

SmartBatch Electronic Batch Record System helps pharmaceutical companies meet the critical challenges of increasing productivity while maintaining compliance levels required by the FDA in the new “Risk based approach to the GMPs for the 21st century.” SmartBatch is a procedure execution and electronic batch record solution. It’s a standard product alternative to complex, highly customized MES systems.

SmartBatch frees operators, supervisors, managers and quality assurance analysts from devoting large amounts of time consumed by manual activities that are done to ensure that batch records are filled in completely and correctly. By automating these labor intensive activities, savings of 50% or more are realized, primarily in areas of data capture, document preparation, and QA review.

Operators use SmartBatch as they use paper batch records. A procedure is opened electronically, data captured electronically, and then the operator signs. Another operator can sign in to continue that procedure, while the original operator moves on to another record. Managers can assign, review, and approve operators’ work. Trending reports and batch certificates can be automatically generated for review. Data can be exported to other corporate systems such as LIMS, MES, or ERP.



Risk of non-Compliance is reduced by SmartBatch. The system assures:

- Proper initiation of a procedure, preventing usage of outdated SOPs
- Only trained operators use approved supplies and equipment
- Alerts operators to usage of non-approved components in real-time
- All collected data values are within approved and validated limits, reducing downstream investigations
- Elimination of transcription errors from paper or data entry to other systems

Productivity is increased by SmartBatch. The system automates:

- Batch Administration
- Electronic availability of procedures—no need for paper printouts
- Collection of data—no more paper logbooks, binders, or data forms!
- Calculations—built into the procedure and validated (no more manual calculators)
- Electronic Batch data review—cut review cycle times by 75%
- Transfer of data to corporate systems

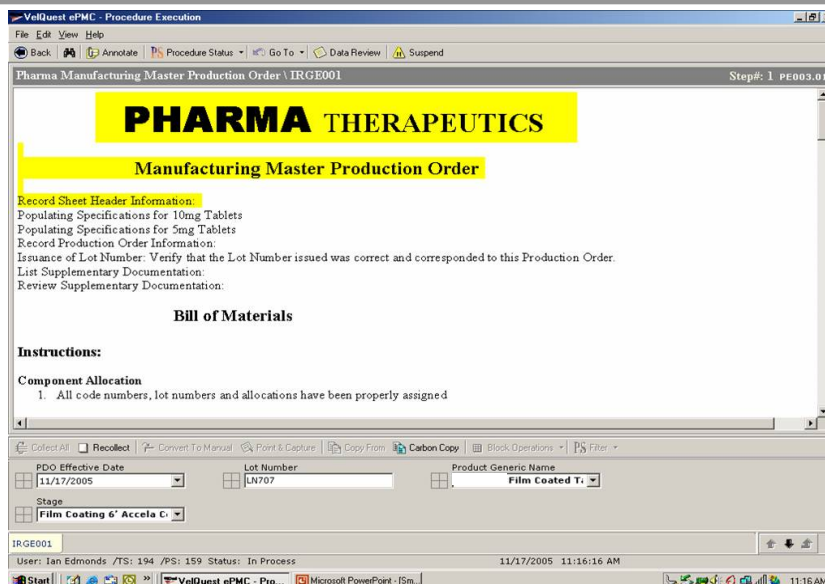
Routines followed by operators are readily transferred to the SmartBatch system.

- SOPs and batch records are maintained in a Microsoft Word or *.RTF format. They can be stored in an existing Document Management System, or as files on a secure server.
- Loading procedures into the system is direct and efficient by using a wizard.
- Wireless tablet PC's allow operators mobility on the plant floor while executing the batch record.

Procedure steps are always highlighted, making it easy for the operator to see the current step in order of implementation.

Other information important to the operator can be displayed electronically, such as:

- Bill of Materials
- Protective gear
- MSDS
- Environmental conditions



PHARMA THERAPEUTICS
Manufacturing Master Production Order

Record Sheet Header Information:
 Populating Specifications for 10mg Tablets
 Populating Specifications for 5mg Tablets
 Record Production Order Information:
 Issuance of Lot Number: Verify that the Lot Number issued was correct and corresponded to this Production Order.
 List Supplementary Documentation:
 Review Supplementary Documentation:

Bill of Materials

Instructions:

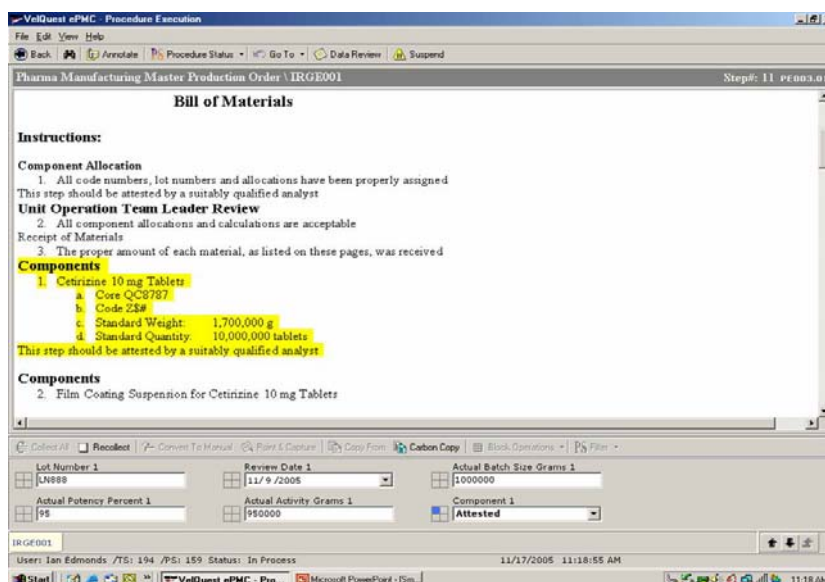
Component Allocation
 1. All code numbers, lot numbers and allocations have been properly assigned

Buttons: Collect All, Recollect, Convert To Manual, Point & Capture, Copy From, Carbon Copy, Block Operations, PS Filter

Fields: PDO Effective Date (11/17/2005), Lot Number (LN707), Product Generic Name (Film Coated T...)

Stage: Film Coating 6' Accela C

IRGE001
 User: Ian Edmonds /TS: 194 /PS: 159 Status: In Process
 11/17/2005 11:16:16 AM



Bill of Materials

Instructions:

Component Allocation
 1. All code numbers, lot numbers and allocations have been properly assigned
 This step should be attested by a suitably qualified analyst

Unit Operation Team Leader Review
 2. All component allocations and calculations are acceptable
 Receipt of Materials
 3. The proper amount of each material, as listed on these pages, was received

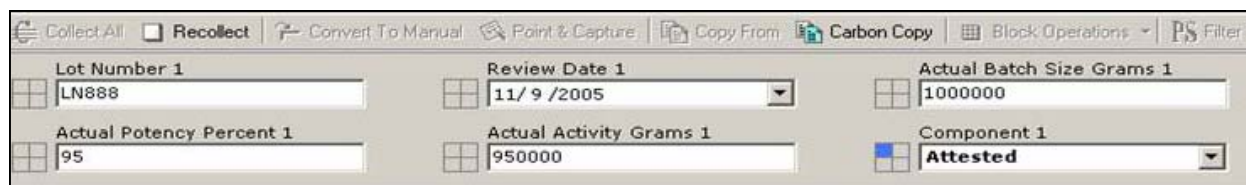
Components
 1. Cetrizine 10 mg Tablets
 a. Core QCB787
 b. Code 234
 c. Standard Weight: 1,700,000 g
 d. Standard Quantity: 10,000,000 tablets
 This step should be attested by a suitably qualified analyst

Components
 2. Film Coating Suspension for Cetrizine 10 mg Tablets

Buttons: Collect All, Recollect, Convert To Manual, Point & Capture, Copy From, Carbon Copy, Block Operations, PS Filter

Fields: Lot Number 1 (LN888), Review Date 1 (11/9/2005), Actual Batch Size Grams 1 (1000000), Actual Potency Percent 1 (95), Actual Activity Grams 1 (950000), Component 1 (Attested)

IRGE001
 User: Ian Edmonds /TS: 194 /PS: 159 Status: In Process
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Buttons: Collect All, Recollect, Convert To Manual, Point & Capture, Copy From, Carbon Copy, Block Operations, PS Filter

| | | |
|--------------------------|-------------------------|---------------------------|
| Lot Number 1 | Review Date 1 | Actual Batch Size Grams 1 |
| LN888 | 11/9/2005 | 1000000 |
| Actual Potency Percent 1 | Actual Activity Grams 1 | Component 1 |
| 95 | 950000 | Attested |

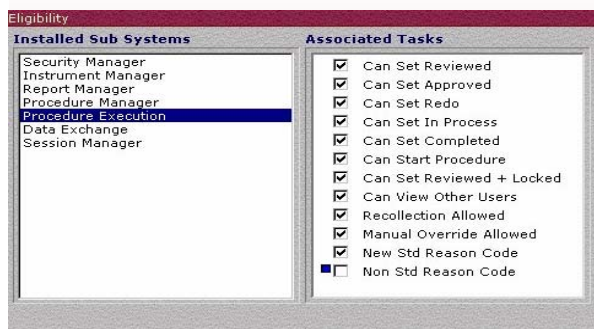
Data collection Boxes are created dynamically, automatically conforming to the procedure step. Error checking routines and limits are built into the procedure, eliminating out of range data before it is accepted.



Compliance Flags alert the operator and reviewer to issues such as out of specification results, audit trails, and date expirations. Files can be viewed by clicking the flag.

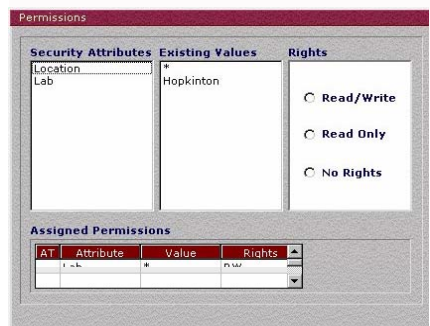
Security and access control is centrally administered. A manager can change the **Status** of users, as appropriate. The Security Manager maintains a complete **audit trail** for all changes. **Reason Codes**, as well as e-signatures, are required and maintained for changes made.

Users can be entered and tracked. New Users are easily entered as a standard template or an existing user may be cloned and then modified. Former users who have left the company or changed roles may be designated as "inactive", to deny access but maintain history.

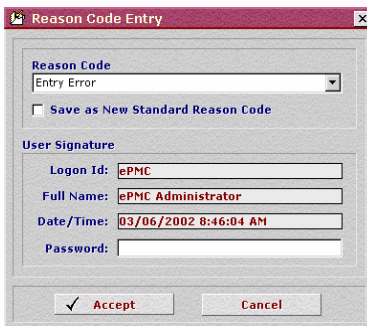


Audit Trail information is maintained and can be reviewed for any changes made to each operator, system and instrument in the SmartBatch system.

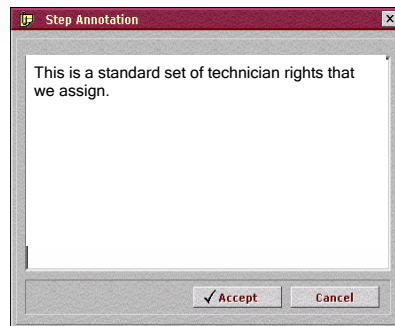
A **Blue Compliance flag** alerts a reviewer to the presence of a change.



Security Manager controls **Data Exchange** and the viewing rights between operators, using such configuration factors as: assigned production line, location, project number or product type.

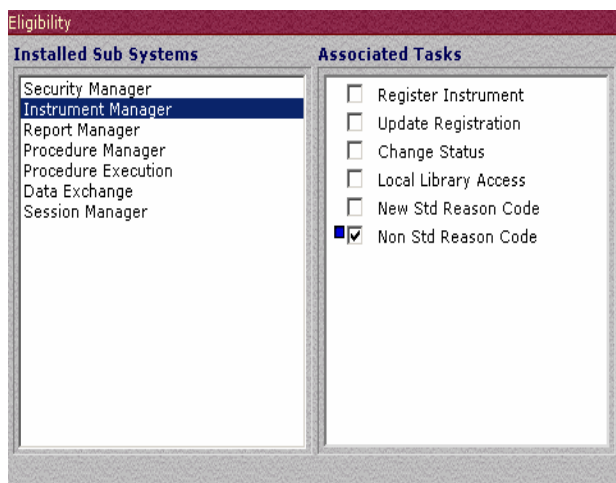


Audit Trails are maintained for all changes made to individual's rights including the user name, time/date stamp and a reason code.



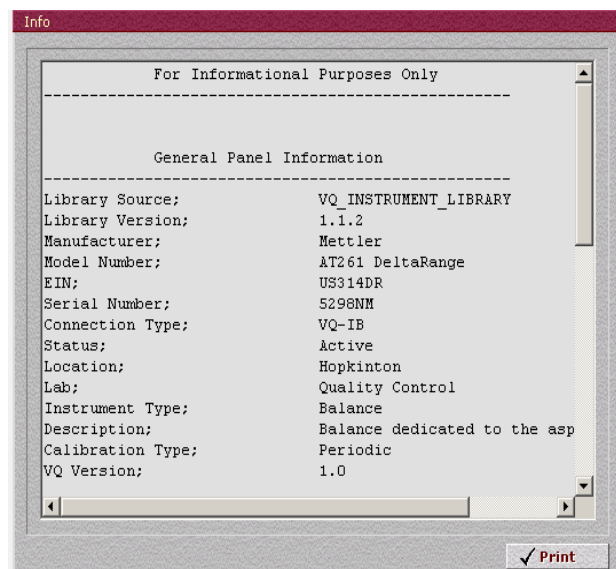
Annotations are available to document special notations and rationale for all changes made.

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

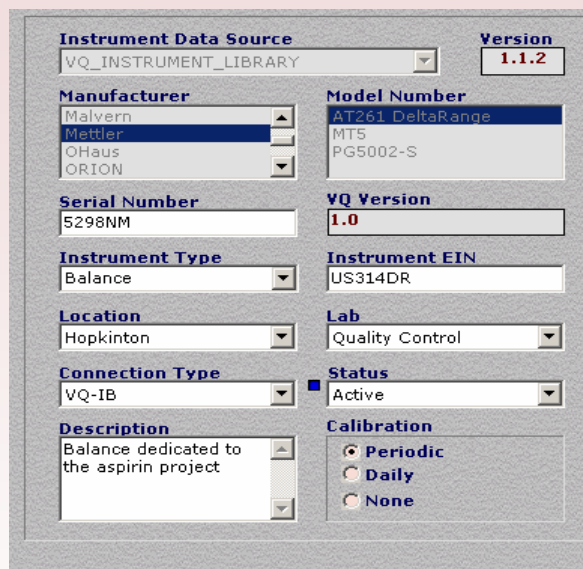


Equipment and Instrument Eligibilities are very granular. Each task associated with equipment management and operation can be granted to individual operators and technicians.

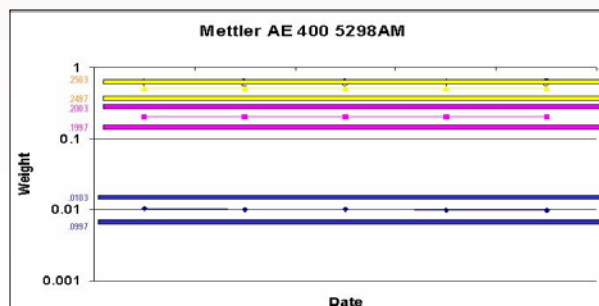
Audit Trails are maintained for every change to an operator's eligibility. A blue flag identifies the presence of an audit trail.



Device and System Libraries are provided to facilitate installing and validating most common production equipment and systems.

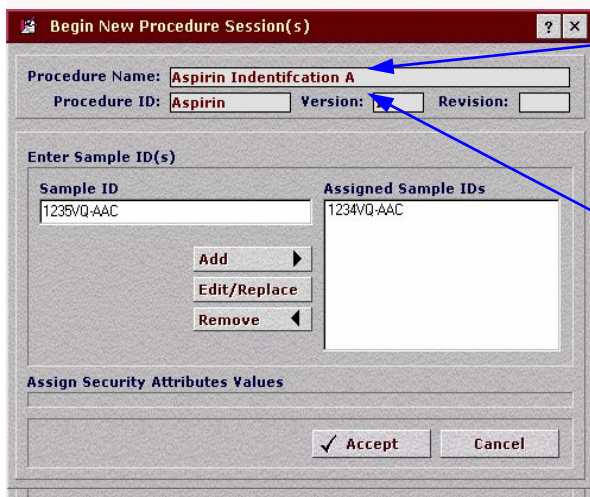


Instrument and Equipment Trending Reports can be used to review individual system performance against validation and calibration criterion.



SmartBatch Session Manager allows you to perform batch administration in the plant. You can easily create work orders for individual tests or process steps, which can be forwarded to a manager for assignment to individual operators. Simply establish a standard suite of steps for a product or product code. Enter the product code and link it to a batch, and all of the individual procedures are automatically set up and forwarded. A supervisor can then review the requests and assign them to appropriate operators.

Either the **Session Manager, LIMS system or ERP system** can be used to enter the products, create the necessary batch settings, and assign the work to individual operators. If the information is set up in LIMS, or an ERP system, the Session Manager will verify the selections and forward the work to the individual operator's clipboard for implementation.



The dialog box 'Begin New Procedure Session(s)' contains the following fields and controls:

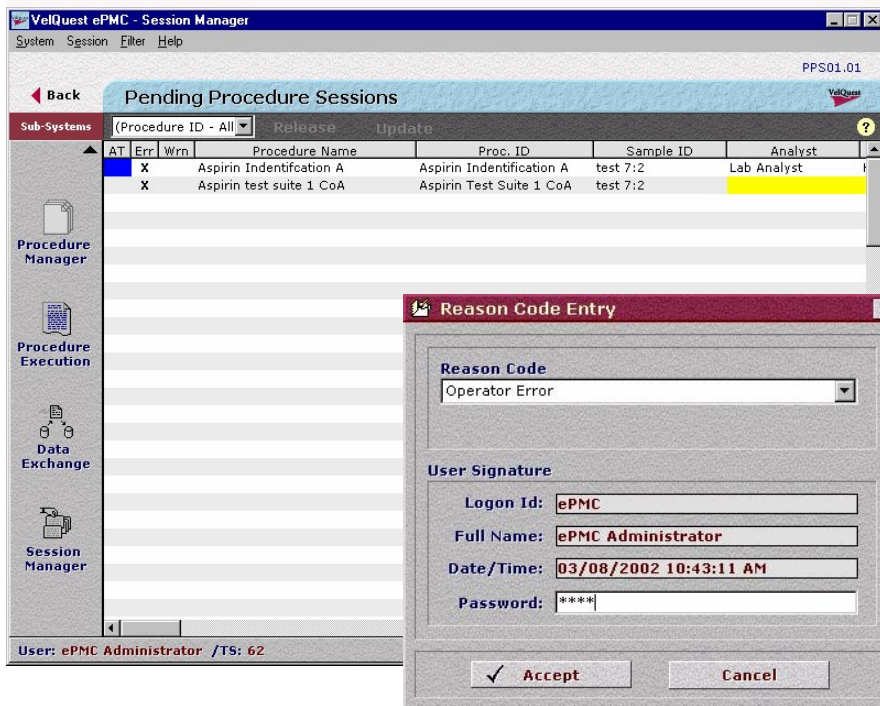
- Procedure Name: Aspirin Identification A
- Procedure ID: Aspirin
- Version: [empty]
- Revision: [empty]
- Enter Sample ID(s):
 - Sample ID: 1235VQ-AAC
 - Assigned Sample IDs: 1234VQ-AAC
 - Buttons: Add, Edit/Replace, Remove
- Assign Security Attributes Values: [empty]
- Buttons: Accept, Cancel

Product Groups can be entered so a suite of operations can be automatically linked to a batch.

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

Materials are logged in and assigned to a location and a particular plant area directly in the Session Manager. All of this information may also be sent to the SmartBatch system from a LIMS or ERP system.

The system maintains a complete **21 CFR part 11 Audit Trail** noting all necessary aspects of the batch request and subsequent changes.



The main window shows 'Pending Procedure Sessions' with the following table:

| AT | Err | Wrn | Procedure Name | Proc. ID | Sample ID | Analyst |
|----|-----|-----|--------------------------|--------------------------|-----------|-------------|
| X | | | Aspirin Identification A | Aspirin Identification A | test 7:2 | Lab Analyst |
| X | | | Aspirin test suite 1 CoA | Aspirin Test Suite 1 CoA | test 7:2 | Lab Analyst |

The 'Analyst' column for the second row is highlighted in yellow. A 'Reason Code Entry' dialog box is open over the table, containing:

- Reason Code: Operator Error
- User Signature:
 - Logon Id: ePMC
 - Full Name: ePMC Administrator
 - Date/Time: 03/08/2002 10:43:11 AM
 - Password: ****
- Buttons: Accept, Cancel

Areas of Concern will be highlighted in yellow.

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

Session Manager transfers ready-to-implement work lists automatically to the operator's tablet PC.



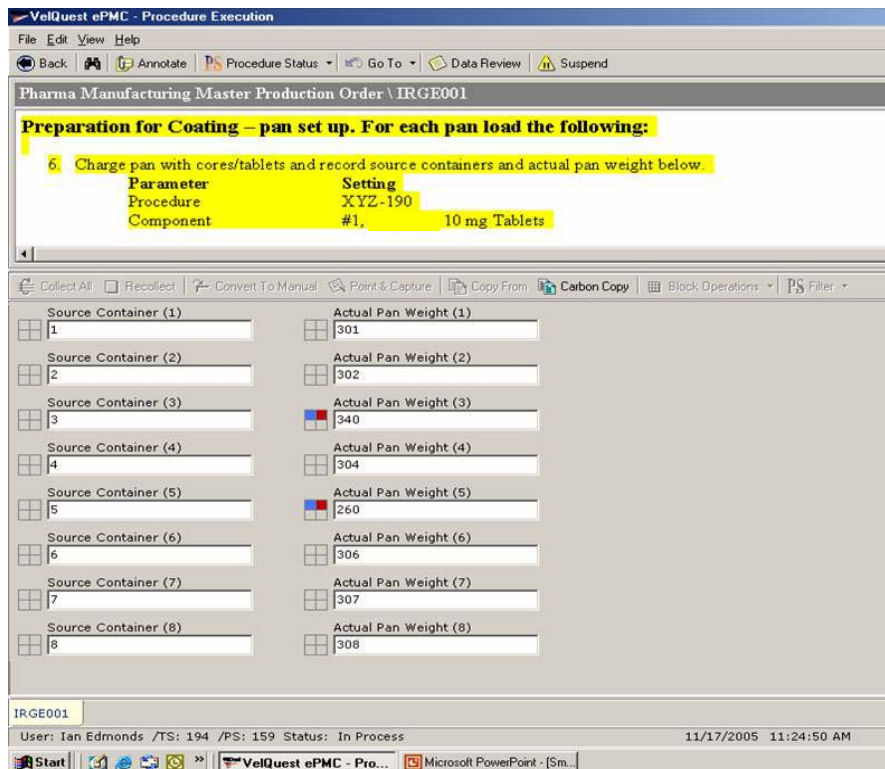
Process equipment and instruments are connected directly to the system for automated data capture.

Process steps are viewed electronically in the upper portion of the screen for the operator to follow, and the data capture boxes are presented in the lower part of the screen for each process step.

Data can be captured in several ways:

- Electronically
- Drop down menu
- Free text

Should any captured data values fall outside of an expected norm, the user will see a compliance flag pop up on screen. The flag will alert the operator to the problem, and advises a specified action step(s) to follow, as defined by production line managers.



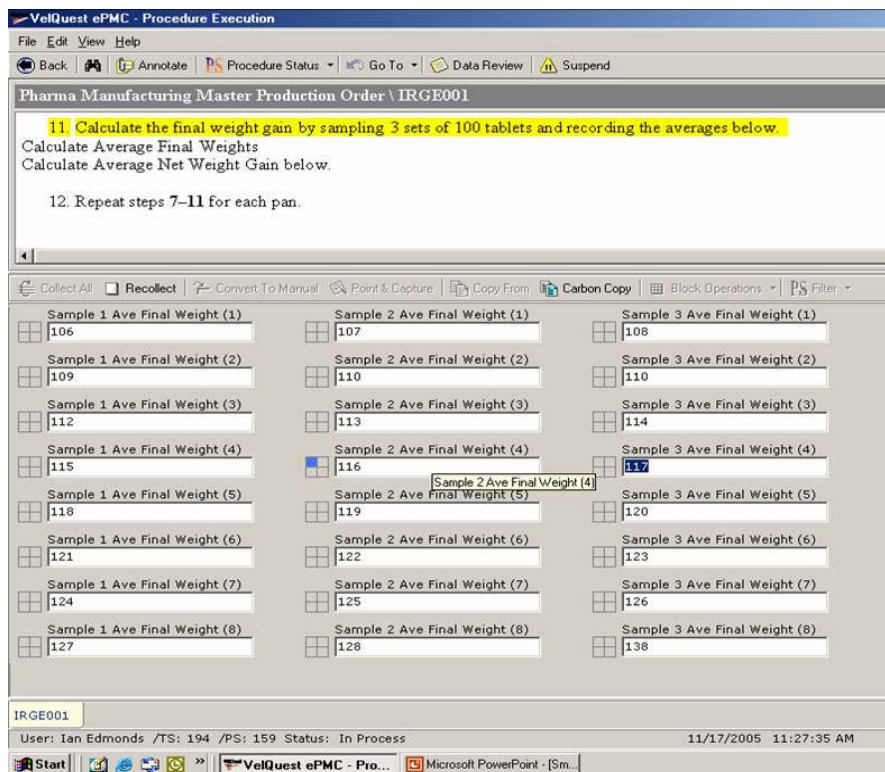
Preparation for Coating – pan set up. For each pan load the following:

6. Charge pan with cores/tablets and record source containers and actual pan weight below.

| Parameter | Setting |
|-----------|-------------------|
| Procedure | XYZ-190 |
| Component | #1, 10 mg Tablets |

| Source Container (1) | Actual Pan Weight (1) |
|----------------------|-----------------------|
| 1 | 301 |
| 2 | 302 |
| 3 | 340 |
| 4 | 304 |
| 5 | 260 |
| 6 | 306 |
| 7 | 307 |
| 8 | 308 |

IRGE001
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11. Calculate the final weight gain by sampling 3 sets of 100 tablets and recording the averages below.
Calculate Average Final Weights
Calculate Average Net Weight Gain below.

12. Repeat steps 7–11 for each pan.

| Sample 1 Ave Final Weight (1) | Sample 2 Ave Final Weight (1) | Sample 3 Ave Final Weight (1) |
|-------------------------------|-------------------------------|-------------------------------|
| 106 | 107 | 108 |
| 109 | 110 | 110 |
| 112 | 113 | 114 |
| 115 | 116 | 117 |
| 118 | 119 | 120 |
| 121 | 122 | 123 |
| 124 | 125 | 126 |
| 127 | 128 | 138 |

IRGE001
User: Ian Edmonds /TS: 194 /PS: 159 Status: In Process 11/17/2005 11:27:35 AM

Batch Record Review time is reduced by as much as 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 metadata is captured electronically and immediately available to the reviewer.

| Sample ID | AT | Notes | OL | OD | SD | An. | App. | Att. | Rev. | Step | Field Label | Field Value | Who | Logon... | How | Date/Time |
|-----------|----|-------|----|----|----|-----|------|------|------|------|------------------------------|--------------|-------------|----------|-------|---------------------|
| IRGE001 | | | | | | | | | | 17 | Slippery When Wet | Understood | Ian Edmonds | iane | MN | 11/17/2005 10:57:30 |
| | | | | | | | | | | 18 | Temperature deg F | 70.9 | Ian Edmonds | iane | EC | 11/17/2005 10:57:50 |
| | | | | | | | | | | 19 | Relative Humidity % | 67.1 | Ian Edmonds | iane | EC | 11/17/2005 10:57:53 |
| | | | | | | | | | | 18 | Environmental Measureme... | Out of Range | Ian Edmonds | iane | MN | 11/17/2005 11:29:02 |
| | | | | | | | | | | 19 | Reported to Supervisor | | | | | |
| | | | | | | | | | | 20 | Nozzle Size and Air Cap | Verified | Ian Edmonds | iane | MN | 11/17/2005 10:58:24 |
| | | | | | | | | | | 21 | Spray Guns | Calibrated | Ian Edmonds | iane | MN | 11/17/2005 10:58:31 |
| | | | | | | | | | | 22 | Procedure | XYZ-98 | Ian Edmonds | iane | MN DB | 11/17/2005 10:58:52 |
| | | | | | | | | | | 22 | Min Pan Weight | 270 | Ian Edmonds | iane | MN DB | 11/17/2005 10:58:52 |
| | | | | | | | | | | 22 | Max Pan Weight | 330 | Ian Edmonds | iane | MN DB | 11/17/2005 10:58:53 |
| | | | | | | | | | | 22 | Desired Pan Load Weight | 301 | Ian Edmonds | iane | MN DB | 11/17/2005 10:58:54 |
| | | | | | | | | | | 23 | Equipment ID | EQUID987 | Ian Edmonds | iane | MN | 11/17/2005 10:59:19 |
| | | | | | | | | | | 24 | Source Container (1) | 1 | Ian Edmonds | iane | MN | 11/17/2005 11:00:22 |
| | | | | | | | | | | 24 | Actual Pan Weight (1) | 301 | Ian Edmonds | iane | MN | 11/17/2005 11:00:23 |
| | | | | | | | | | | 24 | Source Container (2) | 2 | Ian Edmonds | iane | MN | 11/17/2005 11:00:23 |
| | | | | | | | | | | 24 | Actual Pan Weight (2) | 302 | Ian Edmonds | iane | MN | 11/17/2005 11:00:24 |
| | | | | | | | | | | 24 | Source Container (3) | 3 | Ian Edmonds | iane | MN | 11/17/2005 11:00:24 |
| | | | | | | | | | | 24 | Actual Pan Weight (3) | 340 | Ian Edmonds | iane | MN | 11/17/2005 11:00:25 |
| | | | | | | | | | | 24 | Source Container (4) | 4 | Ian Edmonds | iane | MN | 11/17/2005 11:00:25 |
| | | | | | | | | | | 24 | Actual Pan Weight (4) | 304 | Ian Edmonds | iane | MN | 11/17/2005 11:00:25 |
| | | | | | | | | | | 24 | Source Container (5) | 5 | Ian Edmonds | iane | MN | 11/17/2005 11:00:25 |
| | | | | | | | | | | 24 | Actual Pan Weight (5) | 260 | Ian Edmonds | iane | MN | 11/17/2005 11:00:27 |
| | | | | | | | | | | 24 | Source Container (6) | 6 | Ian Edmonds | iane | MN | 11/17/2005 11:00:26 |
| | | | | | | | | | | 24 | Actual Pan Weight (6) | 306 | Ian Edmonds | iane | MN | 11/17/2005 11:00:27 |
| | | | | | | | | | | 24 | Source Container (7) | 7 | Ian Edmonds | iane | MN | 11/17/2005 11:00:27 |
| | | | | | | | | | | 24 | Actual Pan Weight (7) | 307 | Ian Edmonds | iane | MN | 11/17/2005 11:00:27 |
| | | | | | | | | | | 24 | Source Container (8) | 8 | Ian Edmonds | iane | MN | 11/17/2005 11:00:28 |
| | | | | | | | | | | 24 | Actual Pan Weight (8) | 308 | Ian Edmonds | iane | MN | 11/17/2005 11:00:28 |
| | | | | | | | | | | 25 | Gun to Bed Distance | 8.1 | Ian Edmonds | iane | MN | 11/17/2005 11:01:14 |
| | | | | | | | | | | 26 | Sample 1 Ave Initial Weig... | 101 | Ian Edmonds | iane | MN | 11/17/2005 11:03:30 |
| | | | | | | | | | | 26 | Sample 2 Ave Initial Weig... | 102 | Ian Edmonds | iane | MN | 11/17/2005 11:03:31 |
| | | | | | | | | | | 26 | Sample 3 Ave Initial Weig... | 103 | Ian Edmonds | iane | MN | 11/17/2005 11:03:31 |
| | | | | | | | | | | 26 | Sample 1 Ave Initial Weig... | 104 | Ian Edmonds | iane | MN | 11/17/2005 11:03:32 |
| | | | | | | | | | | 26 | Sample 2 Ave Initial Weig... | 105 | Ian Edmonds | iane | MN | 11/17/2005 11:03:32 |
| | | | | | | | | | | 26 | Sample 3 Ave Initial Weig... | 106 | Ian Edmonds | iane | MN | 11/17/2005 11:03:32 |

Data Approval with signatures is done electronically. Final batch approval and electronic signatures are fully electronic. Each electronic signature is accompanied by a time and date audit trail.

| Sample ID | AT | Notes | OL | OD | SD | An. | App. | Att. | Rev. | Step | Field Label | Field Value | Who | Logon... | How | Date/Time |
|-----------|----|-------|----|----|----|-----|------|------|------|------|----------------------------|-------------|-------------|----------|-----|---------------------|
| IRGE001 | | | | | | | | | | 37 | Production Doc Review | Attested | Ian Edmonds | iane | MN | 11/17/2005 11:09:03 |
| | | | | | | | | | | 37 | Quality Control Doc Review | Attested | Ian Edmonds | iane | MN | 11/17/2005 11:09:07 |
| | | | | | | | | | | 38 | Production | Approved | Ian Edmonds | iane | MN | 11/17/2005 11:10:18 |
| | | | | | | | | | | 38 | Quality Control | Approved | Ian Edmonds | iane | MN | 11/17/2005 11:10:22 |

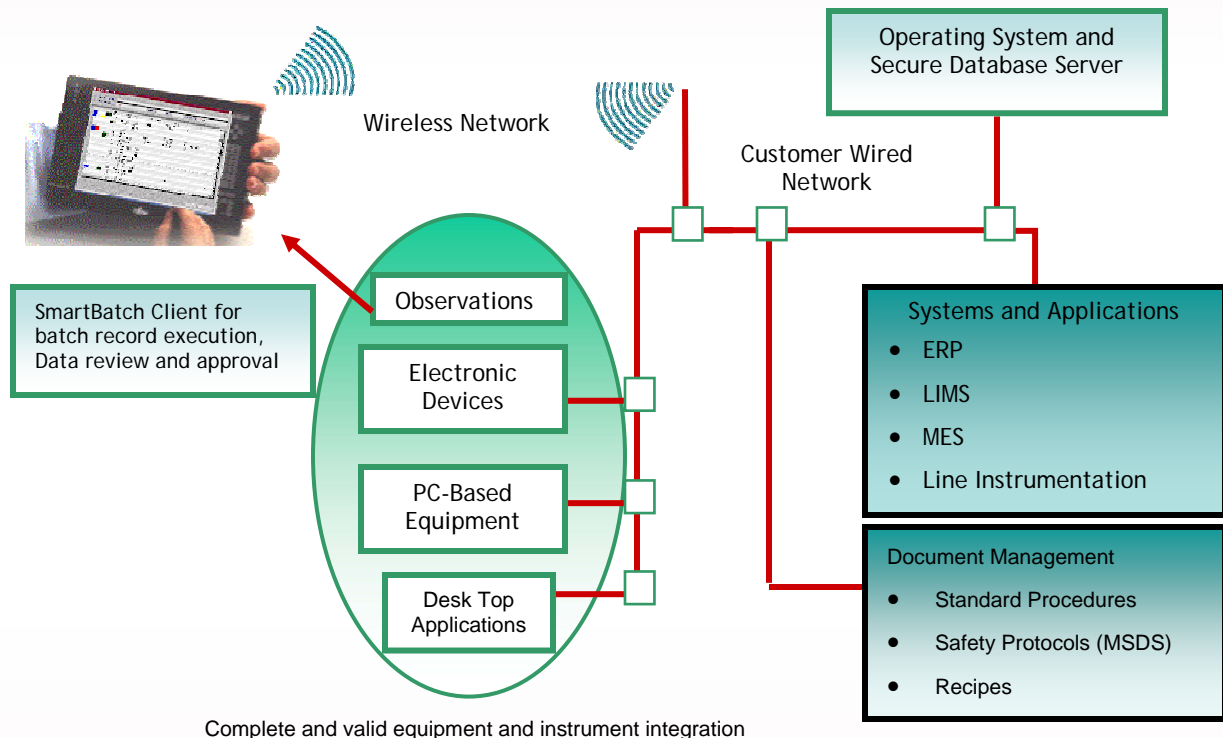
| VelQuest ePMC - Procedure Session Summary Report | | | | | | | | | |
|--|--------------------------|--------------------------|--------------------------|--|-----------------|---|----------------------------------|------------------|--|
| Report Name: 3 | | | | | | | | | |
| PHARMA THERAPEUTICS | | Production Order | | Manufacturing Instructions | | | PDO Effective Date 11/17/2005 | Lot No. LN707 | |
| Product Generic Name Film Coated Tablets 10mg | | | | Stage Film Coating 6' Accela Cota with Comp Contr | | Revision - Alternate Number MPRAN001 | Product Code PCMP002 | Page 10 of 10 | |
| Pan | Ave Final Wt Sample 1 mg | Ave Final Wt Sample 2 mg | Ave Final Wt Sample 3 mg | Final Ave Wt mg | Ave Net Wt Gain | Performed By | Verified By | Date | |
| 1 | 106 | 107 | 108 | 107.0 | 5.0 | Ian Edmonds | | | |
| 2 | 109 | 110 | 110 | 109.7 | 4.7 | Ian Edmonds | | | |
| 3 | 112 | 113 | 114 | 113.0 | 5.0 | Ian Edmonds | | | |
| 4 | 115 | 116 | 117 | 116.0 | 5.3 | Ian Edmonds | | | |
| 5 | 118 | 119 | 120 | 119.0 | 5.0 | Ian Edmonds | | | |
| 6 | 121 | 122 | 123 | 122.0 | 5.0 | Ian Edmonds | | | |
| 7 | 124 | 125 | 126 | 125.0 | 5.0 | Ian Edmonds | | | |
| 8 | 127 | 128 | 138 | 131.0 | 8.0 | Ian Edmonds | | | |

SmartBatch allows use of standard report writers to create configurable reports. Typical reports provide trending information on areas such as number and types of batches that each operator has completed, environmental monitoring results, people and equipment performance, vendor and materials tracking metrics, as well as compliance to procedures by monitoring and displaying the number of unplanned deviations.

| VelQuest ePMC - Procedure Session Summary Report | | | | | | | | | |
|---|---|---|--|--|---------------------------------|---|----------------------------------|-----------------|--|
| Report Name: 1 | | | | | | | | | |
| PHARMA THERAPEUTICS | | Production Order | | Master Signature Page | | | PDO Effective Date 11/17/2005 | Lot No. LN707 | |
| Product Generic Name Film Coated Tablets 10mg | | | | Stage Film Coating 6' Accela Cota with Comp Contr | | Revision - Alternate Number MPRAN001 | Product Code PCMP002 | Page 1 of 10 | |
| Manufacturing Master Production Order | | | | | | | | | |
| Originator: Sign & Date Ian Edmonds AM 11/17/2005 10:48:42 | | Development: Sign & Date | | Quality Control: Sign & Date | | Production: Sign & Date | | | |
| Theoretical Yield: No Data tablets | | Activity of Standard Batch HCL 100,000 | | DFM Number: DFM707 | | DFM Effective Date: 11/9/2005 | | | |
| Instructions | | | | | | | Signature | Date | |
| 1. | Document Reproduction: This Production Order is an accurate reproduction of the master. No Data | | | | | | | | |
| 2. | Issuance of Lot Number: Lot number issued was verified to be correct and to correspond to this Production Order. Correct & Corresponds | | | | | | | | |
| List of Supplementary Documentation | | | | | | | | | |
| Name of Document | | | | Name of Document | | | | | |
| 1. | Coater Cleaning Checklist | | | 8. | Yield and Accountability Form | | | | |
| 2. | Sanitization Checklist | | | 9. | Move Forms | | | | |
| 3. | Tank Cleaning Checklist | | | 10. | Returns for Later Disposition | | | | |
| 4. | Module Clearance | | | 11. | Scale Calibration Record | | | | |
| 5. | Film Coating Suspension Prep Production Order | | | 12. | Coating Setup Stop Record Sheet | | | | |

The **Data Exchange Manager** in SmartBatch provides bi-directional communication with other enterprise IT systems, such as LIMS, ERP, and Document Management Systems. System administrators have the ability to register connections to these other systems within Security Manager.

A wide range of communications formats are supported including XML and ASCII. The Data Exchange technology enables configuration of process input information, work lists, and output information.



External source data can be processed via the Data Exchange module in SmartBatch. Data Exchange stores the data in the SmartBatch database, then exports it via a template format to the location specified in the URL. Internal interface file definitions link the application to external systems, such as ERP, etc. SmartBatch uses an *Input* and *Output* type interface for this link.

- The *Input* interface types use a listener service to detect and import an external system file, which is then assigned to the Session Manager for processing.
- The *Output* interface types export the file system after the data has been processed to the originating user.
- SmartBatch provides a user interface method for checking, confirming and releasing pending user sessions.
- Work lists created in other systems can be automatically transferred to SmartBatch.
- Data generated in SmartBatch can be transferred to other central computer systems.

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 operation. We believe in practical, effective, and 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 (VelQuest headquarters)
- System Operator Training (Customer Site)
- System Administrator Training
- Procedure Conversion Training
- Instrument—Equipment Interfacing
- Train-the-Trainer Certification

Customer statements about measurable gains with VelQuest software:

- 65% Liberation of resources from Data/Results Review.
- 50% Liberation from Paper Notebook and Log book activities.
- 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/procedures.
- First Time Quality reduces rework loops, will prevent errors.