

# SmartLab

## Automated Compliance System



The Pharmaceutical industry is facing major challenges in how to meet compliance regulations while increasing productivity. Meeting compliance requirements is mandatory. Liberating and reallocating resources from compliance activities to developing new candidates is critical to new product development. The industry has recognized that meeting these goals is becoming increasingly difficult using today's paper based compliance management systems. Evolving from paper to an electronic laboratory notebook system will be the only manner to have confident compliance with breakthrough productivity. Changing the paradigm will provide the ultimate goal of electronic submissions, audits, reviews and investigations.

It is estimated that 70% of all laboratory resources are dedicated to compliance activities. Evolving from a paper based system to an automated compliance system must initially mimic existing policies and procedures in order to minimize disruptions to current operations. Once electronic laboratory Notebooks are implemented, SOPs and test methods can be optimized with key elements that increase both quality levels and productivity.

**Data Review** time is reduced by 80% using a "Review at a Glance" summary screen. Data collected for each step is displayed along with a series of compliance flags indicating any issues or notations that should be reviewed. Compliance meta data is captured electronically and immediately available.

**Error Checking** routines can be built into the procedures to alert operators to acceptable ranges for data at the time of data acquisition.

**Work Flow** can be set up and assigned to an individual operator. Sample Administration lists can be created inside the SmartLab system or transferred from a LIMS system.

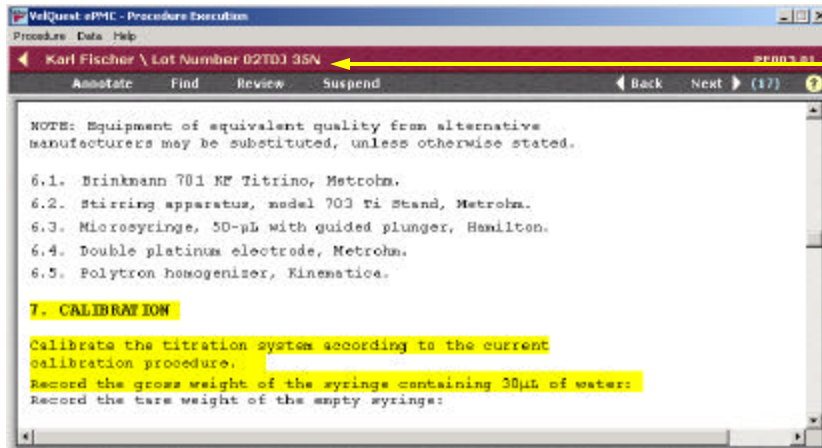
**Data Acquisition** is direct from PC based and electronic instruments. Data is automatically transferred from validated transmitters to the operator's clipboard, eliminating transcription errors. Productivity increases through direct data capture as well as eliminating the need for secondary verification operators.

**Security of data and people** is addressed. All data is maintained on a secure, Part 11 compliant server. Access controls are extremely granular allowing rights and permissions to be set for performing laboratory tasks as well as accessing existing data.

**Leveraging existing Investments** in networks, data archiving, LIMS and knowledge management systems is a key element of a laboratory eNotebook system. A Unified Data Exchange Manager allows seamless transfer of data using industry standard XML language.

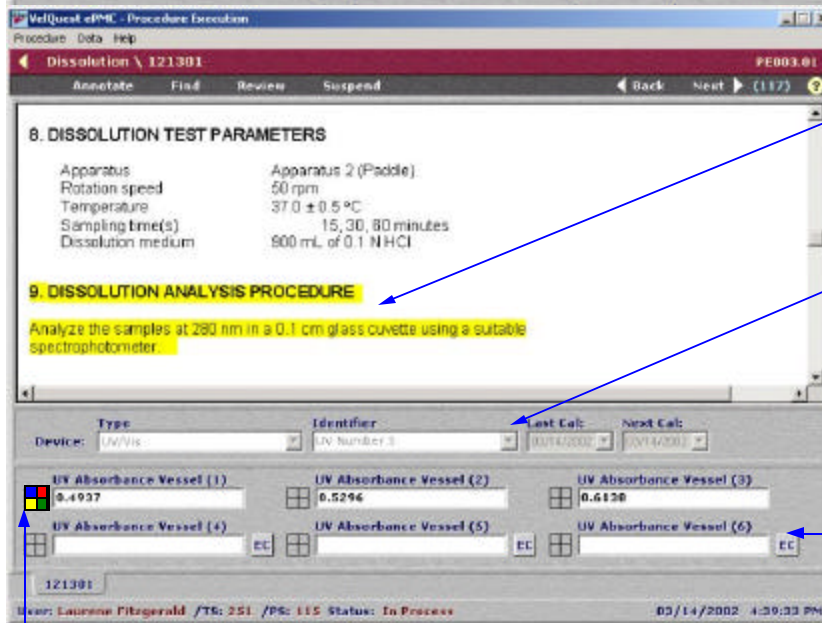


# Procedure Management



The **Current Procedure and Revision** are automatically retrieved and displayed.

For review purposes, the correct version of a procedure will be retrieved with every set of sample data.

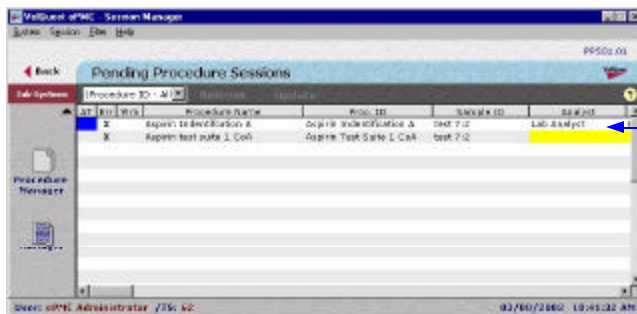


**Steps** are highlighted in order of implementation.

**Meta Data** is displayed and collected and acceptable ranges for data are checked before data is collected.

**Data collection Boxes** are automatically created with error checking routines that eliminate out of range data before it is accepted.

**Compliance Flags** alert the operator and reviewer to issues such as out of specification results, audit trails, out of date data and allow raw data files to be viewed.



**Procedures** are retrieved from existing document management systems. The SmartLab system assures that the correct procedure and version are assigned or retrieved for each task.

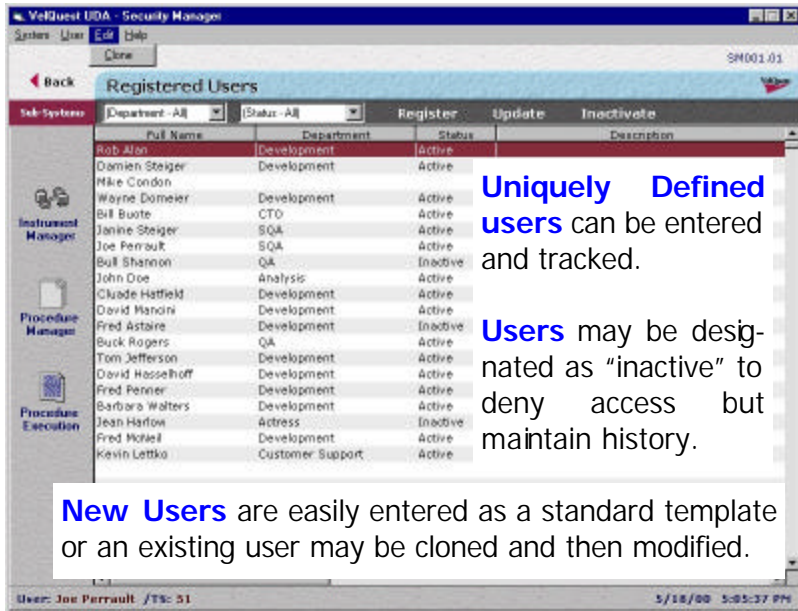
**Areas of concern or missing commands** are highlighted. Issues must be addressed before work is assigned.



# Security & Access Control

Security and access control can be centrally administered. A laboratory manager can change the **Status** of users, as appropriate.

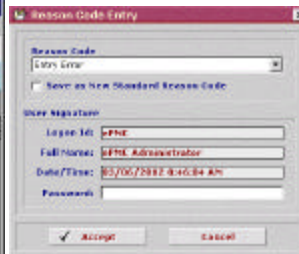
The Security Manager maintains a complete **audit trail** for all changes.



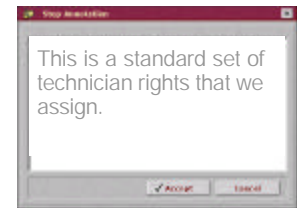
**Uniquely Defined users** can be entered and tracked.

**Users** may be designated as "inactive" to deny access but maintain history.

**New Users** are easily entered as a standard template or an existing user may be cloned and then modified.

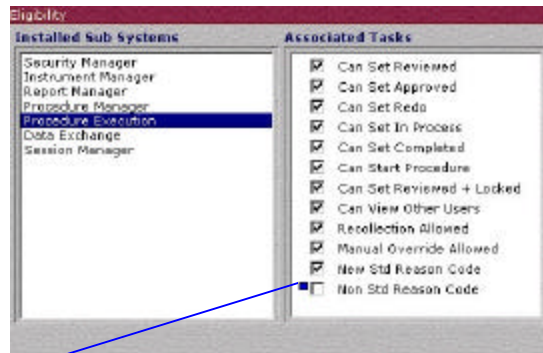


**Audit Trails** are maintained for all changes made to individual's rights including the user name, time/date stamp and a reason code.

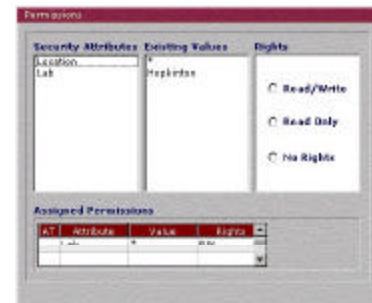


**Annotations** are available to document the rationale and special notations for all changes made to an individual's rights.

## Rights and Permissions



**Audit Trail** information is maintained and can be reviewed for any changes made to each operator, system and instrument in the SmartLab system. A **Blue Compliance flag** alerts a reviewer to the presence of a change.



The Security manager can facilitate, or limit, **Data Exchange** between technicians using configuration factors such as assigned lab, operator location, project number or product type. You can also set a designation that allows a person to view other technician's data in any ePMC location.

# Instrument Management

Certain key activities must be routinely performed and the results become critical elements of the compliance meta data required to assure that the only systems being used to generate data are current. **Installation** of new systems requires validation. The SmartLab software allows new systems to be added directly from a library in a similar manner to adding a new printer to a computer. **Central Administration** of the systems facilitates implementation and increases compliance.

**Eligibility**

Installed Sub Systems	Associated Tasks
<ul style="list-style-type: none"> <li>Security Manager</li> <li style="background-color: #e0e0e0;">Instrument Manager</li> <li>Report Manager</li> <li>Procedure Manager</li> <li>Procedure Execution</li> <li>Data Exchange</li> <li>Session Manager</li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Register Instrument</li> <li><input type="checkbox"/> Update Registration</li> <li><input type="checkbox"/> Change Status</li> <li><input type="checkbox"/> Local Library Access</li> <li><input type="checkbox"/> New Std Reason Code</li> <li><input checked="" type="checkbox"/> Non Std Reason Code</li> </ul>

**Audit Trails** are maintained for every change to an analyst's eligibility. A blue flag identifies the presence of an audit trail.

**Instrument Eligibilities** are very granular. Each task associated with instrument management and operation can be granted to individual analysts and technicians.

**Instrument and System Libraries** are provided to facilitate installing and validating most common laboratory instruments and systems.

**Info**

For Informational Purposes Only

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General Panel Information

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Library Source:	VQ_INSTRUMENT_LIBRARY
Library Version:	1.1.2
Manufacturer:	Mettler
Model Number:	AT201 DeltaRange
EIN:	08314DR
Serial Number:	5298NM
Connection Type:	VQ-IB
Status:	Active
Location:	Hopkinton
Lab:	Quality Control
Instrument Type:	Balance
Description:	Balance dedicated to the asp
Calibration Type:	Periodic
VQ Version:	1.0

Print

**Instrument Data Source** **Version** 1.1.2

VQ\_INSTRUMENT\_LIBRARY

<b>Manufacturer</b>	<b>Model Number</b>
Mettler	AT201 DeltaRange
Mettler	M15
Ohaus	PD5002-S
ORION	

<b>Serial Number</b>	<b>VQ Version</b>
5298NM	1.0

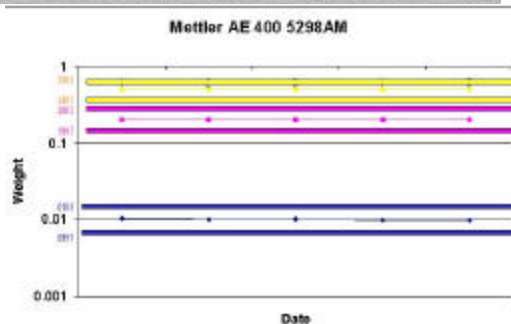
<b>Instrument Type</b>	<b>Instrument EIN</b>
Balance	US314DR

<b>Location</b>	<b>Lab</b>
Hopkinton	Quality Control

<b>Connection Type</b>	<b>Status</b>
VQ-IB	Active

<b>Description</b>	<b>Calibration</b>
Balance dedicated to the aspirin project	<input checked="" type="radio"/> Periodic <input type="radio"/> Daily <input type="radio"/> None

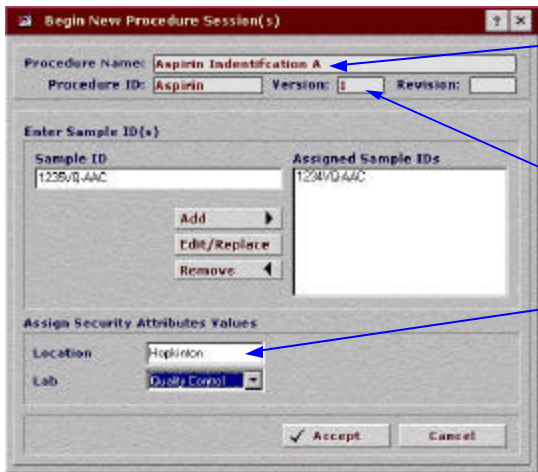
**Instrument Trending Reports** can be used to review the performance of an individual system against validation and calibration criterion.



# Sample Management

The **ePMC Session Manager** allows you to perform sample administration in the laboratory. You can easily create work orders for individual tests or test suites, which can be forwarded to a laboratory manager for assignment to individual analysts. Simply establish a standard suite of tests for a product or product code. Enter the product code and link it to a sample, and all of the individual tests are automatically set up and forwarded. A supervisor can then review the requests and assign them to appropriate analysts.

Either the **Session Manager** or a **LIMS system** can be used to enter the samples, create the necessary tests and assign the work to individual analysts. If the information is set up in LIMS, Session Manager will verify the selections and forward the work to the individual analyst's clipboards for implementation.



By entering **Product Groups** a suite of tests can be automatically linked to a sample

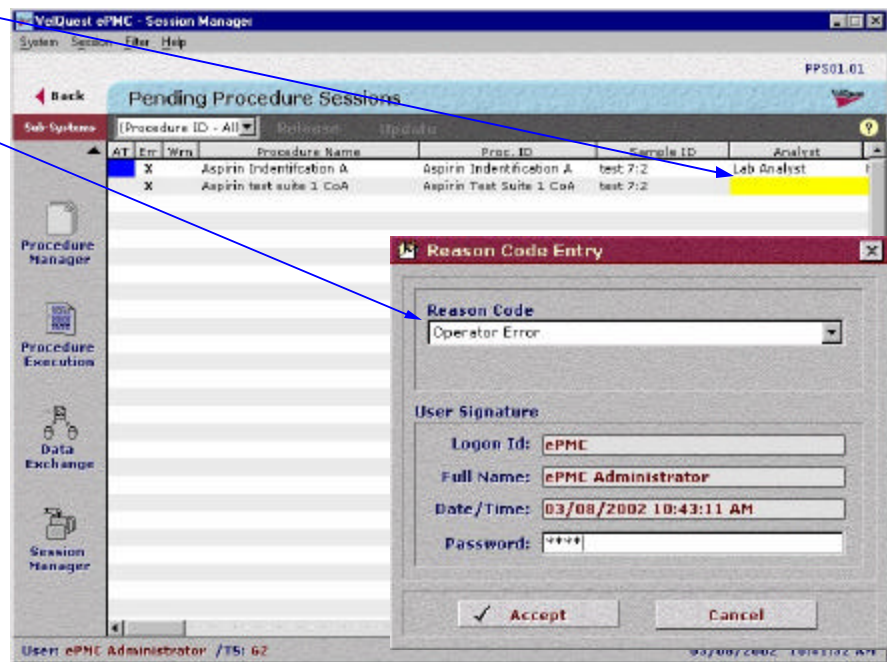
The **Correct Version** will be provided to the analyst. A manager may select a previous version for comparison testing.

**Samples** can be logged in and assigned to a location and a particular laboratory directly in the Session Manager. All of this information may also be sent to the ePMC system from a LIMS.

**Areas of Concern** will be highlighted in yellow.

**Reason codes** will be linked to each change in the sample assignment.

The Session Manager automatically transfers ready-to-implement **Work Lists** to the Analysts' individual clipboard.



# Data Review

**Data Review**

Procedure Name: **Data Collection and summary report**  
 Procedure ID: **DCASR001** Ver: **0** Rev: **0** Sample ID: **RU201101a**  
 Hyperlink: **D:\Program Files\UDA\core\Drilldown\D1E136F5-6592-47AF-B69E-C1E798574171.uda**

AT	OL	OD	SD	An	A/A	Step	Field Label	Field Value	eSig	Who	Logon	How
						4	MeOH Manufacturer	test		Gordon Johnston	Gordon MN	
						4	MeOH Lot Number	2222		Gordon Johnston	Gordon MN	
						4	MeOH Expiration	11/20/2001		Gordon Johnston	Gordon MN	
						5	Weight g (1)	+ 5.347	True	Gordon Johnston	Gordon EC	
						5	Weight g (2)	152.1	True	Russell Upton	Russell EC	
						6	10_Percent Part Size	0.27		Russell Upton	Russell FC	
						6	50_Percent Part Size	0.61		Russell Upton	Russell FC	
						7	Annotation	Test Annotation		Russell Upton	Russell	
						7	Solvent Weight g (1)	+ 5.344		Gordon Johnston	Gordon EC	
						7	Solvent Weight g (2)	+ 5.344	True	Russell Upton	Russell EC	
						7	Solvent Weight g (3)	+ 5.344		Gordon Johnston	Gordon EC	
						8	Mean Solvent Weight	5.3443	True	Russell Upton	Russell FM	
						9	Product Name	Pseudosole		Gordon Johnston	Gordon MN	
						12	Working Standard C	1.2		Gordon Johnston	Gordon MN	
						13	Reference Standard			Gordon Johnston	Gordon MN	
						14	%RSD of Working St	22		Gordon Johnston	Gordon MN	

**Attest / Approve**  
**Annotation**  
**Source Data Captured**  
**Out of Date**  
**Out of Limit**  
**Audit Trail**

**Data Review** time is reduced by 80% using a "Review at a Glance" summary screen.

Data collected for each step is displayed along with a series of compliance flags indicating any issues or notations that should be reviewed. Compliance meta data is captured electronically and immediately available.

# Data Exchange

A Unified Data Exchange Manager allows seamless transfer of data using industry standard XML language.

Files and supportive compliance meta data are linked and available electronically.

Operators and reviewers can instantly have access to critical elements such as raw data, processed results, audit trails, annotations for multiple revisions of documents, SOPs, test methods, batch records and test method sheets.

**LIMS**

**File Archiving**

**Get the right answer faster.**

**Data Review**

Procedure Name: **Data Collection and summary report**  
 Procedure ID: **DCASR001** Ver: **0** Rev: **0** Sample ID: **RU150102t**  
 Hyperlink: **\\Vqserver02\UDA\core\Drilldown\0F8AF682-099E-11D6-B217-00D0590D302C.uda**

AT	OL	OD	SD	An	A/A	Step	Field Label	Field Value	e	wt
						4	MeOH Manufacturer	Pison		Russell Up
						4	MeOH Lot Number	A-110892		Russell Up
						4	MeOH Expiration	11/10/2002		Russell Up
						5	Weight g (1)	1.287		
						5	Weight g (2)	1.287		
						6	10_Percent Part Size	0.27		
						6	50_Percent Part Size	0.61		
						7	Solvent Weight g (1)	+ 5.349		
						7	Solvent Weight g (2)	+ 5.349		
						7	Solvent Weight g (3)	+ 5.349		
						8	Mean Solvent Weight g	5.3490		
						9	Product Name	Standard Compound		
						10	Standard Compound Conc mg	75.6		
						10	Standard Compound Conc. Result	Greater than 75 mg/0.05g		
						12	Working Standard Concentration	0.9953		
						13	Reference Standard Concentration	1.002		
						14	%RSD of Working Standard	1.003		
						15	Forward	\\Vqserver02\DemoFiles\Tablet Data.txt		
						16	Forward	VQC Interface Output		

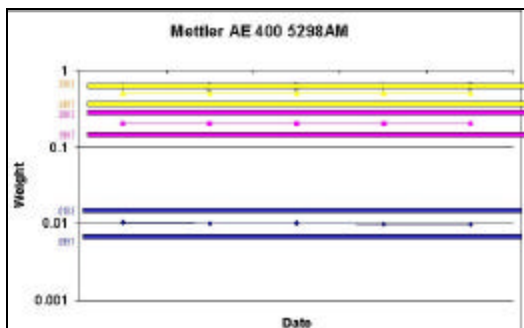


# Data Reporting & Trending

Use of data for trend analysis has been recognized as an important tool to improve quality. The key to making trend analysis practical is to provide standard reports that have easy access to data that is linked to all of the compliance meta data. The SmartLab software allows use of standard report writers to create configurable reports. Typical reports provide trending information on areas such as number and types of samples each analyst has completed, environmental monitoring results, people and instrument performance, vendor and materials tracking metrics as well as compliance to procedures by monitoring and displaying the number of unplanned deviations.

**Standard Reports** for instruments allow key elements of instrument management to be tracked and trended. Every sample run on an instrument is easily identified and linked to the system allowing meta data to be available on demand.

<b>Instrument Group:</b>	Balance				
<b>Equipment ID:</b>	US314DR				
	<b>Manufacturer</b>	<b>Model</b>	<b>Serial Number</b>	<b>Location</b>	<b>Status</b>
	Mettler	AE400	5298NM	Hopkinton	Active
<b>Procedure Name</b>	<b>Sample ID</b>	<b>Technician</b>	<b>Date / Time</b>		
EQ-0034	CA-0034A	Alberto Correia	3/1/2002 9:41		
EQ-0034	CA-0034B	Alberto Correia	12/1/2001 11:41		
EQ-0034	CA-0034C	Alberto Correia	9/1/2001 8:46		



**Instrument Trending Reports** can be used to review the performance of an individual system against validation and calibration criterion. The performance of a single system in relation to all other identical systems can easily be evaluated and corrective action developed.

**People Trending Reports** can be used to review the performance of an individual analyst against expected procedure performance metrics. Every sample run is linked to each analyst. Deviations whether preplanned or unplanned can be used as indicators of changes required to procedures or additional training required for an analyst and specific corrective action programs to be developed.

Procedure	Weight Measurements & Input	Samples Run	Rate of Test Action	Location	Status
Procedure: CONDO Analysis	File 1	2000000	0%	0%	Completed
	File 2	2000000	0%	0%	Completed
	File Method 1	2000000	0%	0%	In Process
	g101	2000000	0%	0%	Completed
	g110	2000000	0%	0%	In Process
	g111	2000000	0%	0%	Completed
	g112	2000000	0%	0%	In Process
	g113	2000000	0%	0%	Completed
	g114	2000000	0%	0%	In Process
	g115	2000000	0%	0%	Completed
Number of Samples Processed:		13			
Procedure: Manual Input	File Method 1	2000000	0%	0%	In Process
	File Method 2	2000000	0%	0%	In Process
	File Method 3	2000000	0%	0%	In Process
Number of Samples Processed:		3			
Total number of Samples processed for this procedure:		16			

# Training Programs for Operator and Trainer

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At VelQuest's Customer Education Center, we are committed to providing you with the knowledge and competencies that guarantee your success with VelQuest's products and their application within your laboratory. We believe in practical, effective, targeted training that transfers the necessary knowledge to our customers and assures a successful implementation of your solutions. Our philosophy enables you to independently operate and expand the system throughout your company using internal resources. VelQuest can partner with you to supplement your staff.

- **System Operator Training (Hopkinton, MA)**
- **System Operator Training (Customer Site)**
- **System Administrator Training**
- **Procedure Conversion Training**
- **Instrument Interfacing**
- **Train-the-Trainer Certification**

## ***Customer Statements regarding measurable gains with Electronic Laboratory Notebooks running ePMC software:***

- **2/3'rds Liberation of resources from Data/Results Review.**
- **50% Liberation from Paper Notebook activities.**
- **Takes no longer to prepare samples with Electronic Laboratory Notebooks.**
- **75% reduction in Data/Results Review Cycle Time.**
- **Eliminate 1 Month Review Process in Stability Programs with on-line Review.**
- **Very easy to use relative to paper based methods/analytical procedures.**

