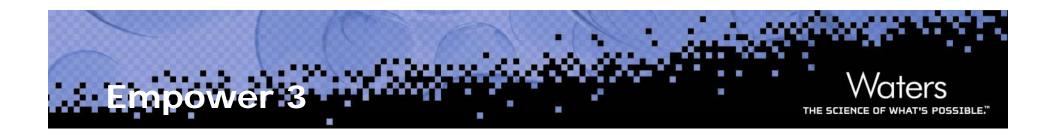


Empower 3 Software

Lauren Wood

September 2010

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- Architecture
- Web based licensing
- ACQUITY improvements
- Fraction Collection
- Usability and Workflow
- Mass Spectrometry
- Method Validation Manager
- Automated Software Validation
- Designed for the Enterprise



Empower 3 Architecture

Technology:

- Oracle 11G R2 Database (64 bit)
- Windows 2008 R2 Server Enterprise (64 bit)
- Windows 7 Professional Operating System (64 bit)
- Windows XP Operating System (32 bit) (clients and LAC/Es)
- Citrix XenApp Server 6.0 running on Windows Server 2008 R2 Enterprise, 64-bit,
- Empower 3 is 32-bit app running in a 64-bit environment

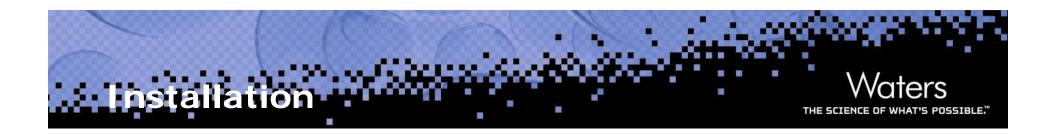


Installation Woters

- Operating Systems not supported
 - Windows NT
 - Windows 2000
 - Windows XP 64-bit
 - Windows 2000 Server.
- Installation will not be allowed on these OS's
- Windows Vista 32-bit, Vista 64-bit, Windows 7 32-bit and Windows Server 2003 are not supported; however, installation will be allowed on these operating systems.
- Installation on Oracle < 11.2 will be prevented; higher versions allowed</p>
- LAC/E³² configurations 10 -13 supported
 - Config 10 and 11 need additional memory-2 GB minimum
 - Config 10 and 11 supported on Windows XP 32 bit only

Installation from Previous Versions Woters THE SCIENCE OF WHAT'S POSSIBLE."

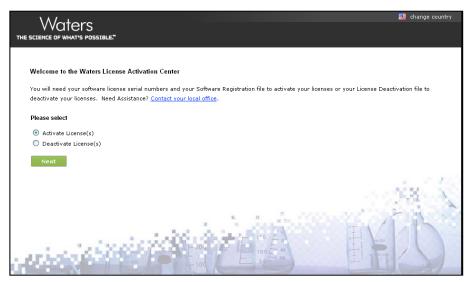
- Installation includes ability to perform a system object export prior to the removal of the previous version of software.
- Server installation allows you to bring the exported information into Empower 3.
 - no system object export or import offered as part of the personal installer
- System object export supported from the following versions:
 - Empower 2154 FR 3
 - Empower 2154 FR 4
 - Empower 2154 FR 5
 - Empower 1154 SP M for English
 - Empower 1154 SP SystemsQT for Japanese
 - Empower 1154 SP ISSP1 for Chinese or Korean



- Project restore will be supported for projects backed up in Millennium³² version 2.15 or higher.
- Push installations
 - Client software
 - Instrument control software
 - Waters is testing with Microsoft PSExec
 - Local + Network log file
 - Log file name = 'computer name' + 'date/time stamp'
 - 'Err' is indicated at beginning of log file name if installation unsuccessful

Software Licensing

- Waters License Activation Center Web
 - Used to activate and export licenses selected from order number
 - User provides contact information
 - User selects desired software serial numbers
 - License activation file is created for download
 - User executes License Wizard to activate license on computer
- Splitable user licenses
- Multi database user license



ACOUITY eCord Information

- Sample Set Information
 - Date
 - Sample Set Name
 - User Name
 - System Name
 - Injection Count
 - Sample Count
 - Max Pressure
 - Max Temperature
 - Sample Set Complete
- Injection information associated with injections
 - eCord Name
 - Serial Number
 - Injection Count

- Summary information
 - Injection Count
 - Date Of First Injection
 - Date Of Last Injection
 - Sample Count
 - Maximum Pressure
 - Maximum Temperature
- Information updated after each injection
 - Requires updated ICS (driver)



ACQUITY eCord Information

- eCord data viewed and managed in
 - **Configuration Manager**
 - eCord Summary Table
 - eCord Sample Sets table



- eCords added automatically when data is acquired using system containing eCord
- Enumerated custom fields called Column Name and Column Serial Number (for non-ACQUITY systems)



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🖶 System/Administrator - Configurat	ion M	anager									
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Empower Configuration	6	Date Started	Sample Set Name	User Name	System Name	Injections	Samples	Max psi	Max °⊂	Sample Set Complete	
Projects	294	8/31/2006	data10	Xcalibur_System	SOFTWARE-LAB	1	1	10005	27.54	Yes	
	295	8/31/2006	data01_060831224	Xcalibur_System	SOFTWARE-LAB	1	1	10005	27.54	Yes	
🕀 🎻 Libraries — 🕅 eCord	296	8/31/2006	data01_060831224	Xcalibur_System	SOFTWARE-LAB	1	1	10005	27.54	Yes	
M41451F02	297	8/31/2006	data01_060831224	Xcalibur_System	SOFTWARE-LAB	1	1	10005	27.54	Yes	
	298	8/31/2006	data01_060831224	Xcalibur_System	SOFTWARE-LAB	1	1	10005	27.54	Yes	
M41451F05	299	8/31/2006	data01_060831224	Xcalibur_System	SOFTWARE-LAB	1	1	10005	27.54	Yes	
₩41451F06	300	8/31/2006	data01_060831224	Xcalibur_System	SOFTWARE-LAB	1	1	10005	27.54	Yes	
👷 User Groups	301	8/31/2006	data01_060831224	Xcalibur_System	SOFTWARE-LAB	1	1	10005	27.54	Yes	
Q? User Types Q Plate Types	302	8/31/2006	data01_060831224	Xcalibur_System	SOFTWARE-LAB	1	1	10005	27.54	Yes	
📲 System Audit Trail	303	8/31/2006	data01_060831224	Xcalibur_System	SOFTWARE-LAB	1	1	10005	27.54	Yes	
- 🖏 Offline System Audit Trail	304	8/31/2006	data01_060831224	Xcalibur_System	SOFTWARE-LAB	1	1	10005	27.54	Yes	
🗗 Sample Archives	305	9/1/2006		Administrator	SOFTWARE-LAB	1	1	7	24.75	Yes	
Offline Project Archives	2000	0.14.100000			0057-405-140	~	_	40			

ACOUITY Injection Modes

Run Samples and QuickStart

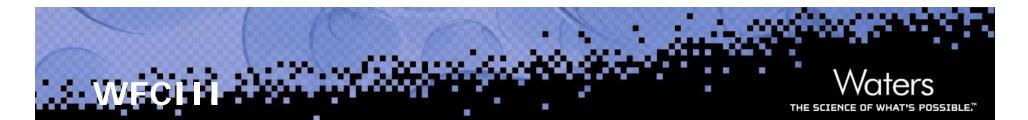
Full Loop Mode

- Injection volume field automatically filled in with the loop volume
- Field not editable

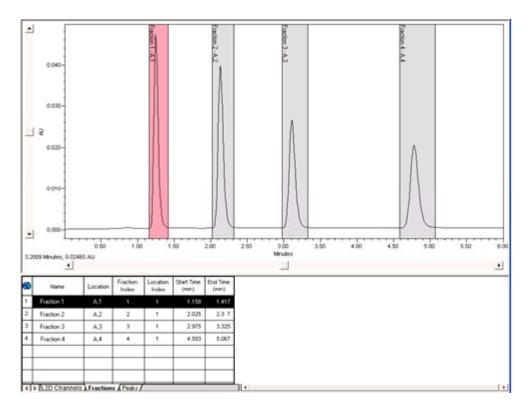
Partial Loop Mode / with Needle Overfill

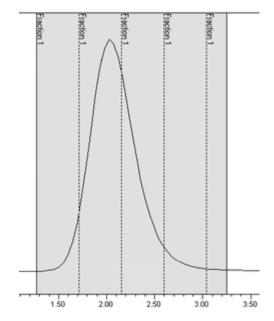
- Injection volume must be within the valid injectable volume range defined by the instrument
- Editable field





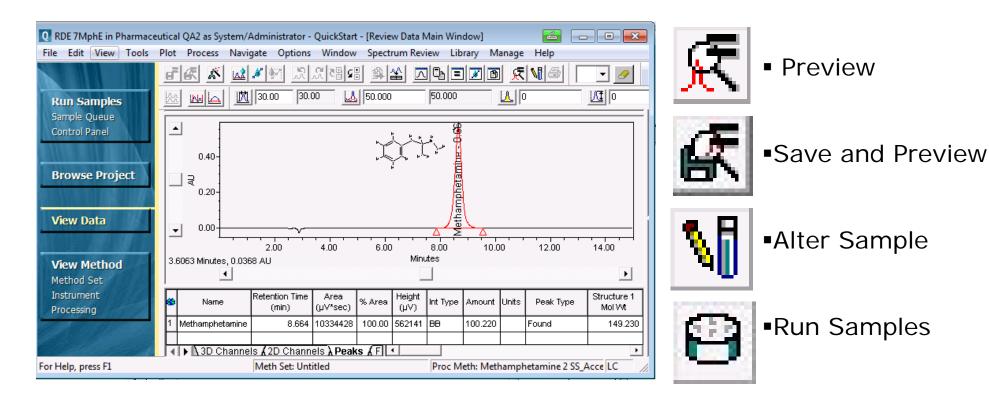
- WFC III control in Empower 2
- Enhancements in Empower 3
 - Fraction annotations on chromatogram
 - Fraction table
 - Fraction tab in Project window







Navigate from Review to....



Navigate tree using arrow keys

Process Only Sample Sets

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MVM Defaults	s as System/Administrator - Pro	niect											
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2 100% N 3 100% N 4 100% N	New Method New Validation Study	Þ	5/5/2006 1:2: 5/5/2006 1:1: 5/5/2006 1:0'	6	Vial	Inj Vol (uL)	# of Injs	Label	SampleName	Sample Type	Level	Function	
5 100% N 6 100% N	Review Preview/Publisher		5/5/2006 12:5 5/5/2006 12:3	1	1:D,1 1:D,2	1.0 1.0	1		100% Nominal p1 100% Nominal p2	Unknown Unknown	100% 100%	Inject Samples	A
7 Blank 8 1000% I	Process		5/5/2006 12:/ 5/4/2006 6:0:	3	1:D,3	1.0	1		100% Nominal p3	Unknown	100%	Inject Samples	A
9 1000%1	Print Export		5/4/2006 5:53	4 5	1:A,1 1:a,2	1.0 1.0	1		Blank Std 100%	Unknown Standard	100%	Inject Samples Inject Standards	A
10 1000% 11 100% I	Alter Sample		5/4/2006 5:4) 5/4/2006 5:31	6	1:8,4 1:8,5	1.0 1.0	1		10% Nominal 1pmol p1 10% Nominal 1pmol p2	Unknown Unknown	10% 10%	Inject Samples	A
ואסיידיין	Create Process Only Samp Run Samples	le Set	5/4/2006 5:20 5/4/2006 5:09	8	1:8,5 1:8,6	1.0	1		10% Nominal 1pmol p2	Unknown	10%	Inject Samples	A
14 10% No 15 10% No	Copy To Project		5/4/2006 4:58 5/4/2006 4:48	F									
16 10% No 17 Std 100'	⊳ No Lock Channel 5/4/2006 4:3:						F1	"	1				
18 Blank	Unlock Channel View As	•	5/4/2006 4:13:	20 P	M EDT	Norma	il Level L	_inearity(050406				
	Came								©2	2010 Waters Corpor	ation CON	IPANY CONFIDENTIAL	13

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Process Only Sample Sets

- Allows combining disparate injections into a sample set postacquisition
 - Allows flexibility in processing
 - Allows combination for use of individual injections in MVM
 - Allows combination for use in Dissolution/CU multi-phase studies
- Privilege called Manage Process Only Sample Set
- Fully audit trailed
- Creating and editing as in Alter Sample -is similar to altering a regular sample set.

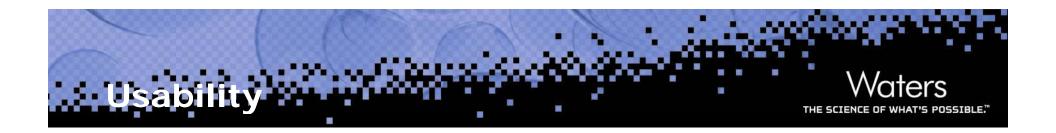
Process Only Sample Sets Waters THE SCIENCE OF WHAT'S POSSIBLE.™

	🚺 File	MVM_Defaults as System// e Edit View Tools D			S	ample	Set Type	1		/1	Process Only ample Sets	
	⊞			7 N M Ø 🛇	Pro	cess (Dnly	1	/		4	
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	2 3	POSS for Trending Analysis Validation Study POSS	8	2/10/2010 2:44:33 PM EST 2/10/2010 2:44:00 PM EST	Pro	cess (Dnly				1	
	4	4 uuu 2/10/2010 2:30:41 PM EST		Acquired			Update Max Rows: 10		1			
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	7 8	4Day Sample Stability 10C Robustness Study ESG050	906	5/11/2006 4:22:10 PM EDT 5/9/2006 12:48:43 PM EDT	Acquired			Date Acquired # of Proce Sample				ne
			1	Condition 1 day 3 prep 2	2:e,2	1	Unknown	5/15/2006 3:54:20 PM EDT		4	Sample Stability 22C	
			2	Condition 4 day 3 prep 2	2:e,8	1	Unknown	5/14/2006 6:17:21 PM EDT		4	4Day Sample Stability	10C
~ <i>w</i>		o ento d	3	MP Blank	2:a,1	2	Unknown	5/16/2006 3:32:20 PM EDT		4	Sample Stability 22C	
		ported	4	Condition 3 day 4 prep 1	2:e,1	1	Unknøwn	5/15/2006 5:43:33 PM EDT		4	4Day Sample Stability	10C
•C	op	bied	5	Condition 1 day 4 prep 2	2:e,2	1	Unknown	5/16/2006 3:54:42 PM EDT		1	Sample Stability 22C	
•P	roi	cess only	6	Condition 4 day 4 prep 2	2:F,2	7	Unknown	5/15/2006 6:16:32 PM EDT		1	4Day Sample Stability	10C
• •			7	MP Blank	2:a,1	1	Unknown	5/15/2006 5:21:38 PM EDT		1	1 4Day Sample Stability 100	
			8	SyzSuit_A	5	6	Standard	8/1/2005 3:50:48 PM EDT	/	0	D4_InterP_2F_21	
			9	SysSuit_A	5	5	Standard	8/1/2005 3:40:02 PM EDT	\backslash	0	Ø4_InterP_2F_21	

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- Project integrity errors won't stop batch project backup/restore
 - Log file is generated to document errors
 - Time zone and database update request also won't stop backup
- Multiple application windows locked due to timeout
 - Unlock once to unlock all
 - Does not pertain to 6-button window
- Run Samples Control Panel Position saved as preference



- View Message Center for All Users privilege
 - Allows granularity to specify users that see all messages or only their own
- ApexTrack Use appropriate peak width for USP Plate Count USP Resolution and Relative Resolution determination
 - Values dependant on inflection points \rightarrow Width@Tangent
 - Incorrect peak width parameter could over smooth data in previous versions
 - Software will recalculate peak's inflection points using a peak width that is appropriate (correct) for the peak instead of the possibly inappropriate peak width in the method
 - Affects peaks using PW outside of 2X Auto-PeakWidth range
 - No more message regarding "Inappropriate Peak Width"



The signal-to-noise ratio (S/N) is a useful system suitability parameter. The S/N is calculated as follows:

S/N = 2H/h

where H is the height of the peak measured from the peak apex to a baseline extrapolated over a distance ≥ 5 times the peak width at its half-height; and h is the difference between the largest and smallest noise values observed over a distance ≥ 5 times the width at the half-height of the peak and, if possible, situated equally around the peak of interest after the injection or application of a blank (see <u>Figure 5</u>).

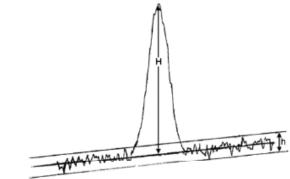


Figure 5. Noise and chromatographic peak, components of the S/N ratio.

🔽 Calculate USP, EP, and JP s/n 🛛

Use noise centered on peak region in blank injection.

Half Height Multiplier for USP s/n Noise Region 5

Half Height Multiplier for EP s/n Noise Region

Half Height Multiplier for JP s/n Noise Region





- Allows determination of noise within a blank injection centered on the peak region
- Allows user to specify a noise segment based on peak width at half height:
 - USP Half Height Multiplier for Noise Region
 - EP Half Height Multiplier for Noise Region
 - JP Half Height Multiplier for Noise Region

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66	Plate//Vell	Inj Vol (uL)	#of I⊓js	Label	Blank	SampleName	Sample Type	Level	Function	Method Set / Report Method
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2									Condition Column	AccQTag Val
3	1:A,1	1.0	1		V	Blank	Unknown		Inject Samples	AccQTag Val
4	1:a,2	1.0	1			Std 100%	Standard	100%	Inject Standards	AccQTag Val
5	1:B,4	1.0	1			10% Nominal 1pmol p1	Unknown	10%	Inject Samples	AccQTag Val
6	1:B,5	1.0	1			10% Nominal 1pmol p2	Unknown	10%	Inject Samples	AccQTag Val
7	1.00	1.0				1000 11 1 14 1 0		1.000		A AT 111



- For defensible compound confirmation
- Area or Height ratio of 1° Channel : 2° Channel (1 4) in same injection
- Acceptance tolerance on result as compared to a reference injection
- Failed values are faulted

3	Sulfas Target Masses in Waters S	QD Familari	ization as System/Adm	ninistrator - Proces	sing Method E	ditor - MS Processing Method			
File	View Help								
0									
	Integration Smoothing/Offsel		ry Search MS Centro	id MS Expected I	Mass Compo	nents Peak Ratios (MS Ion Ratios) Default Amo	unts Named Gro	ups Timed Groups Su	itabilit
60	Component	P	Primary eak Identifier	Primar Channel M		Primary Channel Description		Peak Response	
1	Sulfamerazine	Primary 1		TQ 1: MRM Ch1		1: MRM Ch1 265.08>92.04 ES+, CV=36 CE=28	Heigh	t	
					5				
Sec	condary Peak Table (Secondary MS	lon lon)							
6	Secondary Peak Identifier		Seconda Channel Na	2 A		Secondary Channel Description		Peak Ratio Tolerance (%)	
1	Sulfamerazine2	т	Q 1: MRM Ch2		1: MRM Ch2 265	5.08>155.99 ES+, CV=36 CE=14		20.0	.00
1				"					
Read	ły							N	AS /

MS Target Masses

- Open Access, Run Samples, QuickStart, Alter Sample
- Specify up to 5 base monoisotopic masses in sample table (not processing method) 🚱 System/Administrator - Open Access
- Poss
- Obta wh pre

MS Mass Editor

Target Mass 1 (Da) 264.10

sible adducts entered in PM ain Yes/No answer as to ether the target mass is sent in sample	File View Actions Help Project: Waters SQD Familarization Image: Comparison of the second sec
lass 2 Mass 3 Mass 4 Mass 5 Method (Da) (Da) (Da) (Da)	MS Calibration Method
278.10 310.20 Waters SQD LCMS System Check	Bruce_20_1974_4714D et: 3 Sulfas MRM Ex MS
	>s: 1 : In: 10.0 : In: 10.0 : In: 10.0 : In: 10.0 : In: 10.00 : In: 10.00 : In: 10.00 : In: 10.00 : In: In: : In: In: : In: : : : In: : : : In: : : : <tr< td=""></tr<>
	Ie: Sulfa Screening

THE SCIENCE

POSSIBLE.

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MS Target Masses

Masses specified in Run Samples supersede the one in the processing method

THE SCIENCE

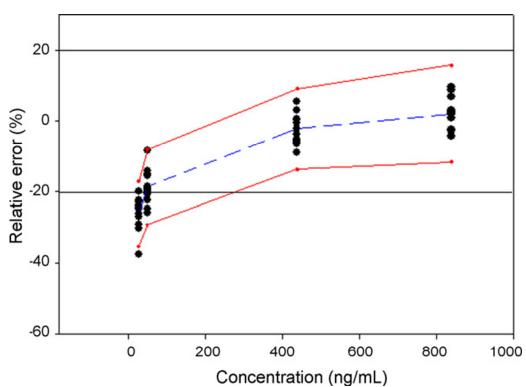
POSSIBLE."

le Vi	as Target Masses in ew Help 🗃 🗔 📔	Waters SQD Familar	ization as Systen	n/Administrat	or - Process	ing Method	Editor - MS	Processing I	Method		
		ion il un in	e lue			.].	. [n			sterr u	• • • •
	tegration Smoothi		ary Search MS (Centroid	Expected N	lass (Com	onents Pe	ak Ratios (N	MS Ion Ratio	is) Default	Amounts
	pected mass process	ing									
Inject	ion-based processing			,		-					
Ba	se Mass:	 Intensity: 	📩 Pea	k Separation:	1.00						
6	lonization Mode	Adduct Delta Mass (Da)	Adduct Intensity (%)	Percentage of (%							
1	Positive	1.00									
2	Positive	3.00									
3	Positive	21.00									
4	Negative	1.00									
5	Negative	3.00									
6	Negative	21.00									
Comp	u ponent-based processi	ng		<u> </u>							
	Enter the expected com	mass/intensity values	for the componen s, please use the C	ts shown belov Component tab.	v. To alter th	e					
		Expe			Expected	Expected	Expected	Expected	Expected	Expected	Expected

MVM : SFSTP Calculations

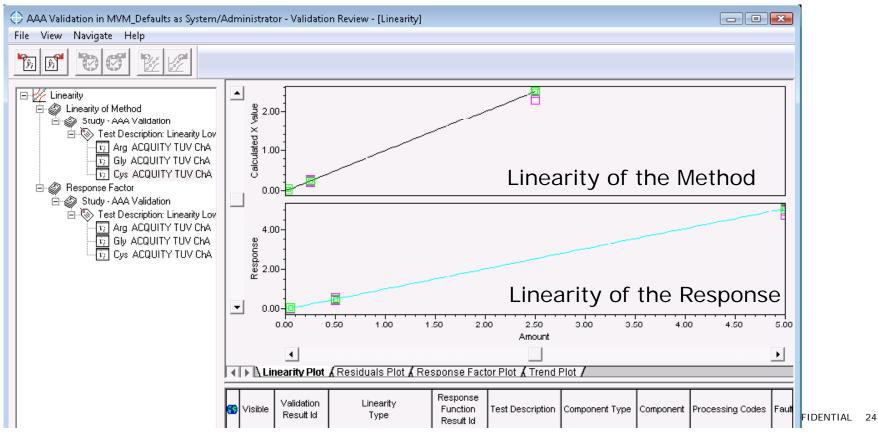
- Accuracy Total Error
 - Sums intermediate precision and bias
 - % Total Error
 - % Relative Error
 - % Relative Error Mean
 - Tolerance Interval
 - Upper/Lower Limit of Quantitation

- Accuracy Profile Plot
- % Relative Error vs. X Value



MVM – Linearity of the Method

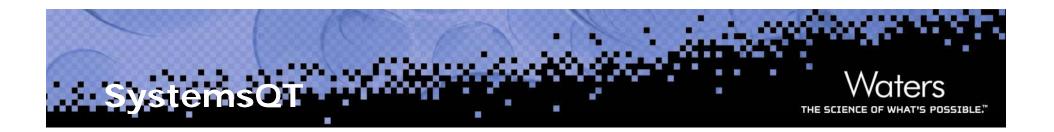
- Linearity of the Response (current) Response vs. Amount/Concentration
- Linearity of the Method Calculated value (from linearity of response) vs. Amount/Concentration



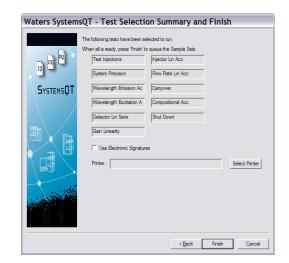
Validation Services

- Validation: barrier to adopting new software & updates
- Leverage ESS Proven record of success in > 40 Empower customers + 10 years validation experience
- Automation of existing test execution
 - Estimates suggest that automating tests will take half the time for execution
- Complementary service to Connections AQT and SystemsQT





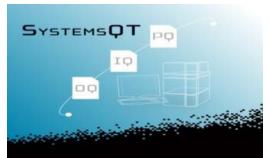
- Service offering for new chromatographic system qualification tool for system level test
- Integrated Empower 3 Software
 - Launch SystemsQT Wizard from Run Samples to Qualify System
- Wizard guides user through the system qualification setup
- Each system configuration includes an Empower project with predefined sample sets, calculations and reports





Supported Configuration with SystemsQT

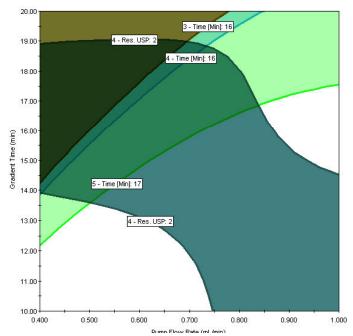
- All ACQUITY Configurations
 - All modules including the ACQUITY Fluorescence Detector, ACQUITY Photodiode Array Detector, ACQUITY Tunable UV Detector, ACQUITY Evaporative Light Scattering Detector, ACQUITY SQD single quadrupole Mass Detector and ACQUITY TQD tandem quadrupole Mass Detector
- All Alliance 2695/2795 Configurations
 - Including the Waters UV/Visible Detectors, Waters PDA Detector, Waters FLR Detector, Waters RI Detectors, Waters 3100 SQ and TQD tandem quadrupole Mass Detectors
- Modular HPLC Systems
 - Including 1515/1525 Pumps, 2707 injector and RI/UV detectors
- Agilent LC Configurations
 - Including UV, DAD, RI and FLR Detectors
- Agilent GC Configurations
 - 7890, 6890, 6850 and G1888 HS



Fusion Method Development Software with ACQUITY UPLC

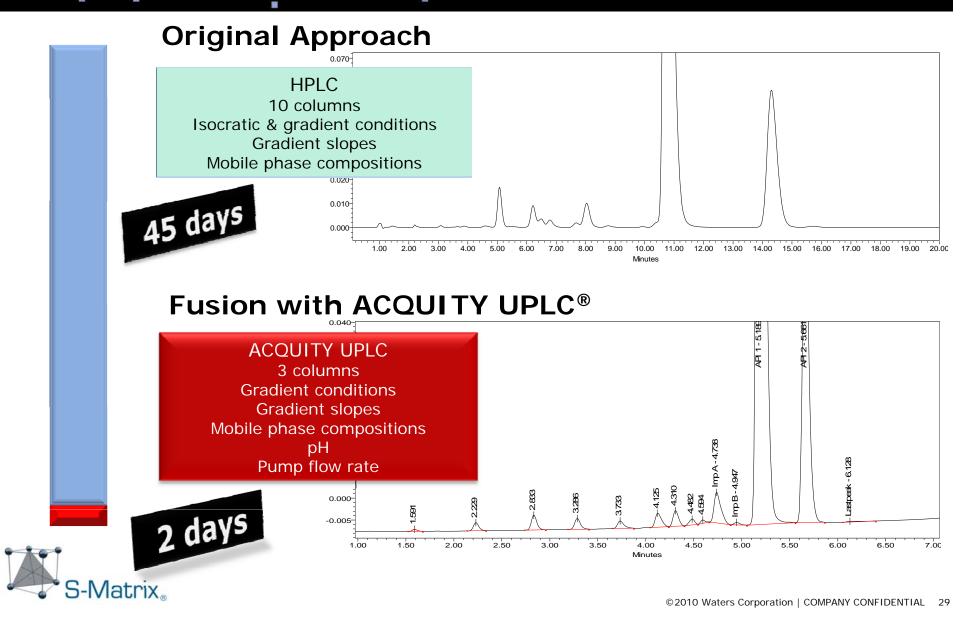


- Reduces method development time from weeks to days
- Create and builds statistically valid experimental designs
- Predict optimal conditions for the process under study
- Builds robustness in for the long-term viability and transferability of the method
- Generates a statistically valid design space
 - Characterizes the impact of chromatographic parameters on separation performance
 - Eliminates/reduces method re-validation re-work
 - Aligned with QbD guidelines
- Increased efficiency and confidence that methods will Validate and transfer





Fusion Method Development Software with ACOUITY UPLC



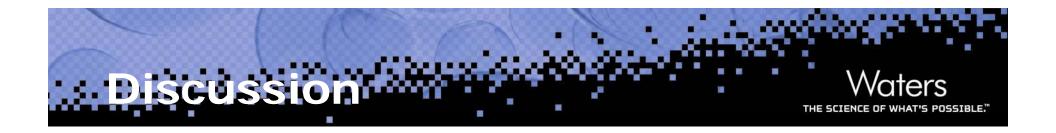
Empower 3 Software

- Tools for the Chemist
 - New Instrument Control
 - o Usability features
 - o Option enhancement
 - Process only Sample Sets
- Tools for the Lab Managers and Administrators
 - Help with Deployment in complex architectures
 - o Simpler License management
 - Easier Global deployment
 - Tools to streamline the software validation process

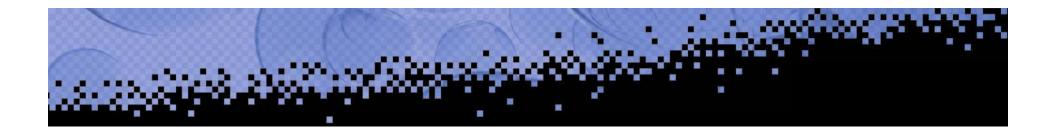


POSSTRIE









Waters The science of what's possible."

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