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# Managing the eLife-cycle of your CDS data

75 Jaar 1939 2014 kvcv


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# Agenda

- Waters Informatics
- Empower 3 CDS
- NuGenesis SDMS
- Managing the eLife-cycle of your Empower data
- Case study

  NuGenesis SDMS bij Centraal Laboratorium van **Covestro N.V.** te Antwerpen
- Questions

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# Customer Success is our Mission!

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- Established in 1958
- $1.85 billion in annual revenue
- Publicly traded (NYSE:WAT)
- Multiple manufacturing and distribution centers worldwide
  - All facilities are cGMP-compliant
  - ISO 9001-2000 certified
- 2000 Direct sales/service personnel in 97 offices serving 54 countries worldwide
- 5,900 employees with an average of 10 years of service

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# Technology Portfolio + Expertise

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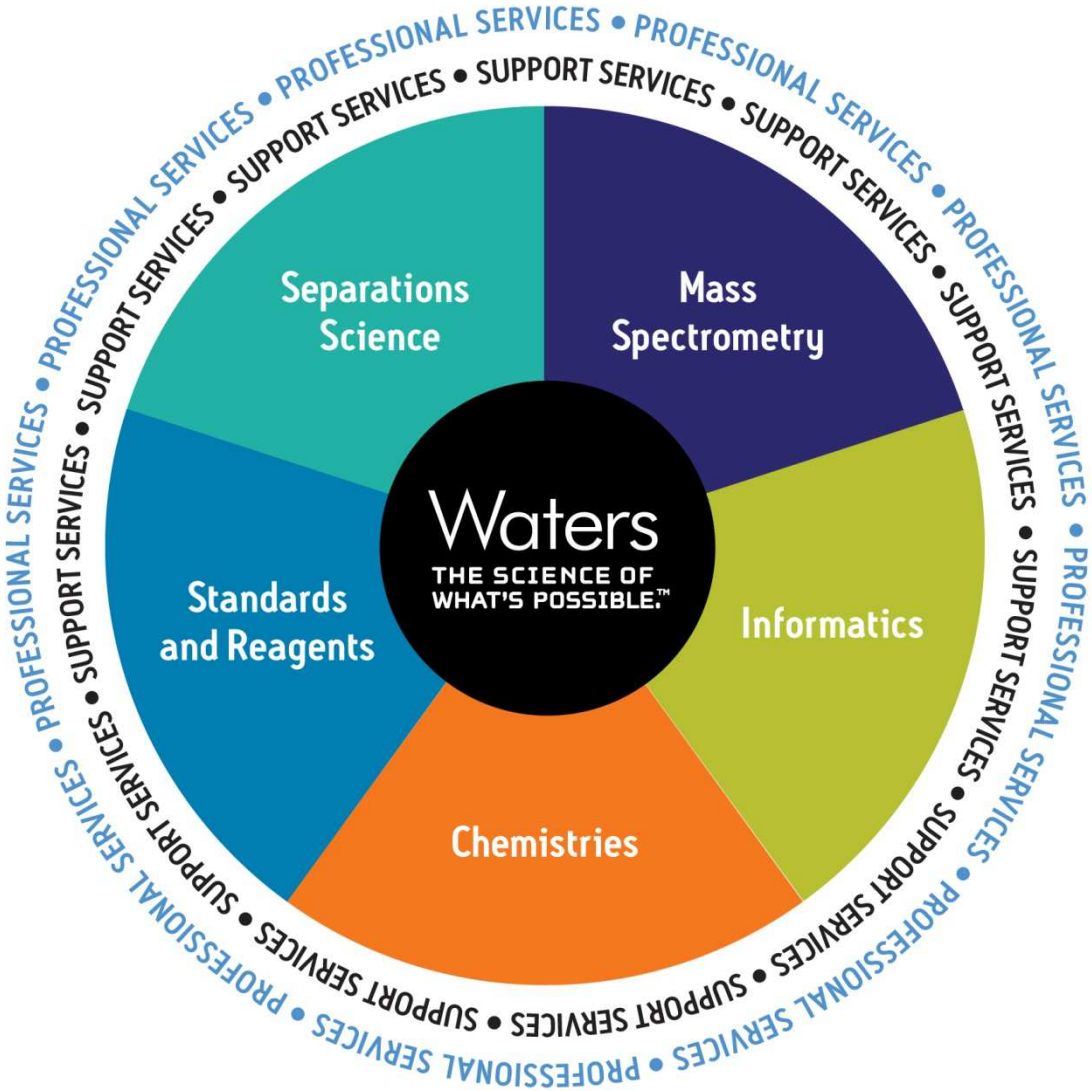


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# Waters Belgium

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- 45 people working from office in Brussels (Zellik)
- Waters key contacts in Vlaanderen

**Gert Martens**
Accountmanager

**Kim de Kock**
Accountmanager

**Frederic Delaruelle**
Laboratory Informatics Sales

**Evelien Dejaegere**
Accountmanager Consumables

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# Waters Laboratory Informatics

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- Laboratory Informatics development and service centers:
  - Milford, MA, USA - Frechen, Germany
  - Manchester, UK - Brasov, Romania

- Metrics on our division
  - # Employees .....550
  - # Networks
    - Empower.....4000
    - NuGenesis .....500
  - # Licenses .....450,000

Waters Corporation
Milford, Massachusetts, USA

Waters Center of Excellence
Manchester, England

Waters Development Center
Frechen, Germany

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# [inform] 2016 – Save the Date!

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**WHEN:**
May 17–20

**WHERE:**
Sheraton Lisboa Hotel, Lisbon, Portugal

## Maximize the value of your Waters' software

Choose from over **35 workshops**, tutorials, partner sessions, and plenary presentations on Empower, NuGenesis LMS, UNIFI, Regulatory Compliance, System Administration & Integration, and more.

## Why Attend?

- Influence future product features and direction through direct contact with our product management team.
- Network with colleagues, share experiences and knowledge, and pick up helpful tips from other Waters software users.
- Meet with Waters experts – interact with our technical teams in the workshops or schedule a one-on-one session to discuss your individual software needs and requirements.

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Accurate, rapid decision making

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Greater scientific insight

Easier collaborations

Laboratory efficiency

Shorter time to market

Less waste and lower costs

Connecting lab and business

# [re]imagine...

Fewer errors

Information accessibility

Meeting regulatory requirements

Ensuring product quality

Streamlined workflows

User personalization

Analytical effectiveness

Software integration and standardization

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Empower 3

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*Chromatography Data Software*

# Eliminate Risk in your Chromatography workflow

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Empower 3

- Market leading CDS worldwide - corporate standard for instrument control, data acquisition, processing and reporting
- Success based on several key attributes
  - Flexible and easy to use
  - Data management with embedded relational database
  - Expanded portfolio for instrument control
  - Most comprehensive compliant ready solution
  - Integrated advanced detection and application specific software
  - Enterprise scalability

Empower™ 3

Empower 3

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# Standardize on one CDS

- Standardized Data format
  - Exchange of information easier
  - Reduced time for Review and sign-off
- Reduced Training Effort
  - Training required for only 1 software package
- Improved Data Integrity & Compliance
  - Relational database provides better traceability
  - Eliminate excel for processing
- Promotes Collaboration
  - Sharing methods easier
  - Data review from different geographies possible

Empower 3

# From Personal to Enterprise

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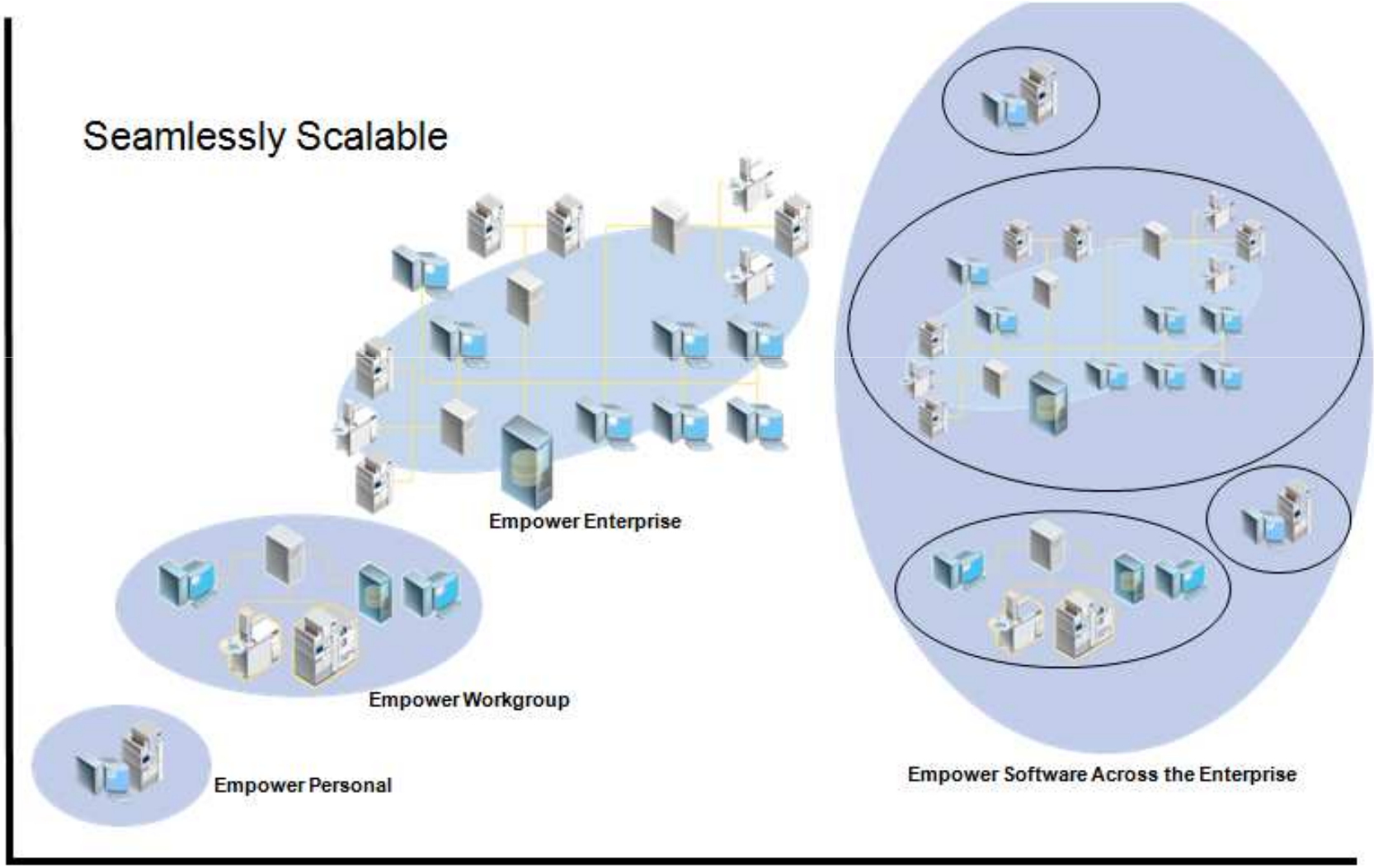

Empower 3

# Advantages network based CDS

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- Globalization of Operations
  - Centralization & Harmonization IT systems
  - Increased flexibility
- Cost Reduction
  - Centralized Administration & Data Management
  - Lower Requirements for computer hardware
  - Qualification & Validation
  - Rapid Deployment & Easy Upgrade
- Integration with other software
  - SDMS, ELN, LES and/or LIMS
  - Eliminate Manual Transcription
  - Optimize Review & Approval process
- Security & Traceability
  - Paperless initiatives (eSignature)

# Data Traceability & Integrity

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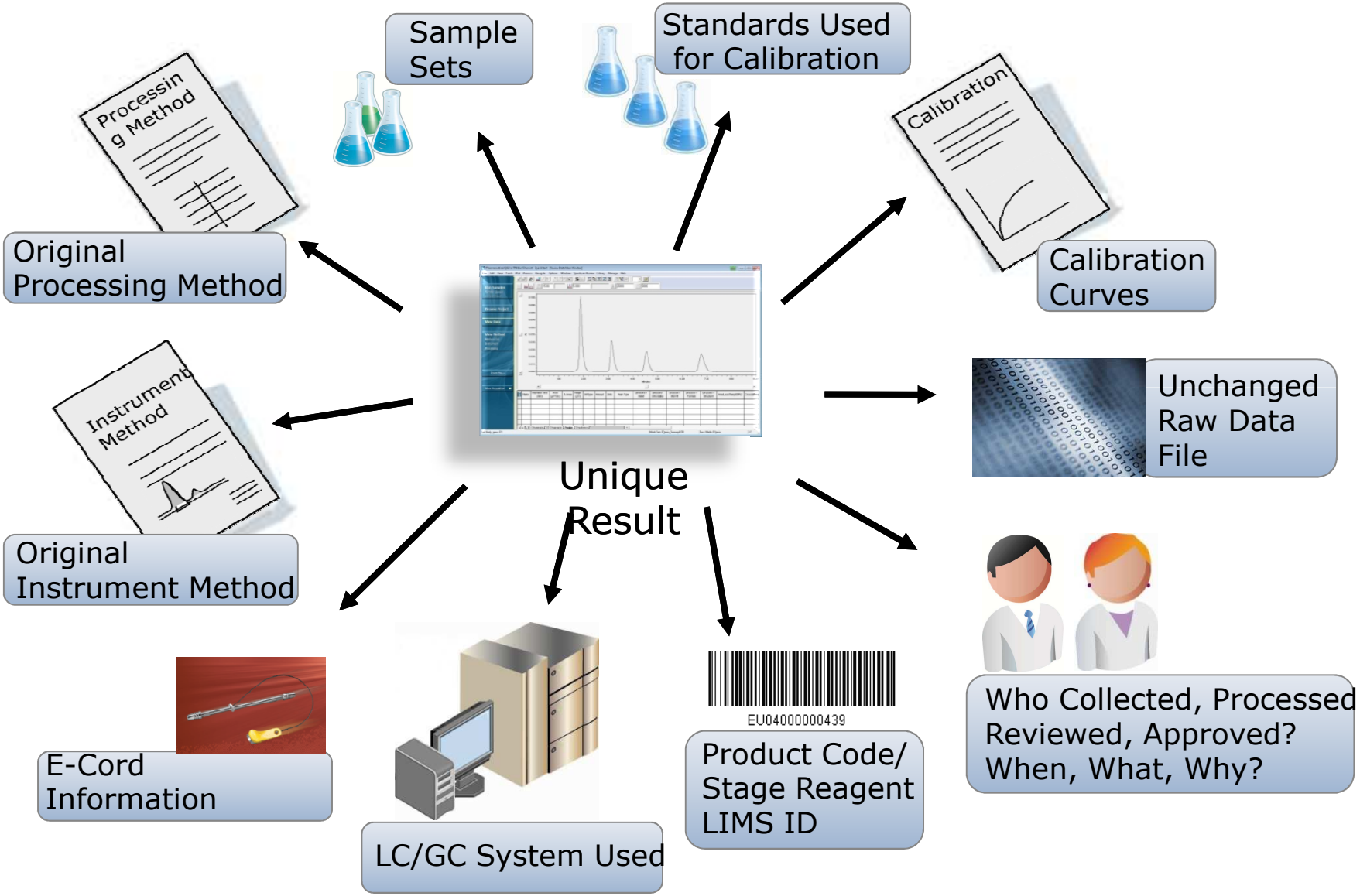

# Single User Experience for Equipment from Many Vendors

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Empower 3

All Major HPLC

QDa, SQD, TQD

All Major GC

Empower® 3

UPLC

UPC²

APC

PATROL

CE

Dissolution

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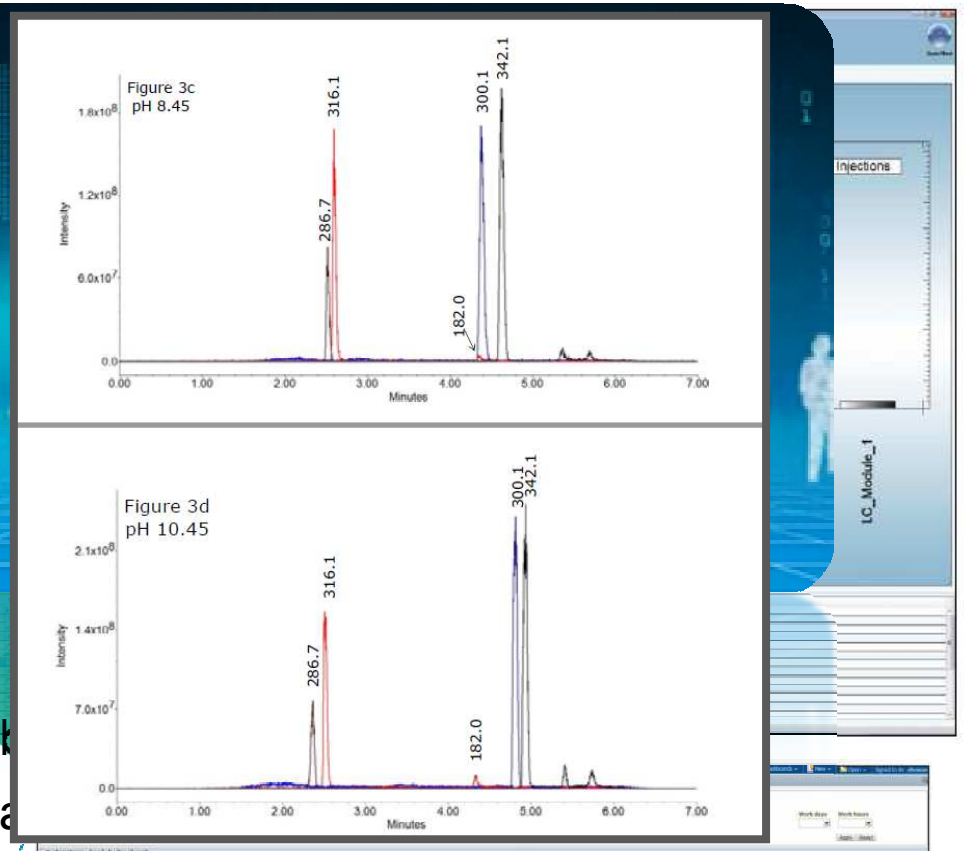
# Empower 3

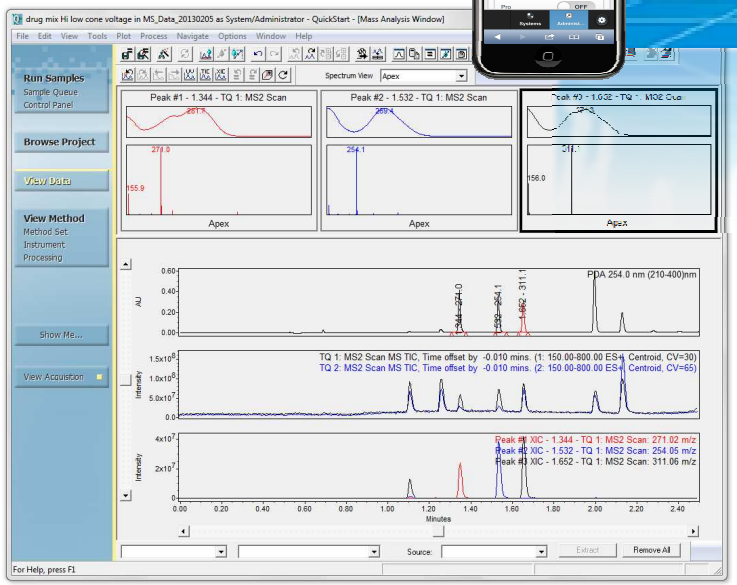
## Analytics

Mass Spectron

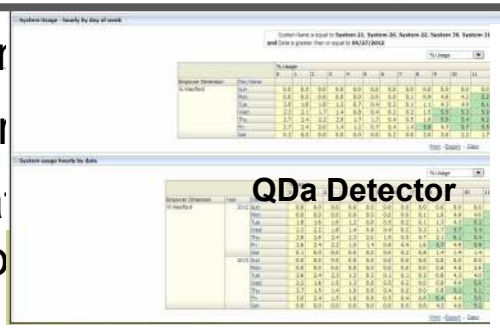
**MS Peak Tracking**




**Empower Laboratory Analytics**




**Mass Analysis Window**



**QDa Detector**

**Empower Driven Services 365**

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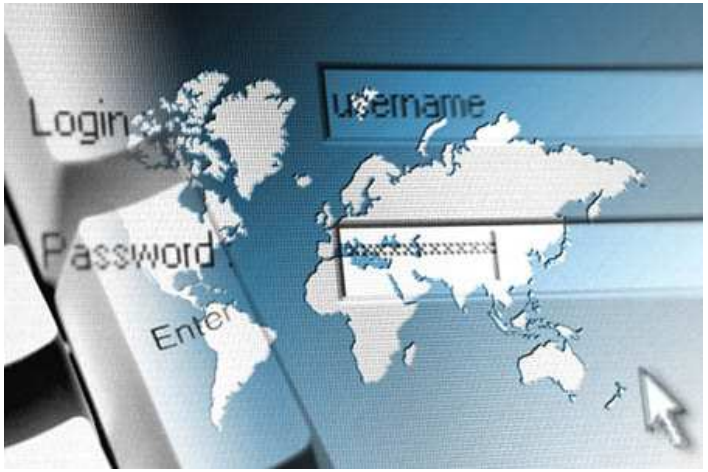
Quality & Traceability

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## Easily Configured for GxP Use in Your Lab

- Advanced Transaction Safeguards
- Granular User Privileges
- Electronic Record Controls
- Electronic Review & Signature Controls
- Embedded Suitability Calculations
- Audit Trails

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Regulatory Compliance

- Increase efficiency and reduce compliance risks
  - Supporting data integrity with leading security features
  - Facilitating audit-readiness, traceability, and eData review
  - Supporting data authenticity through eSignature workflows
  - Eliminating risks of spreadsheet-based calculations
  - Leveraging well-established technologies to facilitate validation
- Empower's compliance-minded design affords decreased reliance on procedural controls.

# NuGenesis SDMS

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# NuGenesis SDMS Patented Technology

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NuGenesis SDMS

## File Capture

- NuGenesis File Capture is a means of collecting files from instruments
  - It could be from a workstation or from a file share in the lab
  - It could also collect Office Documents and PDFs
  - All this happens automatically in the background

## Print Capture

- NuGenesis Print Capture is a way of printing to the database
  - It's just like printing to a networked printer
  - You get a permanent record of the print in NuGenesis
  - Once in the database you can reuse all the content of the report

# Scientific Data Management System (SDMS)

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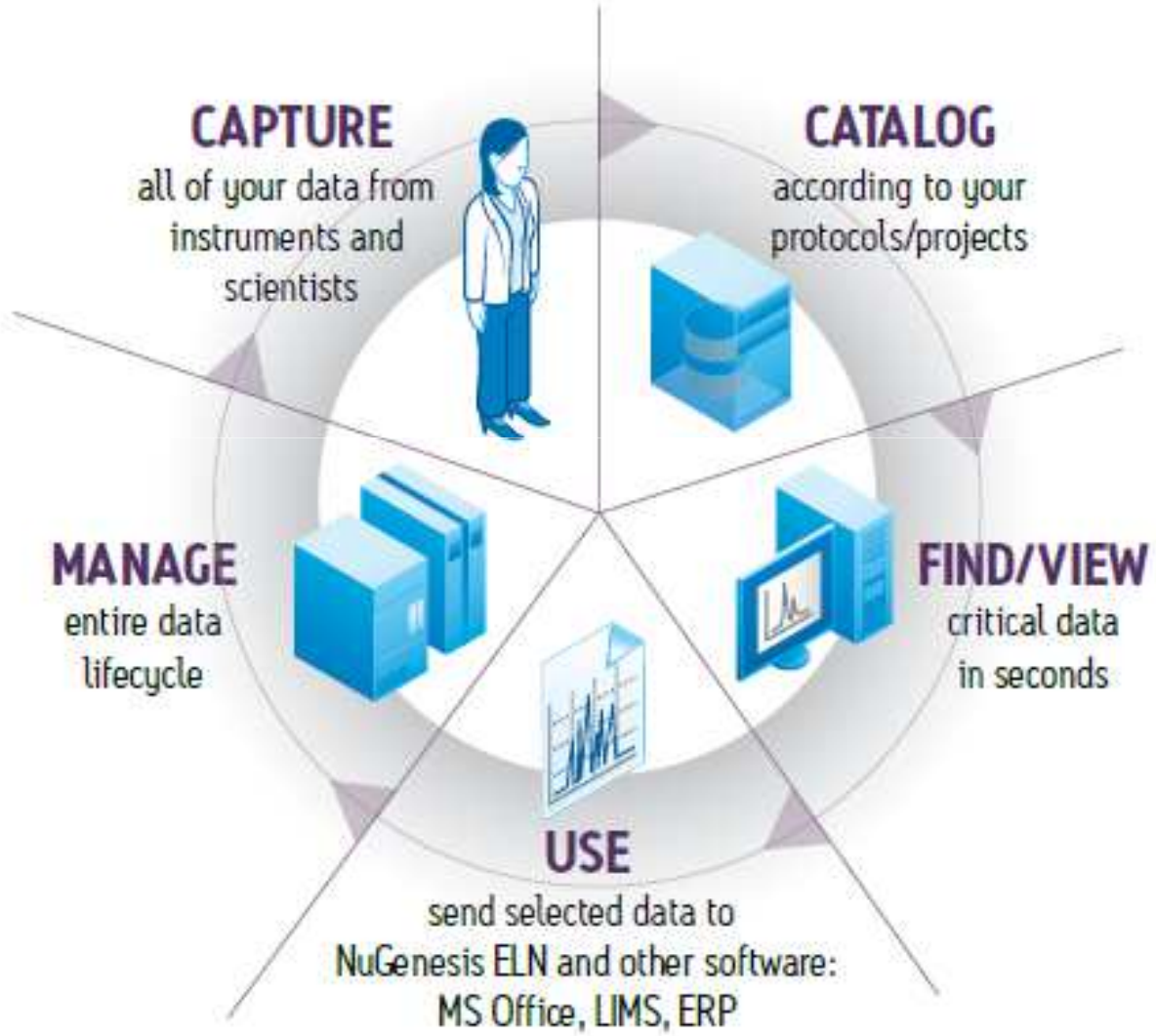
NuGenesis SDMS



# NuGenesis Laboratory Management System (LMS)

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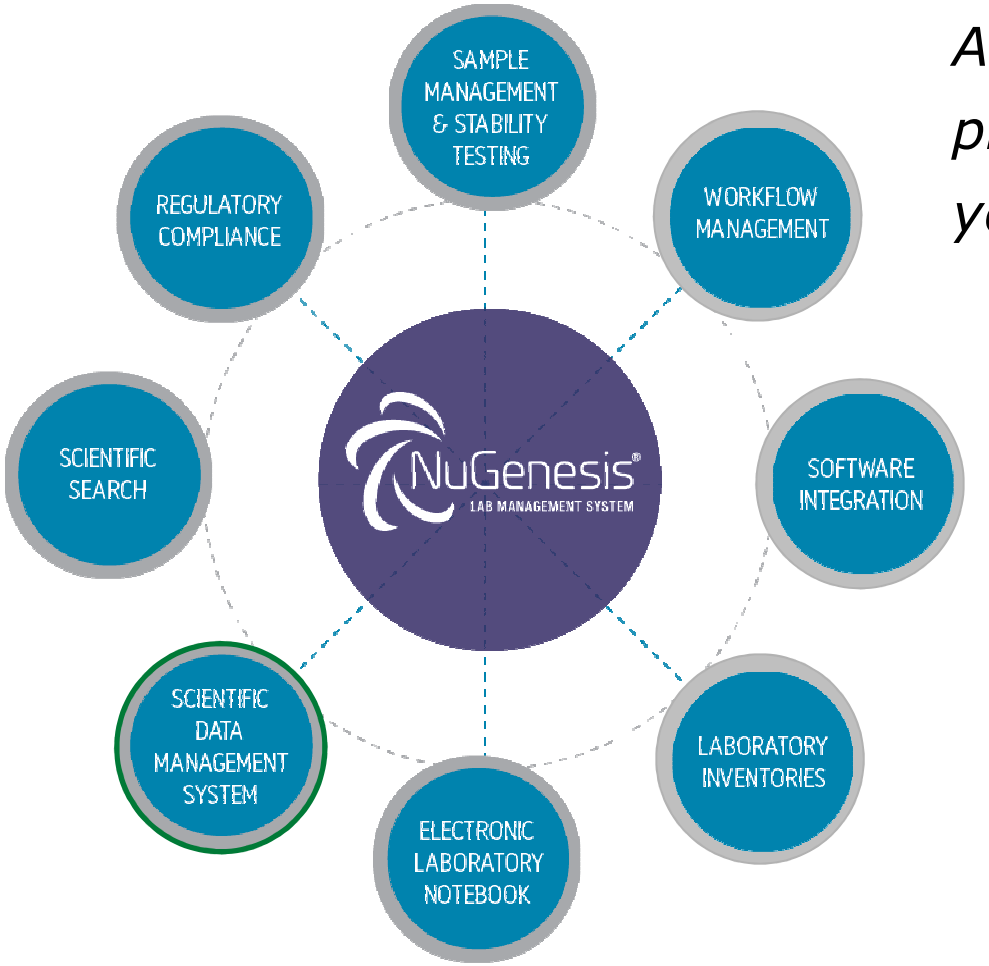
NuGenesis LMS




*A **laboratory-oriented** platform that allows you to…*

- Capture, protect, and find scientifically-relevant information
- Document laboratory-based processes
- Manage samples and laboratory workflows

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# Managing the eLife-cycle of your Empower CDS Data

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# eLife-cycle of Data

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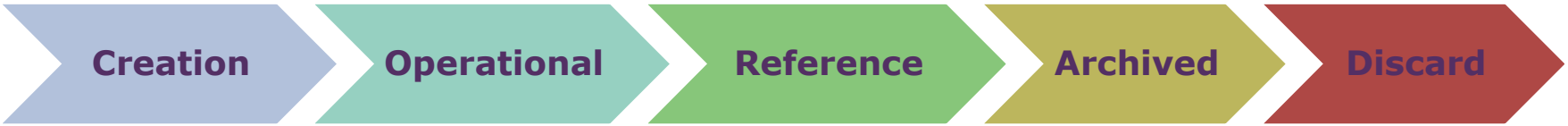
- **5 phases:**




- **Backup**
  - copying and archiving of *changeable* data so it may be used to restore the original after a data loss event
    - Applied to whole database

- **Archiving**
  - removing selected data records from operational databases that are not expected to be referenced again and storing them in an archive data store where they can be retrieved if needed.
    - Protecting long-term retention of *unchangeable* data for regulatory or legal purpose.
    - Applied to selected parts (projects) of the database
    - data must be readily accessible without requiring a lot of manual intervention
    - Retention policies are applied

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# Why Archiving your Empower CDS ?

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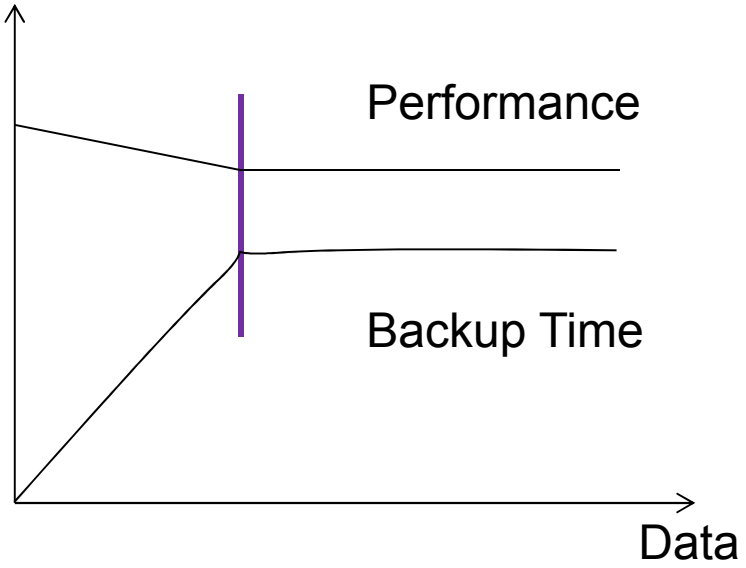
- Archive Projects
  - Keep performance high
  - Keep backup times low
  - Manage project life time
  - *Provide a mechanism to save e-records and their metadata for future reference*




**Keep Empower LEAN !**

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# What are the Challenges ?

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"Our Empower projects need to be **archived**, but we will need to access them again."

"We need to look at the Empower data **before** we decide to **restore** them. The more we can do without restoring the better."

"The chromatographic runs leading to the final results need to be **accessible** during an audit."

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# What are the Challenges ?

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"The consequences of losing data are not acceptable. Our projects need to be **secure** - inside as well as outside Empower."

"Identifying projects by just name is not enough for **searching.** We need to find data by their LIMS ID."

"We need **easy access** to our reports, also for non Empower users, such as Lab Managers, QA…"

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# Who are the consumers of CDS Data?

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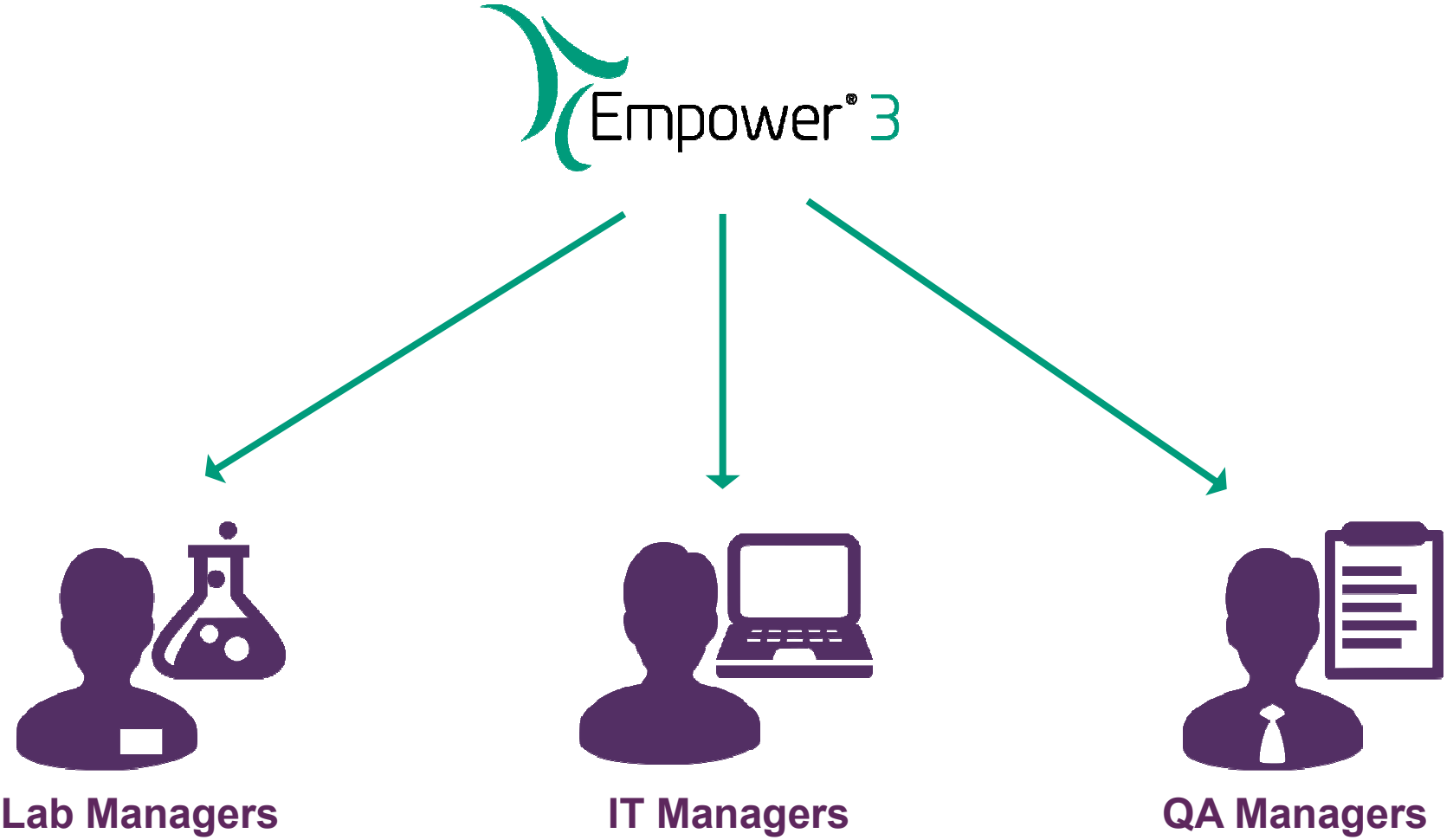


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# What are their requirements?

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## Lab Manager

- Streamlined Empower system
- Optimize sign offs
- Less time archiving

## IT Manager

- Compliance worries
- Easy to maintain Empower system
- Easy Data Management and Retention

## QA Manager

- Quality confidence and audit readiness
- Want to support electronic submissions

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# Why is this important?
## …example recent FDA Warning Letter ( May 2015)

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*…Our inspection noted that **your firm did not retain complete raw data from testing performed to assure the quality of (b)(4), API** …*

*…"While investigating these discrepancies, our investigator requested the original electronic raw data. Your quality unit, after consulting with the Information Technology (IT) department, stated they were unable to retrieve the original electronic raw data because **back-up discs were unreadable**. Your quality unit then stated that back-up disks **have been unreadable since at least 2013**. Your HPLC system is used to test **(b)(4)**, API for batch release. However, without complete, accurate, reliable, or retrievable raw data about the HPLC system's qualification, you lacked complete assurance that the system was operating as intended."…*

*… This **lack of control over the integrity of your data** raises questions about your analytical data's authenticity and reliability, and about the quality of your APIs….*

http:/www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm448433.htm/

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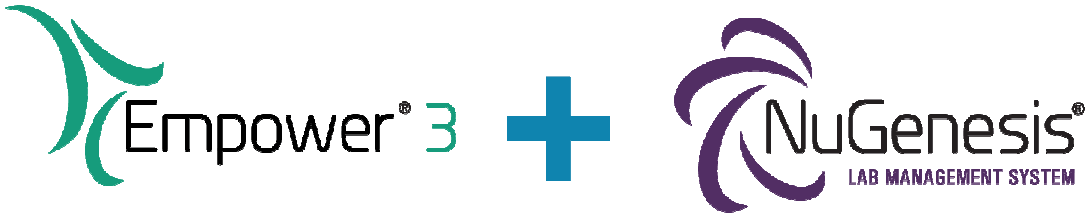
# Solution:
# Archiving Empower Data to NuGenesis SDMS

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# NuGenesis Central Empower Archive

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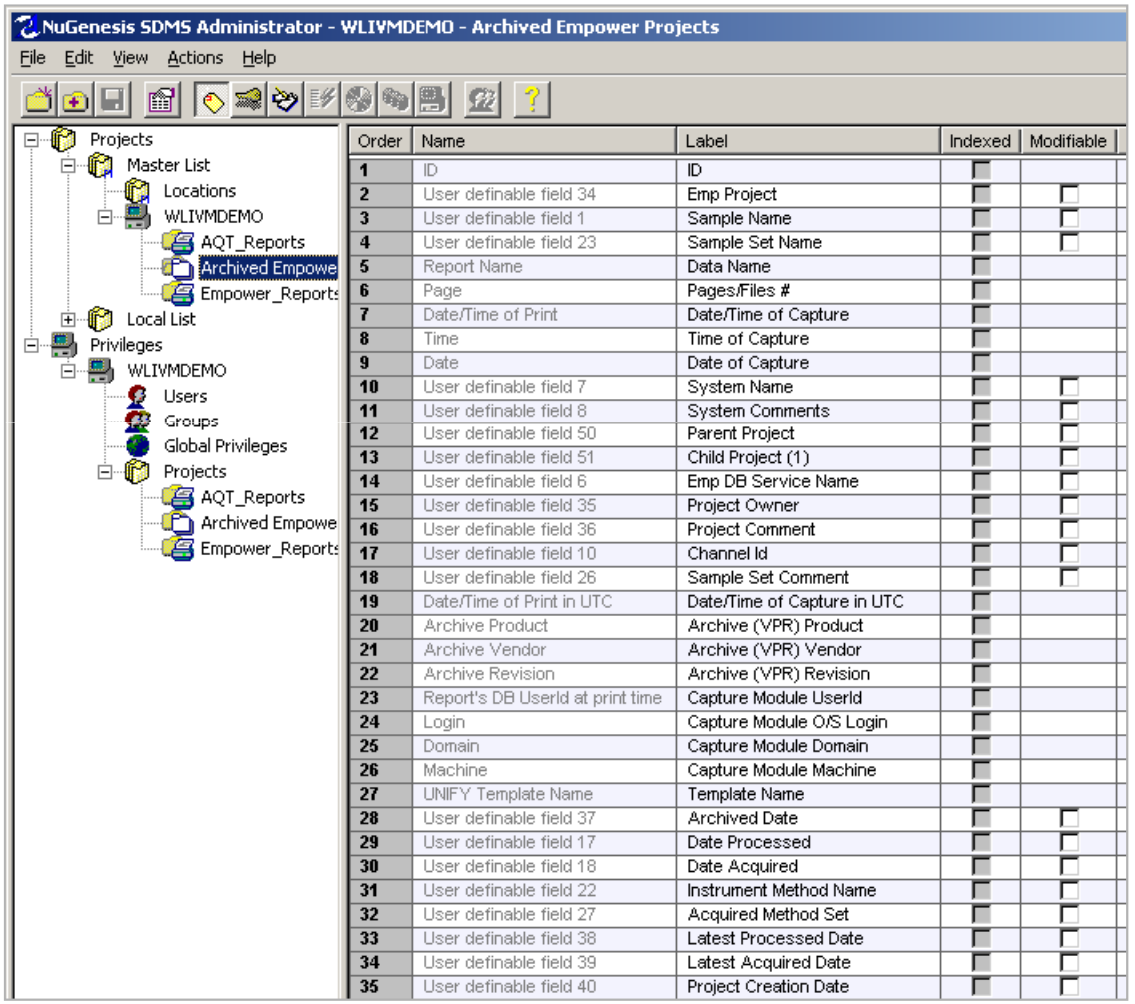
Includes the following pre-defined labels:

- Project
- Sample Name
- Emp DB Service Name
- System Name
- System Comments
- Injection Id
- Channel Id
- Date Processed
- Date Acquired
- Instrument Method Name
- Sample Set Name
- Acquired Method Set
- Acquired By

…And more




| Order | Name | Label | Indexed | Modifiable |
|---|---|---|---|---|
| 1 | ID | ID | ☐ | |
| 2 | User definable field 34 | Emp Project | ☐ | ☐ |
| 3 | User definable field 1 | Sample Name | ☐ | ☐ |
| 4 | User definable field 23 | Sample Set Name | ☐ | ☐ |
| 5 | Report Name | Data Name | ☐ | |
| 6 | Page | Pages/Files # | ☐ | |
| 7 | Date/Time of Print | Date/Time of Capture | ☐ | |
| 8 | Time | Time of Capture | ☐ | |
| 9 | Date | Date of Capture | ☐ | |
| 10 | User definable field 7 | System Name | ☐ | ☐ |
| 11 | User definable field 8 | System Comments | ☐ | ☐ |
| 12 | User definable field 50 | Parent Project | ☐ | ☐ |
| 13 | User definable field 51 | Child Project (1) | ☐ | ☐ |
| 14 | User definable field 6 | Emp DB Service Name | ☐ | ☐ |
| 15 | User definable field 35 | Project Owner | ☐ | ☐ |
| 16 | User definable field 36 | Project Comment | ☐ | ☐ |
| 17 | User definable field 10 | Channel Id | ☐ | ☐ |
| 18 | User definable field 26 | Sample Set Comment | ☐ | ☐ |
| 19 | Date/Time of Print in UTC | Date/Time of Capture in UTC | ☐ | |
| 20 | Archive Product | Archive (VPR) Product | ☐ | |
| 21 | Archive Vendor | Archive (VPR) Vendor | ☐ | |
| 22 | Archive Revision | Archive (VPR) Revision | ☐ | |
| 23 | Report's DB UserId at print time | Capture Module UserId | ☐ | |
| 24 | Login | Capture Module O/S Login | ☐ | |
| 25 | Domain | Capture Module Domain | ☐ | |
| 26 | Machine | Capture Module Machine | ☐ | |
| 27 | UNIFY Template Name | Template Name | ☐ | |
| 28 | User definable field 37 | Archived Date | ☐ | ☐ |
| 29 | User definable field 17 | Date Processed | ☐ | ☐ |
| 30 | User definable field 18 | Date Acquired | ☐ | ☐ |
| 31 | User definable field 22 | Instrument Method Name | ☐ | ☐ |
| 32 | User definable field 27 | Acquired Method Set | ☐ | ☐ |
| 33 | User definable field 38 | Latest Processed Date | ☐ | ☐ |
| 34 | User definable field 39 | Latest Acquired Date | ☐ | ☐ |
| 35 | User definable field 40 | Project Creation Date | ☐ | ☐ |

NuGenesis®
LAB MANAGEMENT SYSTEM

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# Advanced Archive Logic

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- Easily manage your Empower projects.
- Central administration of the project archive process for one or more Empower servers or workstations
- Automated scheduling of the project archive process based on predefined rules
- Automated archive verification prior to project deletion
- Long term archival on external media

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# Archive reports after Sign Off

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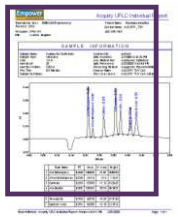
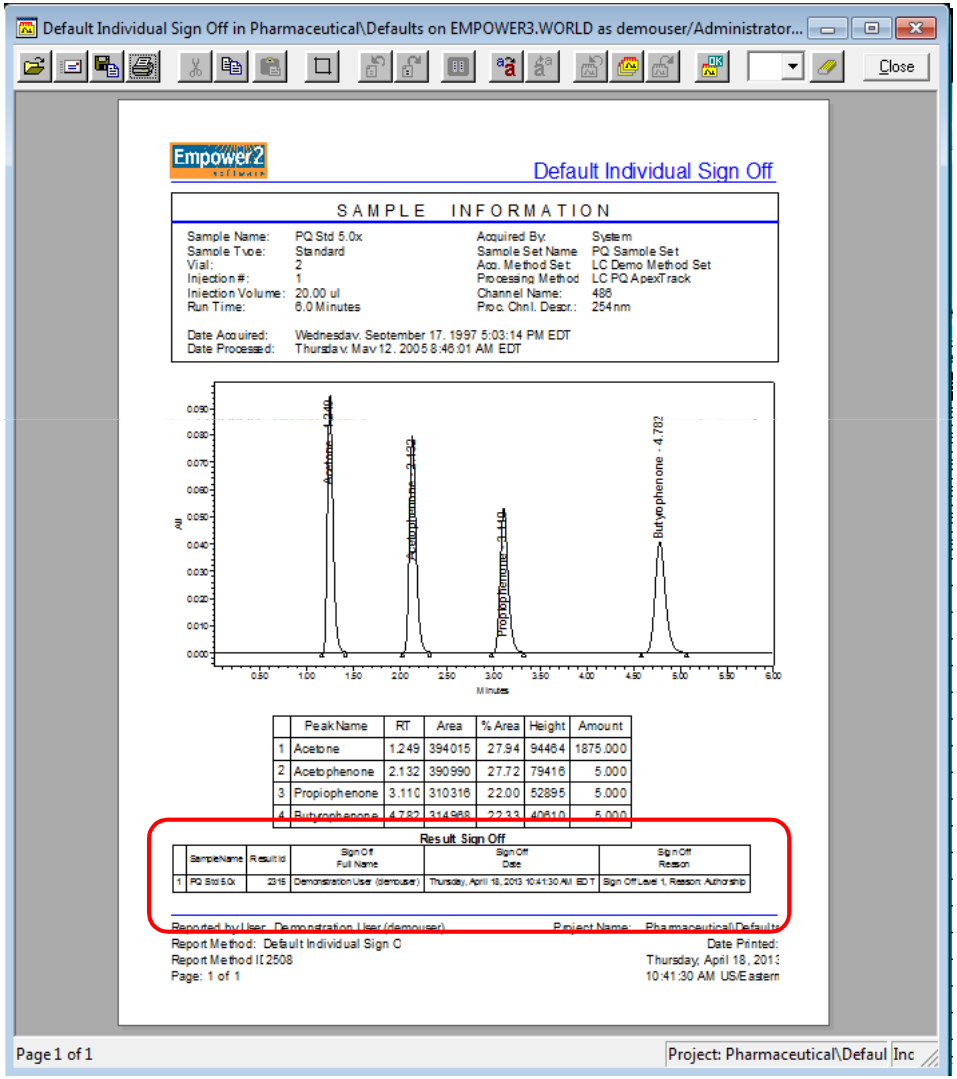
- Review the report
- Click the sign off button
- Automatically prints to NuGenesis SDMS



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# Empower Project Data in NuGenesis SDMS

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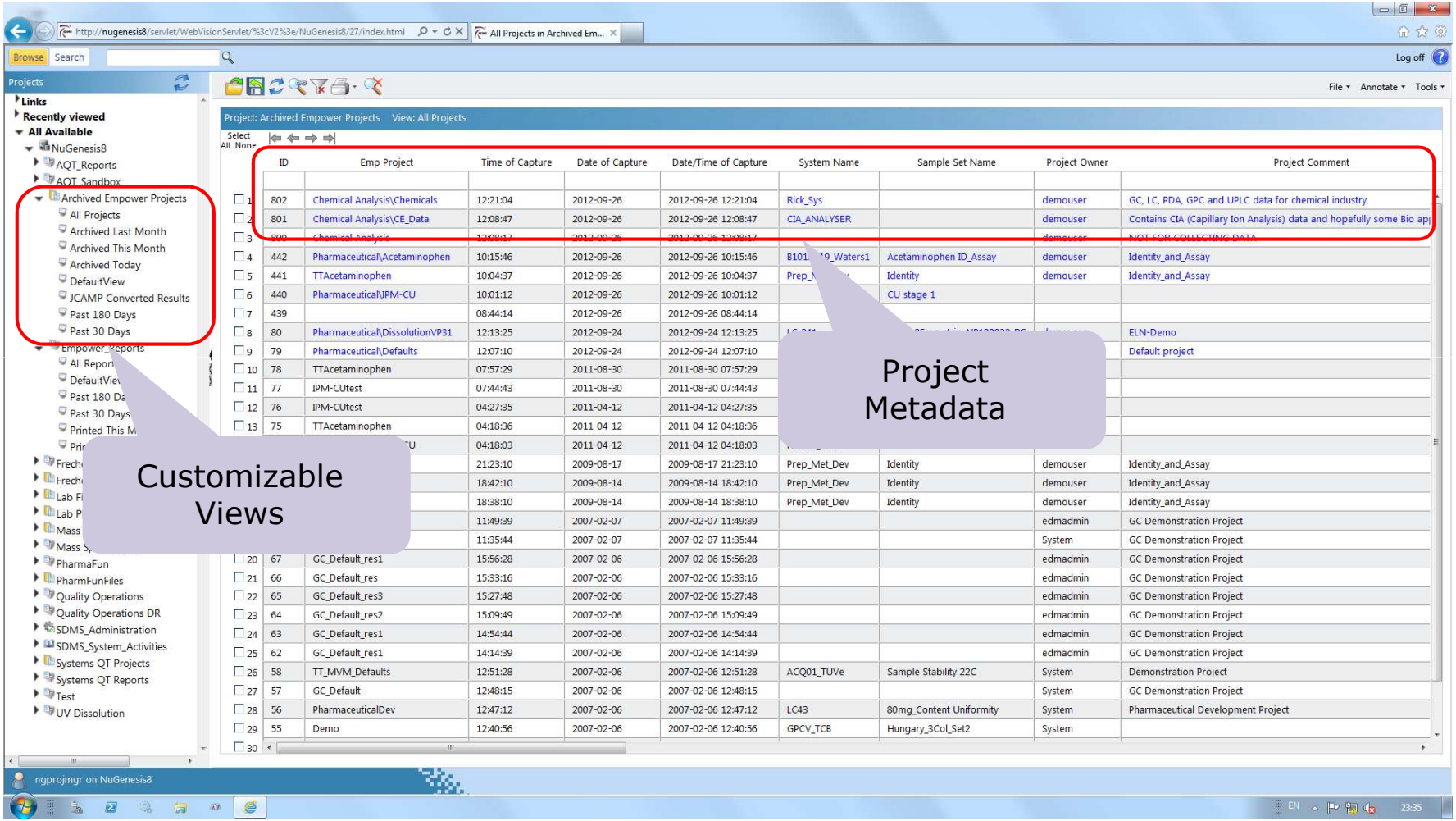


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# View Project Details

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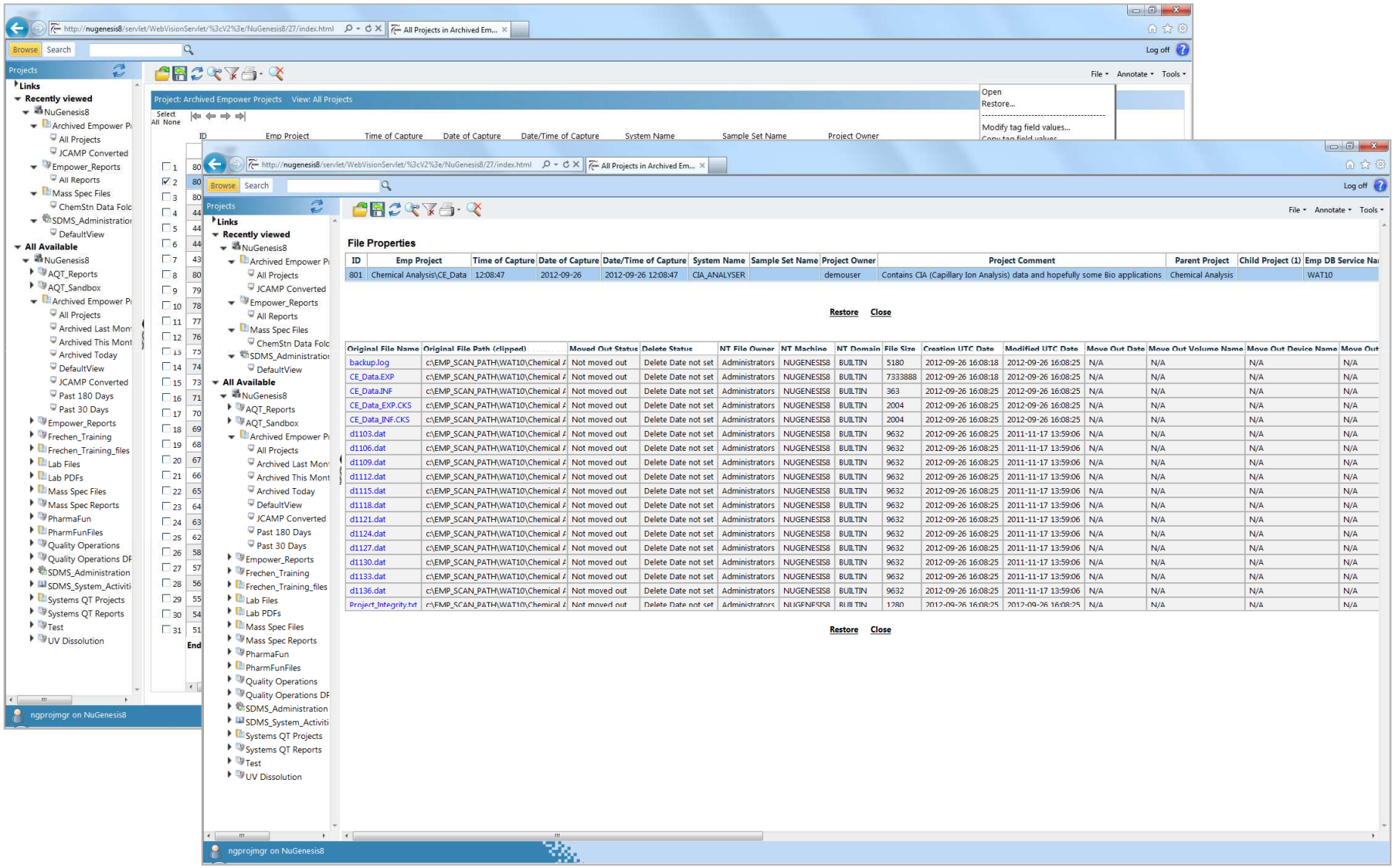


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# Easily Review data without original application

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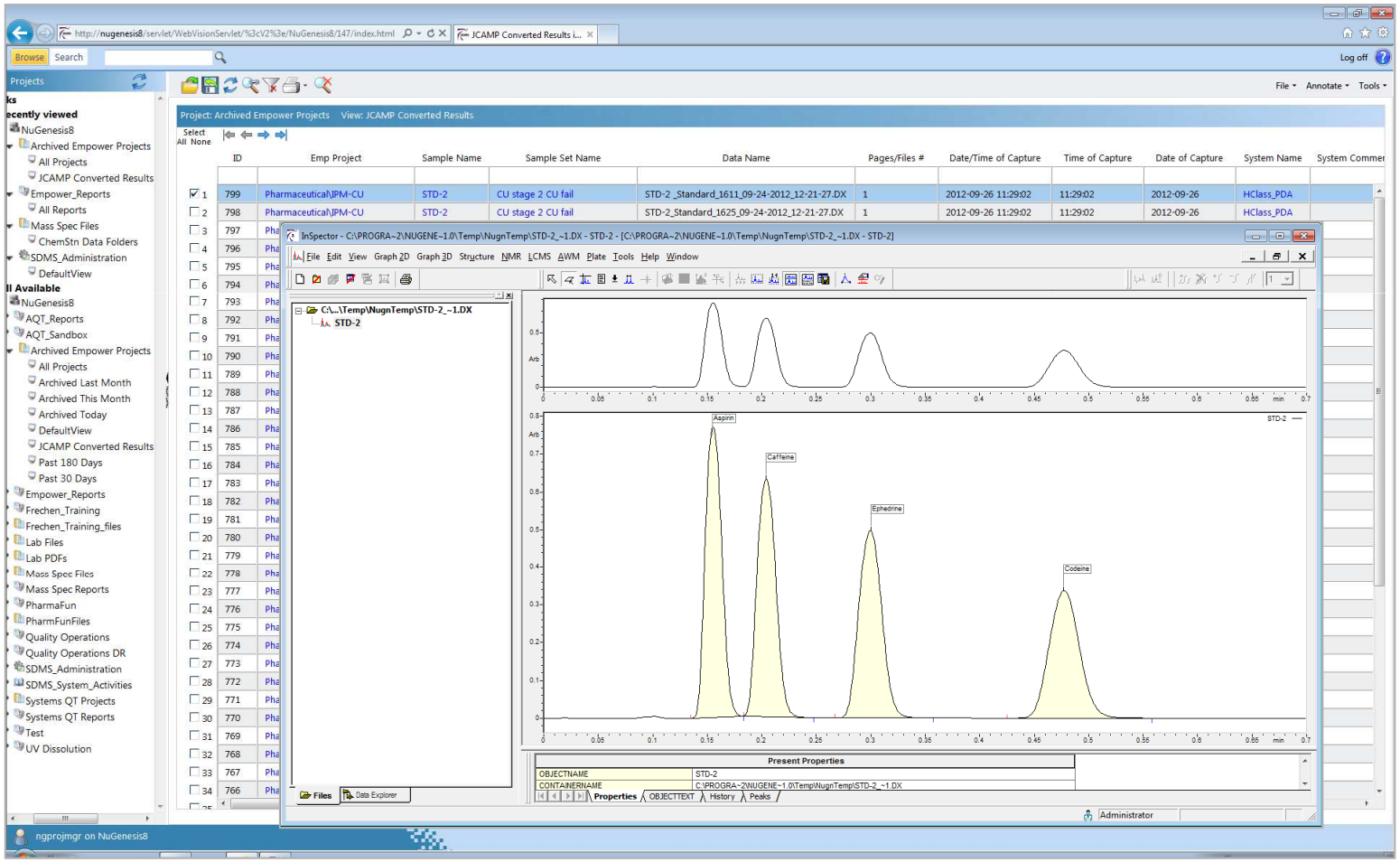
Convert final result to JCAMP.DX at point of archive…

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# Empower Reports

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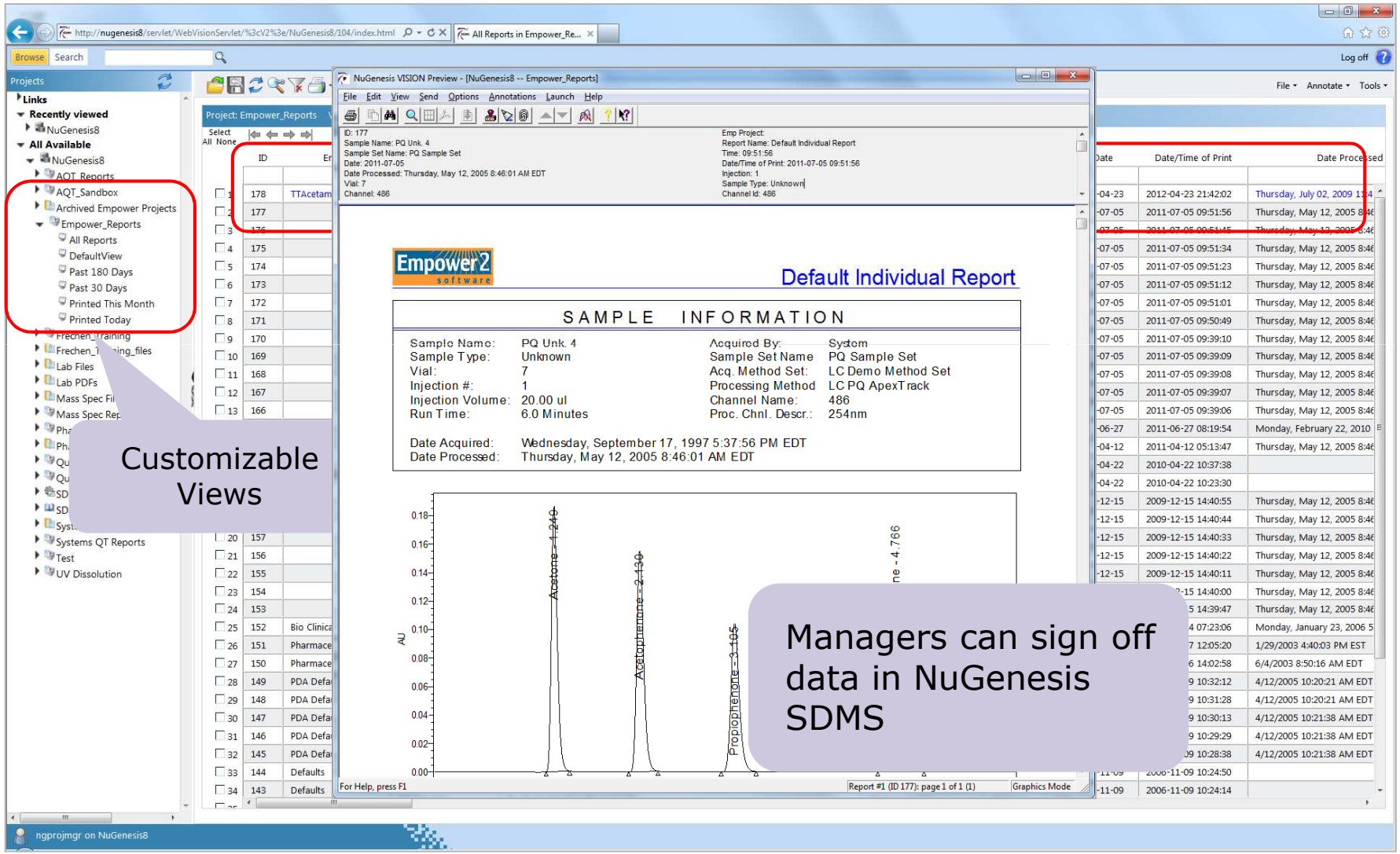


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# Easy Searching of Content – structured metadata

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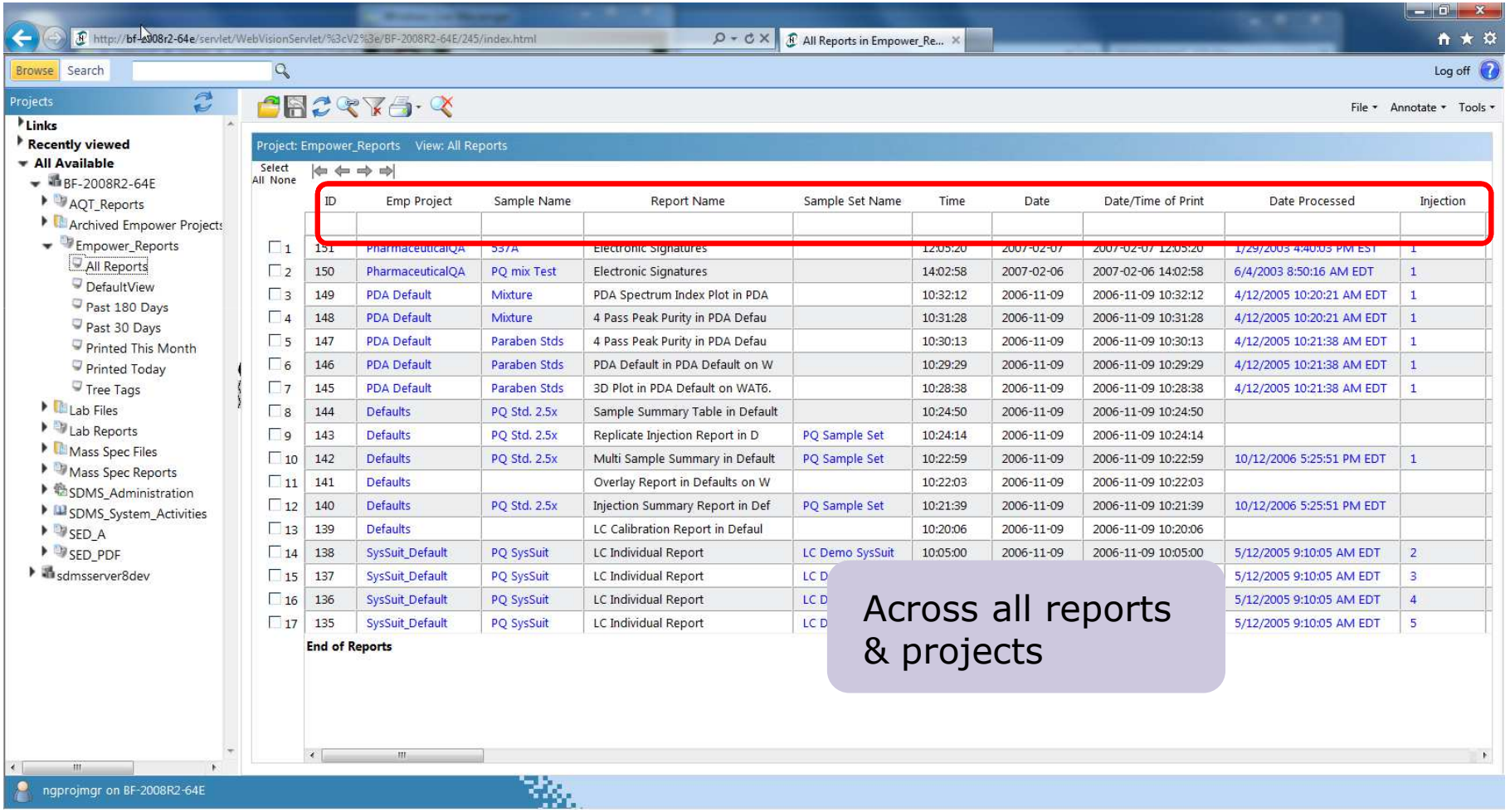


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# Integrated Scientific Search to search for unstructured data

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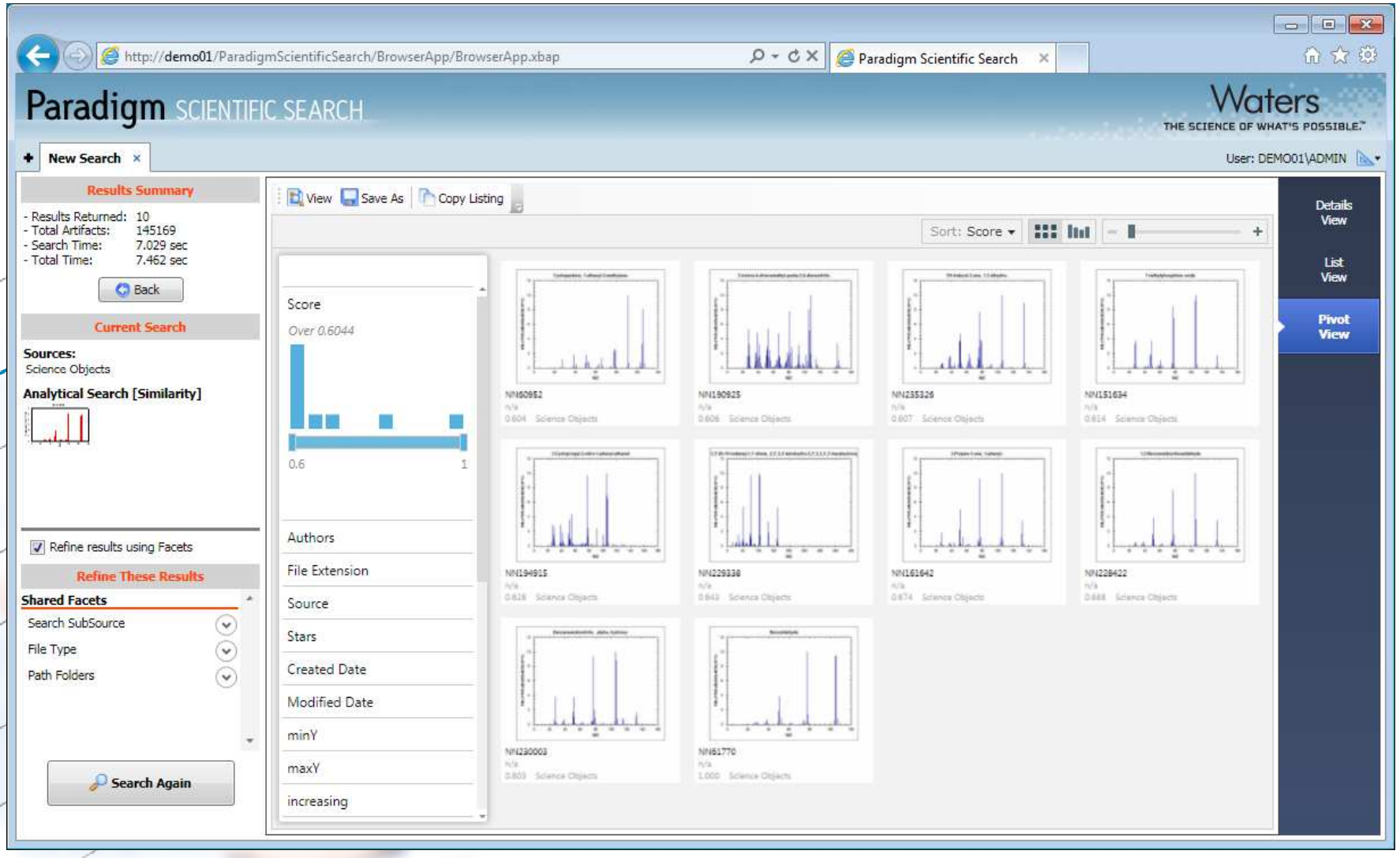


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# Empower Reports Beyond The Lab

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- View electronic reports via a web browser years after the data or report was compiled
- Review reports without needing to have Empower Software installed locally
- Extend electronic reports through the corporate network
- Reduce paper and hard-copy storage costs with a compliant electronic process
- Improved search to quickly find results during a quality audit

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# Eliminate manual transcription - Reuse Report Content

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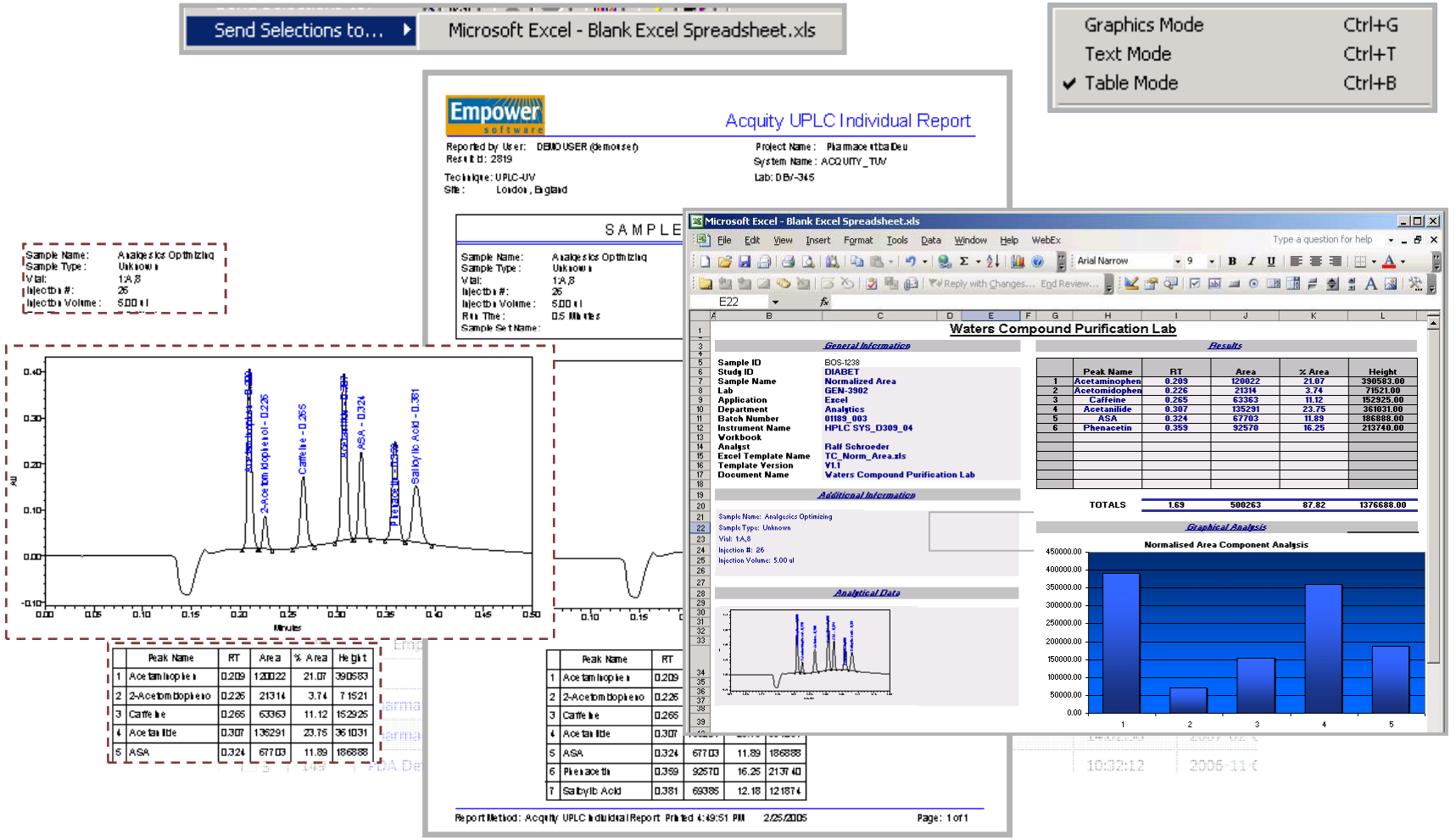


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# What are the benefits?

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## Lab Manager

- Easy archiving (time saving)
- Easy data access
- Easy data search (one single system for all)

## IT Manager

- Easy sharing of data within the organization
- Intellectual property protection (secure and traceable)
- Long-term solution for data retention

## QA Manager

- Traceability & Data Integrity
- Compliance-Ready system (21 CFR Part 11, Annex 11 etc.)
- Peace of mind at Audit

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# Benefits NuGenesis SDMS for Empower...

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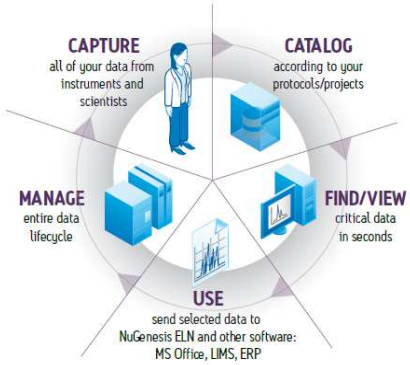
- Empower project Archival
  - Automatically archives Empower projects
  - Removes projects from Empower (based on rules)
  - Indexes for Searching

- Empower Report Management
  - Collect & maintain all Empower reports (background printing)
  - Automatic Indexing via templates
  - Reviewing without need to have Empower available

- Empower result transfer to LIMS & SAP




- … Not only for Empower...
  - Universal interface to devices & instrument software
  - Non-specific sample management (LC/MS, NMR, ICP/MS, etc)
  - Scientific (raw) Data Management

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# Connect Your Whole Lab in One Place

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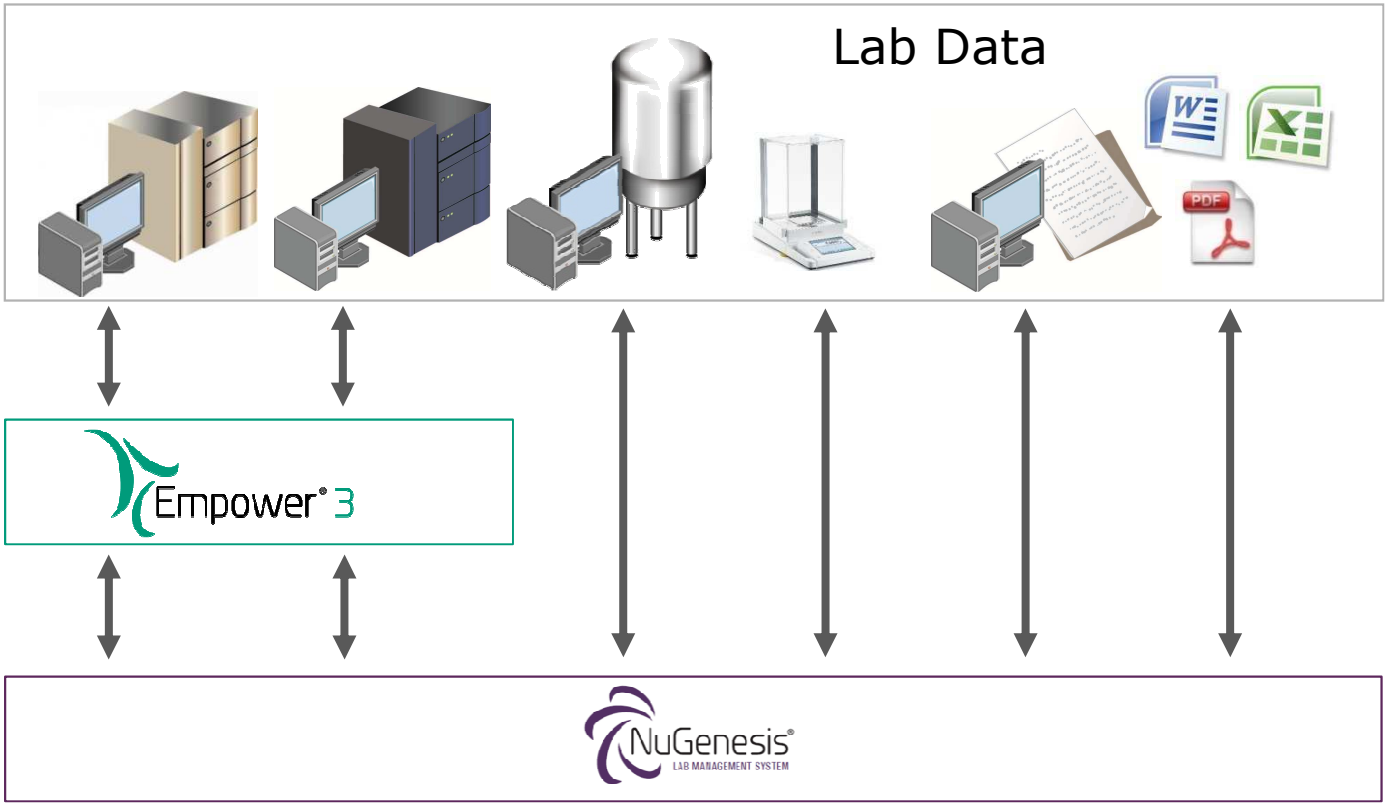


...a stepwise approach to build an Integrated (Paperless) Lab

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# Covestro NV

## Centraal laboratorium

## NuGenesis SDMS

*Version 8.0.0.21 SR-2*

*W Bogaerts, A Verbueken*

*KVCV 26 november 2015*

*Grobbendonk*

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# Bedankt voor uw Aandacht!

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Any
Questions ?