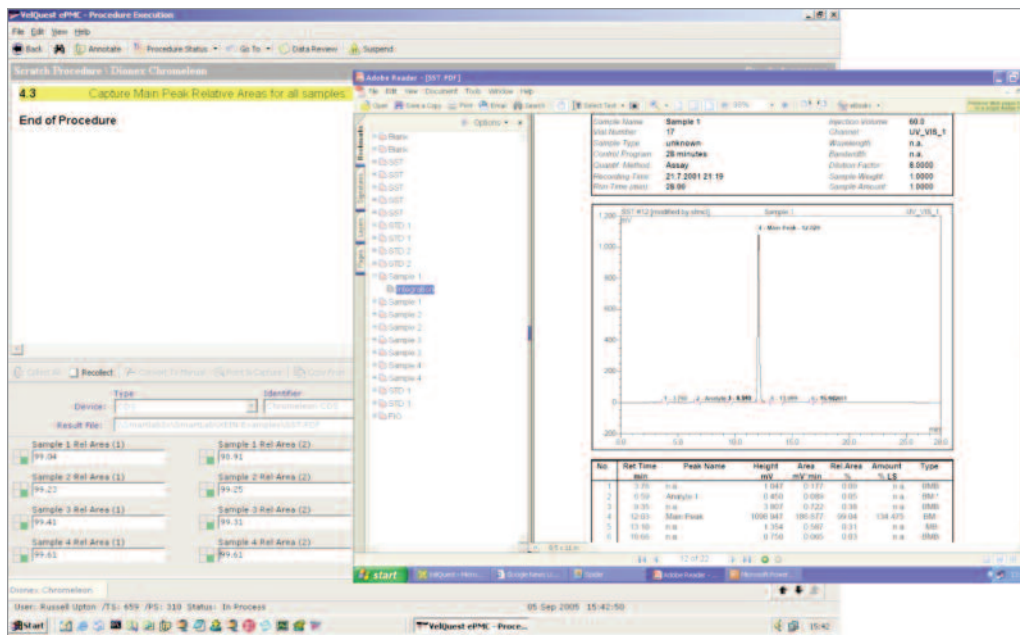
Sample preparation information on sample weights, dilution factors, etc. are captured electronically with the SmartLab HPLC Prep Workstation



Sample set data is forwarded to the CDS (eg. To Empower)



Sample set data is forwarded to the CDS (eg. Agilent Open Lab)



Sample analysis data integrated with Dionex Chromeleon CDS

About VelQuest Corporation

VelQuest Corporation was founded in 1999 to address a critical requirement of the life science industry: *How to leverage scientific resources to meet compliance regulations while increasing the productivity of people, reduce operational costs, and move finished product off the shipping dock faster than ever before.*

We remain committed to this mission, with GxP data management our ONLY business. Our flagship product is the award-winning SmartLab GMP Lab Execution System (LES) and Electronic Notebook. The LES is an innovative software platform designed to provide the foundation for compliance-based activities in the life science markets. The core software embraces the ICH Q-10 initiatives, as well as the FDA's "cGMPs for the 21st Century: A Risk Based Approach", and "Quality by Design" (QBD) initiatives, and supports the company's SmartLab™ Applications for a fully compliant electronic laboratory and SmartBatch™ manufacturing batch record system.

This patented technology eliminates compliance bottlenecks from paper-based processes in regulated development and quality operations. It captures all lab data at the source in real time, and seamlessly links procedures and SOPs with the data capture process. So not only does it reduce your compliance risk, it virtually eliminates tedious paperwork and dramatically simplifies reviews and audits.

For more information visit VelQuest's website at www.velquest.com.

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John P. Helfrich is the Vice President, GMP Automation Programs at VelQuest Corporation. At VelQuest, Mr. Helfrich is involved in the method translation of QC lab test methods to the software conventions used in the VelQuest SmartLab platform. Prior to VelQuest, Mr. Helfrich was the Director, Research Programs at NuGenesis Technologies Corporation. At NuGenesis his group was involved in the integration of the Scientific Data Management Software (SDMS) platform for instrumentation involved in proteomics, high throughput screening and bioanalytical applications of the biopharmaceutical industry.

Mr. Helfrich has over 30 years experience in the biopharmaceutical industry as a research analytical chemist and divisional management of several high technology companies that service the life sciences industry. Prior to NuGenesis Technologies, Mr. Helfrich was the Vice President of Precision Detectors, a laser light scattering company involved in the characterization of proteins and antibodies. Mr. Helfrich spent 10 years with Waters Corporation as a business unit director in the pharmaceutical division and 8 years with Zymark Corporation as marketing manager and Vice President of the bioanalytical group. Mr. Helfrich began his research career as an analytical chemist in the pre-clinical research division of the Rohm and Haas Company. He has a B.Sc. degree in Chemistry and has authored 28 analytical chemistry and bio-characterization publications.