

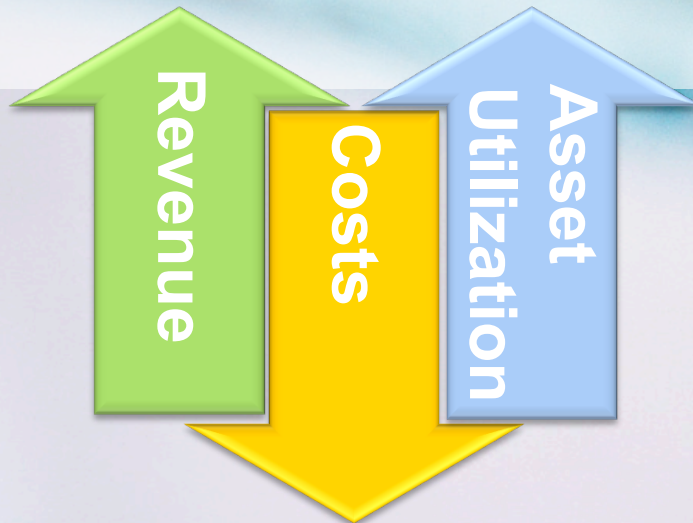
# **Addressing Lean Processes in an analytical Laboratory: Harmonizing LIMS, Instruments and SOP's**

KVCV Dag – 8 december, 2009

Stefaan Thielemans

Strategic Business Manager,  
Waters, Informatics Europe

- **Open Design**
- **Interoperability**
- **Integrations**
- **Application Specific Solutions**



- IT challenge:

- Approx. 300 applications to be supported and maintained



- Lab Challenge:

- 50% of analyst time spent at:
  - Manual data transfer
  - Documenting experiments
  - Peer Review
  - SOP's
- Compliancy
  - QA relations
  - Signature workflows
  - Compliancy (GxP/part 11)

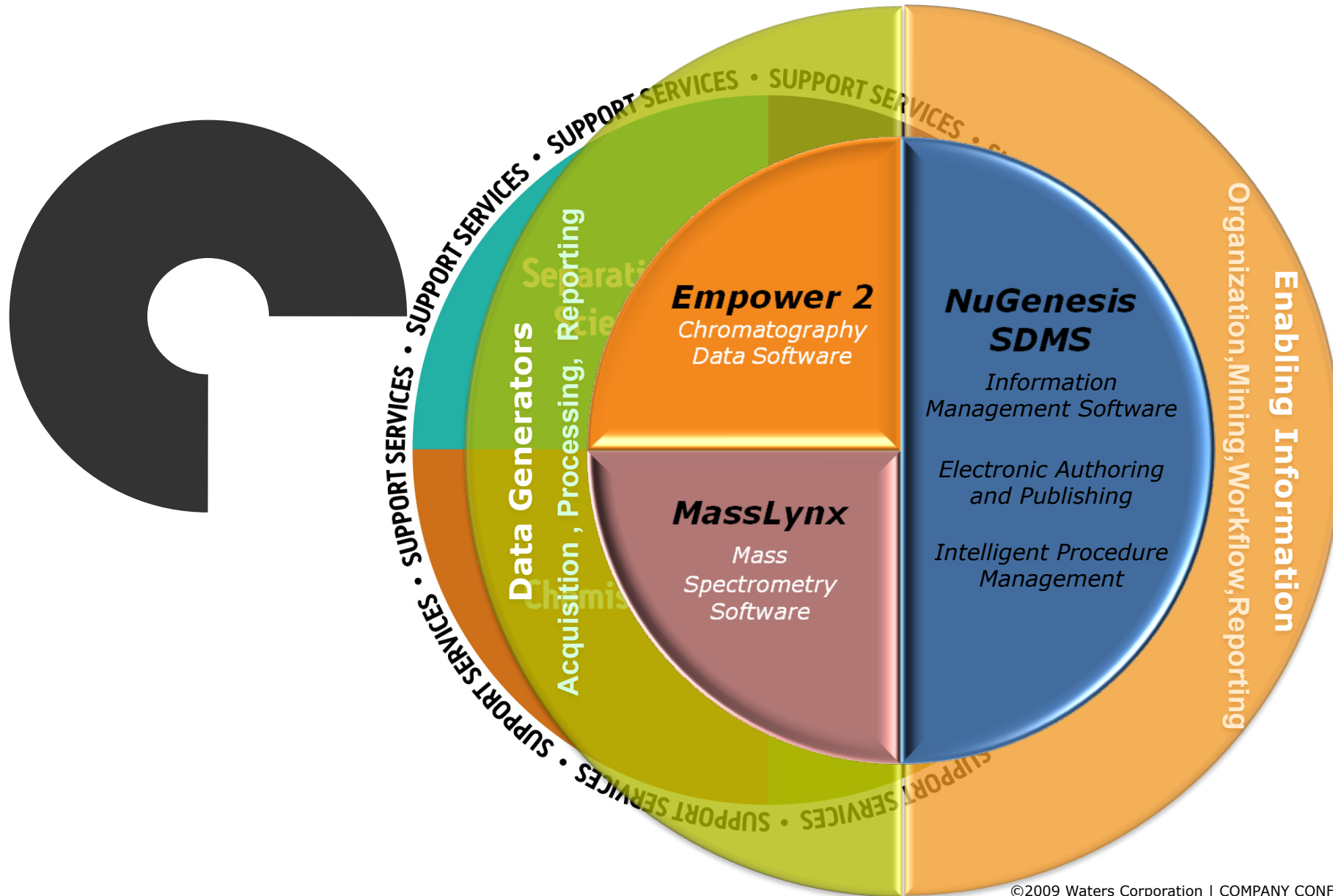


lean6sigma



# Technology Portfolio+ Expertise

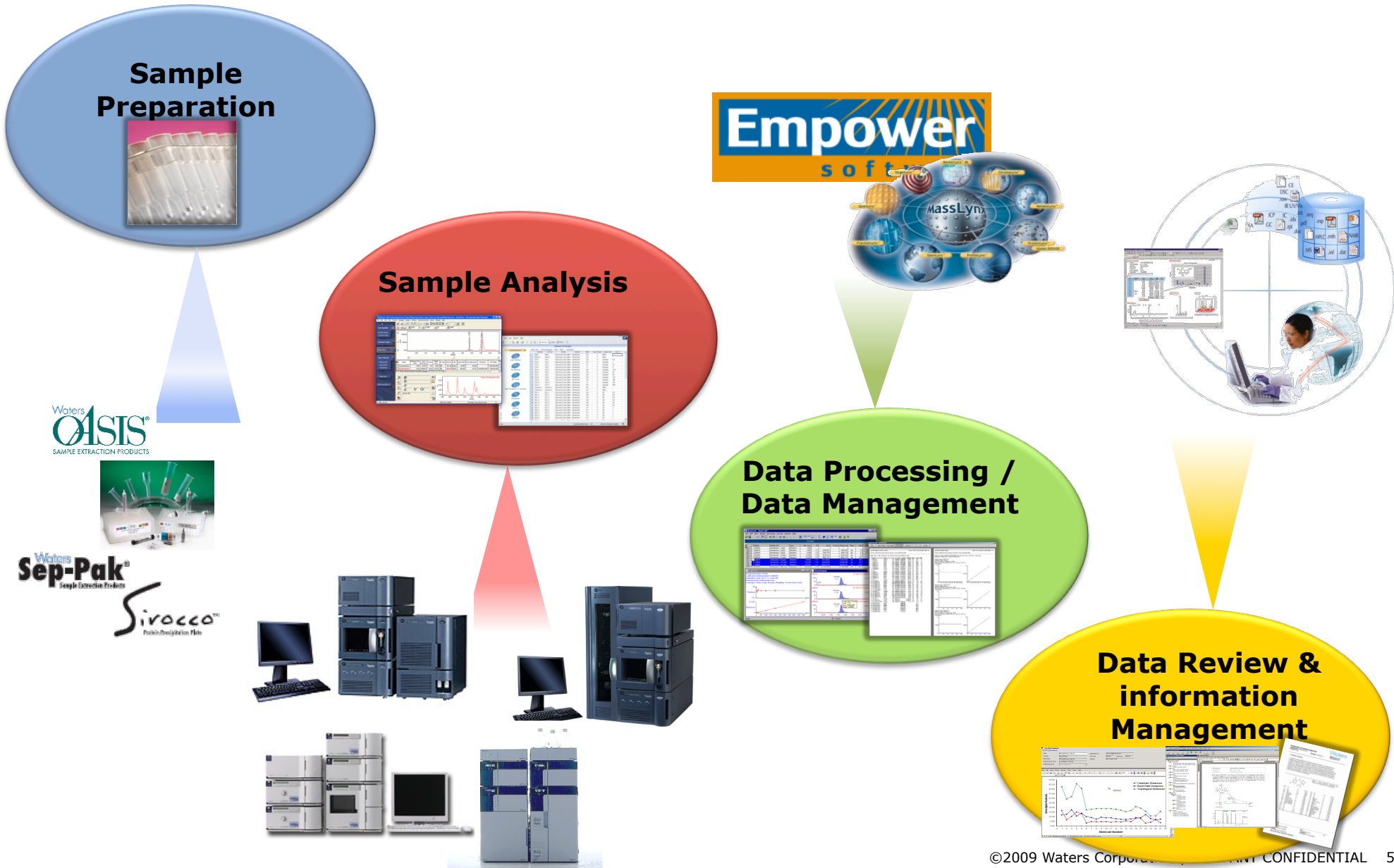
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# Strategic integrations 'from vial-to-file': Where are your data touch points?

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# Open Design: Empower 2 Multi Vendor Control

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- Benefit to the Customers: One Software solution for all chromatographic systems
  - Reduced Training, Validation and Support
- Available Today
  - 14 Vendors with 180 Instrument modules
    - 78 New Modules added since introduction
  - Instrument Control Available from all major LC Vendors including Waters, Agilent, Shimadzu and Hitachi
  - Instrument Control Available from major GC Vendors including Agilent , PerkinElmer, Shimadzu and Varian
- More instrument control to come

“Since Waters added full control of functionality for Agilent’s 1100 LCs and 6890 GCs to the Millennium/Empower software, we can now use all of our chromatographic instrumentation with a software package which is state-of-the art for both productivity and compliance.”  
— Analyst, Global Pharmaceutical R&D Business



# Open Architecture : SDMS Data Adapters

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**AB** Applied Biosystems | **MDS SCIEX**



**Agilent Technologies**



**Microsoft**



**ThermoFisher**  
SCIENTIFIC





# A Typical Paper Based SOP Workflow

**1. Assign Test.**



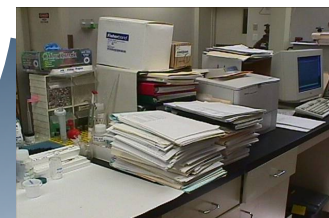
**2. Analyst performs analytical test.**



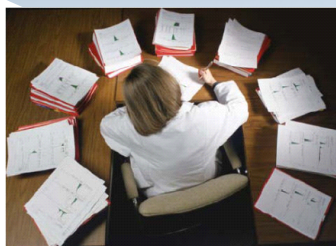
**5. QA team monitors process to ensure process efficiency and compliance.**



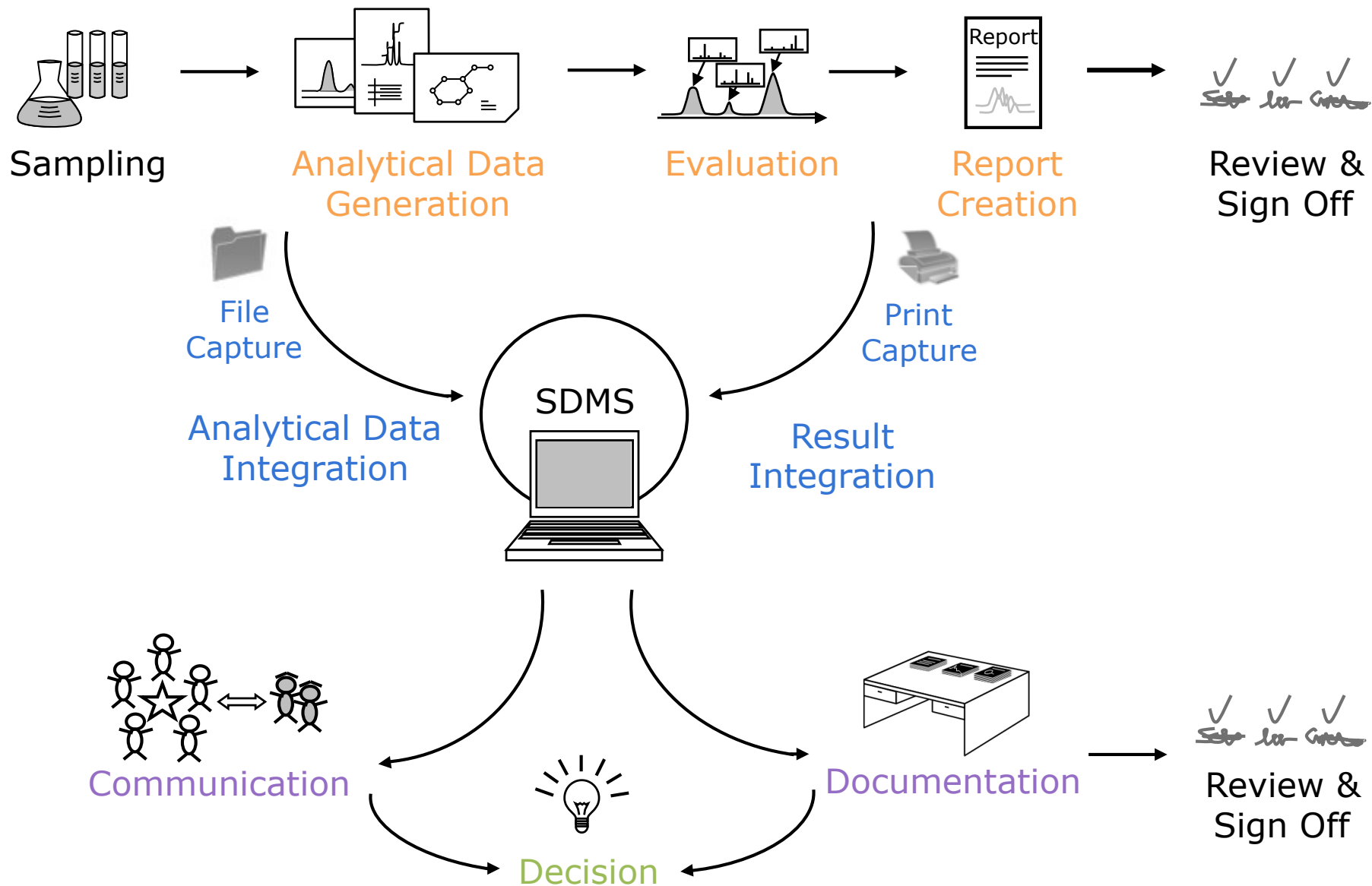
**3. Analytical data acquired and form documents completed.**



**4. Supervisor/manager reviews completed tests and provides wet signature.**



# Laboratory Workflow



# Reuse Report Content

Send Selections to... Microsoft Excel - Blank Excel Spreadsheet.xls

Graphics Mode      Ctrl+G  
Text Mode            Ctrl+T  
✓ Table Mode        Ctrl+B

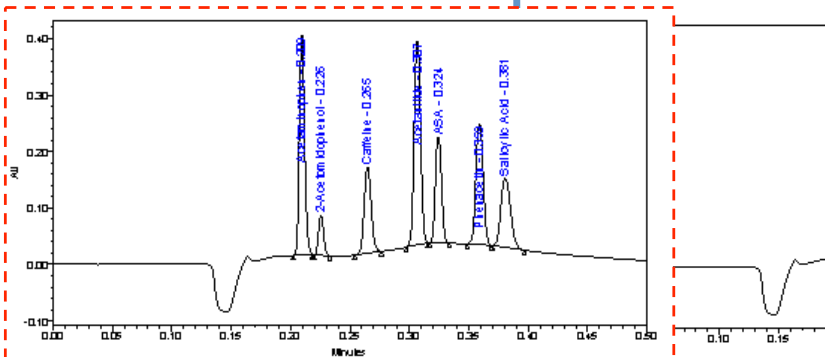


## Acquity UPLC Individual Report

Reported by User: DEMOUSER (demo user)      Project Name: Pharmacokinetics  
 Result ID: 2819      System Name: ACQUITY\_TUV  
 Technique: UPLC-UV      Lab: DBV-345  
 Site: London, England

Sample Name: Analgesics Optimizing  
 Sample Type: Unknown  
 Vial: 1A.8  
 Injection #: 26  
 Injection Volume: 5.00 µl

SAMPLE  
 Sample Name: Analgesics Optimizing  
 Sample Type: Unknown  
 Vial: 1A.8  
 Injection #: 26  
 Injection Volume: 5.00 µl  
 Ret. Time: 0.5 Minutes  
 Sample Set Name:



Peak Name	RT	Area	% Area	Height
1 Acetaminophen	0.209	120022	21.07	390583
2 2-Acetaminopheno	0.226	21314	3.74	71521
3 Caffeine	0.265	63063	11.12	152925
4 Acetanilide	0.307	135291	23.75	361031
5 ASA	0.324	67703	11.89	186888

Peak Name	RT
1 Acetaminophen	0.209
2 2-Acetaminopheno	0.226
3 Caffeine	0.265
4 Acetanilide	0.307
5 ASA	0.324
6 Phenacetin	0.359
7 Salicylic Acid	0.381

Microsoft Excel - Blank Excel Spreadsheet.xls

Waters Compound Purification Lab

General Information		Results				
Sample ID	BOS-1238	Peak Name	RT	Area	% Area	Height
Study ID	DIABET	1 Acetaminophen	0.209	120022	21.07	390583.00
Sample Name	Normalized Area	2 Acetaminophen	0.226	21314	3.74	71521.00
Lab	GEM-3902	3 Caffeine	0.265	63063	11.12	152925.00
Application	Excel	4 Acetanilide	0.307	135291	23.75	361031.00
Department	Analytics	5 ASA	0.324	67703	11.89	186888.00
Batch Number	01189_003	6 Phenacetin	0.359	92570	16.25	213740.00
Instrument Name	HPLC SYS_0309_04					
Workbook	Ralf Schroeder					
Analyst	TC_Norm_Area.xls					
Excel Template Name	Y1.1					
Template Version	Waters Compound Purification Lab					
Document Name						
Additional Information		TOTALS				
Sample Name:	Analgesics Optimizing	1.69	500263	87.82	1376688.00	
Sample Type:	Unknown	Graphical Analysis				
Vial:	1A.8	Normalized Area Component Analysis				
Injection #:	26	450000.00				
Injection Volume:	5.00 µl	400000.00				
Analytical Data		350000.00				
		300000.00				
		250000.00				
		200000.00				
		150000.00				
		100000.00				
		50000.00				
		0.00				



# "Connecting Science to Business"

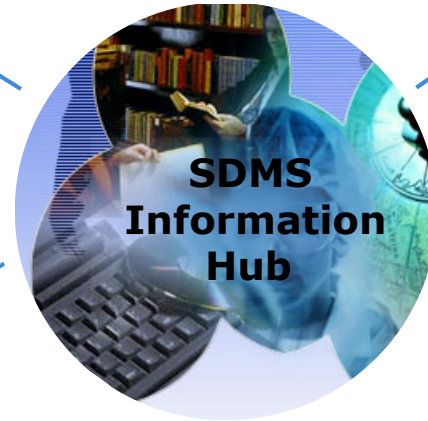
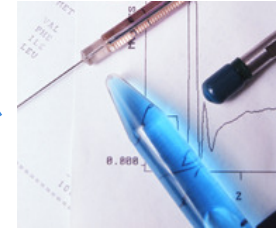
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Scientific  
Content  
Capturing

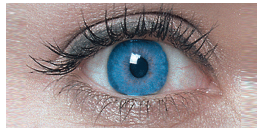
File Capture



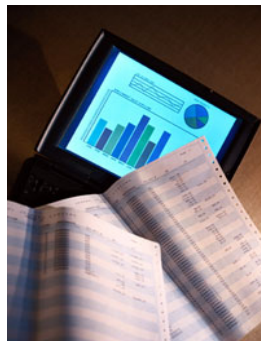
Print Capture



Web Vision



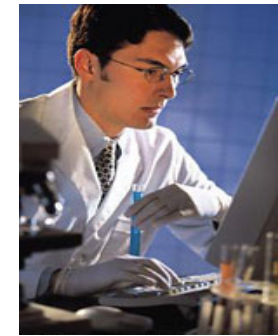
Business  
Connection



Statistical Analysis



Specialized Elab Notebooks



LIMS

# "Connecting Science to Business"

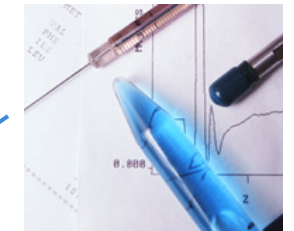
**Waters**  
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Scientific  
Content  
Capturing

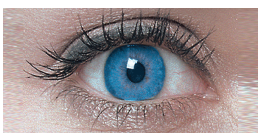
File Capture



Print Capture



Web Vision



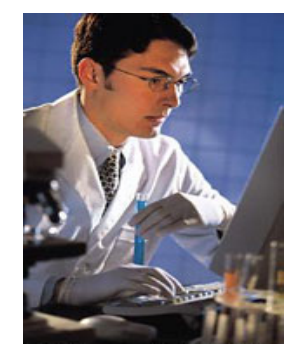
Business  
Connection



Statistical Analysis



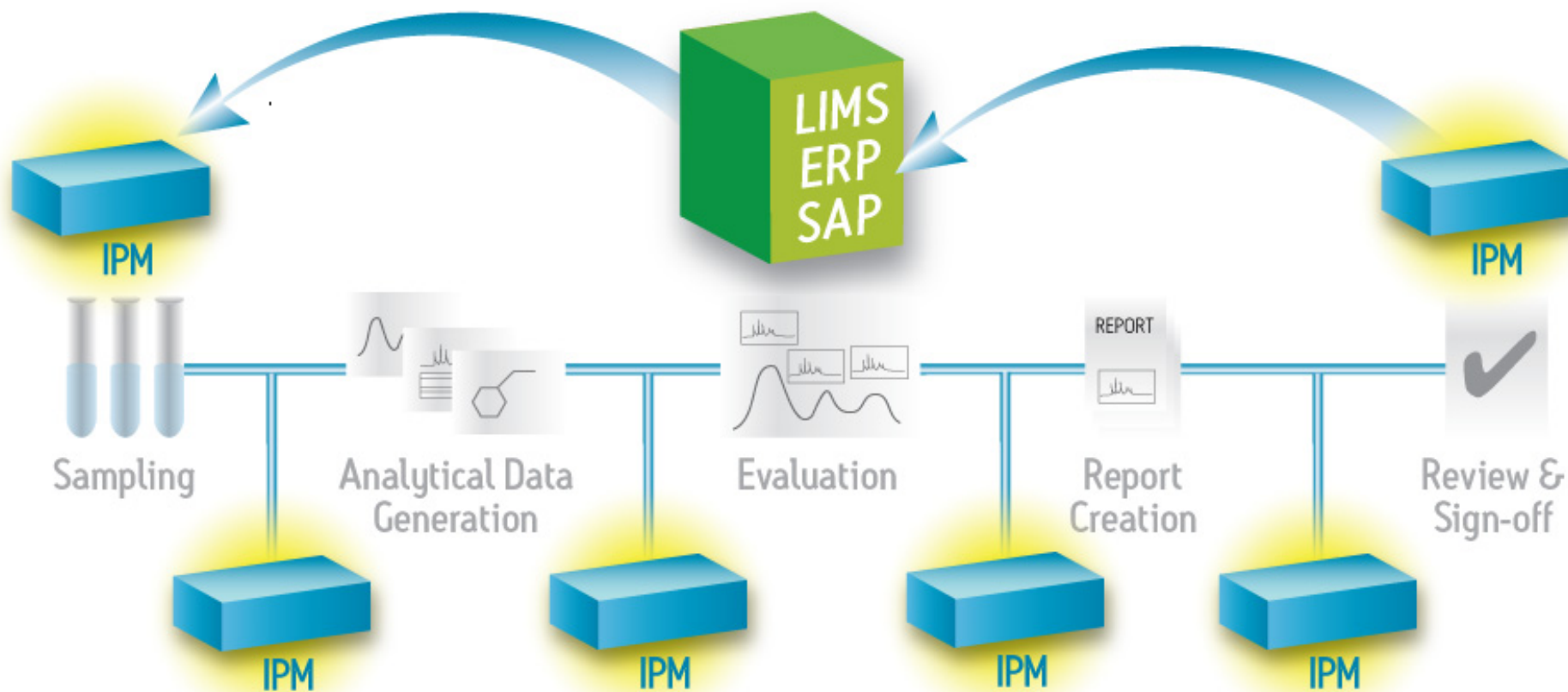
Specialized Elab Notebooks



LIMS

# Intelligent Procedure Manager streamlines the Documentation Lifecycle

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# Example: Template for Karl Fischer Analysis

- The final value (only the single numerical value) is transferred to LIMS after approval

File Edit Experiment Chemistry Workspace Services Administration Options Window Help

Messages Experiments New Experiment Templates Workspaces New Workspace Results Entries Projects

Append Delete View Properties Notebook Sign Options Reload Save Transfer Print

Filter: [Icons] Title: 06000151-AW/012007A-V3170 Experiment ID: 070131\_HPLC\_0001

1 LIMS-QM 1  
2 Method 2  
3 Calculation 2

where the specimen under test is tablets, use powder from not fewer than 4 tablets ground to a fine powder in an atmosphere of temperature and relative humidity known not to influence the results.

**Water Equivalence Factor**

	1	2	3	4	5
m(H <sub>2</sub> O) [mg]	57.4	47.5	50.5	67.8	43.0
V(Titrant) [ml]	12.01	10.09	10.35	14.01	8.86
WE [mg/ml]	4.77935	4.70763	4.87923	4.83940	4.85327
used for average (1=Yes, 0=No)	1	1	0	1	1

Average WE [mg/ml] = 4.79491

**Weight of the Analysis in a 100ml flask**

m(full flask) [g]	129.32750
m(empty flask) [g]	54.64380
m(Analysis) [g]	74.68370

**Analysis**

	1	2	3	4	5	6
V(Titrant) [ml]	3.74	3.62	4.32	4.60	3.88	4.82
m(Analysis) [g]	4.0119	3.8827	4.6173	4.9085	3.8307	5.1062
m(H <sub>2</sub> O) [g]	333.83213	333.87305	335.04434	335.59515	362.71058	338.03047
used for average (1=Yes, 0=No)	1	0	0	0	1	1

Average Content [mg] = 344.85773 to LIMS

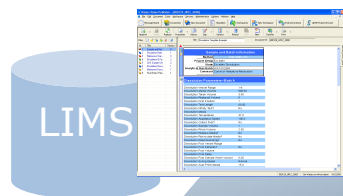
070131\_HPLC\_0001

070131\_HPLC\_0001 Creon Labcontrol on ELN SERVER 1/31/2007

# Moving to an Electronic Procedure Stream-lines Production

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## 1. Assign Test.



## 2. Analyst guided through procedure with SDMS IPM.



## 5. QA team monitors process to ensure process efficiency and compliance.

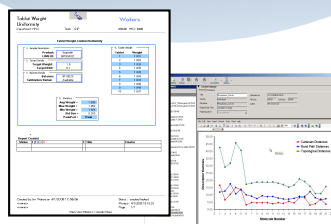


## 3. Procedural forms and analytical data collected and cataloged in IPM.



- Capture and catalog:
- Original file
  - Project data
  - Printed Report
  - Meta data

## 4. Review of final reports in IPM and approve with e-signatures.





# Strategic Partnerships and Opportunity

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## Integrations/ Workflow

LabWare LIMS  
LabVantage LIMS  
StarLIMS  
Labtronics  
Symyx Tech.  
CambridgeSoft  
Mettler Toledo

## Integrations/ Data Analysis

Dotmatic  
Umetrics  
ACDLabs  
S-Matrix  
SpotFire  
Novatia  
Pharsight  
MaxEnt

## Integrations/ Services

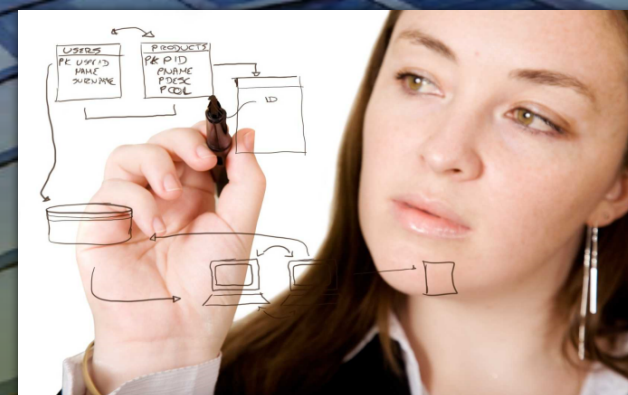
Da Vinci Europe  
MindTech  
Mphasis  
Informatech  
Patni LS  
Csol  
Lab Answer  
Scimcon

## Reseller/Distributor

ChemWare  
Shimadzu  
Hitachi

## Technology/ Platform Ecosystem

Oracle  
IBM  
SAP  
Microsoft  
Citrix  
Lenovo





- SDMS' central repository for
  - File and Print Capture
  - Embedded Database
  - Personalized Database views
  - GxP compliant Ready

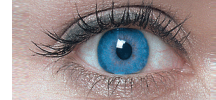
SDMS File Capture



SDMS Print Capture



Web Vision



SDMS Vision  
Publisher



- SDMS Vision Publisher
  - Interactive information use
  - Connection Business to Science Results

- Automating Lab Workflows in a "paperless" environment

# Waters

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