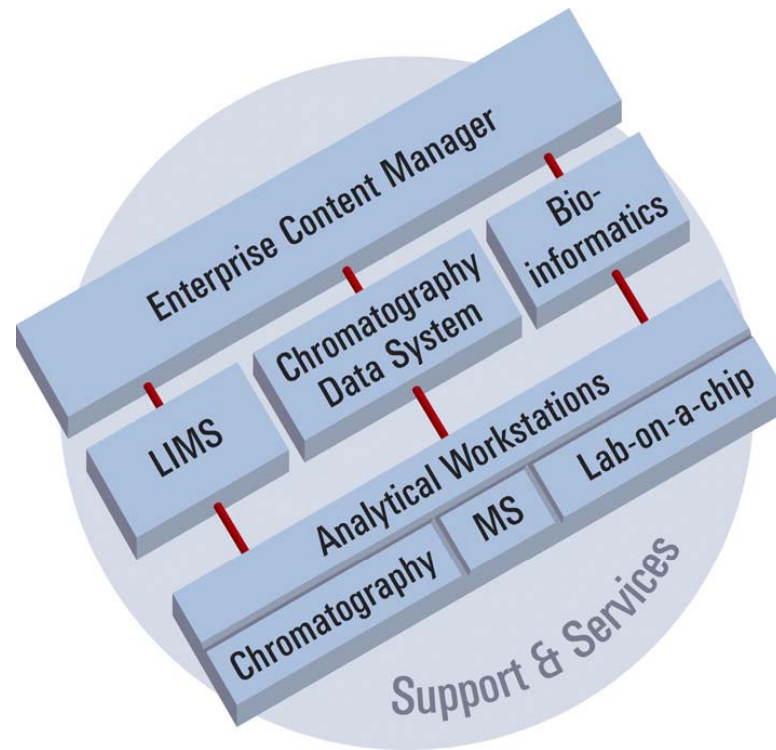


The Use of an Automated  
Compliance  
Engine (ACE) with an Automated  
Business Process Manager (BPM) to  
Ensure  
Instrument Compliance  
Abstract Number: 2790 - 6P

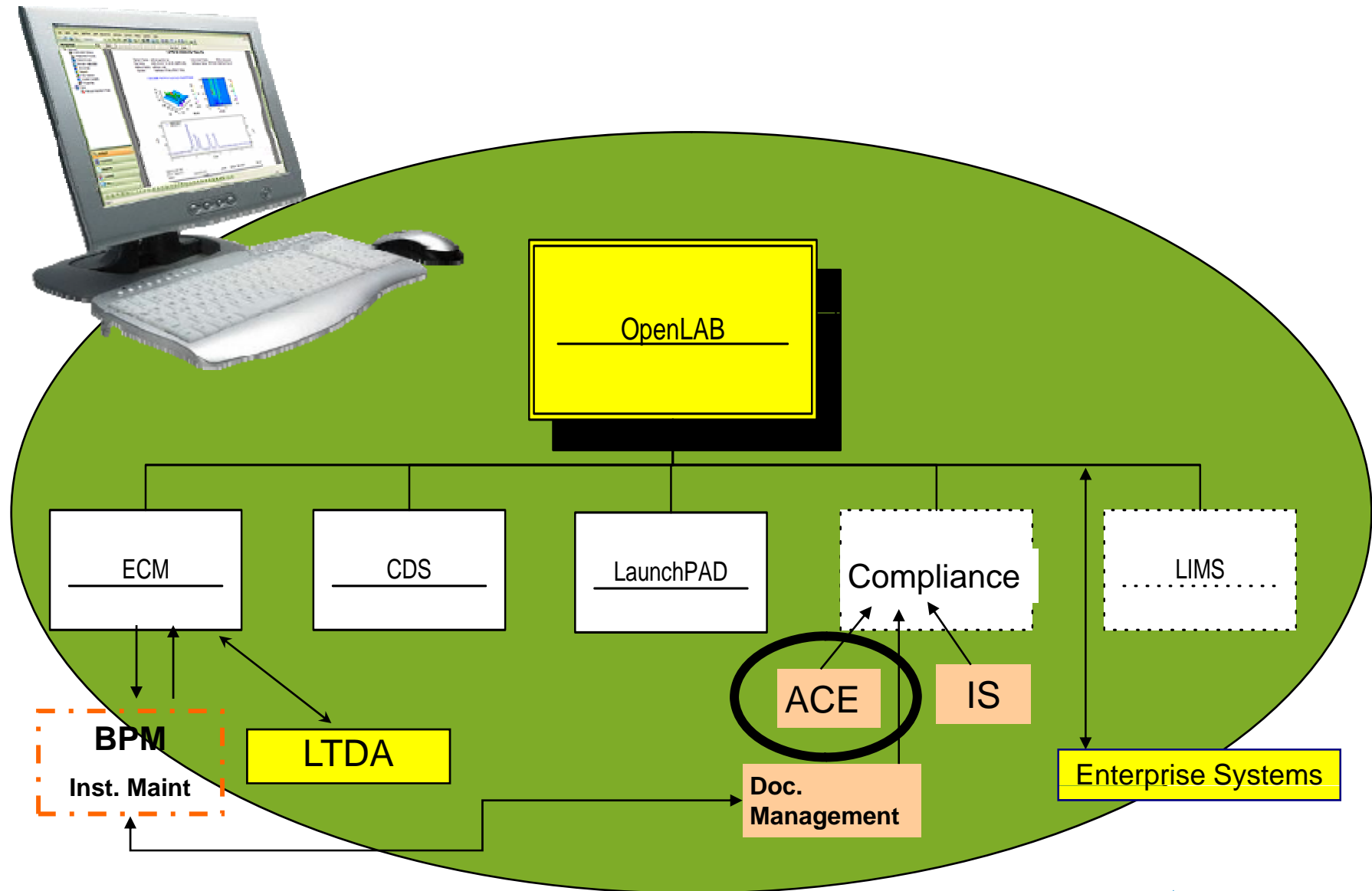
*Laboratory data collection, analysis, interpretation and management*

# Agilent Informatics



*OpenLAB ECM is the core of Agilent Lab Informatics*

# What is OpenLAB?

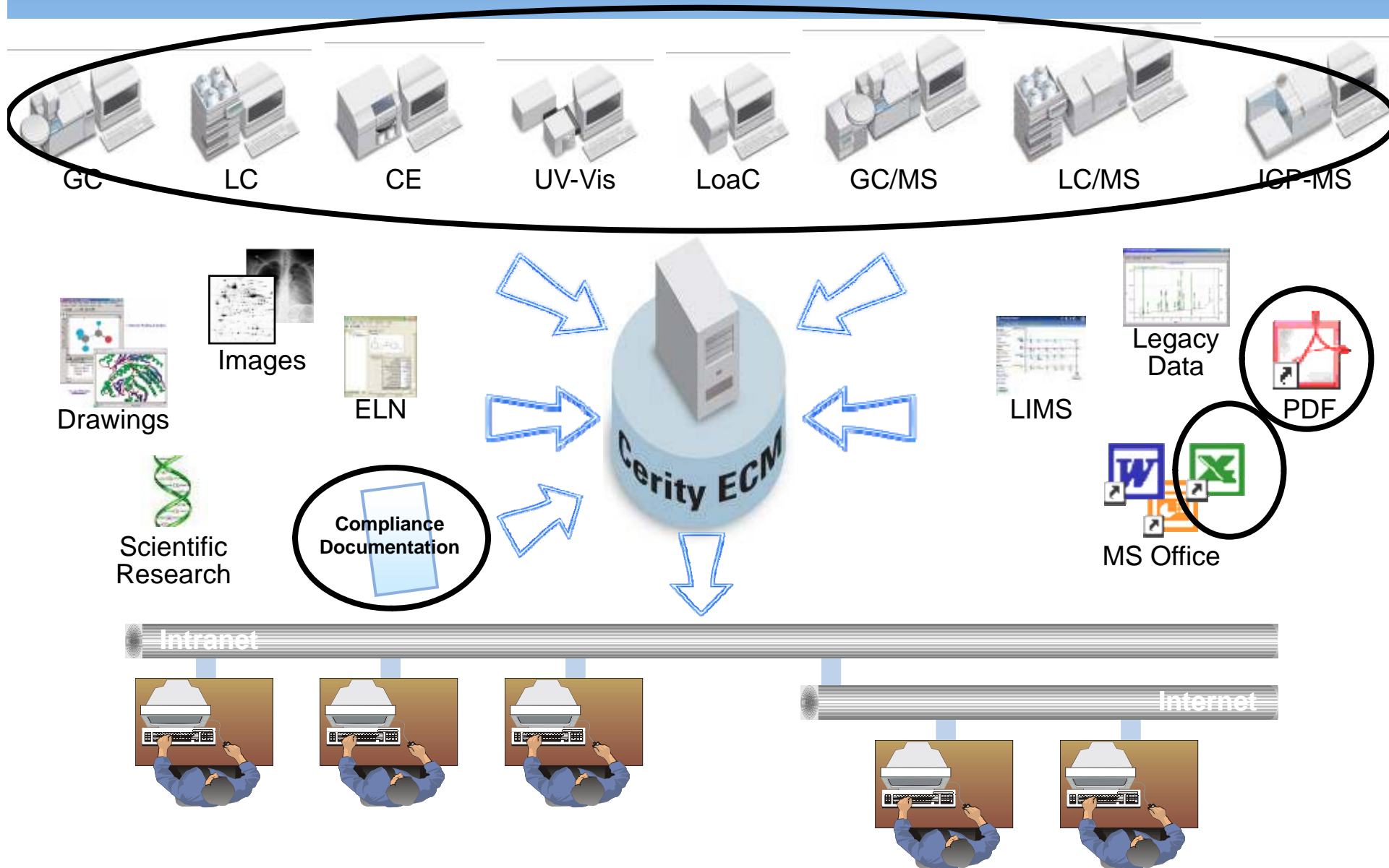


# What Is Openlab ECM?

- **Enterprise Content Manager**
- is a web-based electronic library that collects, organizes, indexes, stores, archives, and shares any electronic file – from analytical raw data and lab reports to compliance records, molecular drawings, Adobe Acrobat documents, Microsoft Office documents, web pages, pictures, video and audio.
- ECM allows users to easily search and review all of their data. ECM automatically extracts searchable metadata from files and provides powerful search capabilities
- Backend DB of ORACLE / SQLServer



# Why Agilent OpenLAB ECM?



# How Data is imported into Openlab

## ■ Manually

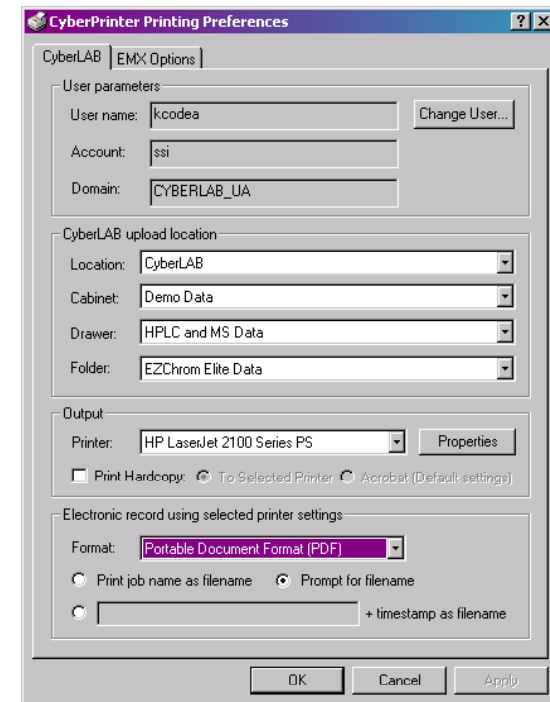
- Add Files (explorer right mouse click)
- Office integration (Excel, Word, PowerPoint, Outlook, Explorer)
- Tool Bar (Microsoft)

## ■ Scheduler

- Push or Pull
- Configurable on options for data collection

## ■ Cyberprinter

- Acts as a printer driver
- Transparent
- Adobe pdf format (ACE Reports)



# Regulatory Compliance Features

- 21 CFR Part 11
- Password Protection
- Complete Access Security by User/Roles
- Data can be locked down
- Electronic Signatures / Signoff
- Audit Trail (System and Data)
- Data Versioning (Can never delete data)
- Complete Document Chain of Custody (with Adobe Forms)
- Complete integration with office products
  - Word, Excel, PowerPoint, Outlook, Explorer
- Compare multiple versions
- Composite Reports with traceability



# What is ACE?



A software to manage the protocols, work-flow, raw data & reports involved in lab instrument qualification programs (IQ, OQ, RQ, PM, repair)



# Key aspects of ACE

- ACE is a standalone application that links with OpenLAB, ECM
- Self-contained software on laptop/tablet PC for portability
- Connect the laptop to any network connection or wireless connection to CDS and ECM components
- XML, pdf, EZChrom, .net
- E-sigs provided by Acrobat Digital Signature or ECM

# ACE/Openlab configuration

The image shows two overlapping windows from the Agilent ACE/Openlab software. The background window is titled "Ace Ecm Application" and has three tabs: "Create PDF Template", "Select PDFs to Unlock", and "Log In To ECM". The "Create PDF Template" tab is active. It features a "Browse" button to select an "EQR Excel Report (csv) File". The "Selected File" field shows the path "D:\VACE-ECM\VACEReports\GC\2007Feb21.15.22.34.csv". Below this, there are two lists: "Available Keys for ECM PDF Template creation" and "Selected Keys". The available keys list includes items like "Corrective and Preventative Actions:", "Date:", "Digital Flowmeter", "Digital Mass Flowmeter", "Digital Thermometer", "Electronic database management system: electronic s", "Expiration Date:", "Ink signature on EQR CD", "Ink signature on printed EQR", "Instance Type:", "Logged On User Name:", "Lot Number:", "Model Number:", "Model:", "Operator Job Title:", "Part Number:", "Previous Qualification Date:", "Problem Description and Evaluation of Cause:", "Qualification Date:", "Runs:", "Scheduled:", "Section Name:", "Section Page", "Serial Number:", "Specification:", "Status:", "System ID:", "Test:", "Thermometer Probe", and "Time:". There are navigation buttons (>, >>, <, <<) between the lists. A "Create PDF" button is at the bottom right of this window.

The foreground window is titled "ECM Login" and is divided into four numbered sections:

- 1 Login:** Contains fields for "ECM Uri" (http://ecmsys01.lfs.agilent.com), "Username", "Password", "Account" (demo), and "Domain" (agilent). A "Login" button is present. A note says "(use your Agilent NT Account and password to login)".
- 2 Add PDF Template To ECM:** Contains a "PDF XML Template File" field (c:\ACESw\OQ.xml) and a "PDF Template Name" field (MyTestTemplate). An "Add PDF template to ECM" button is present.
- 3 Select ECM Server folder to Apply PDF Template:** Contains four dropdown menus for folder selection and an "Apply Template to selected folder" button.
- 4 Upload PDF File:** Contains a "Source file:" field (C:\EQR.pdf) and an "Upload file" button.

# Laboratory Objectives

- ✓ *A totally paperless system used to perform validation on; computer systems, **laboratory instruments**, facilities, and even process.*
- ✓ *The application would manage the validation life cycle for any of the mentioned validation systems.*
- ✓ *Users would create validation documents based on approved templates in the system. These documents would then be routed for approvals via electronic signature.*
- ✓ *Protocols and test cases would be created as well. The system would not permit the execution of a protocol prior to approval.*
- ✓ *Execution of the approved protocol can be performed electronically. Screen captures or evidence of execution can be electronically attached to the executed protocol*
- ✓ *Executed documents are routed for review/approval electronically.*
- ✓ *Incidents are managed electronically.*
- ✓ *There is some type of management feature to view the status of a validation exercise while underway.*
- ✓ *The system would manage the periodic system review scheduling.*

# Key aspects of ACE

- Data integrity provided by application security, locked pdf's, ECM database security
- Post-event data analysis of instrument qualification results provided by ECM using pdf 'reading' or .csv tables
- PM and repair records included in ACE for export to ECM
- Working instructions and other utilities contained in ACE
- ACE is fully validated by vendor, all instances have IQ and OQ of the ACE application. Automated IQ&OQ of ACE software can be performed anytime.

# Structure of ACE

Folders

- AgilentComplianceEngine
  - Attachments
  - Bin
  - CustomTemplates
  - Default
    - Method
    - Sequence
  - FormTemplates
  - IQTFiles
  - MethodTemplates
  - Nls
  - Results
  - SequenceTemplates
  - Support
  - Temp
  - WorkingInstructions

Name	Size	Type
testspeconf.xml	1 KB	XML Docu...
TestSpec.pdf	2,020 KB	PDF File
test99.pdf	385 KB	PDF File
reportdefconf.xml	1 KB	XML Docu...
ReportDef.pdf	192 KB	PDF File
protocolconf.xml	1 KB	XML Docu...
protocol.pdf	157 KB	PDF File

# Structure of ACE

The screenshot illustrates the structure of the ACE (Agilent Compliance Engine) software. On the left, a file explorer shows a directory tree under 'TestData' with folders named Test1 through Test57. An arrow points from the 'Test1' folder to a document viewer window. The document viewer displays a document titled 'Test1' with three attachments: 'test1.pdf', 'test1.xml', and 'test1conf.xml'. Below the document viewer, a data entry form is shown, divided into two columns. The left column contains a 'Restriction Capillary' section with fields for Part Number (5022-2159), T-Piece Part Number (0100-0969), and Guard Column Cartridge Part Number (820960-925). It also includes a 'Procedure' section with three steps and two 'Flow Rate' input fields. The right column contains 'Measurements' and 'Results' sections, each with six 'Flow Rate' input fields and a 'Flow Rate 1' field. The bottom of the interface shows a status bar with a 57% zoom level and a '2 of 4' page indicator.

# Structure of ACE

## test specification (acrobat form)

### Column Temperature Accuracy and Stability

This test uses a calibrated digital thermometer to determine the accuracy and stability of column temperature. Column temperature accuracy is calculated as the absolute difference between the measured temperature and setpoint. Temperature stability is calculated as the absolute difference between the highest and lowest measured temperatures.

Run the test?: Run

Customer Reference: Equivalent to GSK\_Cork\_TestSpec01 but for A.1.30 forms plus FLD tests

Temperature 1: 60.0 °C

Accuracy

(Limit 1:) <= 2.0 °C

(Limit 2:) <= 3.0 °C

Temperature 2: 35.0 °C

Accuracy

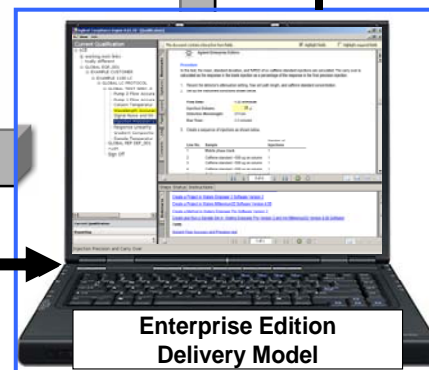
(Limit 1:) <= 2.0 °C

(Limit 2:) <= 3.0 °C

Stability

(Limit 1:) <= 0.5 °C

(Limit 2:) <= 1.0 °C



- TestData
  - Test1
  - Test10
  - Test11
  - Test12
  - Test13
  - Test14
  - Test15
  - Test16
  - Test17
  - Test18
  - Test19
  - Test2
  - Test20
  - Test21
  - Test22
  - Test23
  - Test24
  - Test25
  - Test26
  - Test27
  - Test28
  - Test29
  - Test3
  - Test4
  - Test5
  - Test50
  - Test51
  - Test52
  - Test53
  - Test54
  - Test55
  - Test56
  - Test57

# User Authentication

Agilent Compliance Engine A.01.30  
View Tools Help

Agilent Compliance Engine  
**Enterprise Edition** Welcome to the Agilent Compliance Engine

Us take  
Choosin preparation  
The F on the

**Login Required!**

**Warning!**  
This is a proprietary product intended for the exclusive use of employees, contractors and authorized agents of Agilent Technologies Inc. Use, reproduction, decompilation, adaptation, or translation of the protocol or the creation program without prior written permission is strictly prohibited.

Copyright 2006 Agilent Technologies Inc.  
All rights reserved.

Enter User Name :   
Enter Password :

Authorized Users: For help with this product please go to the Product Support page at,  
<http://services-caq.pal.agilent.com/support>

English Language Version

© Agilent Technologies, Inc. 2005



# License module

License Manager

File Activate/Upgrade Help

Customer Details | License File Details | License Allocation Details | License Use Details

Drag a column header here to group by that column.

Qualification Type	Instrument/System Type	License Allocation Date	License Expiry Date	License Count	License Allocation Description
IQ	LC	08/24/2006	02/27/2007	250	LC IQ
OQ	LC	08/24/2006	02/27/2007	250	LC OQ
RQ	LC	08/24/2006	02/27/2007	250	LC RQ
OQ	ACE	08/24/2006	02/27/2007	250	ACE OQ
Grand Summaries				Sum = 1000	

Customer Details | License File Details | License Allocation Details | License Use Details

Drag a column header or card label here to group by that column.

Qualification Type	Instrument/System Type	License Use Date
OQ	LC	08/28/2006
User Details		
User Name	paul_coombes@agilent.com	
E-mail		
Qualification Type	Instrument/System Type	License Use Date
OQ	LC	08/30/2006
OQ	LC	09/03/2006
OQ	LC	09/03/2006
OQ	LC	09/03/2006
OQ	LC	09/11/2006
OQ	LC	09/12/2006
OQ	LC	09/13/2006
OQ	LC	09/14/2006
OQ	LC	09/15/2006
Grand Summaries		
Count = 10		

Ready... License File: C:\

# Ace Enterprise Edition

Agilent Compliance Engine A.01.30 - [Protocol Preparation Wizard]

View Tools Help

- PDF Viewer
- Working Instructions
- Data Copier
- Installation Qualification Tool

Step 1: Select Configuration Details

Step 2: Select Configurations

Step 3: Configure EQP LC-OQ Test Specificati...

Step 4: Configure EQP LC-OQ Report Definition

Step 5: Configure LC-OQ Protocol Details

Step 6: Configure LC Instrument Details

Step 7: Configure Qualification Details

Step 8: Preview Protocol Configuration

Agilent Compliance Engine  
Enterprise Edition

Welcome to the Protocol Preparation Wizard

Step through the Wizard to prepare the protocol components for the instrument under test

The protocol is defined by selecting the elements of the EQP and associating these with instrument and qualification details

The tree will update at points when enough information has been provided

Once the Wizard is completed you may run the qualification from the Run Qualification Menu

# Qualification Report

The screenshot shows a web browser window with the following details:

- Address Bar:** C:\AgilentComplianceEngine\IQTFiles\AgilentComplianceEngine\_A.01.30\_Report\_16-Sep-2006\_13-59.htm
- Page Title:** Installation Qualification Report
- Report Content:**
  - Date:** 16, Sep 2006
  - Time:** 17:59:16 GMT
  - Host Name:** A0053209
  - Windows User Name:** pcoombes
  - Revision Number:** A.01.30
  - Product Name:** Agilent Compliance Engine
  - Install Type:** N/A
  - Additional Packages:** None
- Base Reference File Name:** [agilentcomplianceengine\\_a.01.30.xml](#)
- Summary:**
  - Overall Evaluation of Installation Check: PASS
  - File Report Summary
    - No missing files or invalid files found
    - No system file differences found
  - Registry Report Summary
    - No invalid registry entries found
  - Files Registration Report Summary
    - Not registered files: NONE

The browser's status bar at the bottom shows "Done" and "My Computer".

# Use Preset Templates

Agilent Compliance Engine A.01.30 - [Protocol Preparation Wizard]

View Tools Help

Step 1: Configure EQP Customer Details ▲

- Create New from Template
- Create New from Existing
- Update Existing

Step 2: Select Configurations ▼

Step 3: Configure EQP LC-OQ Test Specific... ▼

Step 4: Configure EQP LC-OQ Report Defini... ▼

Step 5: Configure LC-OQ Protocol Details ▼

Step 6: Configure LC Instrument Details ▼

Step 7: Configure Qualification Details ▼

Step 8: Preview Protocol Configuration ▲

ace oq  
Example\_Roche  
organon example  
EQP\_A1200\_001  
1200\_cds\_EQP\_001  
nonACEtest

This document contains interactive form fields.  Highlight fields  Highlight required fields

**Signatures**

**Pages**

**Attachments**

**Comments**

**Approval**

Approvals of the EQP are as follows:

- The version of tests (including set points and limits)
- The use of Agilent Compliance Engine to manage the execution of tests and reports.
- The use of recommended data analysis tools (e.g. Non-Volatility, using digital conversion etc.) when not calibration certificates are included in the qualification reports.
- Clearance and/or repair of a test at the time of testing to investigate or troubleshoot only when approved by an approved test deviation report form included in the qualification reports.

Review of approval signatures may be kept separately on paper records or electronic approval using Agilent's digital signature technology or electronic document management systems can be used.

Space is provided below for Attached if digital signatures or typed if paper-based records signatures made digitally with a printed paper copy of the document discussed. All signatures must appear in the signature block record of this EQP.

Name	Role	Head Office	Signature	Date

**EQUIPMENT QUALIFICATION PLAN (EQP)**

Document Version: 1.0.0.0

Customer Details

Document Identifier

EQP Name: 1200\_cds\_EQP\_001

EQP Author Name: Agilent

EQP Author Role: Developer

EQP Comment: Test spec for 1200 LC systems connected to non-Agilent CDS (plus proof of control [1200cde\_testspec] & [1200\_cds\_eqp\_001])

Organization Details

Organization Name: type your customer firm name

Organization Location: type your city & country

Approval Date

Approval Date: 20 September 2008

35% 4 of 5

Enter Title 1200\_cds\_EQP\_001 Save Cancel Browse

# Ace May Use Customer Protocols

Agilent Compliance Engine A0130 [Qualification]

View Tools Help

This document contains interactive form fields.  Highlight fields  Highlight required fields

**Current Qualification**

- EQP\_A1200\_001
  - 1200\_cds\_EQP\_001
    - your dept.
      - LC
        - HPLC Named FRED
          - HPLC101
            - OQ
              - 1200cds\_protocol
                - 1200cdsTestSpec
                  - Pump 2 Flow A
                  - Pump 1 Flow A
                  - Column Tempe
                  - Wavelength Ac
                  - Signal Noise an
                  - Injection Precis
                  - Injection Carry
                  - Signal to Noise
                  - Response Linea
                  - Gradient Comp**
                  - Sample Tempe
                  - Injection Linea
                  - Full\_OQ\_RepDef\_
                  - Audit
                  - Sign Off
                - HPLC103
                - HPLC102
                - HPLC100
                - your LC name
              - nonACEtest
                - lab abc

**Procedure**

In this test, accuracy is calculated as the absolute difference between the mean composition and each set composition. Stability is the slope of the linear regression of all composition versus time points in each composition step. Linearity is the coefficient of determination (r2) of the composition values versus time measured in three sections from 95% to 5% in the linear portion of the gradient.

- Record the pump flow rate.
- Set up the instrument conditions shown below.

|                    |                       |        |   |        |
|--------------------|-----------------------|--------|---|--------|
| <b>Flow Rate:</b>  | 2.00 ml/minute        |        |   |        |
| <b>Composition</b> | Start                 | 0.00   | % | tracer |
| <b>Timetable:</b>  | Hold at               | 0.00   | % | tracer |
|                    | Immediate increase to | 20.00  | % | tracer |
|                    | Hold at               | 20.00  | % | tracer |
|                    | Immediate increase to | 40.00  | % | tracer |
|                    | Hold at               | 40.00  | % | tracer |
|                    | Immediate increase to | 60.00  | % | tracer |
|                    | Hold at               | 60.00  | % | tracer |
|                    | Immediate increase to | 80.00  | % | tracer |
|                    | Hold at               | 80.00  | % | tracer |
|                    | Immediate increase to | 100.00 | % | tracer |

3 of 9

Steps Status

Process/Reprocess Close

Gradient Composition

# Users May Given Detailed Protocols

The screenshot displays a software interface with a left-hand navigation pane and a main content area. The navigation pane is titled 'Operational Qualification' and contains a tree view with folders for 'Flow Accuracy and Precision', 'Column Temperature...', 'Wavelength Accuracy', 'Signal Noise and Drift', 'Injection Precision', 'Injection Carry Over', 'Signal to Noise', 'Response Linearity', 'Gradient Composition', 'Sample Temperature...', 'Injection Linearity', 'Injection Response', and 'Import AIA Files'. The 'Gradient Composition' folder is selected. The main content area is titled 'Working Instructions: Gradient Composition' and includes the following text:

**Working Instructions:**  
**Gradient Composition**  
Revision A.01.30, July 2006  
© 2005-2006 by Agilent Technologies  
Agilent Confidential: Reproduction, adaptation, or translation is prohibited.

**Pre-Requisites**  
Make sure that the instrument has been prepared as described in the *Working Instructions – Instrument Preparation* document.

**General Procedure**  
Some subsections of this general procedure vary depending upon the acquisition method (SS420x or the customer data station [CDS]) used to acquire the signal. Therefore, read through all subsections of this general procedure and skip those that don't apply to your acquisition method.

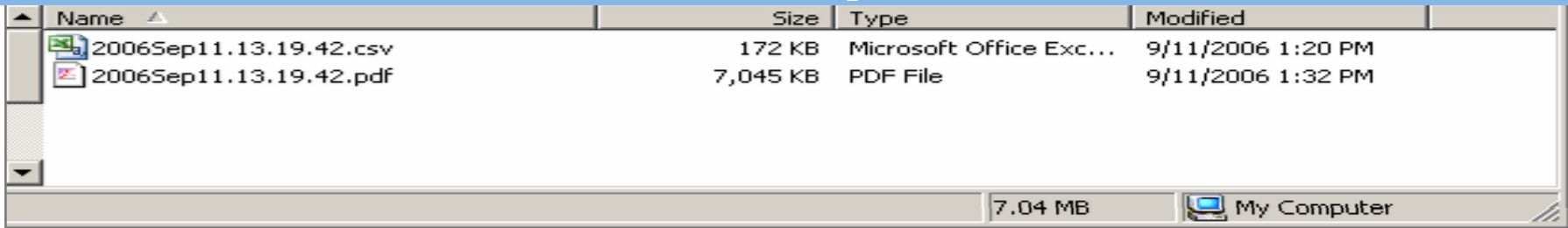
**General Setup**  
*For any acquisition method*

1. From the Agilent Compliance Engine's Run Qualification screen, select Gradient Composition.
2. In the instrument or system, set up a method as follows:  
**Pump Flow Rate:** 2.0 ml/minute of HPLC-grade water  
For the initial channel's setup and the gradient timetable, refer to the Model-Specific Notes section  
**Injection Volume On Column:** 0.0 ul of mobile phase or smallest volume possible  
**Column Compartment:** Stability temperature (Temperature 2 of Column Temperature Accuracy and Stability) as specified in the EQP  
**Detection Wavelength:** 265 nm (See Model-Specific Notes for additional setting )  
**Run Time:** 26.0 minutes (short delay volume with 3 minute step)/41.0 minutes (long delay volume with 5 minute step) as determined in the scouting run
3. *(For acquisition with a CDS only)* Make sure that the zero offset for the baseline is set to 1% (not 5%).
4. Create a single sample injection in the instrument or system as follows:  
**Sample:** Mobile phase blank (0.0 ul)
5. Right before you start the test, flush the acetone tracer lines and degasser channels.

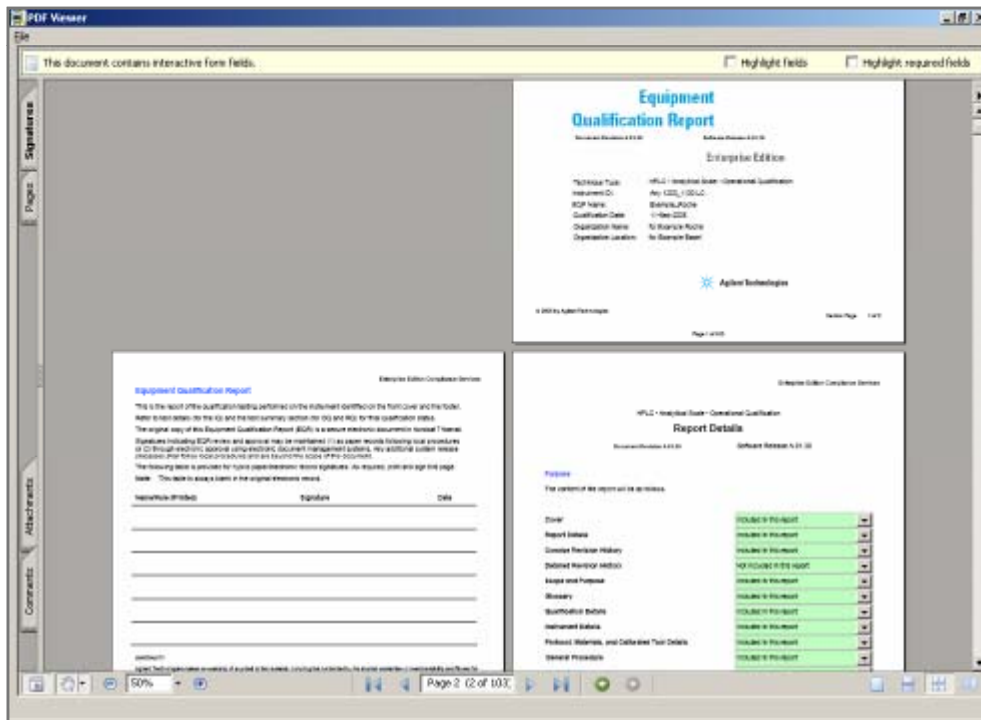
The interface also features a 'Pages' tab, an 'Attachments' section, and a 'Comments' section. At the bottom, there is a status bar showing '1 of 7' and navigation icons. The breadcrumb trail at the bottom left reads 'Operational Qualification > Gradient Composition'.



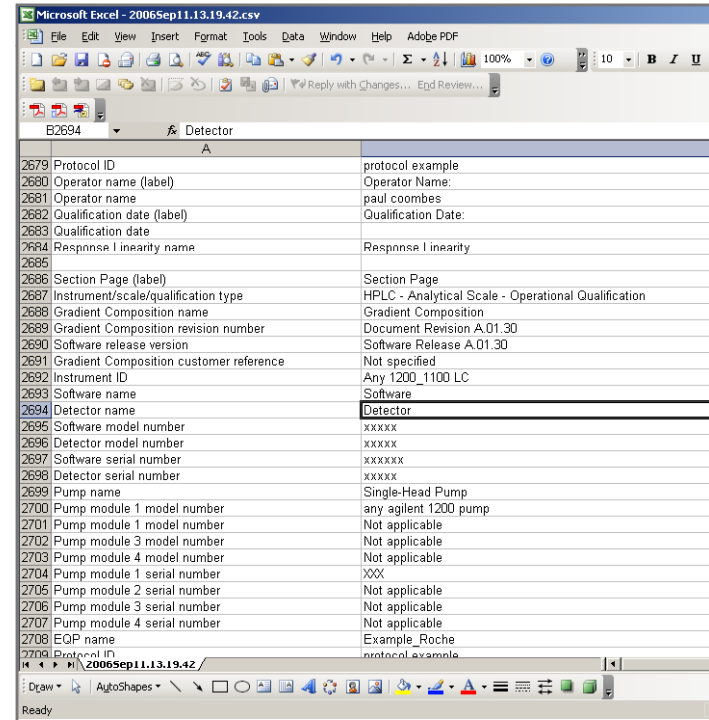
# Completed Reports Automatically Moved Into Openlab



*The pdf report and companion .csv file generated by ACE are automatically swept up by ECM*



**FDA audit ready report in pdf**



**Database ready report in .csv**



# Repair & Test Results

Agilent Compliance Engine A.01.30 - [Protocol Preparation Wizard]

View Tools Help

Step 1: Configure EQP Customer Details

Step 2: Select Configurations

Technique  
Liquid Chromatography(LC)

Qualification Type  
Repair Qualification(RQ)

Step 3: Configure EQP LC-RQ Test Specifica...

Step 4: Configure EQP LC-RQ Report Defini...

Step 5: Configure LC-RQ Protocol Details

Step 6: Configure LC Instrument Details

Step 7: Configure Qualification Details

Step 8: Preview Protocol Configuration

ACE

- 1200\_cds\_EQP\_001
  - your dept.
    - LC
      - HPLC Named FRED
        - OQ
          - 1200cds\_protocol
            - 1200cdsTestSpec01
              - Pump 2 Flow Accur
              - Pump 1 Flow Accur
              - Column Temperatu
              - Wavelength Accura
              - Signal Noise and Dr

This document contains interactive form fields.  Highlight fields  Highlight required fields

HPLC - Analytical Scale - Re-Qualification After Repair

## Repair and Test Activities

Document Revision A.01.30 Software Release A.01.30

**Pump Strategies**

Gradient composition is only required for instruments with a UV detector.

| Repair/Replace Strategy  | Modules                         | OQ/PV Testing                                     | Action         |
|--|---------------------------------|---|----------------|
| Internal pump head parts, active inlet valve (or A/V cartridge), (parts of) check valves, reference valves, inlet manifold or pump drive, or taking pump head apart to clean (versus repair) | Any pump                        | Flow Accuracy & Precision                         | Repaired       |
| Pulse damper, pressure transducer  | Any pump                        | Flow Accuracy & Precision                         | Not applicable |
| Multi-channel gradient valve   | Quaternary                      | Flow Accuracy & Precision<br>Gradient Composition | Repaired       |
| Main board, pump driver board(s)   | Isocratic                       | Flow Accuracy & Precision                         | Not applicable |
| Main board, pump driver board(s)   | Binary<br>Ternary<br>Quaternary | Flow Accuracy & Precision<br>Gradient Composition | Not applicable |
| Solvent selection valve  | Binary                          | Flow Accuracy & Precision                         | Not applicable |
| Leak handling parts, interface board, fan, power supply, leak sensor, active seal wash components  | Any pump                        | None  | Not applicable |

Enter Title  Save Cancel Browse

# Value Proposition

Instrument Qualification.

Save 66% Review time.

No Risk.



# Reduce Instrument Downtime

Reduce the  
downtime  
to 1 day



*Get your analysts back to work*

5 to 6 hours work to deliver full OQ/RQ,  
complete single pdf report provided to QA and/or system owner.  
Parallel and remote review is possible, 30 minutes to 2 hours  
review & approval time.

With ACE Agilent engineer can achieve:  
8 HPLC's fully OQ'd, reports reviewed  
and systems released in 5 days Mon-Friday

**Reducing review time from 3 days to 1 day is 66%  
saving in review costs and downtime.**

# Minimize Risk

Validated, medium-risk configurable COTS 'out-of-the-box' solution – minimal validation effort for corporate computer validation team

20 months investment in protocol development & testing done by Agilent not the customer (typical competitor programs take 9-18 months to implement, validate and release for pilot use in one lab)

FDA and EMEA readily accept Agilent Compliance products

Automation ensures adherence to protocol, consistent execution in every lab, can be reviewed remotely – allows corporate oversight reduces risk of rogue labs/sites.

Can be executed by Agilent or 3rd party or firm's personnel – eliminates risk of losing delivery capability and ensures the program's longevity

This is Agilent's new platform – industry standard acceptability world-wide.

# Summary

## Agilent Compliance Engine (ACE)

### Single Protocol for...

- Agilent Technologies
- Waters Corporation
- Thermo Electron Corporation
- Shimadzu Corporation
- PerkinElmer, Inc.
- Gilson
- CTC samplers and others

### Flexible tests...

Agilent Compliance Engine A.01.10 - [Protocol Preparation Wizard]

Run the test?: Run

Customer Reference: Company SCP 123 URS section 5.1  
The specifications meet user requirements.

Flow Rate 1: 2.000 ml/minute

Accuracy (Limit 1): 1.000, 1.500, 2.000, 2.500

Accuracy (Limit 2): 5.00 %

Precision (Limit 1): 2.000, 3.000, 5.000

Precision (Limit 2): 0.50 %RSD

### Single signature...

Agilent Compliance Engine  
Reporting

Welcome to Your Qualification

Completion Statement

The tested operator has executed the qualification and generated the Equipment Qualification Report (EQR) in accordance with the DQP and all appropriate working instructions. Therefore, this qualification is completed and the DQR is ready for review and approval by the customer representative(s).

Operator Name: Cloud Dept

Complete Date: 22nd February 2006

Operator Signature Methods

- Acrobat 7 digital signature
- Electronic database management system
- Link signature on DSR CD
- Link signature on printed DQR

### Electronic records

Equipment Qualification Report

| Test Name | Result | Status |
|-----------|--------|--------|
| Test 1    | 1.000  | PASS   |
| Test 2    | 1.500  | PASS   |
| Test 3    | 2.000  | PASS   |
| Test 4    | 2.500  | PASS   |

### Flexible reports...

Default Name and Description

Limit 1: This name describes the Limit 1 selectable value. If a two-limit evaluation model is used, this limit should be the more stringent requirement.

Limit 2: This name describes the Limit 2 selectable value. If a two-limit evaluation model is used, this limit should be the less stringent requirement.

Status Names

Default Name and Description

Pass: If test result meets applicable limit(s), report test status as:

Pass Recommended Limit Only: If test result meets less (but not more) stringent user limit, report test status as:

Fail: If test result does not meet applicable limit(s) report test status as:

SCP Name:

Approval Date:

User-Specified Limit Name: User Limit

Recommended Limit

User-Specified Status Name: PASS

Contains to recommended limit

Fail

Out of specification

Action

Saves time & money ...

# Files Stored in Native Format in Openlab

The screenshot displays the OpenLAB ECM Explorer interface within a Microsoft Internet Explorer browser. The browser's address bar shows the URL `http://vidar/ecm/Enterprise.asp?SessID=220423`. The application header includes the Agilent Technologies logo and navigation options like 'Action', 'View', 'Favorites', 'Help', and 'Logoff'. A search bar is also present.

The main content area features a tree view on the left and a file list on the right. The file list table is as follows:

| Name                          | Status | Date Modified           | Version # | File Size | # of si |
|-------------------------------|--------|-------------------------|-----------|-----------|---------|
| 2007Jan22.19.46.11.print2.pdf |        | 1/26/2007 7:37:58 PM... | 8         | 228 KB    | 0       |
| 2007Jan22.19.46.33.print2.pdf |        | 1/26/2007 7:37:58 PM... | 4         | 228 KB    | 0       |
| 2007Jan29.11.51.13.print.pdf  |        | 1/29/2007 1:01:20 PM... | 3         | 220 KB    | 0       |
| 2007Jan29.11.51.22.print.pdf  |        | 1/29/2007 1:01:20 PM... | 2         | 220 KB    | 0       |

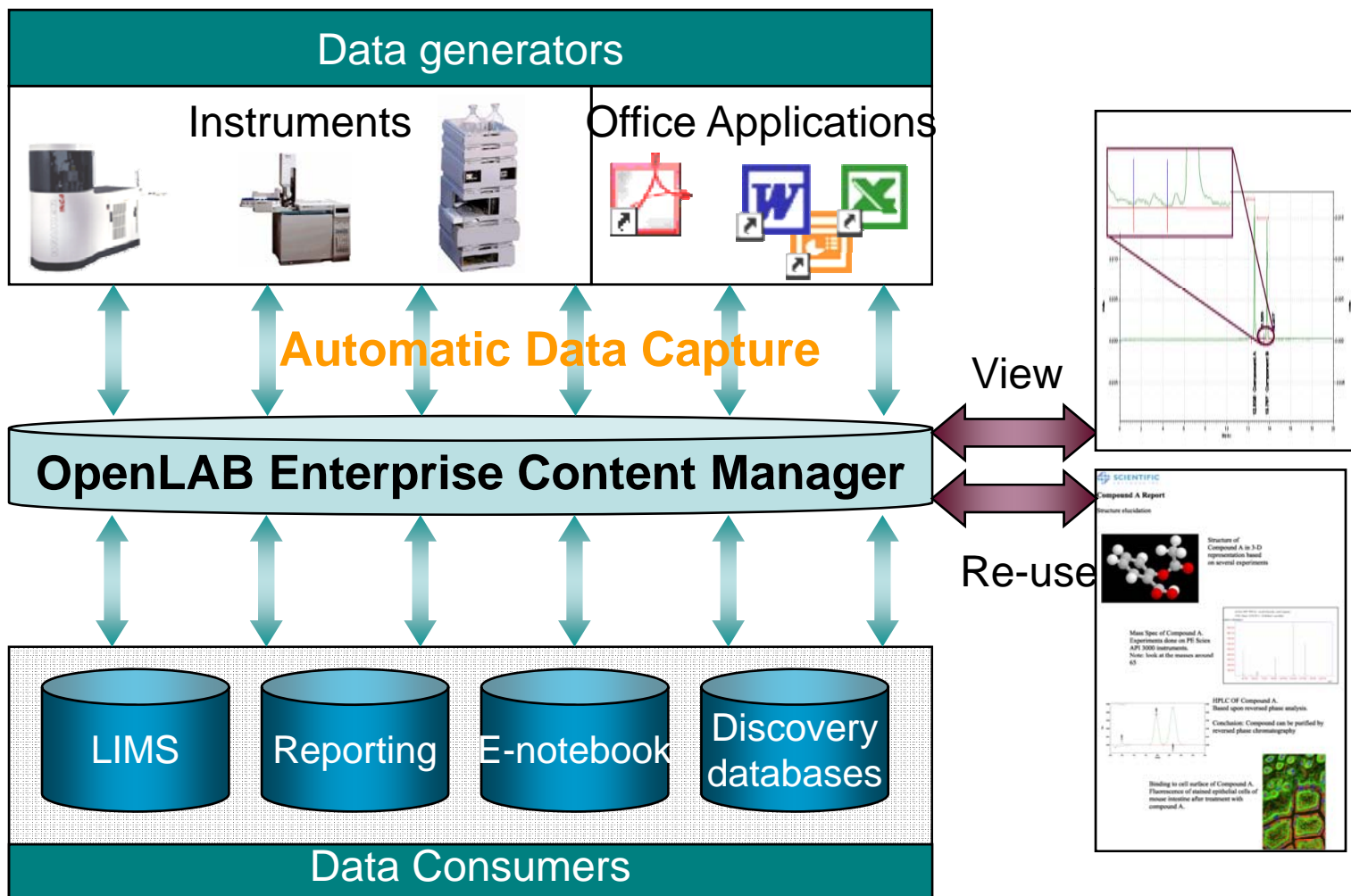
An arrow points from the first file in the list to a preview window of Adobe Acrobat Professional. The preview window shows a PDF document titled 'Equipment Qualification Report'. The report includes a header with the Agilent logo and a photograph of a person in a lab. Below the title, there are fields for 'Document Revision A.01.30', 'Software Release A.01.30', and 'Enterprise Edition'. A table of technical details is also visible:

| Field                 | Value   |
|-----------------------|---|
| Technique Type        | HPLC - Analytical Scale - Operational Qualification |
| System ID             | LC26  |
| EQP Name              | GSK_PA_demo1  |
| Qualification Date    | 22-Jan-2007   |
| Organization Name     | GSK   |
| Organization Location | King of Prussia                                     |

The bottom of the screenshot shows the Windows taskbar with several open applications, including Internet Explorer and Adobe Acrobat Professional.

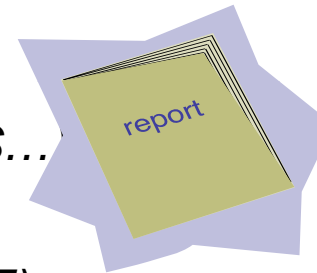
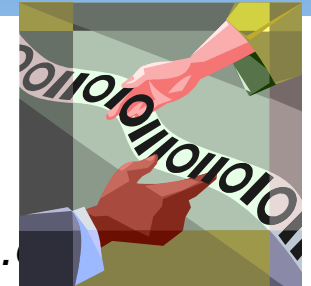


# OpenLAB ECM Managing Data



# ECM Driven Solutions (just some of many examples)

- *Data Archiving*
- *Central Data Storage (PROTECTED), Methods, SOP, Documents...*
- *Regulatory Compliance (21CFRPart11, GALP, Sarbanes Oxley, HIPPA)*
- *Document Management*
- *SOP maintenance*
- *Legacy Data ! (viewers, TNF, data, CDS, LIMS...*
- *Excel Remediation*
- *Validation/Compliance Documentation (i.e. ACE)*
- *ELN*
- *Data Management Searching and Reporting*
- *IP Protection*
- *Chain of Custody (reports, data...)*
- *Instrument and Training records*





# How Data is imported into ECM

## ■ Manually

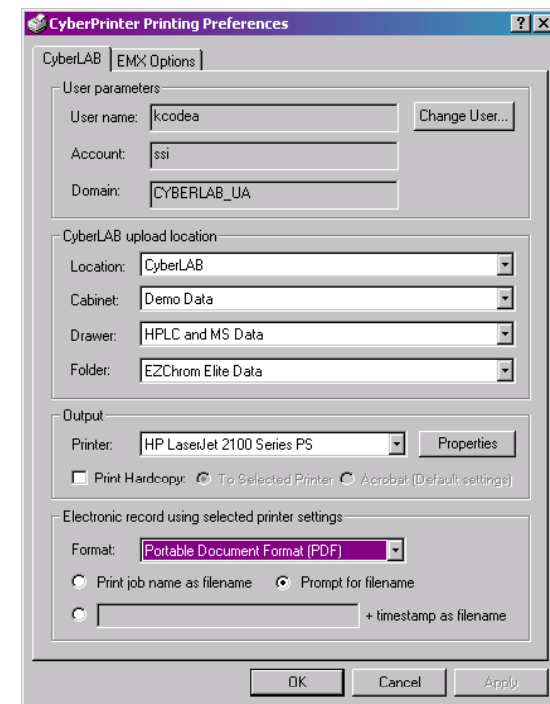
- Add Files (explorer right mouse click)
- Office integration (Excel, Word, PowerPoint, Outlook, Explorer)
- Tool Bar (Microsoft)

## ■ Scheduler

- Push or Pull
- Configurable on options for data collection

## ■ Cyberprinter

- Acts as a printer driver
- Transparent
- Adobe pdf format (ACE Reports)



# OpenLAB ECM User Interface

- **OpenLAB ECM uses the standard MS Explorer look and feel to access content**

- Fully Web based – thin client
  - Not just running in a browser as a fat client

- Single Application – 1 login machine readable, human readable in same application

- LCDF concept - organize

- Account

- Location

- Cabinet

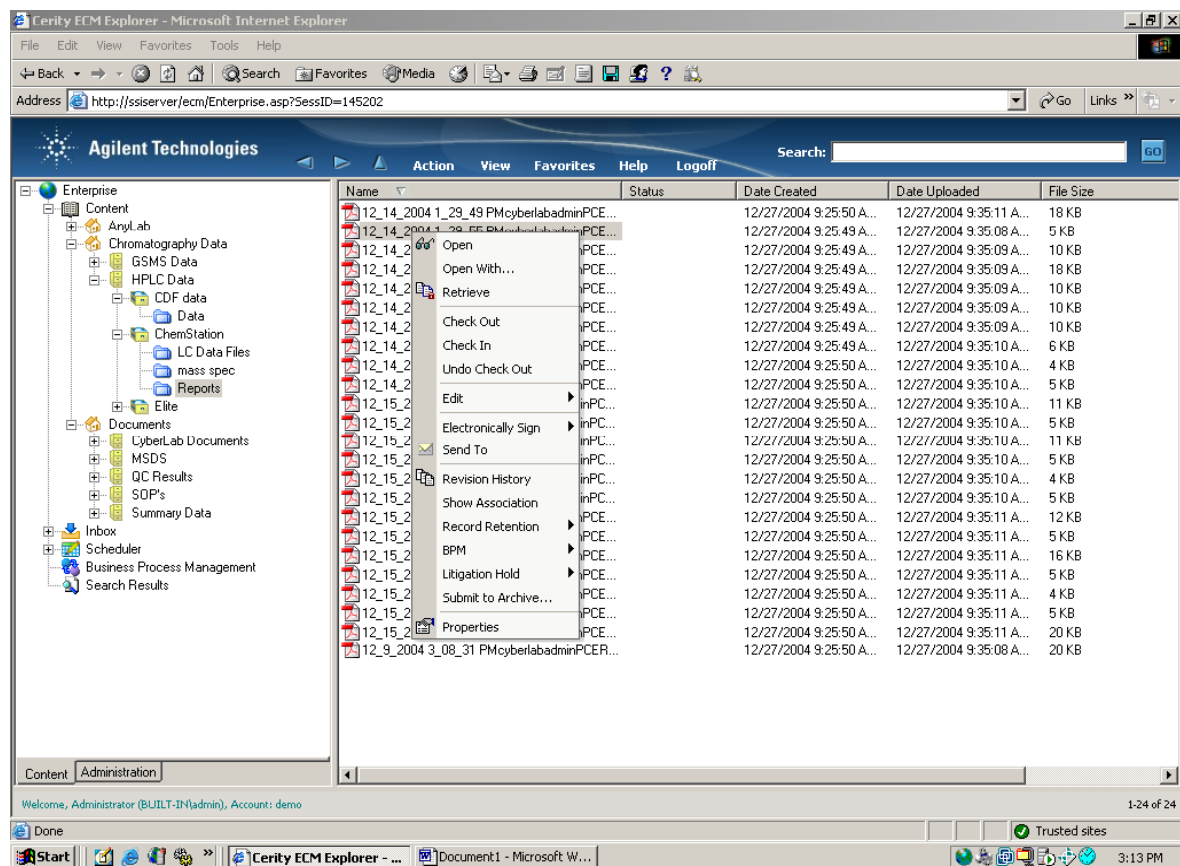
- Drawer

- Folder

- A visual organization of data

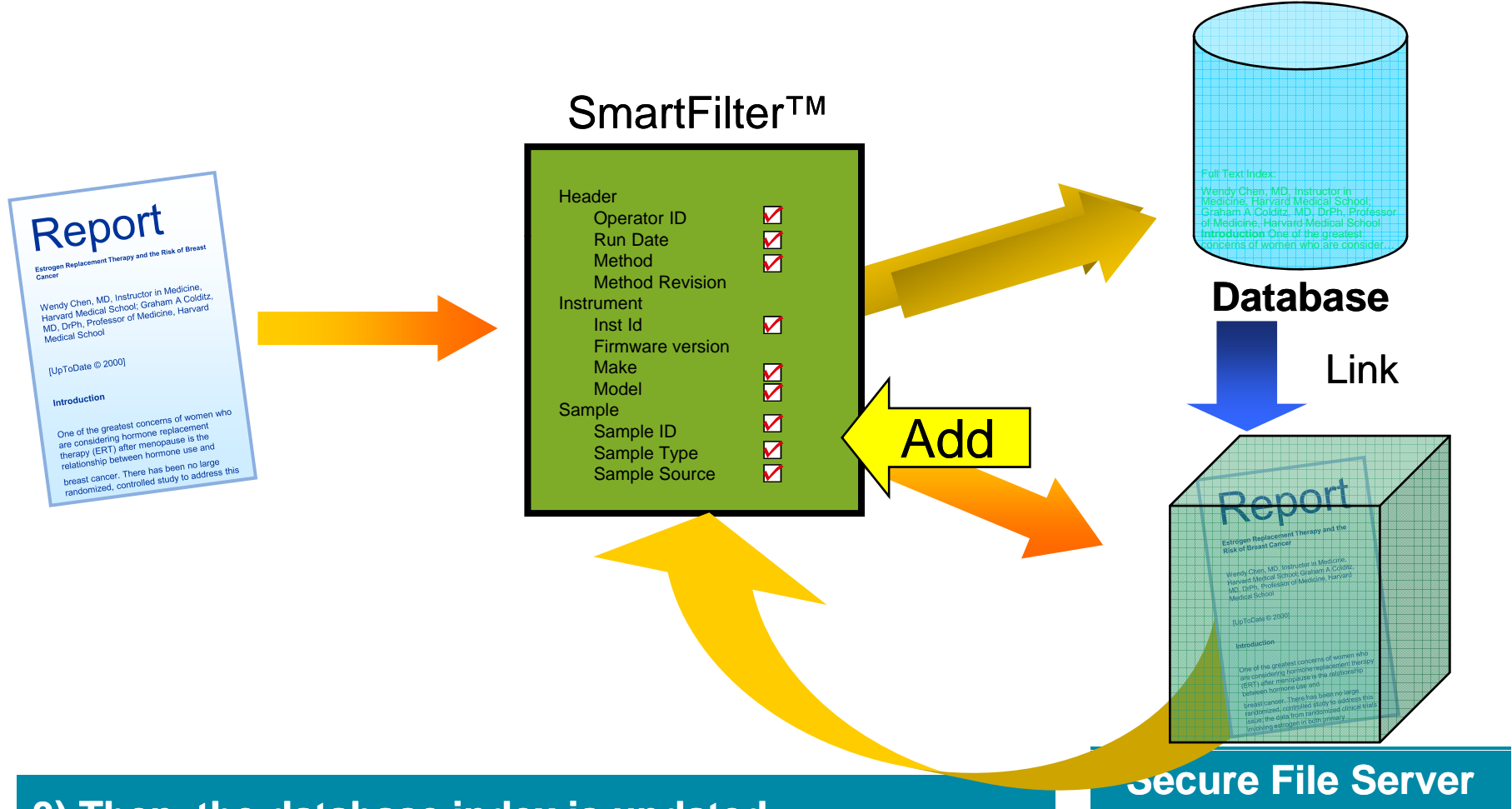
- Data is also searchable with “Google-like” or advanced search engines

Pittsburgh Conference 2008



# Intelligent Indexing for Advanced Searching

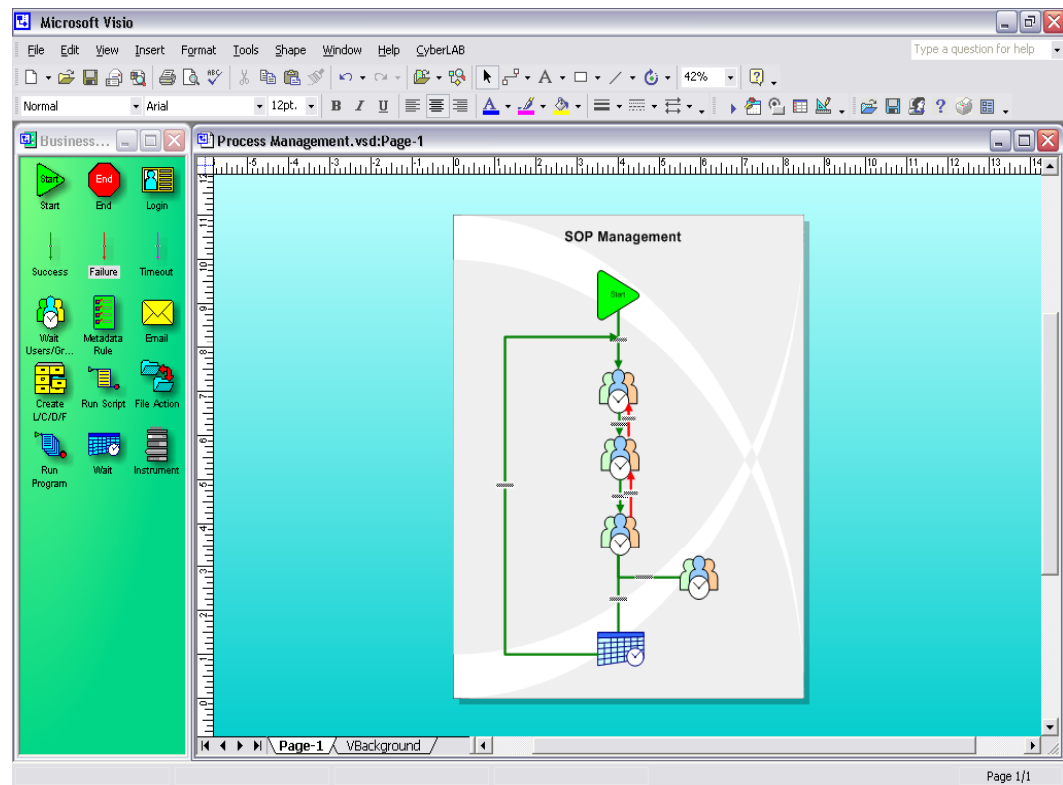
For machine and human readable files



3) Then, the database index is updated

# Business Process Management (BPM)

- A plug-in for OpenLAB ECM
- Manage flow of work throughout the enterprise by:
  - Automating processes
  - Streamlining processes
  - Optimizing processes



# BPM Template Design

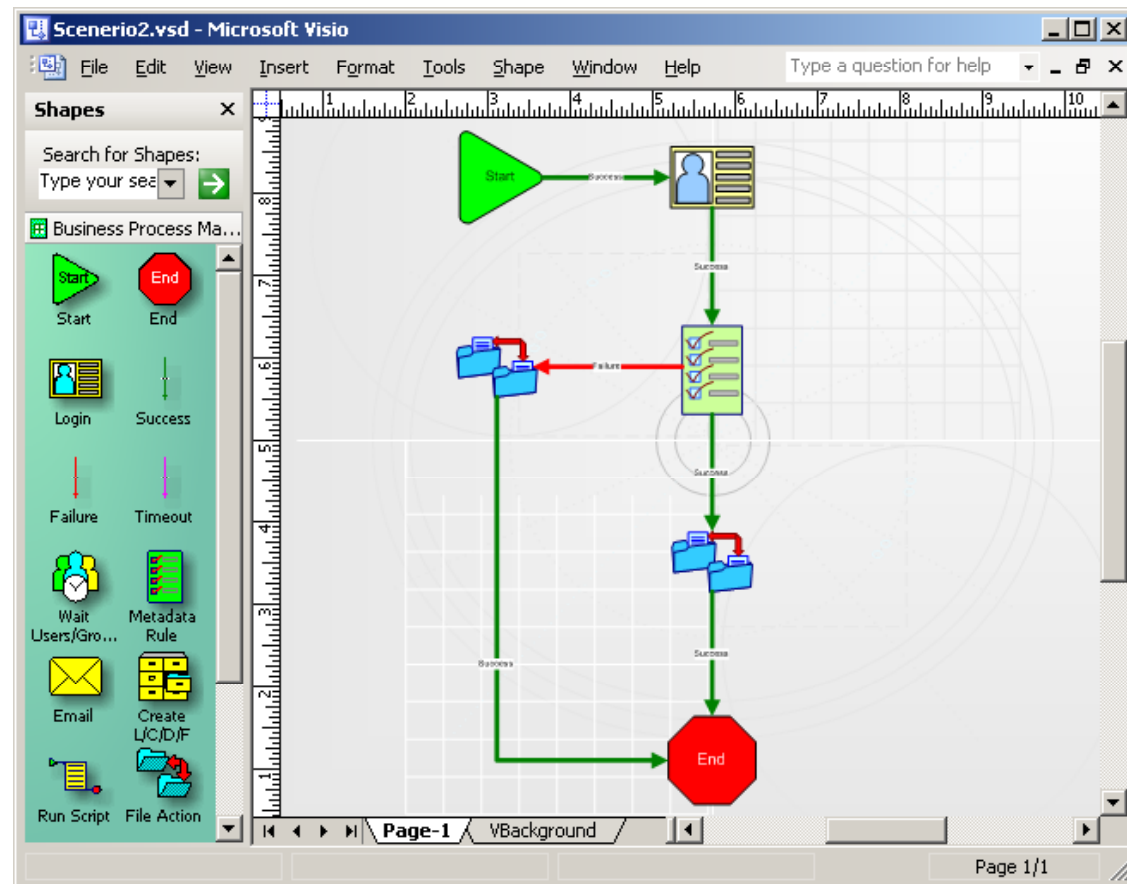
## Utilizes Microsoft Visio

Provides Visio objects and tools for various business tasks

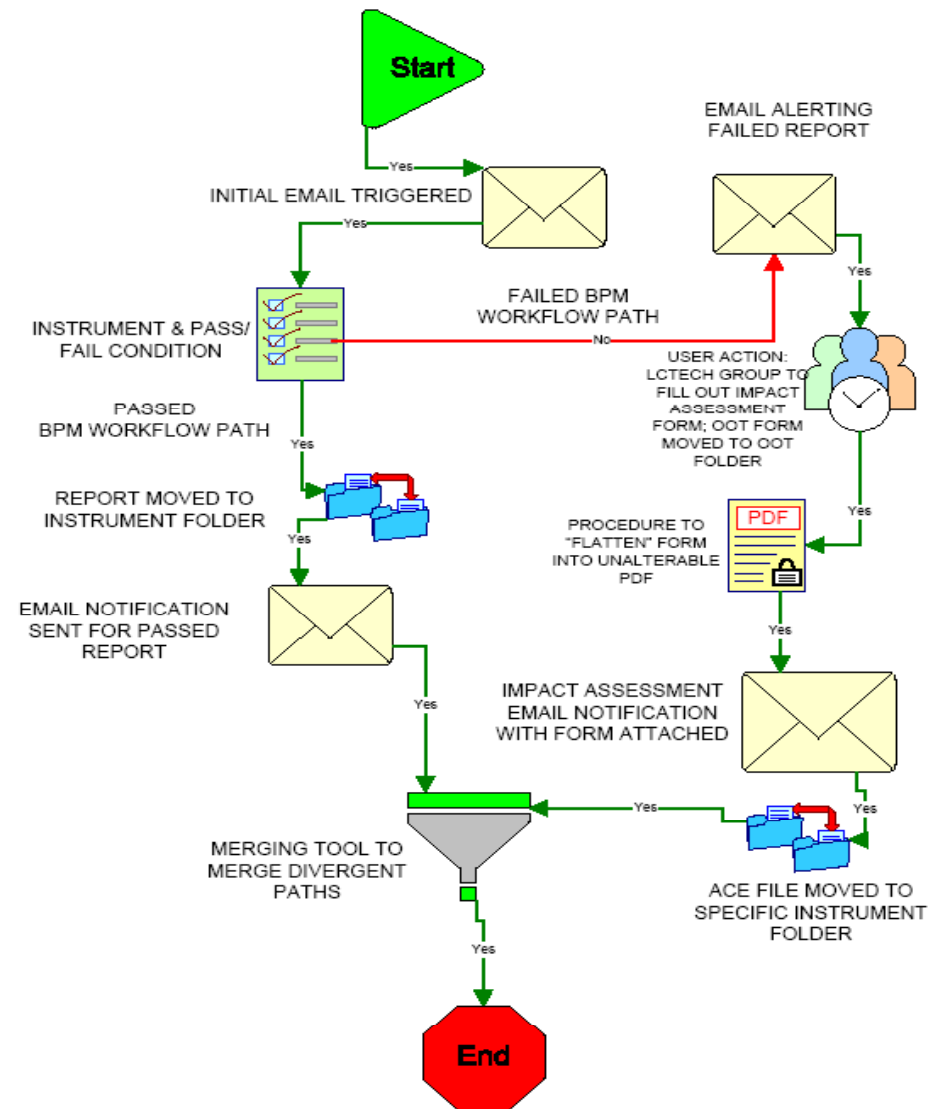
- Workflow modeling is frequently done with Visio now

These tasks have standard programmatic actions configured into them

Build and configure your own workflow based on document or file activities



# BPM Template Design



# WorkFlow: ECM with ACE

