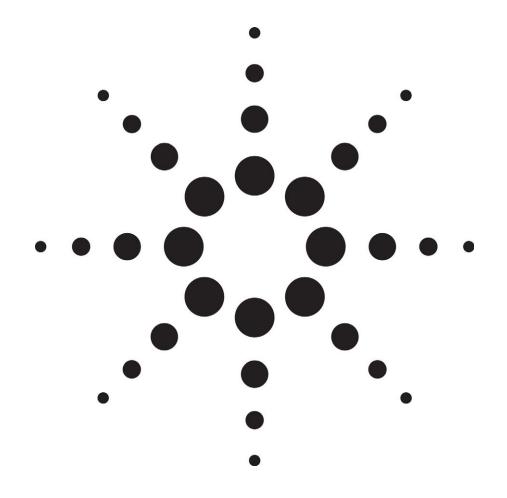
Agilent OL with Business Process Manager

Automated System Performance Verification

White Paper



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Agilent Technologies

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Introduction

Verification of instrument performance is a routine task that all analytical laboratories must perform on a periodic basis. This is particularly important if the instruments are used for mission-critical applications, in regulated environments, or critical sample analysis.

Routine Operational Qualification (00) may be done on the basis of a periodic service cycle. Every six months or so, the instruments may be taken off-line for a period of time while the testing and servicing is performed. Ideally, however, the extent of maintenance could be reduced if key portions of Performance Verification (PV) can be conducted more frequently or in the course of routine analysis. A concern with this approach is that the response to a failed PV test may be considered too time consuming to be done on a routine basis.

Although modern analytical data systems may offer automation to conduct the PV tests, most do not tie into or facilitate the necessary follow-up steps required to take corrective actions such as:

- Automated assessment of performance criteria
- Notifying appropriate individuals of required steps, corrective actions and approval process
- Ensuring correct management, versioning, and routing of administrative and laboratory documentation

Agilent OL manages this combination of technical, administrative, scientific, and business process requirements. This tightly integrated operating system combines the ability to control and acquire data from over 260 instrument models, manage any electronic content, and uses a Business Process Manager (BPM) that does not require programming. Agilent OL brings together people, content, and processes to improve the operation in the enterprise.

This white paper illustrates a business case that reflects actual needs in today's laboratory and serves as an example of how Agilent OL facilitates the entire process from data acquisition, to automated assessment of instrument performance, to taking appropriate actions defined by the individual enterprise.

Maintenance	Task 🗙
Description:	Routine DQ for Generic Instrument
Template:	GlobalPharm-East\Results\BPM\Procedures\Routine 0Q BPM.vdx
Start:	1/ 3/2005 8:00 AM
🗖 Begin pre	-maintenance state 🕕 days and 1 hours prior to task
Required	maintenance
	nce
C Daily	O Day 5 of every 1 month(s)
C Weekly	The first ▼ Friday ▼ of every 6 month(s)
Monthly	
C Yearly	
	OK Cancel

Figure 1: Agilent OL's Instrument Maintenance Task.

Routine Monitoring of Instrument Performance – Business Case

In this example we continue to reference the hypothetical organization called General Pharmaceutical Products, Inc. (GPP), producers of tablets for the OTC market.

To ensure that quality data is produced from each of their instruments, GPP performs a full OQ on a regular 6-month cycle; this is managed within Agilent OL's Instrument Maintenance feature illustrated in Figure 1.

GPP scientists, however, have determined that certain key performance indicators can be monitored more frequently offering the following benefits.

- Increase overall output from each instrument by reducing the extent of service required at each interval.
- Reduce the downtime and expense involved in maintenance by responding earlier to changes in performance.
- Reduce costs by performing only required repairs

The analytical method is also being monitored as part of this PV. This provides an added bonus because the analyst can be routinely reminded when mobile phases and standards need to be refreshed.

As described elsewhere, Agilent OL addresses all these needs by integrating CDS, ECM and BPM functionality. Below we describe the details and user experiences once the system is deployed.

Details

PV Test Criteria

The 4 criteria for routine PV are:

 Asymmetry (Asy): This assesses peak shape of a key component in routine standards. Acceptable asymmetry must be 1.1 or less.

- **Resolution (Res):** This assesses efficiency of separation between 2 key components in routine standards. Acceptable resolution must be 1.5 or grater.
- **Repeatability (Rep):** This assesses the autosampler performance. Acceptable repeatability must be less than or equal to 0.80%
- **Detector Performance (Det):** GPP has determined that an early symptom of detector lamp failure manifests in STD1 to STD2 ratio that is below 0.875 due to relative molar absorptivity of the key standards.

Criteria:	P =	Pass.	F =	= Fail
ontonu.	-	i uoo,		- 1 411

Asy	Res	Rep	Det	Diagnosis / Action
Р	Р	Р	Р	System performance is acceptable, no action required.
Р	F	Р	Р	Mobile phase or Standard mix should be made fresh.
F	F	Р	Р	Column needs to be replaced and a spare re-ordered.
Р	Р	F	Р	Autosampler maintenance must be performed.
Р	Р	Р	F	Lamp performance is degrading, replace lamp.

Table 1: Abbreviated PV	Assessment Criteria
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These criteria are associated with a Responsibility Matrix defined in GPP's SOP document as indicated in the table below:

Asy	Res	Rep	Det	Analyst Action	Approver Action
Р	Р	Р	Р	None	None
Р	F	Р	Р	Replace Mob. Phase and Standards.	Approve action in Instrument Log.
F	F	Р	Р	Purchase new column, submit form for approval.	Approve action in Inst. Log and E-Sign Purch. Order request.
Р	Р	F	Р	Complete Serv. Order for approval.	Approve action in Inst. Log and E-Sign Serv. Order request.
Р	Р	Р	F	Purchase new Det. Lamp, submit form for approval.	Approve action in Inst. Log and E-Sign Purch. Order request.

Table 2: Responsibility Matrix

Mapping the Business Process to Agilent OL

The criteria, reports, responsibility matrix, and forms associated with this business process are mapped to Agilent OL in the following manner:

- 1. The CDS portion of Agilent OL is used to analyze data and generate the adhoc abbreviated PV report.
- 2. BPMs are designed to automatically and transparently evaluate the PV reports, as they are placed in specific locations.
- 3. Anomalous reports immediately trigger the appropriate user actions that include:
 - a. Require the analyst to review a responsibility matrix in an SOP
 - b. Update an instrument log within Agilent OL's ECM
 - c. Fill out a standard Purchase Order or Service Request depending on the criterion

PV Report Generation

Agilent OL's Advanced Report Designer is used to create a template for PV Testing. This results in a single page report that summarizes each of the test criteria as shown in the figure below.

Agilent OL's SmartSequence[™] technology is used to create and run sequence or reanalyze previously acquired data. The appropriate records are tagged as Summary Runs and the PV Report Template is invoked within this sequence.

The sequence produces a result package called an OL.SSIZIP file that is placed in a predetermined location in the ECM. This fully indexed package contains all the data, templates, methods, sequence, and report files that generated the result

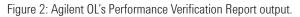
Business Process Design

The PV report file is contained in the OL.SSIZIP. All the files contained in the package are indexed. In this example, we are only interested in the 4 keys extracted from the PV Summary Report that reflect the business criteria for performance verification.

Because multiple criteria are being evaluated, GPP chose an embedded BPM approach. The top-level process performs the initial evaluation of metadata of the PV Summary report. If one of the failure criteria is encountered, an embedded process that contains user activities, forms and requires user actions then treats the report.

The top-level process is transparently triggered by the appearance of the OL.SSIZIP package generated by the instrument sequence. This is one benefit of the seamless interaction between the data system and content management parts of Agilent OL.

	Instrument name:		Acceptance Criteria	Test 1	Test 2
	Sequence name:		Asymm 10%		1.1
	Analyst:	DFAdmin (BUILT-IN/dfad	USP Resolution	1.5	
	Date printed:	03-May-05	AS Repeatability		D.80%
			Det. Intensity	0.875	31000
	Criterion 1	Asymmetry			
	Data file name	Compound		Asymm 10%	
1	SysSull001.dat SysSull002.dat	Car		1.0028	
3	SysSuB03.dat	Caff		1.0037	
ĩ	SysSu10048 dat	Car		1.0040	
5	SysSui005.dat	Caff		1.0020	
8	SysSu1006.dat	Caff		1.0014	
	Max			1.0040	
	Mean			1.0028	
	Std Dev: %RSD:			0.0010	
	and0		STATUS:	PASS	
			51A100.	FA33	
_	Criterion 2	Recolution			
1	Data file name SysSuB001.dat	Compound		USP Resolution 1.6830	
1	SysSuB02.dat	Call		1.7028	
3	SysSul003.dat	Car		1.6857	
4	SysSu10048.dat	Caff		1.6620	
5	SysSu1005.dat	Caff		1.6612	
8	SysSu1006.dat	Caff		1.6807	
	Min:			1.6612	
	Mean: Std Dev:			1.6792 0.0157	
	SEG Dev.			0.0157	
			STATUS:	PASS	
	Criterion 3	Repeatability			
	Data file name	PK2	PK1	Comb. Stats	
1	SysSui001.dat	44948	34752		
2	SysSu1002.dat	44928	34574		
3	SysSul003.dat	44804	34625		
•	SysSul0048.dat	35417	45716		
5	SysSu1005.dat SysSu1006.dat	44850	34914 35064		
	SysSuBOB.cat Mean:	45088	30064	399998	
	Std Dev:	3882	4440	4161	
	%RSD:	8.95%	12.11%	10.54%	
			STATUS:	FAIL	
	Criterion 4	Deteotor Performance			
	Data file name	PK2	PK1	PK1:PK2	
1	SysSui001.dat	44948	34752	0.773	
2	SysSul002.dat	44928	34574	0.776	
3	SysSuB03.dat	44804	34625	0.773	
4	SysSu10048.dat SysSu1005.dat	35417 44850	45716 34914	1.291 0.778	
8	SysSuiD06.dat	45088	35064	0.778	
	Mean:	1.010		0.862	
			STATUS:	PASS	
		Descend to the	institle California inc		
5/3/2	005 10:35:08 AM	Prepared by Sc	ientfic Software, Inc.		1/1 -



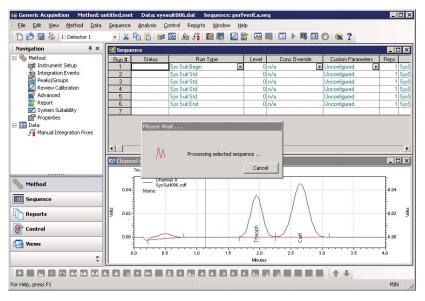


Figure 3: Agilent OL's sequence engine generates PV reports.

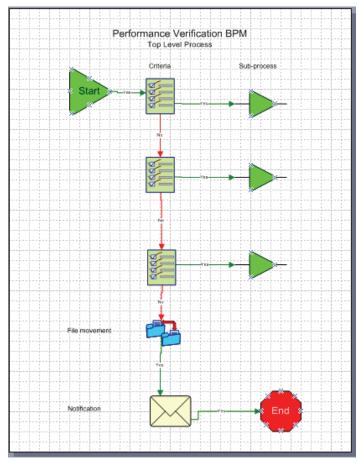
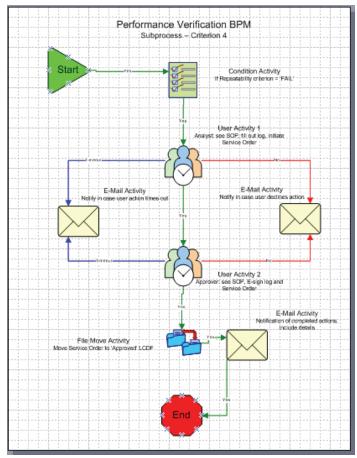


Figure 4a: Top level PV business process.



Top Level BPM

The top-level process is shown in figure 4a. It is assigned at a folder level of the content manager so that any file placed in that folder can be evaluated automatically. If a file or file package contains the appropriate metadata keys specified within this process, it will be either sent to an embedded process or moved to a different location.

Embedded BPMs

The more detailed activities occur in the embedded BPMs. These are designed to follow the assessment criteria and responsibility matrix summarized in Tables 1 and 2 on page 3. The structure of the processes is very similar. In figure 4b, we analyze the process designed to respond to the case where autosampler reproducibility is out of specification.

Figure 4b: One of the subordinate business processes.

The BPM performs the following tasks:

• **Criterion Activity:** This is used to confirm that the PV Report is properly evaluated.

Image: System 1 Image: System 2 Image: Sys	× Delete			
Attribute	Operator	Value	Condition	
Default {}				
😑 🎝 PDF Templates.PerfVerif_A ()				
	=	PASS		
- Triterion2Status	-	PASS		
	=	FAIL		
Criterion4Status	=	PASS		
			OK Can	

- User Activity 1: The user is required to:
 - **Review an SOP:** this is supplied as part of the process. From this he/ she will know exactly what is expected.
 - Review the PV Report: This is also conveniently supplied.
 - **Update and attach an Instrument Log:** this readies the log for sign-off by an approver.
 - Fill out and attach a Service Order request: this readies the service request for sign-off to an approver.

-User:	tion s/Groups				
-	LT-IN\dfanalyst				93
	Туре	Instructions	22	File Description	Parameters
Ø Re	eference Document 👻	Review responisibility matrix in the SOP 🛛 👷	V		GlobalPharm-East/Results/BPM/Proc
Co	mment	Review the report that is out of spec		Default	
At	tach ECM File	Add comment or procedure to instrument lo		Instrument Log	GlobalPharm-East/Results/Data/07 Ins
At	tach ECM File	Fill out service request form		Service Request	GlobalPharm-East/Results/Data/03 Pe
*					
		nonth(s) 0 week(s) 0 day(s) ay , March 22,2005 💌 7:52:06 PM	1	hour(s)	Clear Action

• User Activity 2: The approver receives the same SOP and OL.SSIZIP package as the analyst, and is required to assess the analyst's evaluation. If agreeable with the assessment, e-sign with approval, decline if a change is required, or e-sign with rejection.

• Email Activities: These come into play in the event that a user is inactive or declines the required tasks. The messages can be sent to the appropriate individual or group to merely alert or initiate an escalation process. A significant amount of information may be included in the message because of the available keys extracted by the ECM.

Email Pro	perties				х
To:	dfiore@scisw.com				
Cc:					
Subject	Action Timeout Alert	<initiating user="">]</initiating>			
Perform	ance verification - Criter	ion 4 path			
🗖 Atta	ch files:				
			ОК	Cancel	

• File Action: this now moves the files into appropriate locations based on file type.

ile	Action	Destination	Reason
Default	Move	GlobalPharm-East\Results\Data\	Summary report resulting in instrume
Service Request	Move	GlobalPharm-East\Results\Data\	Approved documents - ready for act

 Final E-Mail Activity: This is the notification that is sent to appropriate managers and includes enough high-level information to inform them of what occurred. This message may contain a very detailed collection of metadata tags for the associated files in the content repository.

Email Pro	perties	×
To:	dfiore@scisw.com	
Cc:		▶
Subject	Performance verification alert: action required	Þ
Locatio Reques Informa Informa Docum	==== Service Request ======== n: <service information.location="" request::file=""> / <service t::File Information.Location Information.Cabinet> / <service request::file<br="">ion.Location Information.Drawer> / <service information.location<br="" request::file="">ion.Folder> ent: <service information.file="" information.general="" name="" request::file=""> ed by: <service by="" information.e-signature="" information.signed="" request::file=""></service></service></service></service></service </service>	
<u> </u>	ch files:	

Organization of Content

Data, reports, forms and all electronic content are organized using the paradigm of Location, Cabinet, Drawer, and Folder (LCDF) as desired by users and management in the enterprise¹. GPP uses the secure, permission-based ECM for all their electronic content including storage of SOPs, MSDS, compound documents used for NDA submission, information that must be shared with partners and collaborators. In this example we focus only on the data and results needed to perform the PV tests. The OL.SSIZIP content that is produced by the instrument is illustrated below:

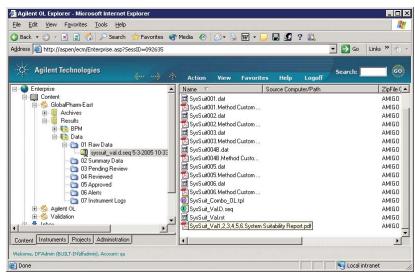


Figure 5: OL.SSIZIP and its contents in the repository.

Ancillary Documents

All ancillary documents are also managed within Agilent OL's ECM, these include:

GPP standard Purchase Order and Service Order templates: the benefit of this integrated approach is that the correct forms are made available at the time that they need to be filled out. The forms are created in PDF format and reflect GPPs documentation templates:

	Global Pharmaceut	ical Products		Parts & Instrument Services, Inc.
CPP	Purchase Orde	r Form		
-				SERVICE REQUEST FORM
		P.O.Date		To better understand your query and provide an accurate response please complete all the required fields. T form will these go directly to a finatrument Service engineer who will work to answer your query to your satisfaction.
Ordered By	Delt	verTo		We make every effort to respond to all e-mail queries within 4 hours, or if received outside of business hour (Mondry to Friday \$.30mm to 5.30mm), we will reply the following morning.
Company	Comp	any Analytical Supplies, Inc.		(Monday to Friday 8.30mm to 5.30pm), we will reply the following monung.
Address 123 Central Ave.	Adda	an 305 Main Flory.		* Required field:
City Metro	City	Northern		* Part Numbers or Product Description related to your request:
State/Trovince NJ 2	Bp/Postal Code 00023 State/	Province NJ Zp(Postal	Code 00019	
Country USA	Count	w USA		Type of Support Requested:
those Number 123-656-784	so those	Number 323-654-6570		- Service and Repair
FasHumber	Facility	aribar		- Accessories
Contact Name	Conta	ctName info@sscam		- Functionality
				*Urgency 0 4 hr C. 1 day 0 2~3 days 0 1 weak
Part No.	Description	Quantity Unit Price	Amoust	* Title (Mr. Ms. Dr.):
				* First Name:
				* Last Name:
				* Position:
				* Posicion: * Company:
				* Company:
Terms and Conditione			etal	* Company:
Terns and Conditions		Tr Sate Tax () Federa Tax ()	eta1 50.00 50.00	* Company:
Terms and Conditione		State Tax @	\$8.00 \$8.00	Company: Address
Terms and Conditions		State Tax⊕ FederalTax⊕	\$8.00 \$8.00	Company: Address Concentration Concentration Concentration
Terns and Condition		State Tax @ Federal Tax @ Shipping Cha	\$8.00 \$8.00	Campany: Address Carp, Post Cede:
		State Tax @ Federal Tax @ Shipping Cha	\$8.00 \$8.00	Company: Address City, Fost Gode: Construct Phene: Phene: YAX:
Authorized by	bi 1 ji (ayalar kay bar ya ciyan 1 fana ra g	State Tax @ Podend Tax @ Shipping Ch Grand Ta	\$400 \$400 rige etal \$9.00	* Company: * Address Clay, Pour Code: * Company: * Please: * E-mail: * E-mail:
Authorized By Arc Darson		State Tax (r)	Saco Saco rge oral So.co	* Company: * Address Clay, Pour Code: * Company: * Please: * E-mail: * E-mail:

Figure 6: Sample Purchase and Service Order forms used in BPM.

Instrument Log Files: in this example, each instrument log file is a separate Excel® spreadsheet. Because these too are managed within Agilent OL, all entries, modifications, and E-Signatures are tracked within the ECM for supervisory or regulatory review.

These ancillary forms are shown in the figure below:

and the second second		strument Log_LC15.xls Insert Format Tools Data Window Help CyberLAB Adobe PDF Type a question	n for help 🔽 🗖		
-					
D	🖻 🖬 🎒 🗠	• Ø ♥ Arial • 10 • B I U ■ ■ ■ \$ % @	🔄 • 🙆 • 🗛 •		
	🚔 🖬 🖩 🛍	£ ? .			
	B8 -	fx			
	A	В	C ·		
1	GPP	HPLC-ANALG-15-UV Instrument Log			
2	B OOK (
3	Date	Comment / Action	Approv		
4		Instrument placed in service	N/A DFApprover		
5		Replace D2 lamp and reorder spare			
õ		Replace D2 lamp and reorder spare [bad supplier] D			
7	4/10/2005	Initiated service request for autosampler maintenance	DFApprover		
3			_!		
0			-		
2					
23					
4					
5					
6					
7					
8					
0	A = /		1		
4	M\Sheet1 /	Sheet2 / Sheet3 /	•		

Figure 7: Sample Instrument Log.

Content Management and BPM Deployment

Assignment of Special metadata keys: Agilent OL provides a PDF Template generation tool that is used when unique report formats need to be managed beyond simple text indexing. PDF Template Keys need only be created once for a given report format. In this example 4 key pairs were designed so that a description and a value could be recognized in any PV Report generated.

Report generation and Packaging Results: each report generated by the CDS portion of Agilent OL is a summary of the chromatographic analyses as described above. Agilent OL's sequence engine automatically produces the reports in PDF format, packages all the content in an 'OL.SSIZZIP' file containing raw data, reports, and all files associated with the execution of the sequence.

Report Indexing: the OL.SSIZIP package is automatically placed in the folder specified by the Analyst and indexed. During the indexing process, any special tags designed with Agilent OL's template tool or user defined keys are also extracted and associated to the indexed file as metadata. The steps described occur completely automatically and do not require user intervention other than launching a sequence (set-and-forget).

Deployment: GPP has chosen to deploy the PV assessment BPM described above as a folder-level process. This enables the unattended monitoring of results as they are being generated by Agilent OL's CDS engine. Only the pertinent summary reports are flagged for user action, other content is routed transparently to a folder location for approved results.

User Experience

Agilent OL eliminates issues that represent significant time drains such as those summarized in the section below called 'Efficiency Gains'. As a result of the well-structured mapping of GPP's business process and the powerful tools available in Agilent OL, the user experience is simple and well directed. Below we describe the experience of the 2 users types involved in this process: the Analyst and the Approver. Remember that these users need only respond to PV results that have been automatically flagged by the BPM engine.

Analyst Experience

The analyst's tasks are significantly simplified, as they only need to be involved with initiating sample runs by launching sequences. Thereafter they simply monitor their Agilent OL Inbox for activities and instructions organized by the BPM engine.

- S Enterprise	Name V	Instructions	Due Date	Received Date	Initiator
🕀 🟢 Content	performance verification sop	Review your role in the SOP	5/11/2005 8:44:42 PM	5/11/2005 7:44:43 PM	BUILT-IN\dfadmi
🖻 🏄 Inbox	🔁 ComboSuit03.pdf	Review Performance Verification sum	5/11/2005 8:44:42 PM	5/11/2005 7:44:43 PM	BUILT-IN\dfadmi
Record Retention	👔 <link ecm="" file=""/>	Update and attach the specific instru	5/11/2005 8:44:42 PM	5/11/2005 7:44:44 PM	BUILT-IN\dfadmi
Eriterion2 BPM @ 2005-05	🚺 <link ecm="" file=""/>	Fill out PO and submit for approval	5/11/2005 8:44:42 PM	5/11/2005 7:44:44 PM	BUILT-IN\dfadmi
F Scheduler					
Scheduler					
Sealer Hestins					

Figure 8: The user only has to follow supplied instructions and focus on specific tasks.

Assessment of PV report content can be done by either reviewing the report itself (seen in Fig. 2 above) or by the reviewing the extracted metadata found in the file properties.

10 General Information OS Owner 0 Unknown 11 General Information Reason 0 Submit 12 General Information Source Computer 0 df-scisw 13 General Information Source Directory 0 V\df-scisw\SharedDoc: 14 General Information Uploaded By 0 DFAdmin (BUILT-IN\df 15 General Information Version # 0 1 16 Document Info Author 1 dfiore 17 Document Info Creator 1 PScript5.dll Version 5.2 18 Document Info Freder 1 Acrobat Distiller 5.0 (W 19 Document Info Title 1 System Suitability Repo 20 General Full Text 1 OpenLABJ Performance/ 21 PerformanceVerification Criterion1Name 2 Asymmetry 22 PerformanceVerification Criterion2Name 2 FAIL 23 PerformanceVerification Criterion2Name 2 FAIL 24 Performan	#	Category	Attribute	Set	Value
11 General Information Reason 0 Submit 12 General Information Source Computer 0 df-scisw 13 General Information Source Directory 0 V\df-scisw\SharedDoc 14 General Information Uploaded By 0 DFAdmin (BUILT-IN\df 15 General Information Version # 0 1 16 Document Info Author 1 dfiore 17 Document Info Creator 1 PScript5.dll Version 5.2 18 Document Info Producer 1 Acrobat Distiller 5.0 (W 19 Document Info Title 1 System Suitability Repo 20 General Full Text 1 OpenLABJ Performance/erification 21 PerformanceVerification Criterion1Name 2 Asymmetry 22 PerformanceVerification Criterion2Name 2 FAIL 23 PerformanceVerification Criterion2Status 2 FAIL 24 PerformanceVerification Criterion3Name 2 Repeatability <td>9</td> <td>General Information</td> <td>File Upload Date</td> <td>0</td> <td>5/11/2005 6:23:25 PM (GI</td>	9	General Information	File Upload Date	0	5/11/2005 6:23:25 PM (GI
12 General Information Source Computer 0 df-scisw 13 General Information Source Directory 0 \\df-scisw\SharedDoc: 14 General Information Uploaded By 0 DFAdmin (BUILT-IN\df 15 General Information Version # 0 1 16 Document Info Author 1 dfiore 17 Document Info Creator 1 PScript5.dll Version 5.2 18 Document Info Producer 1 Acrobat Distiller 5.0 (W 19 Document Info Title 1 System Suitability Report 20 General Full Text 1 OpenLABT Performance 21 PerformanceVerification Criterion1Name 2 Asymmetry 22 PerformanceVerification Criterion2Name 2 FAIL 23 PerformanceVerification Criterion2Name 2 FAIL 24 PerformanceVerification Criterion2Status 2 FAIL 25 PerformanceVerification Criterion3Name 2 Repeatability <td>10</td> <td>General Information</td> <td>OS Owner</td> <td>0</td> <td>Unknown</td>	10	General Information	OS Owner	0	Unknown
13 General Information Source Directory 0 \\\dfscisw\SharedDoc: 14 General Information Uploaded By 0 DFAdmin (BUILT-IN\df 15 General Information Version # 0 1 16 Document Info Author 1 dfiore 17 Document Info Creator 1 PScript5.dll Version 5.2 18 Document Info Producer 1 Acrobat Distiller 5.0 [W 19 Document Info Title 1 System Suitability Report 20 General Full Text 1 OpenLABI Performance 21 PerformanceVerification Criterion1Name 2 Asymmetry 22 PerformanceVerification Criterion2Name 2 FAIL 23 PerformanceVerification Criterion2Status 2 FAIL 24 PerformanceVerification Criterion2Status 2 FAIL 25 PerformanceVerification Criterion3Name 2 Repeatability	11	General Information	Reason	0	Submit
14 General Information Uploaded By 0 DFAdmin (BUILT-IN\df 15 General Information Version # 0 1 16 Document Info Author 1 dfiore 17 Document Info Creator 1 PScript5.dll Version 5.2 18 Document Info Producer 1 Acrobat Distiller 5.0 (W 19 Document Info Title 1 System Suitability Repo 20 General Full Text 1 OpenLABI Performance 21 PerformanceVerification Criterion1Name 2 Asymmetry 22 PerformanceVerification Criterion2Name 2 FAIL 23 PerformanceVerification Criterion2Name 2 FAIL 24 PerformanceVerification Criterion2Status 2 FAIL 25 PerformanceVerification Criterion3Name 2 Repeatability	12	General Information	Source Computer	0	df-scisw
15 General Information Version # 0 1 16 Document Info Author 1 dfiore 17 Document Info Creator 1 PScript5.dll Version 5.2 18 Document Info Producer 1 Acrobat Distiller 5.0 [W 19 Document Info Title 1 System Suitability Repc 20 General Full Text 1 OpenLABI Performance 21 PerformanceVerification Criterion1Name 2 Asymmetry 22 PerformanceVerification Criterion2Name 2 FAIL 23 PerformanceVerification Criterion2Status 2 FAIL 24 PerformanceVerification Criterion3Name 2 Repeatability	13	General Information	Source Directory	0	\\df-scisw\SharedDocs\M
16 Document Info Author 1 dfiore 17 Document Info Creator 1 PScript5.dll Version 5.2 18 Document Info Producer 1 Acrobat Distiller 5.0 (W 19 Document Info Title 1 System Suitability Repc 20 General Full Text 1 OpenLABI Performance/Verification 21 Performance/Verification Criterion1Name 2 Asymmetry 22 Performance/Verification Criterion2Name 2 Resolution 24 Performance/Verification Criterion2Status 2 FAIL 25 Performance/Verification Criterion3Name 2 Repeatability	14	General Information	Uploaded By	0	DFAdmin (BUILT-IN\dfadm
17 Document Info Creator 1 PScript5.dll Version 5.2 18 Document Info Producer 1 Acrobat Distiller 5.0 [W 19 Document Info Title 1 System Suitability Repo 20 General Full Text 1 OpenLABI Performance 21 PerformanceVerification Criterion1Name 2 Asymmetry 22 PerformanceVerification Criterion1Status 2 FAIL 23 PerformanceVerification Criterion2Name 2 Resolution 24 PerformanceVerification Criterion2Status 2 FAIL 25 PerformanceVerification Criterion3Name 2 Repeatability	15	General Information	Version #	0	1
18 Document Info Producer 1 Acrobat Distiller 5.0 [W] 19 Document Info Title 1 System Suitability Repo 20 General Full Text 1 OpenLABI Performance 21 Performance/Verification Criterion1Name 2 Asymmetry 22 Performance/Verification Criterion1Status 2 FAIL 23 Performance/Verification Criterion2Name 2 Resolution 24 Performance/Verification Criterion2Status 2 FAIL 25 Performance/Verification Criterion3Name 2 Repeatability	16	Document Info	Author	1	dfiore
19 Document Info Title 1 System Suitability Repo 20 General Full Text 1 OpenLABI Performance 21 Performance/Verification Criterion1Name 2 Asymmetry 22 Performance/Verification Criterion1Status 2 FAIL 23 Performance/Verification Criterion2Name 2 Resolution 24 Performance/Verification Criterion2Status 2 FAIL 25 Performance/Verification Criterion3Name 2 Repeatability	17	Document Info	Creator	1	PScript5.dll Version 5.2.2
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Figure 9: Simply reviewing file metadata provides a convenient way to assess results.

Approver Experience

The Approver receives a BPM package after the Analyst's tasks are completed. The Approver sees the same PV results in addition to the Analyst's inputs in the Instrument Log and Purchase or Service Order. Approval of the Analyst's input is indicated by electronically signing both files. With Agilent OL, any electronic document may be e-signed even if the original application does not allow the display of signature watermark as with Adobe® PDF documents.

Enterprise	Name 🗸	Instructions	Due Date	Received Date	Initiator
🗈 🏢 Content	mance verification sop	Review your role in the SOP	5/11/2005 9:04:56 PM	5/11/2005 8:04:56 PM	BUILT-IN\dfac
🗄 💁 Inbox	🔁 ComboSuit03.pdf	Review summary report	5/11/2005 9:04:56 PM	5/11/2005 8:04:57 PM	BUILT-IN\dfac
Record Retention	Instrument Log-HPLC12.xls	Review and sign the Instrument Log	5/11/2005 9:04:56 PM	5/11/2005 8:04:58 PM	BUILT-IN\dfac
E-E BPM Inbox Criterion2 BPM @ 2005-05-12 02	12 PD 04122005-03.pdf	Review and sign the PD	5/11/2005 9:04:56 PM	5/11/2005 8:04:58 PM	BUILT-IN\dfac
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Figure 10: The Approver's Inbox.

- for	Open Open With	Review and sign the Instrument Log Review and sign the PO
	View	
	Approve Reject	
	View Instructions	
P	Properties	

Figure 11: Simple E-sig process.

Notifications

As defined in the embedded BPMs, prior to completing a process, the designated people are notified via e-mail. The e-mails contain significant content detail obtained from Agilent OL and can be directed to desktop or mobile client devices.





Efficiency Gains

By integrating user and role management, CDS, ECM, and BPM functionality, significant efficiencies are gained in ways that perhaps many enterprises have not even calculated. The following are some benefits that are evident just in this example:

- **Analysts:** The time and expertise required for early detection of performance degradation is nearly eliminated. This can represent a significant financial benefit particularly if instruments are used by offsite, offshore, transient analysts or in a 'walk-up' environment where any user can access a particular instrument.
- **Time**: The time involved in administrative tasks such as locating the correct procedure, Service Report, Purchase Order template, Instrument Log, and approved versions of these documents is eliminated. This also represents an intangible benefit as well in environments where scientists prefer to focus on science with minimal time spent on administrative chores.
- Laboratory Managers are assured that any and all instruments managed by Agilent OL are working optimally or quickly attended to.
- Administrative and Purchasing Managers: are assured that submission of purchase orders is done correctly, according to established procedures, and routed correctly. Even submission of orders to vendors can be further automated by using e-mail and E-Fax submissions.
- Informatics Group Managers benefit from supporting a single scalable system that combines users, data of all kinds, and business processes while allowing connectivity to other enterprise systems.
- **Compliance Officers** benefit from knowing that users, raw data, results, and E-Signatures are all managed in an auditable, permission-based closed system.
- **Executives**: CFO and Division VP's can realize ROI benefits by assessing the net efficiency increase per FTE.

SUMMARY

In conclusion, enterprises such as GPP benefit tremendously from the collection of technologies within Agilent OL. A well-defined process, such as the System Performance Verification example described here, is easily and effectively handled by Agilent OL's ability to manage from instrument control to business response and user interactions. As a result efficiencies summarized in the previous section are gained at various levels in the enterprise.

