UNIFI™ 1.5 Scientific Information System for Regulated Bioanalysis

Waters Deminar
June 2012
Waters Regulated Bioanalysis System Solution

Sample Preparation Solutions
• Best in class

ACQUITY UPLC® I-Class
• The fastest and most resolving LC without compromise in robustness

ACQUITY UPLC Columns
• Different choices for best performance

® TQ-S
• Most sensitive MS

UNIFI
• Compliance-ready
• Interactive workflow-driven data platform

Service
• Installation, maintenance & training
• Compliance services
What is UNIFI?

- **A single software platform** that unites our end-to-end system solutions; instrumentation, separations chemistry, methods, reporting templates, and support

- **A single informatics solution for chromatography and mass spectrometry** that simplifies method transfer, minimizes training and improves collaboration

- **Elegant user interface** adjusts to roles and capabilities of users; tailored to workflows and maximizes system usability

- **Industry leading security, compliance configurations;** built in change control tools for the regulated or non-regulated laboratory

- **Scalable, open architecture** provides a future proof system solution that can grow as your needs grow
A task based, work-flow oriented application that unites our end-to-end system solutions
N-tier architecture

PORTAL CLIENT

APPLICATION LAYER
- Reporting
- Data Processing
- Event Center
- Audit Trails
- Document Approval
- Security

ACQUISITION CONTROL
- Xevo TQ-S

DATABASE
N-Tier Deployment

- Layers define logical not physical separation
  - Layers can be physically deployed as necessary to meet system requirements
    - i.e. Workstation or Enterprise
- Allows to scale UNIFI based on customer needs
  - No code changes required
  - Reduces evaluation effort
- UNIFI Installation
  - Always has Single Logical Database and Business Layer
Scalable, open architecture allows for future growth and sharing of information.

Purpose built Application Workflow and Configurable Security

All components on a single secure workstation
Scalable, open architecture allows for future growth and sharing of information

Enables Managed Information Sharing & Simplifies Compliance Efforts

Client PC
Presentation Layer
Client PC
Presentation Layer
Client PC
Presentation Layer
Capture Agent
Laboratory Network Device
Instrument Control

<< LABORATORY NETWORK >>

Secure Data Center
Server
Business Layer
Database Layer
Laboratory Network Device
Instrument Control
Portal Client Deployment

- Minimize Client Footprint
  - Portal Client only
    - Mostly graphical display
    - Reduce End User Software Validation concerns
      - No Data Processing is performed within Portal Client
      - No settings or data stored locally

- Portal Client software automatically deployed as needed –
  - “Trickle Down” using tested executable
  - Built in check process
Localized language support facilitates business globally
From Wikipedia, the free encyclopedia

A workflow consists of a sequence of connected steps. It is a depiction of a sequence of operations, declared as work of a person, a group of persons, an organization of staff, or one or more simple or complex mechanisms.
Simple Bioanalysis Workflow

1. Search for reference document
2. Review quality specifications
3. Develop validated method
4. Review batch results of validated method
5. Verify critical quality criteria
6. Review, sign & release
Search for Reference Document

Step 1
Search for Reference Document

Step 2
Role: Developer, Michelle [Method Developer]

Step 3
Search

Step 4

Step 5

Step 6

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Review Quality Metrics in Regulatory or SOP Documents

B. Accuracy, Precision, and Recovery

The accuracy of an analytical method describes the closeness of mean test results obtained by the method to the true value (concentration) of the analyte. Accuracy is determined by replicate analysis of samples containing known amounts of the analyte. Accuracy should be measured using a minimum of five determinations per concentration. A minimum of three concentrations in the range of expected concentrations is recommended. The mean value should be within 15% of the actual value except at LLOQ, where it should not deviate by more than 20%. The deviation of the mean from the true value serves as the measure of accuracy.

The precision of an analytical method describes the closeness of individual measures of an analyte when the procedure is applied repeatedly to multiple aliquots of a single homogeneous volume of biological matrix. Precision should be measured using a minimum of five determinations per concentration. A minimum of three concentrations in the range of expected concentrations is recommended.
Develop a Validated Method; In This Case the Matrix Effect Analysis

Sample list configured for a post column infusion matrix effect analysis

Step 1: Sample list configured for a post column infusion matrix effect analysis
Step 2: Start running samples
Step 3: Sample list configured for a post column infusion matrix effect analysis
Step 4: Start running samples
Step 5: Sample list configured for a post column infusion matrix effect analysis
Step 6: Start running samples
Review Batch Results; Look for Quality Issues

Batch quality easily assessed

Tools determined by Role

Chemist, Mary [Routine Analysis]
Verify Critical Quality Criteria

Configure Tools to look at critical criteria such as LLOQ automatically
Electronically Review, Sign and Release

Step 1

Step 2

Step 3

Step 4

Step 5

Step 6

Role

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Schematic Workflow for MassLynx 4.1 XML LIMS Interface

MassLynx

• QLD

Pull all data into memory

• XML

ML 4.1 XML LIMS Interface

Push to Watson IM Integration Point

• XML

Thermo Integration Manager

Converted by Watson IM

• LML

Watson LIMS Filter

• Pull into Watson Study

Watson LIMS
Integration with WATSON LIMS

Use Thermo Integration Manager

Will work with all Waters Software
Should work with multiple Thermo LIMS

Watson will provide validation of interface
Thermo Integration Manager with UNIFI

**UNIFI Database**
- UNIFI
- Built in LIMS Interface
- Run and Process Sample Set
  - UDF

**Thermo Integration Manager**
- Create Sample List
- Collects Results
  - XML

- Convert S List
  - Converted Results
  - LML

**Watson LIMS**
- Pull into Watson Study

**Watson UNIFI Filter**
UNIFI Workflow with Watson LIMS

1. Create Analysis from LIMS Sample List
2. Review Results and Verify Quality Measures
3. Electronically approve the batch result report
4. Select batch result analysis for export
5. Verify batch selection then export
Create Analysis Then
Pick a Sample List

Step 1
Step 2
Step 3
Step 4
Step 5
Review Results and Verify Quality Measures
Electronically Approve the Batch Result Report

Step 1

Step 2

Step 3

Step 4

Step 5
Select the Batch Result Analysis for Export

Step 4
Verify Batch Selection
Then Export

Thermo Scientific Watson LIMS™
LIMS for Bioanalytical Laboratories

Step 1
Step 2
Step 3
Step 4
Step 5
How Does UNIFI Help the Customer with Productivity?

- Scalable, open, enterprise architecture provides
  - protection of data,
  - sharing and re-use of information and
  - reduces the cost of change

- Built in Oracle Database
  - Secures records
  - Permits storage of Office or PDF documents such as SOPs
  - Allows you to search and retrieve data quickly

- Single software platform, easily learned once and expanded as desired

- Purpose built work flows/tools for:
  - Secure connection to Watson LIMS
  - Matrix Effect Analyses
  - Batch Quality Analysis/Review
Future of UNIFI and existing solutions

Current Portfolio
- EMPOWER
- MASS LYNX
- SDMS NuGenesis

Business Continuity:
Support → Revenue

Acquity/Xevo ToF
- LC Software
- MS Software
- SDMS

Software Unification:
Prove model

LC/MS configurations
- LC Software
- MS Software
- SDMS

Expand Footprint/
Small Network
Prove scalability & standards viability
Open Architecture
Instruments central → data acquisition

Workstation
- Workgroup
- Expansion of System Solutions → Applications & Instruments

WorkStation
BioPharm System Solution

Enterprise System
Data migration to single platform

Multi-vendor
- LC Software
- MS Software
- SDMS

Enterprise Implementation:
Personalization
More than 10 workgroups
Global

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What Will YOU Do With

No compromises.
More Choices

Focus on Science

Leverage Technology
in real time

Invest for today
and future

Partnering for the complete solution