

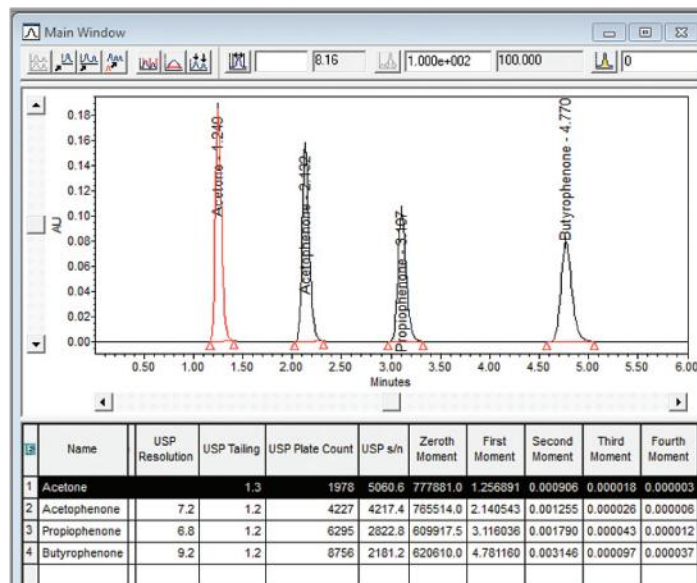
Empower Method Validation Manager (MVM)

a ďalšie...

Michal Belianský

System Suitability (option)

- Využitie automaticky generovaných parametrov ako napríklad Resolution, Tailing and symmetry factor, Plate Count, Peak Height and width, S/N podľa amerického, európskeho a japonskeho lékopisu.



Named Groups Timed Groups **Suitability** Limits Noise and Drift

☒ Calculate Suitability Results

☒ Calculate Suitability Results for Unknown Peaks

System and Separation Efficiency

Void Volume Time (min)

☐ US Pharmacopoeia ☐ European Pharmacopoeia

☐ Japanese Pharmacopoeia ☒ All

Tangent Percent for USP Resolution

Tangent Percent for USP Plate Count

☒ 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

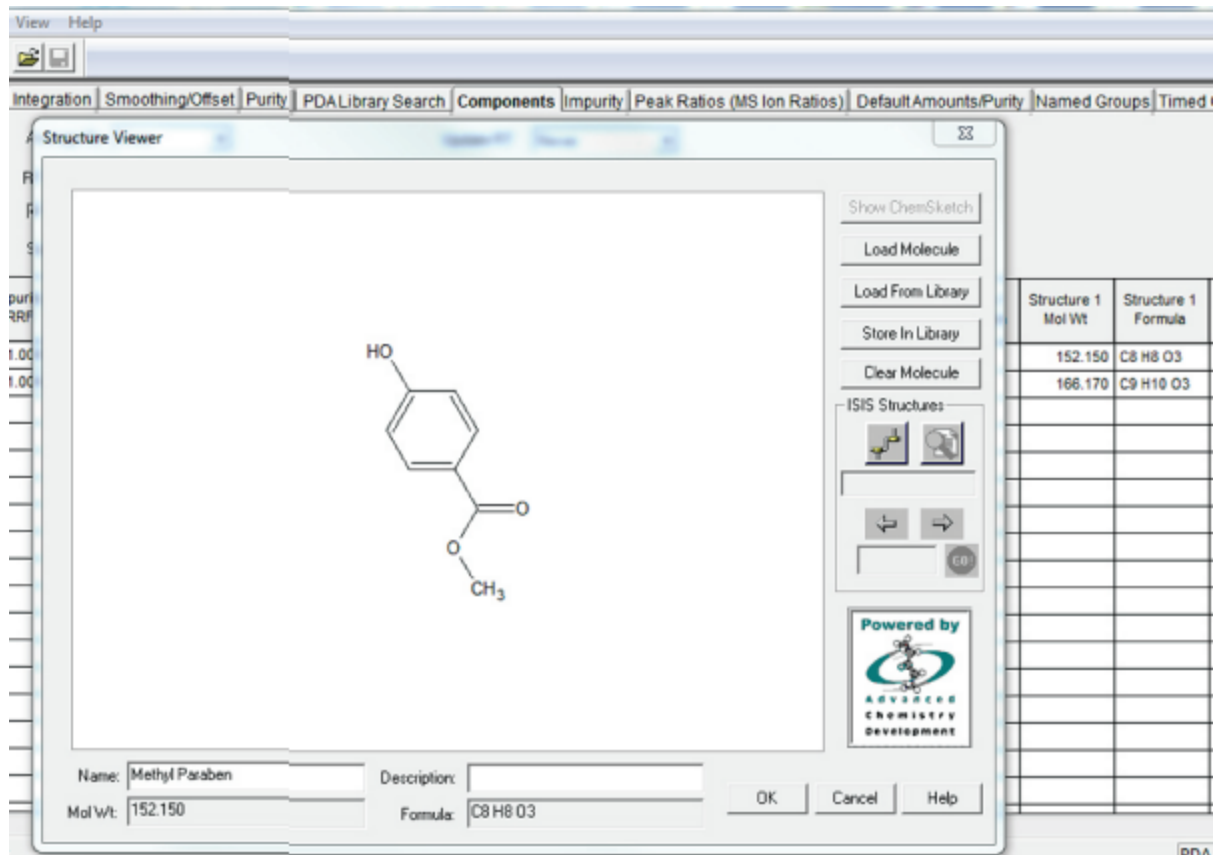
Half Height Multiplier for EP s/n Noise Region

Half Height Multiplier for JP s/n Noise Region

Noise Value for s/n

Chemical Structures (option)

- V spolupráci s ACD labs táto možnosť zahŕňa aj verziu **ACD ChemSketch** integrovanú v Empoweri, ktorá umožňuje vytvárať, upravovať a vyhľadávať chemické štruktúry priamo v Empoweri.
- Umožňuje vytvárať knižnice štruktúr.
- Možnosť vloženia chemickej štruktúry do *Component table* v procesnej metóde a následný reporting.

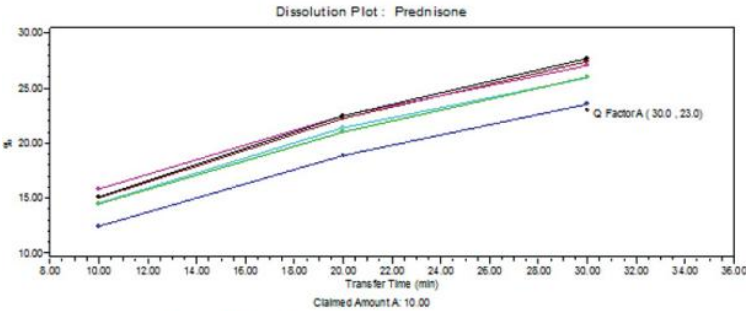


Dissolution (option)

- Za pomoci Wizardu možnosť nastaviť sample set, procesovanie a reportovanie výsledkov
- Kritické parametre ako **f1**, **f2** a **Q faktor** sú automaticky vypočítané a uložené v databáze.
- Reporty je možné vytvárať z templátov tak, aby obsahovali tabuľky a grafy špecifické pre dissoluce.



Dissolution

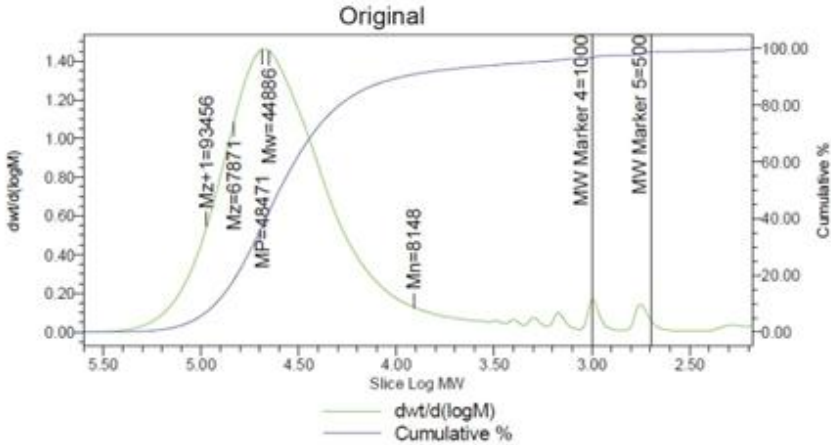


Dissolved Amount for Component: Prednisone Channel: 2487 Channel 1

	Bath	Vessel	Injection	10.0 min	20.0 min	30.0 min
1	A	1	1	1.512	2.248	2.770
2	A	2	1	1.243	1.887	2.353
3	A	3	1	1.449	2.101	2.600
4	A	4	1	1.453	2.139	2.594
5	A	5	1	1.502	2.249	2.706
6	A	6	1	1.502	2.225	2.743
Mean				1.5	2.1	2.6
Max				1.6	2.2	2.8
Min				1.2	1.9	2.4
% RSD				7.9	6.5	5.8

GPC/SEC for Polymer Analysis (option)

- Zjednodušené výpočty molekulových hmotností pre polyméry a biopolyméry.
- Automatické výpočty: Mw, Mn, Mp, Mz alebo Mz+1.
- Zhromažďuje a **kombinuje** dáta z refraktometrického detektora a detektora svetelného rozptylu pomocou GPC-LS.
- Narrow alebo broad standards pre vytvorenie GPC kalibračných kriviek.



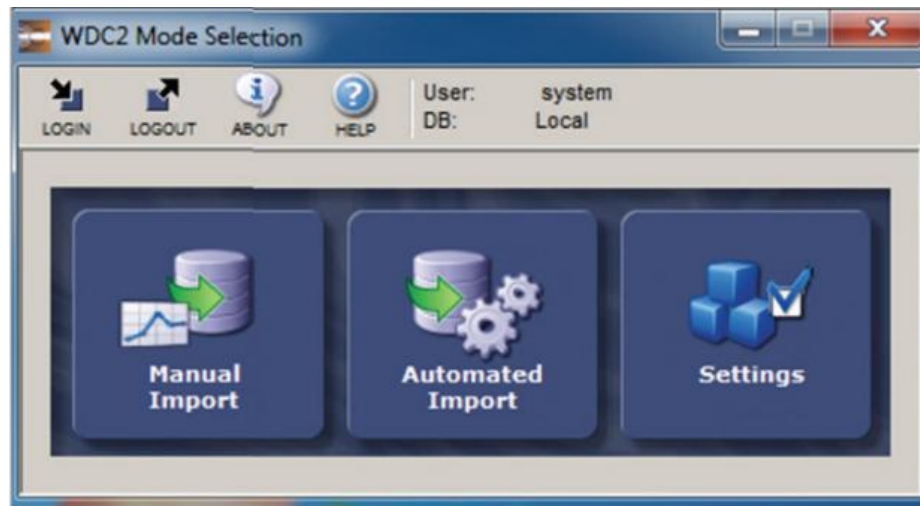
Test result

	SampleName	Mn	Mw	MP	Mz	Mz+1	Polydispersity	%Poly < MW M4	%Poly < MW M5
1	Sample 1	8148	44886	48471	67871	93456	5.508541	2.990	1.051

Waters Data Converter (option)

Waters™

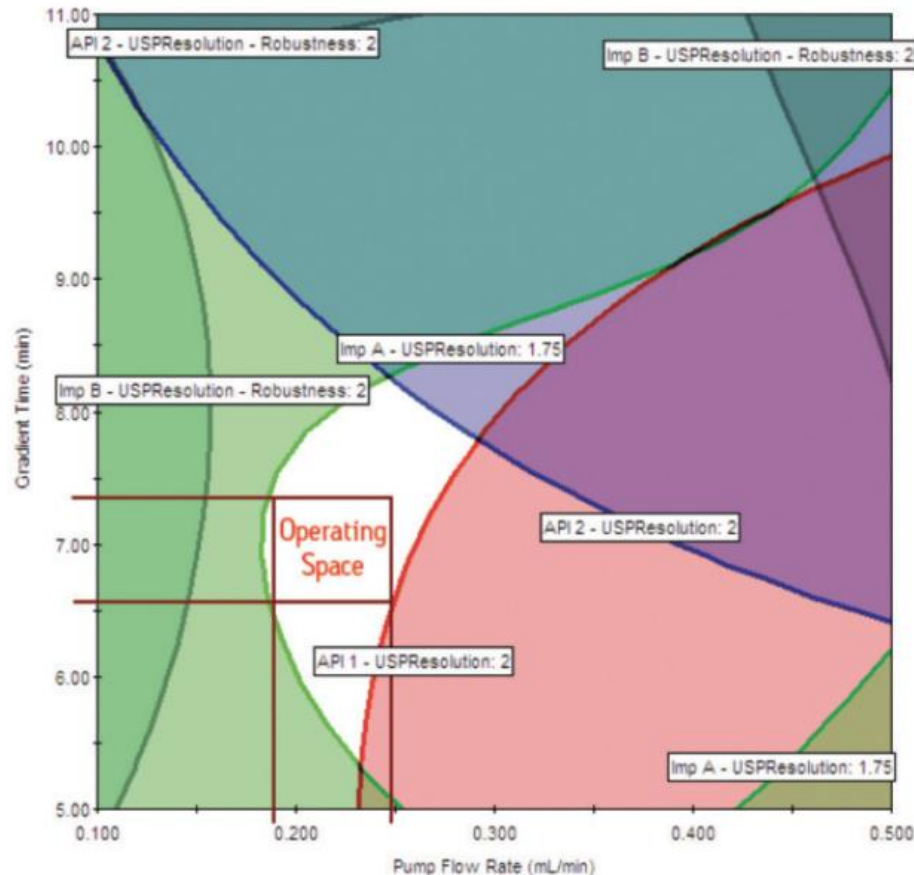
- Nástroj na migráciu a zachovanie dát z iného data systému (CDS).
- Po prenesení dát: zobrazenie, procesovanie, reprocesovanie, a reporting.
- Prenos dát do Empoweru z: Waters MassLynx,™ Agilent ChemStation and OpenLab, PerkinElmer TotalChrom, Thermo Fisher Scientific Chromeleon™, and Bio-Techne ProteinSimple.
- Manuálny alebo automatizovaný prenos.



Method Development – Fusion QbD (option)

Waters™

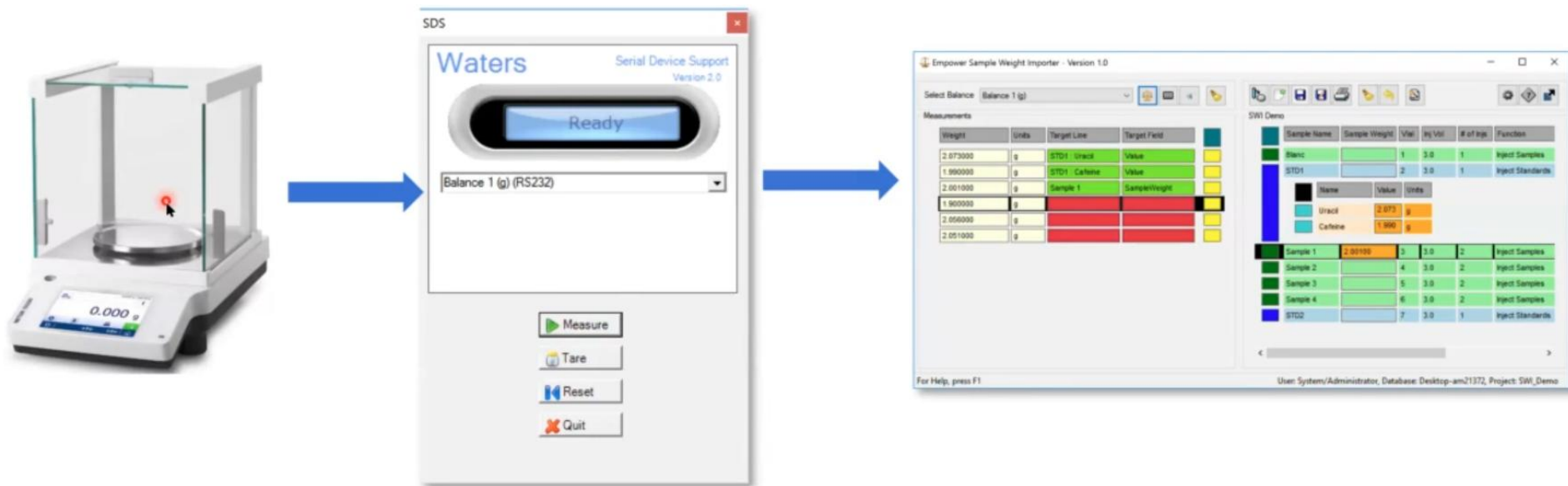
- Rýchlejší automatizovaný vývoj metód s S-Matrix Fusion LC Method Development Software integrovaný so softwarom Empower.
- Skrátenie času vývoja metódy a zníženie spotreby solventov.
- Zaistenie spoľahlivosti testovaním a vizuálnym potvrdením robustnosti LC metódy ešte pred jej validáciou.



Sample Weight Importer (option)

Waters™

- Prenos dát priamo z váh cez Sample Weight Importer priamo do Empoweru
- Full Audit Trail



waters_connect System Monitoring (option)

Waters™

Svoje systémy môžete sledovať kedykoľvek a kdekoľvek.

The screenshot displays the Waters Connect System Monitoring interface. The top navigation bar includes links for Home, Feedback, Help, and a user profile for Ralf S. The main header shows 'System Monitoring' and a team selector set to 'All teams'. Below this, a summary bar indicates '15 Systems total' with color-coded status counts: Running (1), Not ready (1), Idle (5), Error (1), Offline (2), and Unknown (5). A search bar and a dropdown for 'Sort by Name (A-Z)' are also present. The dashboard is organized into a grid of system cards, each showing the system name, status, and time in the current state. The systems listed are:

System Name	Status	Time in current state
Alliance iS	UNKNOWN	204 d 4 h 43 m
Alliance iS	IDLE	17 h 1 m
Arc_HPLC	IDLE	8 d 22 h 49 m
BR_Alliance iS	UNKNOWN	406 d 11 h 43 m
BU_3879	UNKNOWN	31 d 14 h 6 m
BU_8867	IDLE	3 h 40 m
BU_88679	OFFLINE	133 d 12 h 30 m
BU_8979	RUNNING	Injection Running Product_202411API_813211
Iclass_Oligo	UNKNOWN	33 d 19 h 14 m
KBD6124_Premier	ERROR	61 d 57 m
Premier_OligoLC	OFFLINE	42 d 19 h 28 m
QA_3165	IDLE	6 h 47 m
QA_4365	IDLE	16 h 23 m
QU_3467	UNKNOWN	34 d 11 h 56 m
QU_6823	NOT READY	Communication failure

Prístup ku všetkým 700+ chromatografickým systémom a LC-MS systémom riadeným cez Empower na waters_connect.

Vrátane novej Alliance iS



waters_connect System Monitoring (option)

Automatické zaslanie notifikácie podľa nastavenia

System Monitoring

Dashboards

System Monitoring

Devices

Acquisition Devices

Systems

System

AL_2795

Last update: 2 min ago

DetailsHistorySchedule

ERROR

Last reported: Dec 01, 2022 09:14:11 (-5:00)

rQSM-FTN-W2489

System location: Brasov-Lab2

Acquisition device: Lndpc11bv

Edge service: Running

Current sample set

Sample set name: Formulation_Assay_B83245

Sample set status: System Idle - Instrument Failure...

Time remaining: Not available

Sample set user: scub

Sample position: 1:A, 8

Instrument Method: Not available

Project name: Not available

Instrument Modules (3)

#	Type ↑	Status	Alarms	Serial number	Driver	Firmware
1	ACN-FTN	Error	Missing/wrong plate or vial	C105DQ253N	1.76.2842	1.71.395
2	W2489	Idle		K07UPL001N	1.70.2074	1.65.6227
3	ACN-QSM	Idle		C10QSM287M	1.762843	1.72.415

Sample Set queue

Estimated time of completion: Not available

Samples sets in queue: 0

#	Name	Status ↑	Time remaining	Sample set user	Sample position	Injections remaining	Project name
1	Formulation_Assay_B83245	System Idle - Instrument Failure ACQ-FTN8H17VSM677N	Not available	scub	1:A, 8	Not available	Not available

Status History

Status summary: Running: 2d 4h 55m 26s (40%) Idle: 2d 1h 37m (25%) Error: 1d 5h 15m 52s (15%) Offline: 0s (0%) Unknown: 2d 2h 21m 16s (20%)

Configure notifications - AL_2795

Select notifications to receive

☐ Came online

☐ Stopped reporting its status

☐ Went offline

☐ Resumed reporting its status

☐ Sample set started

☒ Sample set ended

☒ Error occurred

☐ Error resolved

Notifications are sent via email

Cancel

Save

waters_connect System Monitoring (option)

Waters™

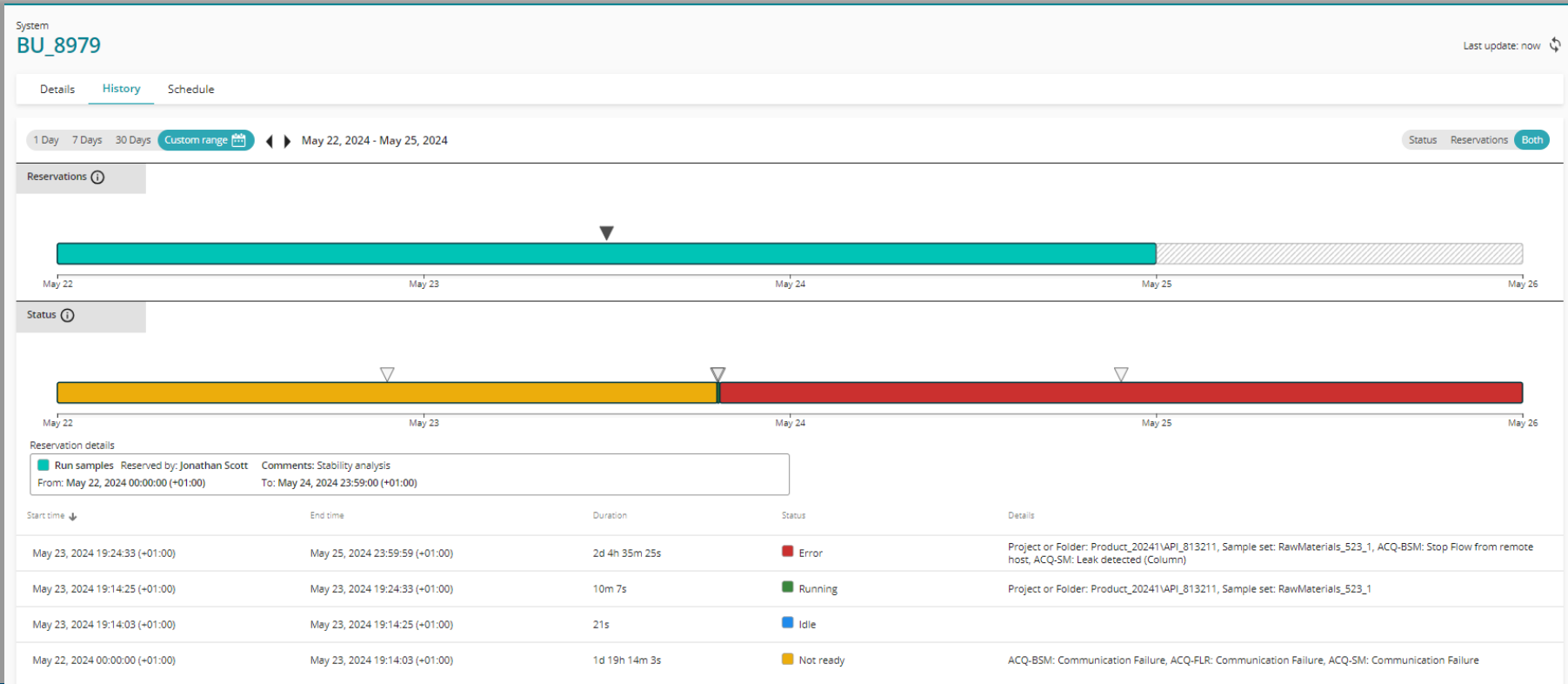
Rezervujte si systém priamo pre Vašu prácu

The screenshot displays the Waters Connect System Monitoring interface. The main view is the 'Reservations' calendar for 'Lab 1', showing a week from November 5, 2023, to November 18, 2023. The calendar is currently set to '2 Weeks' and 'Custom range'. A modal window is open, showing the schedule for 'Monday, November 6, 2023 - BU_8179'. The modal displays a list of reservations for the day, including 'Run samples' and 'First raw materials assay'. The background calendar shows reservations for various systems, including AL_2795, AL_3469, BU_8167, BU_81779, BU_8179, HU_6890, HU_68909, IU_48902, IU_48909, QA_4575, QA_6745, SCP_AgLC2, and SCP_AgilentLC. The interface includes a sidebar with 'Dashboards' (System Monitoring, Reservations) and 'Devices' (Acquisition Devices, Systems). The top navigation bar includes links for Home, Feedback, Help, Language, and a user profile for Scott M.

System name	5 Sunday	6 Monday
AL_2795 rQSM-rFTN-W2489		steve c.
AL_3469 rQSM-rSMFTN-30CH-2489		
BU_8167 BSM_SM_UV		
BU_81779 BSM_SM_FLR_PDA		2 Reservation
BU_8179 BSM_SM_FLR		2 Reservation
HU_6890 QSM_SM_UV		
HU_68909 QSM_SM_UV_ELSO		
IU_48902 BSM_FTIN_FLR		Trish M.
IU_48909 BSM_FTIN_ELSO		Trish M.
QA_4575 Alliance IS HPLC em		steve c.
QA_6745 Alliance IS em		Trish M.
SCP_AgLC2 Agilent Quat Pump ALS TCC V...		
SCP_AgilentLC G1311C_QuatPump G1329B_ALS G13...		

waters_connect System Monitoring (option)

Zvýšte produktivitu svojho laboratória

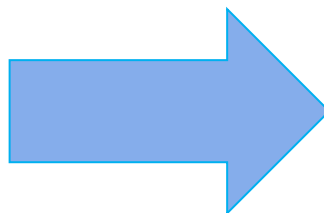


Empower Method Validation Manager (option)

Waters™



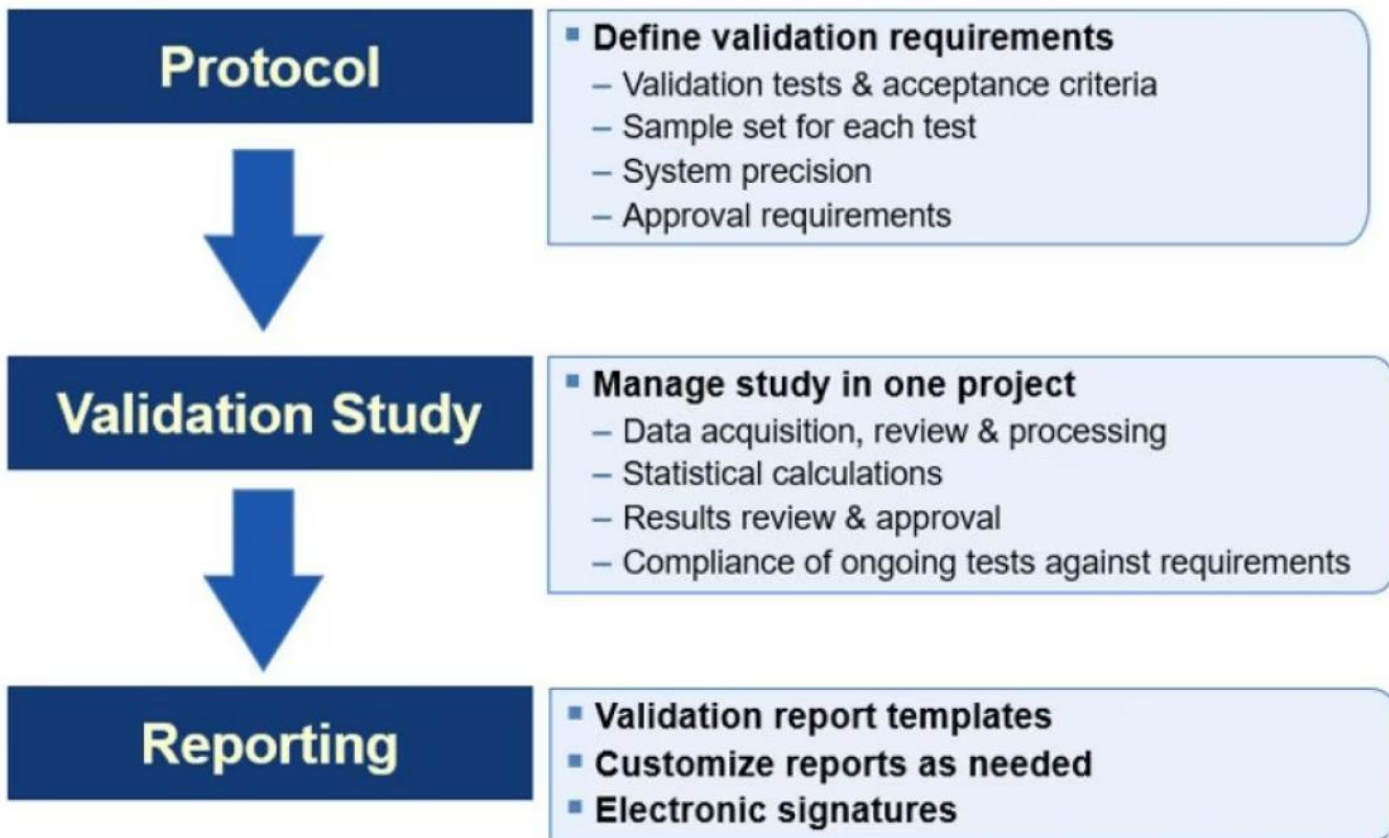
Excel



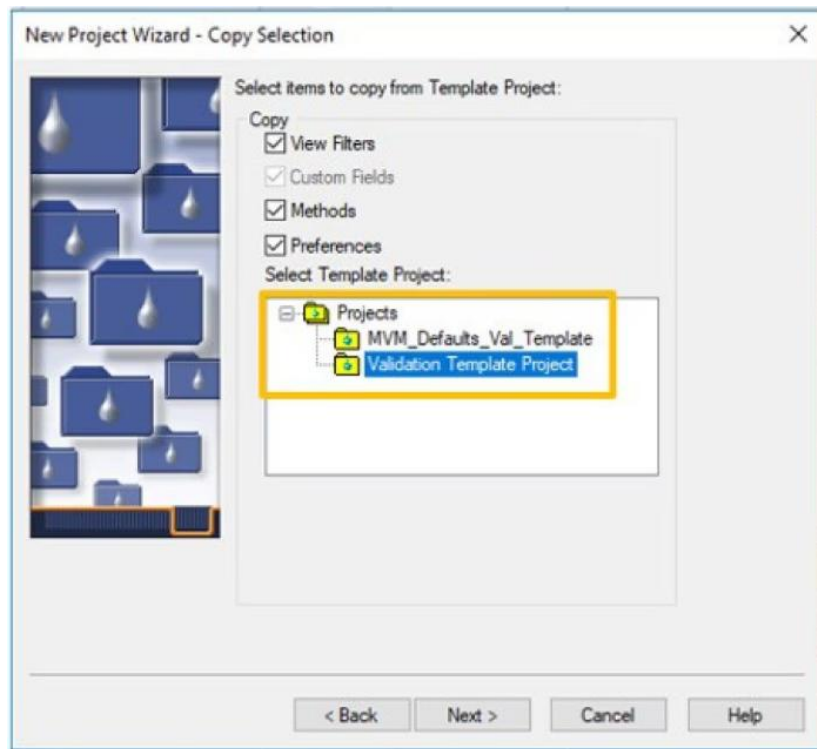
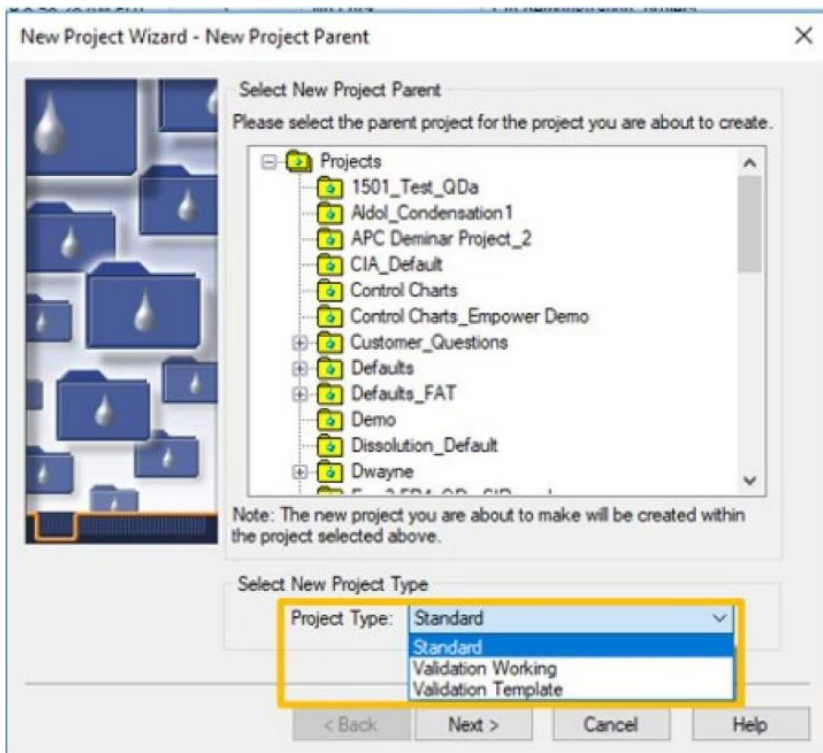
Validačné testy

Method Validation Manager

- System precision
 - Linearity and range
 - Accuracy
 - Specificity
 - LOD a LOQ
 - Repeatability
 - Precision (Intermediate precision)
 - Reproducibility
 - Stability
 - Robustness
- Každý z týchto testov vyžaduje iný počet príprav vzoriek a napichov. Mnohé z týchto testov vyžadujú zmenu v pH, instrumente, teplote, prietoku, kolony atď.
 - Možnosť zahrnúť viac testov v jednom sample sete.
 - Výpočty pre každý validačný test sú jedinečné (výpočet pre test linearity sa líši od výpočtu pre robustnosť).

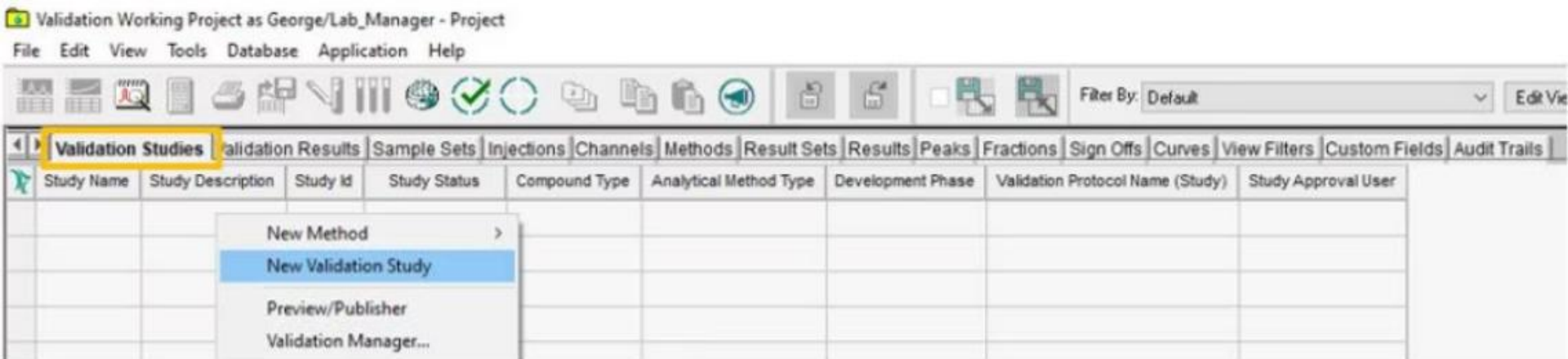


Tvorba Validačního Projektu



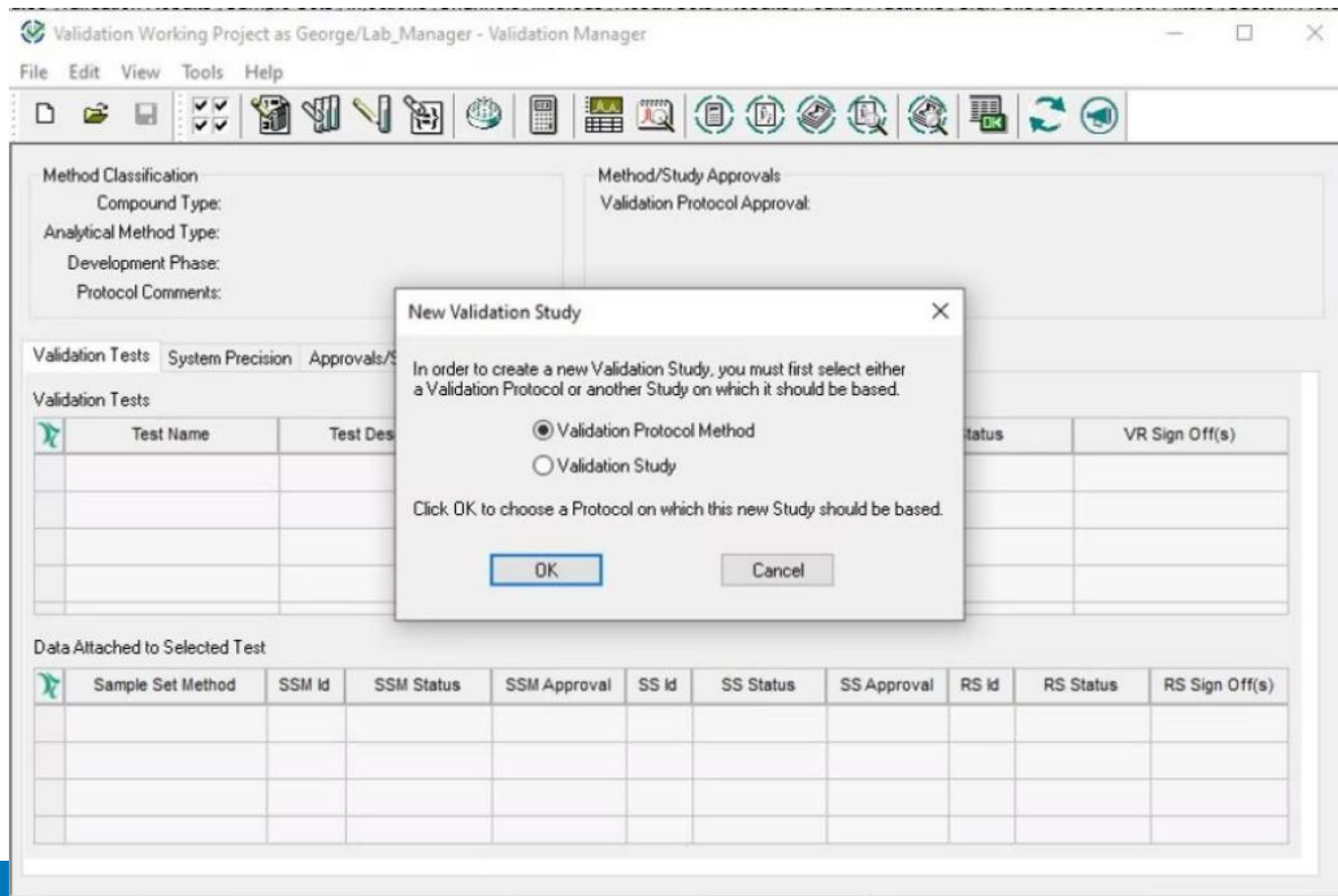
Založenie Validation Study

- MVM projekt má o 2 záložky viac: Validation Studies a Validation Results.
- Ostatné záložky zostávajú nezmenené.



Založenie Validation Protocol Method

- Každá Study by mala mať správne vyplnený:
 - Compound Type
 - Analytical Method Type
 - Development Phase
 - prípadne Protocol Comments
- Validation Study vkladáme pod Validation Protocol Method



Empower Method Validation Manager

Waters™

Validation Study - New Study in MVM_Demo_Working_3 as George/Lab_Manager - Validation Manager

File Edit View Tools Help

Method Classification

Compound Type: Drug Substance

Analytical Method Type: Assay

Development Phase: Phase I

Protocol Comments: Caffeine

Method/Study Approvals

Validation Protocol Approval:

Validation Protocol Name: New Study (Caffeine Validation)

Study Status: Study Incomplete

Validation Study Approval:

Validation Tests | System Precision | Approvals/Sign Offs

Validation Tests

Test Name	Test Description	Required	Test Status	VR Status	VR Sign Off(s)
1 Linearity	Linearity 40%-160%	✓	Test Complete	✓	
2 Repeatability	Repeatability at 100%	✓	Result Sets Incomplete		
3 Accuracy	Accuracy at 40%, 100% and 160%	✓	Sample Sets Incomplete		
4 Specificity	Specificity 1	✓	Test Not Configured		

Data Attached to Selected Test

Sample Set Method	SSM Id	SSM Status	SSM Approval	SS Id	SS Status	SS Approval	RS Id	RS Status	RS Sign Off(s)
1 Caffeine Sample Set	1007	✓		1009	✓		1223	✗	

- Empower Validation Manager window allows you to perform chromatographic method validation from start to finish.

System precision

- Možnosť pridať test overenia systému priamo cez záložku *System Precision* ako „repeatability test“ alebo cez *Validation Tests*.

Validation Study - Validation Study ETOTW in Validation Working Project as George/Lab_Manager - Validation Manager

File Edit View Tools Help

Method Classification
Compound Type: Drug Substance
Analytical Method Type: Assay
Development Phase: Development
Protocol Comments: Empower Tip of the week

Method/Study Approvals
Validation Protocol Approval: George Manager (george)
Validation Protocol Name: Validation Study ETOTW (Validation Protocol ETOTW)
Study Status: Study Incomplete
Validation Study Approval:

Validation Tests **System Precision** Approvals/Sign Offs

Acquisition Parameters
☒ System Precision Required for all Sample Sets
Criteria: Exact
Vials/Sample Set: 1
Injections/Vial: 6
Injections: 6
☐ Ignore System Precision faults when setting VR Status

Processing and Acceptance Criteria
Component Type - Select row to set Acceptance Criteria

	Component Type	Channel	Sample Matrix	Assessed Field	Significance Level
1	Main Component			Area	0.05
2	Main Component			Retention Time	0.05

Acceptance Criteria Tables
Select Criteria Type: Acceptance Criteria

Per Component Type

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)
1	System Precision Result	Assessed Field % RSD	0.000000			2.000

Per Component Type Per Level

	Level	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target

Sample Set pre MVM

File Edit View Help																
</																

Spárovanie Sample Setu s Validačným Testom

Validation Study - New Study in MVM_Demo_Working_3 as George/Lab_Manager - Validation Manager

File Edit View Tools Help

Method Classification

Compound Type: Drug Substance

Analytical Method Type: Assay

Development Phase: Phase I

Protocol Comments: Caffeine

Method/Study Approvals

Validation Protocol Approval:

Validation Protocol Name: New Study (Caffeine Validation)

Study Status: Study Incomplete

Validation Study Approval:

Validation Tests | System Precision | Approvals/Sign Offs

Validation Tests

Test Name	Test Description	Required	Test Status	VR Status	VR Sign Off(s)
1 Linearity	Linearity 40%-160%	✓	Test Complete	✓	
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Data Attached to Selected Test

Sample Set Method	SSM Id	SSM Status	SSM Approval	SS Id	SS Status	SS Approval	RS Id	RS Status	RS Sign Off(s)
1 Caffeine Sample Set	1007	✓		1009	✓		1223	✗	

Empower Coffee Break

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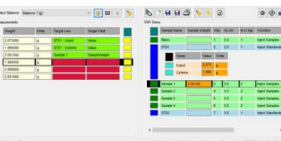
Alliance iS HPLC System & Empower
Reduce human errors, simplify usage, for improved performance



#14 - Reducing Human Errors

VIDEO

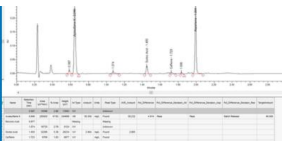
This session shows how to minimize risk, streamline workflows and improve the reliability of your analytical measurements.



#13 - Sample Weights in Empower

VIDEO

In this session we show different options to transfer sample weight to Empower



#12 - Empower Custom Fields

VIDEO

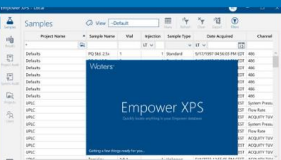
In this session we demonstrate how to create and use Customer Fields to generate workflows in Empower



#11 - Empower LMS Inventories

VIDEO

In this session we show you how you streamline your documentation and replace paper by electronic recording



#10 - Empower search tool

VIDEO

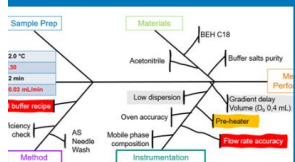
Discover a new tool for multi projects search in Empower. This session shows you how you can use a new tool for answering questions that took a lot of effort...



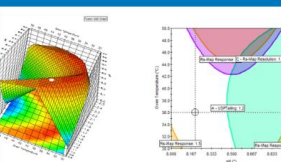
#9 - How can Waters help you with Compliance / Data Integrity

VIDEO

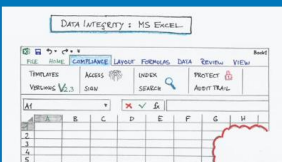
In this session we check the latest features and additions to Empower in relation to Compliance and Data Integrity.



#8 - USP 1220 & ICH Q14-Q2(R2) Part II - Validation & Verification



#7 - USP 1220 & ICH Q14-Q2(R2) using Empower - Part I Development



#6 - Excel and Compliance in Empower LMS

[Webinar Series] How about a 20 minute coffee break along with a bite of Empower?

Elevate your Empower CDS to the next level. Learn in different webinars how additional modules and features can help you to get the most out of Chromatography Data System.

This is the landing page to get access to future and recorded webinars as well as useful links to other resources.

Watch Now

Future Sessions & On Demand Recorded Sessions

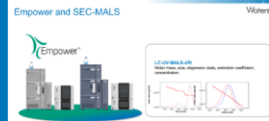


Webinar Registration

Next episode: coming soon

WEBSITE

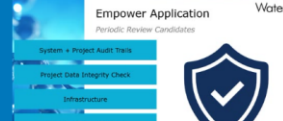
#staytuned



#28 Empower with MALS

VIDEO

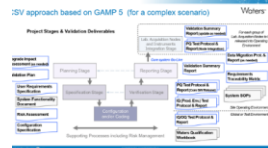
Users of DAWN™ and miniDAWN™ instruments can now take full advantage of Empower's compliance-ready environment for robust characterization and quality control



#27 Empower Message Center Insights

VIDEO

This session is designed for IT professionals looking to strengthen system performance through strategic software reviews.



#26 Computer System Validation

VIDEO

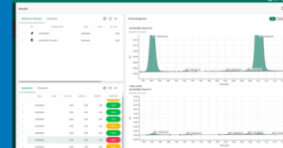
Maintaining compliance in regulated environments requires a strategic approach to Computer System



#25 Empower LMS

VIDEO

FAIR data with Empower LMS - (F)indable - (A)ccessible - (I)nteroperable - (R)eusable



#24 Empower Data Viewer

VIDEO

Empower Data Viewer brings AI/ML into your Laboratory. The Anomaly Detection Module



Ďakujem za pozornosť!

Waters™