Empower 3
Feature Release 2

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Nordic User Training 2013
Empower 3 Feature Release 2

- Platform Support Updates
- Updated User Interface & Software Usability Workflow Enhancements
- Mass Spectrometry & Method Validation Manager Enhancements
- Result Audit Viewer
- Empower Software Labo
- Empower Mobile
## Support for Updated & New Platforms

<table>
<thead>
<tr>
<th>Year</th>
<th>Platform</th>
<th>Version</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>Empower 2</td>
<td>FR3</td>
</tr>
<tr>
<td>2007</td>
<td>Empower 2</td>
<td>FR4</td>
</tr>
<tr>
<td>2008</td>
<td>Empower 2</td>
<td>FR5</td>
</tr>
<tr>
<td>2010</td>
<td>Empower 3</td>
<td></td>
</tr>
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<td>2011</td>
<td>Empower 3</td>
<td>SR1</td>
</tr>
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<td>2012</td>
<td>Empower 3</td>
<td>FR1</td>
</tr>
<tr>
<td>2013</td>
<td>Empower 3</td>
<td>FR2</td>
</tr>
</tbody>
</table>
Empower 3 FR2 Architecture

Technology:
- Oracle 11g(11.2.0.2 Patch set 15) R2 Database (64-bit)
- Windows 2008 R2 Server **Standard*** or Enterprise (64-bit)
- Windows 7 Professional & Enterprise Operating System (64-bit)
- Windows XP Operating System (32-bit) (clients and LAC/Ess)
- Citrix XenApp Server 6.0 /6.5* running on Windows Server 2008 R2 Standard or Enterprise, 64-bit
- Sun Solaris 10 (requires Oracle 11.2.0.3)
- **VMWARE vSphere 5.0 & 5.1***
- **Red Hat Linux Enterprise 6.2*** (requires Oracle 11.2.0.3)

*Bold new for FR2
Usability
Multiple User Interfaces
Show Me... Help in QuickStart

How To...

Perform sample operations
  » Run samples
  » View and process samples
  » Report samples
  » Export and e-mail samples

Perform other procedures
  » Create or Modify a method
  » Manage Empower
Run Samples: Go from Monitor to Start

No need to stop monitoring to go into “Run”
Save Instrument method with Method Set

New
Open...
Save
Save As...
Save with Method Set...
Exit
Navigating the Project Folder

Sample Sets  Injections  View As Previous Jobs

Back/Forward commands new in Feature Release 2

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Maintaining Queued Sample Sets after Instrument Failure or Abort

- Queued Sample Sets stored after instrument failure
- The queued Sample Sets are saved and checked as “dormant”
  - Will automatically be re-queued and run after system is ready
  - Can also select “preserve queue and pause” when aborting
Processing and Review
New Capability - 2 different detector channels e.g. UV and Fluorescence data processed as into a single derived channel.
Processing Method Wizard now includes System Suitability

New in Feature Release 2
RRT Enhancement

- The ability to name peaks based on RRT, not RT. Define components based on RRT, relative to the main component(s) specified in the RT Reference field on the 'components' tab of the processing method screen.
Once the RRT is specified, new peaks can be tabulated

### Component Results

**Component Summary For % Adjusted Area**

<table>
<thead>
<tr>
<th>Sample Name</th>
<th>Time Pt</th>
<th>RRT 0.623</th>
<th>RRT 0.650</th>
<th>RRT 0.701</th>
<th>RRT 0.955</th>
<th>RRT 0.961</th>
<th>RRT 1.190</th>
<th>RRT 1.216</th>
</tr>
</thead>
<tbody>
<tr>
<td>LN XR1582 Time Pt 1</td>
<td>30</td>
<td>0.047</td>
<td></td>
<td>0.021</td>
<td>0.017</td>
<td>0.021</td>
<td>0.028</td>
<td>0.017</td>
</tr>
<tr>
<td>LN XR1582 Time Pt 2</td>
<td>60</td>
<td>0.086</td>
<td></td>
<td>0.021</td>
<td>0.018</td>
<td>0.023</td>
<td>0.037</td>
<td>0.027</td>
</tr>
<tr>
<td>LN XR1582 Time Pt 3</td>
<td>90</td>
<td>0.161</td>
<td></td>
<td>0.020</td>
<td>0.019</td>
<td>0.021</td>
<td>0.027</td>
<td>0.016</td>
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<td>LN XR1582 Time Pt 4</td>
<td>120</td>
<td>0.313</td>
<td></td>
<td>0.020</td>
<td>0.018</td>
<td>0.020</td>
<td>0.033</td>
<td>0.025</td>
</tr>
<tr>
<td>LN XR1582 Time Pt 5</td>
<td>180</td>
<td>0.616</td>
<td></td>
<td>0.020</td>
<td></td>
<td></td>
<td>0.033</td>
<td>0.025</td>
</tr>
<tr>
<td>LN XR1582 Time Pt 6</td>
<td>240</td>
<td>1.239</td>
<td></td>
<td>0.021</td>
<td></td>
<td></td>
<td>0.035</td>
<td>0.021</td>
</tr>
<tr>
<td>LN XR1582 Time Pt 7</td>
<td>300</td>
<td>1.768</td>
<td>0.016</td>
<td>0.019</td>
<td></td>
<td></td>
<td>0.031</td>
<td>0.017</td>
</tr>
<tr>
<td>LN XR1582 Time Pt 8</td>
<td>360</td>
<td>1.824</td>
<td>0.018</td>
<td>0.021</td>
<td></td>
<td></td>
<td>0.032</td>
<td>0.018</td>
</tr>
</tbody>
</table>

**New in Feature Release 2**
Minimize Clicks – Make Changes to Processing Method in Main Window

- Edit and Delete Integration events graphically (not just Add)
Minimize Clicks – Make Changes to Processing Method in Main Window

- Undo and Redo Integration – easily test out different settings

- Update Review Sample Sets or Result Set as injections complete
Component Editor – Displays Sample Type and ID, also new Purity Field

- Component Editor shows Sample Type and ID
- Purity Value corrects amount for standard potency

Example:
Std is 90% pure
Amount = Value * Purity
Amount = 80.22*90/100
= 72.198 µg/mL

Sample Amounts will be calculated using 72.198 µg/mL

New in Feature Release 2
Enhanced Data Review
New Result Audit Viewer (RAV)

Result Table
Result Audit View Tabs
View Differences
After this date
## Enhanced Data Review

New Result Audit Viewer (RAV)

### Result History

<table>
<thead>
<tr>
<th>Result Id</th>
<th>Result Id (Result)</th>
<th>Result Id (Sample Set)</th>
<th>Result Id (Sample)</th>
<th>Result Id (User)</th>
<th>Result Id (Source)</th>
<th>Result Id (Action Type)</th>
<th>Result Id (Reason)</th>
<th>Result Id (Details)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2191</td>
<td>1050</td>
<td>2121</td>
<td>Blank</td>
<td>B, E</td>
<td>N/A</td>
<td>Created Calibration</td>
<td>Failed my data</td>
<td>Details: System ACQUITY1 Method: Soft Drink Analysis: Channel: ACQUITY TUV OVA: Calibration: 2191</td>
</tr>
</tbody>
</table>
| 2193      | 1072               | 2121                   | Sys Bull          | E, A            | N/A               | Created Result Set     | Failed my data     | Details: System ACQUITY1 Method: Soft Drink Analysis: Sample Method: Soft Drink Analysis: Sample Set ID: 2121 | Sample Set Method: 

For Help, press F1
Differences in the results are in blue. Results outside limits are in red.

Manual integration noted in Integration Type field.

New in Feature Release 2
ICH Impurity Processing
ICH Impurity Processing

- Provide a New type of group peak, Impurity Group, used to calculate Total Impurities and other user defined impurity summaries.
- Total Impurities (automatically created group peak).
- Unidentified Impurity (default impurity component type).
- Maximum Impurity (new Boolean peak field).
- Add the ability to set an acceptance criteria of ‘no impurity peak found’.
- The user can select whether the total impurities determined should be the sum of Amount, Concentration or Corrected Area % or peak custom field
- Sum total of degradation products
- The user can specify which component types should be summed (some impurities will be known and hence will use a user-defined component type, other impurities could be quantitated by default and hence be automatically defined as Unnamed Impurities)
Include ICH Limits

ICH Processing Limits

<table>
<thead>
<tr>
<th>Reporting Threshold</th>
<th>Identification Threshold</th>
<th>Qualification Threshold</th>
<th>Maximum Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.050</td>
<td>0.5</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.5</td>
</tr>
</tbody>
</table>

Maximum Impurity Observed for Every Time Point

<table>
<thead>
<tr>
<th>Sample Name</th>
<th>Peak Name</th>
<th>RT</th>
<th>Area</th>
<th>Impurity Response</th>
<th>ICH Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>LN XR1582</td>
<td>Impurity E</td>
<td>3.066</td>
<td>2547</td>
<td>0.225</td>
<td>Above Reporting Threshold</td>
</tr>
<tr>
<td>LN XR1582 Time Pt 1</td>
<td>Impurity E</td>
<td>3.065</td>
<td>6642</td>
<td>0.562</td>
<td>Above Identification Threshold</td>
</tr>
<tr>
<td>LN XR1582 Time Pt 2</td>
<td>Impurity F</td>
<td>2.103</td>
<td>2306</td>
<td>0.218</td>
<td>Above Reporting Threshold</td>
</tr>
<tr>
<td>LN XR1582 Time Pt 8</td>
<td>Impurity F</td>
<td>2.102</td>
<td>46872</td>
<td>4.900</td>
<td>Above Qualification Threshold</td>
</tr>
<tr>
<td>LN XR1582 Time Pt 9</td>
<td>Impurity F</td>
<td>2.102</td>
<td>53894</td>
<td>4.012</td>
<td>Above Qualification Threshold</td>
</tr>
</tbody>
</table>
ICH Impurity Processing

The image shows a software interface for ICH Impurity Processing, which includes fields for specifying impurities, adjusting total areas, and setting thresholds for reporting, identification, and qualification. The interface also allows for the calculation of total impurities and maximum impurity thresholds.

### Specified Impurities

<table>
<thead>
<tr>
<th>Component Name</th>
<th>Reporting Threshold</th>
<th>Identification Threshold</th>
<th>Qualification Threshold</th>
<th>Total Impurity Threshold</th>
<th>Maximum Impurity Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

For Help, press F1.
Automatically Calculate Impurity Values

Custom calculation
Mass Spec Analysis
Mass Analysis Window

UV and MS spectra visible in one view

UV peaks labeled with m/z
MS Enhancements

- Allow users to identify the same component in a PDA channel and in a MS channel using one processing method.
- Add the ability to place the MS mass labels on the UV chromatogram and spectra in both the chromatogram and spectral plots in Review and Report Publisher.
- Add the ability to overlay MS and UV Chromatogram channels without needing to first process the data.
- Add offsets to processing method so the data can be properly aligned.
- Add the ability to determine the monoisotopic mass from the empirical formula and extract based on formula and m/z.
- PCS 29505- Add an improved Library searching/Matching capability. Users will need to create their own libraries and search and match against them.
MS Enhancements

- PCS 29505 - Add an improved Library searching/Matching capability
- PCS 43819 Ability to Report the Relative Intensity of an Isotope Peak.
- Use proper Processed Channel Descriptions for MS data. Example: ES+ or ES- + Cone Voltage + Mass Range, CODA and 3D Blank Subtract.
- PCS 47008: Channel Descriptions from Extracted 3D Channels.
- PCS 44100 and 44313: Fix Cross Channel Quantitation with Curve Reference
- Add the ability to automatically detect all masses present by cleaning up the noise in MS data using CODA
- MS Visualization Window. Allow the UV and MS spectra for each peak to be evaluated in the same window without the need to process.
- PCS 40908, 45573 Provide the ability to do automatic 3D noise subtraction from mass data as a batch processing method.
Mass Channel Processing

- Automated 3D Blank Subtract
  - Allows for batch processing

- CODA for improving TIC trace s/n

New in Feature Release 2
Method Validation Manager
Method Validation Manager

- Allow the user to select **one factor at a time** (PCS 42818, 45081) instead of the existing multi-factor DoE when doing a robustness study.

- PCS 46855 – Evaluate Intermediate Precision/repeatability per **Japanese MHWL guidance** by adding “day” as a factor.

- PCS 40943 – Allow for **grouped peaks** for all validation tests.

- PCS 39152 – Add the ability to **set acceptance criteria** on peak and result fields.

- Validate Compendial procedures per **USP <1225> and ICH Q2(R1)** by including handling of matrix, excipients and peak purity data in stress studies.

- PCS# 40470, 42272, 39018, 42271, 40505, 42717 Verify **Compendial procedures per USP <1226>>**.

- PCS 40769 – Validate methods per the **USP Medicines Compendium Chapter <10>**.

- Reporting Criteria: Add the ability to **report both relative criteria and absolute acceptance criteria** with the values that have the criteria.

- PCS 39883, 41430 Multiple Channels – Ability to add a Channel field to the component type tables for all non-multichannel tests.

- PCS 42887 Multiple Injections: In the Validation Protocol Method, add the ability for the user to control how averaging takes place when multiple injections and or multiple preparations are performed.

- Allow validation projects to be used in **QuickStart.**
Method Validation Manager

- **PCS 39018**, – Any **Empower peak** and **result field** should be available to be an **assessed field** and held to acceptance and relative acceptance criteria
- **PCS# 41380** Allow user to **choose which columns to display in ANOVA tables** in Report Publisher and Validation Review
- **PCS 42191, 45864, 45885** Add logic so that the **Level Values will be sorted numerically**
- **PCS 39096** Pass Validation Test Field: add a **field called Pass Validation Test**.

- **PCS 41984** Overall Study Status: In the Overall Study Status field within Validation Manager, change the status of Study Complete to either ‘Study Complete – All Tests Pass Acceptance Criteria’ or ‘Study Complete with exceptions’
- In a report method, allow the user the ability to **suppress messages** appearing on the report indicating that groups on the report not matching the type of data used to create the report
- **PCS 40622** – Correct Y axis overlay label for all tests
- **PCS 42065, 42067** – Add Component type field to the Acceptance Criteria per Component Type table.
PCS 41003 – For Impurities, have a threshold value that could be Area, Concentration, x value, or all real custom fields.

PCS 42066 – For Impurities, **RRF should be Relative to the Main Component.**

PCS 41076 – For stability and filter validation, add **peak type and all peaks to the relative peak table**

PCS 41258 – For stability and filter validation, calculate the **% change, relative % area and relative % recovery** to the reference.

PCS 40819, **Incorporate ICH Impurities/ USP Related Substances functionality.**

PCS 440432, 40433 – Correct **Japanese translations** for significant level and validation process.

PCS 40561, 40615, 40983 – Allow for **assessing linearity with a quadratic fit** (expect to fail).
Specify Channel

Channel list taken from channels in the project
Allows for grouping based on Sample Matrix

List may be altered based on default strings
New Choices for Assessed Field

for Stability, Filter Validation and Specificity
Enhanced Specificity

Can use PDA peak purity results
Suppress Data Mismatch

New in Feature Release 2

Suppress Errors
- Suppress data mismatch and wrong chrom channel type errors
Administration
User Management: View Current Users, Their Full Name and Status

![User Group ANDA Properties](image)

<table>
<thead>
<tr>
<th>Member</th>
<th>User Name</th>
<th>User Status</th>
<th>User's Full Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>System</td>
<td>Active</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>TuckerT</td>
<td>Active</td>
<td>Tom Tucker</td>
</tr>
<tr>
<td>3</td>
<td>mcsweenr</td>
<td>Active</td>
<td>Romuald McSweeney</td>
</tr>
<tr>
<td>4</td>
<td>stumpfc</td>
<td>Active</td>
<td>Chris Stumpf</td>
</tr>
</tbody>
</table>
Qualification Update

Batch Mode SQT:

New in Feature Release 2
Waters Empower Mobile provides mobile access to targeted Empower functionality for specific users, tasks and workflows.

**BENEFITS OF EMPOWER MOBILE**

- Increase laboratory efficiency
- Increase staff flexibility
- Easily find and share results remotely
- Expedite workflow for signoff on reports
- Lower operating costs for system administration tasks

New in Feature Release 2
General Look and Feel

- Title [Details]
- Back button
- Current information or records
- Refresh button

Top level navigation menu:
- Systems
- Results
- Administration
- Messages

‘Overflow’ menu:
- Configuration
- Help
- Community
- Sign out
Empower 3 Software Laboratory Analytics

- Empower 3 Software Laboratory Analytics offers five prebuilt dashboard types:
  - System summary
  - System usage
  - Project usage analysis
  - User analysis (optional)
  - Methods analysis

**EMPOWER 3 LABORATORY ANALYTICS LETS YOU**

- Access critical system usage information
- Maximize system utilization
- Manage resources
- Identify training needs
- Identify error messages that affect your workflows
- Identify non-robust processing methods
- Plan for capital expenditures
- Identify opportunities to shorten run times with UPLC® technology
Instrument Control
Usability enhancements-Agilent 6890 GC

- Enable the COM ports to allow control of the 6890
- Add the 7693A ALS auto-injector to the 6890

Empower 2 FR2
Usability enhancements—Agilent 6890 GC

- Ability to view syringe size for the complete injected sample set run

- This information will be available in report publisher as injection fields or in the acquisition log.

Field name

- syrInfoGC: Use parameters to check for injection volume
- syrSizeA: Syringe A (Front Injector) Size
- syrNanoA: Syringe A (Front Injector) Nanoliter Adapter
- syrSizeB: Syringe B (Back Injector) Size
- syrNanoB: Syringe B (Back Injector) Nanoliter Adapter

[Image of GC Syringe Size Parameters dialog box]
Waters
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