



UL COMPLIANCE TO PERFORMANCE
LEADERSHIP FORUM 2016

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Integrated Technology Infrastructure:

Moving Your Organization from Compliance to Performance

Scott Barnard

Market Strategy & Innovation Director

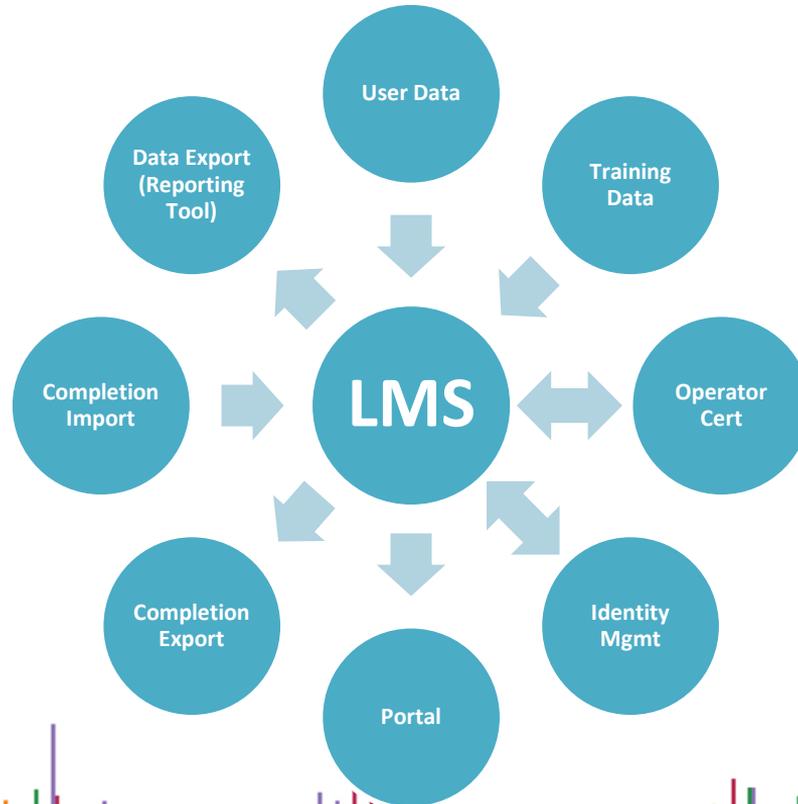
Agenda

- **What Is An Integrated Technology Infrastructure?**
- Why Do We Need It?
- How Does It Work?
- Benefits of An Integrated Technology Infrastructure
- Questions

What If ...

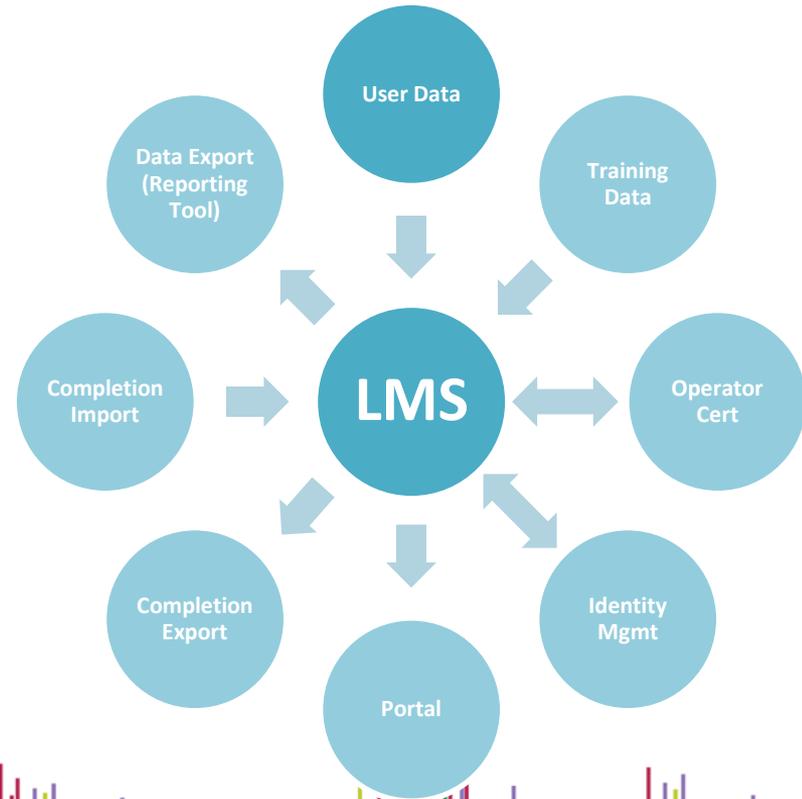


10 LMS Enterprise Integration Opportunities



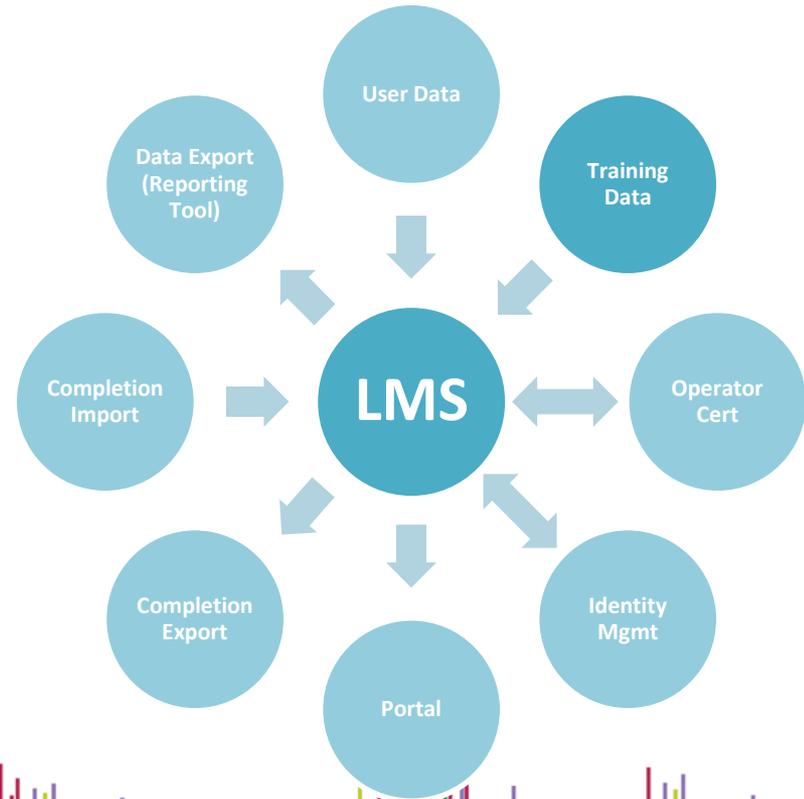
10 LMS Enterprise Integration Opportunities

- User Data:
 - HRMS
 - CTMS
 - Active Directory
 - Any other systems containing user data
- Method:
 - Nightly Batch Feed
 - Real Time Web Service



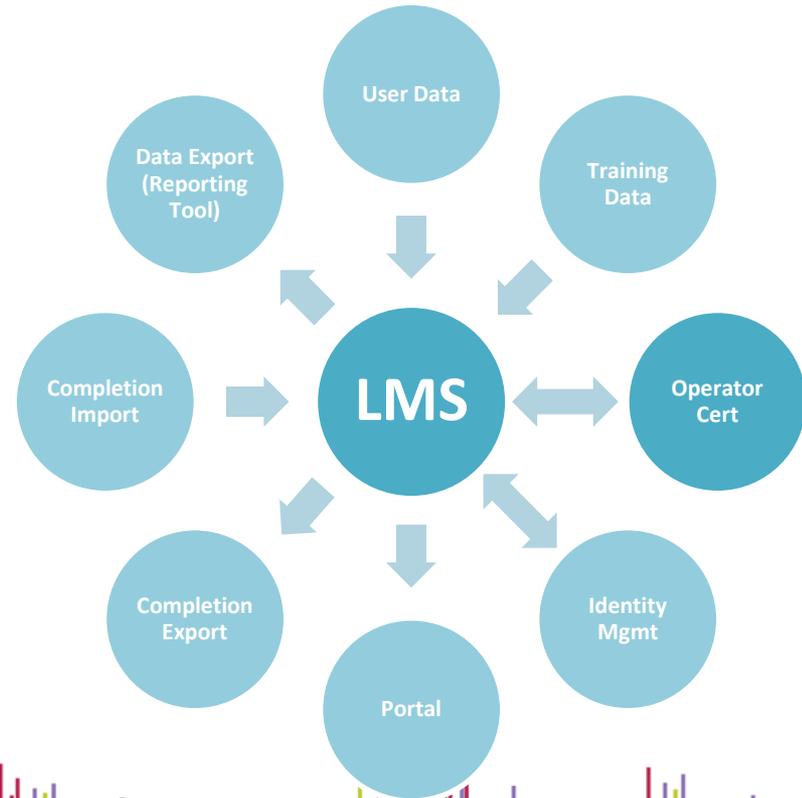
10 LMS Enterprise Integration Opportunities

- Training Item Data:
 - DMS
 - SharePoint
 - Content Hosting
 - Any other systems containing training data
- Method:
 - Nightly Batch Feed
 - Real Time Web Post



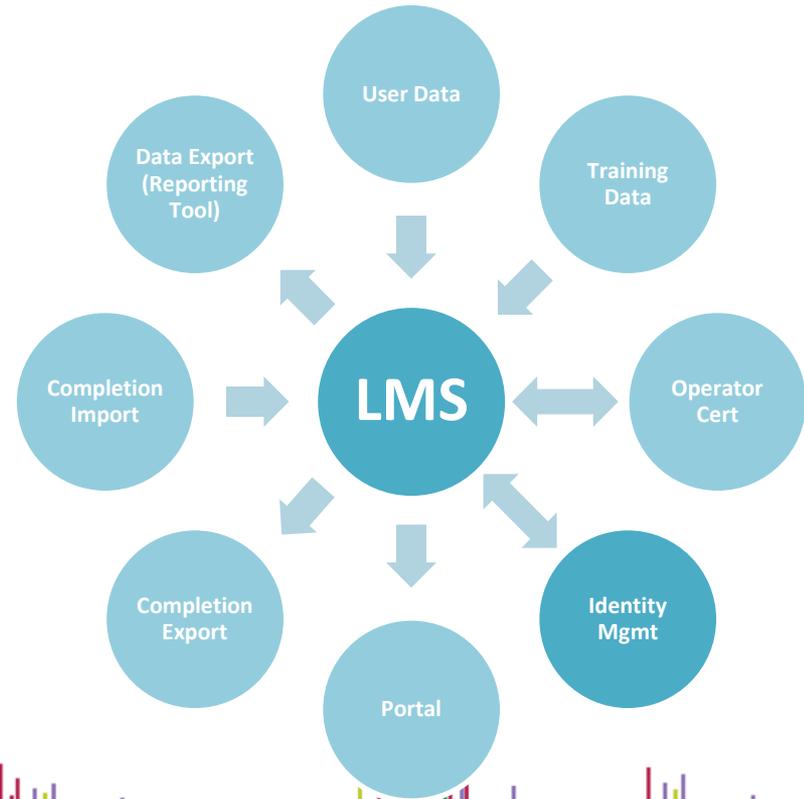
10 LMS Enterprise Integration Opportunities

- Operator Certification Data:
 - MES
 - LIMS
 - ERP
 - Physical Security
- Method:
 - Real Time Web Service
 - Batch Qualification Reports



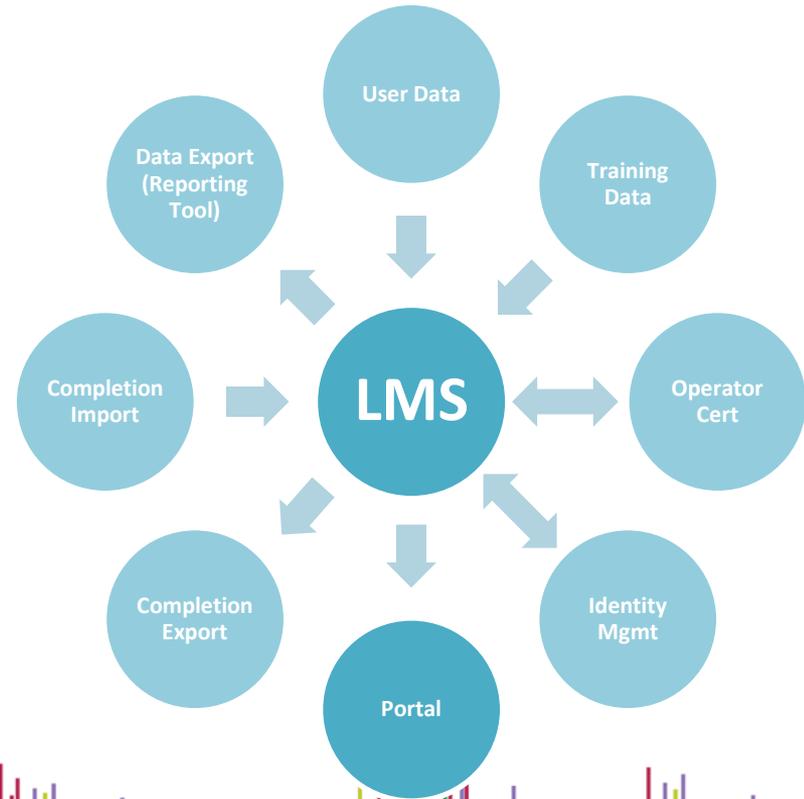
10 LMS Enterprise Integration Opportunities

- Identity Management Data:
 - User Login
 - E-Signature
- Method:
 - SAML
 - Secure LDAP
 - Biometrics



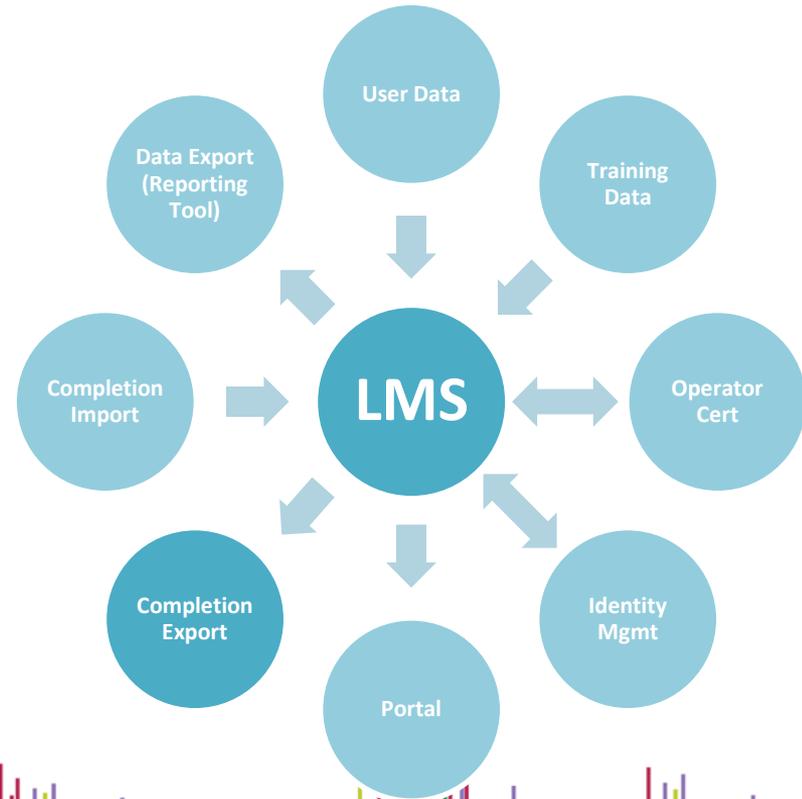
10 LMS Enterprise Integration Opportunities

- Client Portal Data:
 - Customers
 - End Users
 - Sales Force
 - Third Parties
- Method:
 - Web Services



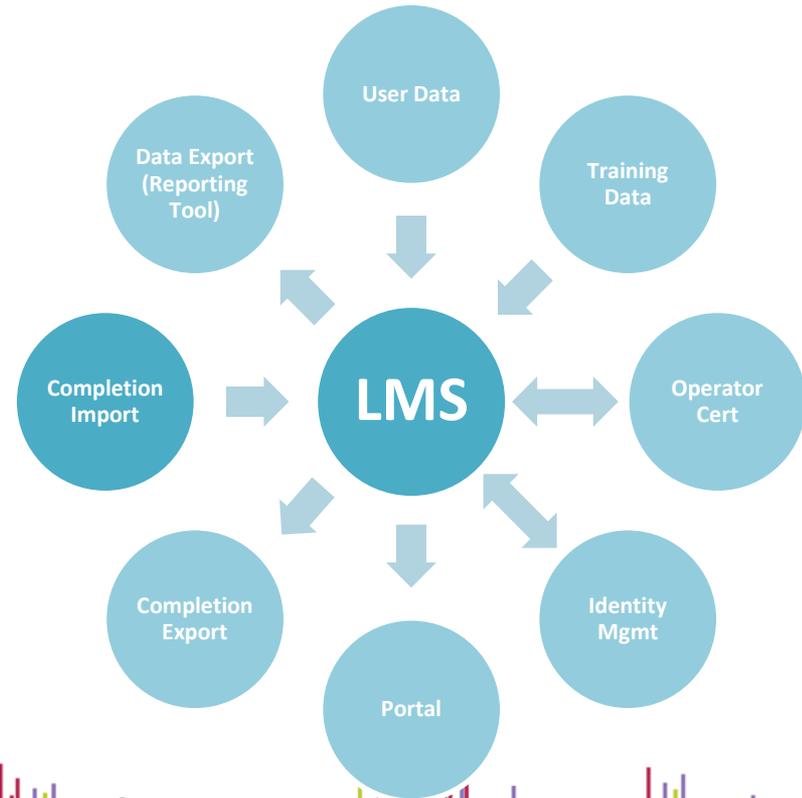
10 LMS Enterprise Integration Opportunities

- Completions Data:
 - Other LMS systems
 - Qualification Services
- Method:
 - Nightly Batch Export
 - Scheduled Report
 - Web Service / API



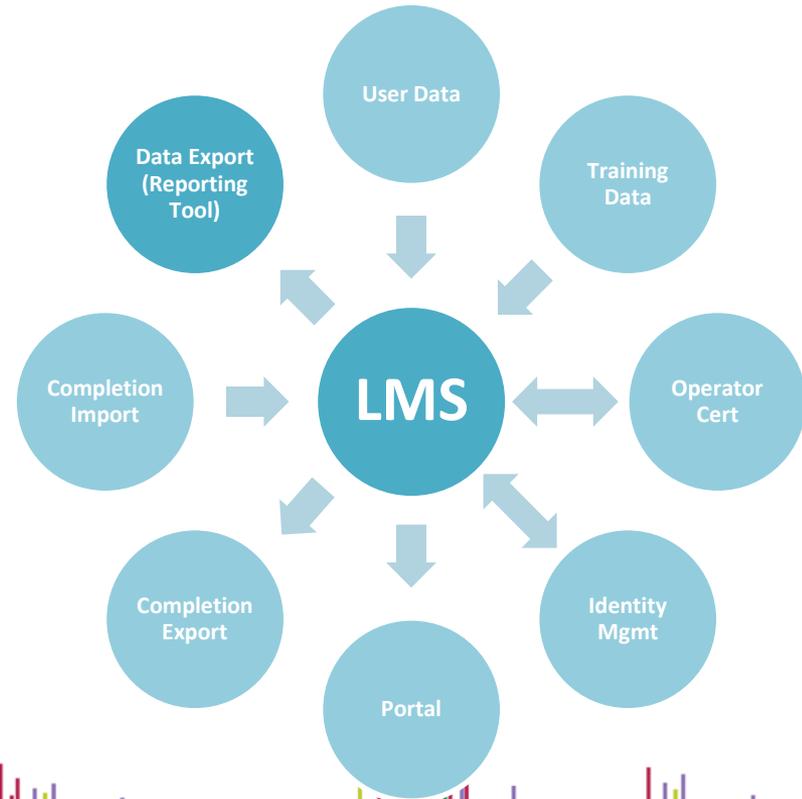
10 LMS Enterprise Integration Opportunities

- Completions Data:
 - Other LMS systems
 - Paper to electronic conversion
- Method:
 - Nightly Batch Feed
 - Historical Completions Upload Tool

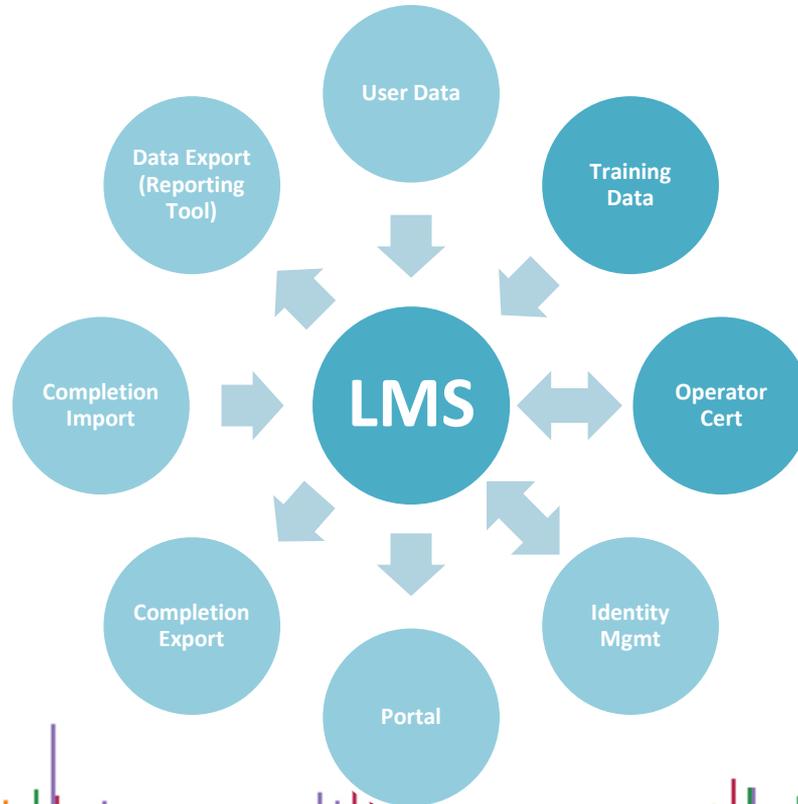


10 LMS Enterprise Integration Opportunities

- LMS Data:
 - Crystal Reports
 - Business Objects
 - Other Internal Reporting Tools
- Method:
 - Nightly Batch Export
 - Scheduled Report



Focus On Two Examples



Agenda

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Top Learning Priorities for 2016

Priorities	2014	2015	2016
Measuring training effectiveness	67%	70%	68%
Improving SOP and policy management	52%	45%	57%
Collecting training data to support the organization's quality or compliance metrics	66%	63%	56%
Conducting more role-based training and credentialing programs	26%	41%	47%
Adding risk-based approaches to training programs	46%	42%	34%



FDA Enforcement Trends in 2015: Procedural-Focused

“Your firm failed to establish and follow appropriate written procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile...”

*“Your firm did **not follow its “Complaint Handling for Medical Device” procedure**, etc.”*

The logo for the U.S. Food and Drug Administration (FDA), featuring the letters 'FDA' in a stylized, white, sans-serif font on a blue rectangular background.

*“Your firm **failed to follow its procedure** Assembling Manual for the time and temperature for...”*

*“**You did not follow your procedure** “Leak Testing of ... Glove” for testing glove integrity. You did not test each glove, as required by the SOP.”*

CDER Enforcement Trends in 2015

2015 FDA CDER Observations		
Frequency	Reference Number	Short Description
160	21 CFR 211.22(d)	Procedures not in writing, fully followed
130	21 CFR 211.160(b)	Scientifically sound laboratory controls
124	21 CFR 211.192	Investigations of discrepancies, failures
104	21 CFR 211.113(b)	Procedures for sterile drug products
95	21 CFR 211.100(a)	Absence of Written Procedures
83	21 CFR 211.42(c)(10)(iv)	Environmental Monitoring System
80	21 CFR 211.165(a)	Testing and release for distribution
69	21 CFR 211.110(a)	Control procedures to monitor and validate performance
68	21 CFR 211.67(a)	Cleaning / Sanitizing / Maintenance
64	21 CFR 211.68(a)	Calibration/Inspection/Checking not done
63	21 CFR 211.166(a)	Lack of written stability program
60	21 CFR 211.42(c)(10)(v)	Cleaning System
56	21 CFR 211.63	Equipment Design, Size and Location
56	21 CFR 211.188	Prepared for each batch, include complete information
53	21 CFR 211.67(b)	Written procedures not established/followed
53	21 CFR 211.113(b)	Validation lacking for sterile drug products
52	21 CFR 211.100(b)	SOPs not followed / documented
50	21 CFR 211.25(a)	Training--operations, GMPs, written procedures
47	21 CFR 211.192	Written record of investigation incomplete
40	21 CFR 211.160(a)	Following/documenting laboratory controls
40	21 CFR 211.198(a)	Complaint Handling Procedure

1507
observations
noted here – 50%
of them (766) are
focused on
“procedures not
in writing” or
“procedures not
followed.”

Source: <http://www.fda.gov/ICECI/Inspections/ucm481432.htm>



CDRH Enforcement Trends in 2015

FDA CDRH Citations 2015		
Frequency	Reference Number	Short Description
377	21 CFR 820.100(a)	Lack of or inadequate procedures
294	21 CFR 820.198(a)	Lack of or inadequate complaint procedures
139	21 CFR 820.50	Purchasing controls, Lack of or inadequate procedures
134	21 CFR 820.75(a)	Lack of or inadequate process validation
129	21 CFR 803.17	Lack of Written MDR Procedures
114	21 CFR 820.90(a)	Nonconforming product, Lack of or inadequate procedures
97	21 CFR 820.100(b)	Documentation
95	21 CFR 820.22	Quality audits - Lack of or inadequate procedures
89	21 CFR 820.30(i)	Design changes - Lack of or Inadequate Procedures
77	21 CFR 820.181	DMR - not or inadequately maintained
72	21 CFR 820.25(b)	Training - Lack of or inadequate procedures
62	21 CFR 820.80(d)	Lack of or inadequate final acceptance procedures
56	21 CFR 820.80(b)	Lack of or inadequate receiving acceptance procedures
56	21 CFR 820.70(a)	Process control procedures, Lack of or inadequate procedures
55	21 CFR 820.184	DHR - not or inadequately maintained
55	21 CFR 820.40	Procedures not adequately established or maintained
54	21 CFR 820.75(a)	Documentation
51	21 CFR 820.70(c)	Environmental control Lack of or inadequate procedures
51	21 CFR 820.30(g)	Design validation- Lack of or inadequate procedures
51	21 CFR 820.184	Lack of or inadequate DHR procedures
51	21 CFR 820.198(c)	Investigation of device failures
50	21 CFR 820.72(a)	Calibration, Inspection, etc. Procedures Lack of or Inadequ

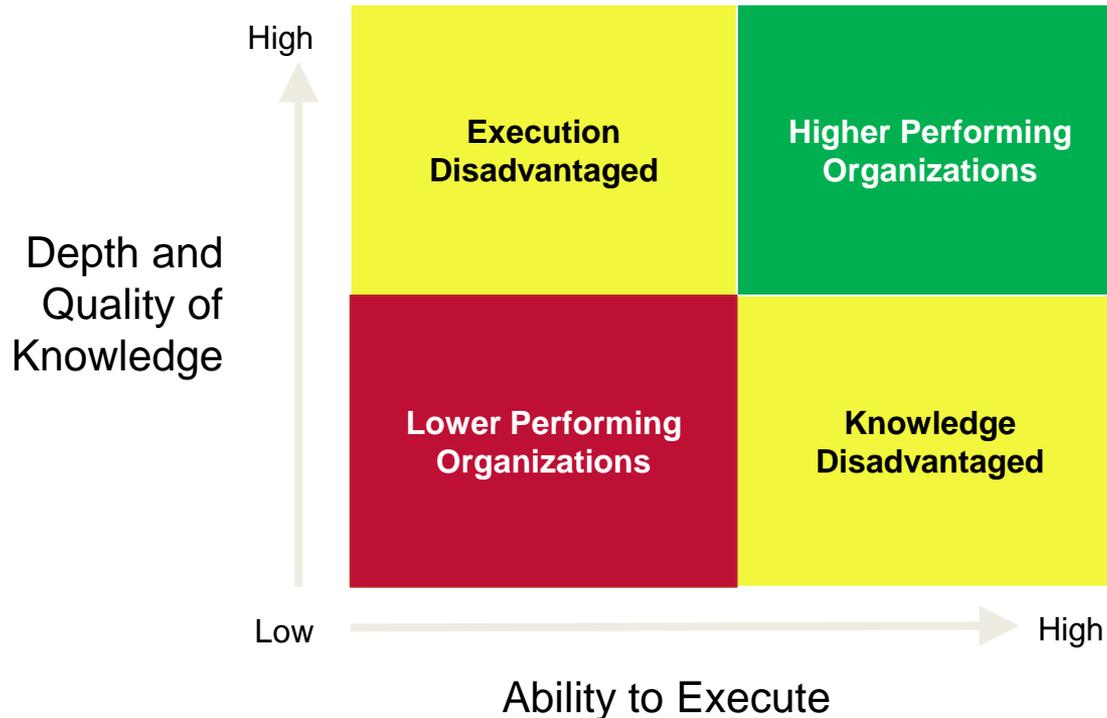
2,207
observations
noted here –
84% of them
(1,875) are
focused on
“lack of or
inadequate
procedures.”

Source: <http://www.fda.gov/ICECI/Inspections/ucm481432.htm>



High Performing Organizations

Performance is the function of knowledge and the ability to execute with that knowledge.



Outcomes:

- Learning cultures
- Knowledgeable staff
- Higher retention rates
- Skills development
- Higher quality processes
- Lower business risks
- Agility and speed
- Improved financial results

Knowledge Disadvantaged

Missing or Ineffective:

- Role Based Training Qualification Program
- Integrated Corporate, Leadership & Technical Competency Programs
- Accurate & Real-Time Measure of Qualification and Competency
- Effective, Current, & Localized Compliance, Qualification & Performance Support Content
- Integration of Qualification & Competence with Employee Performance Management



Execution Disadvantaged

Missing or Ineffective:

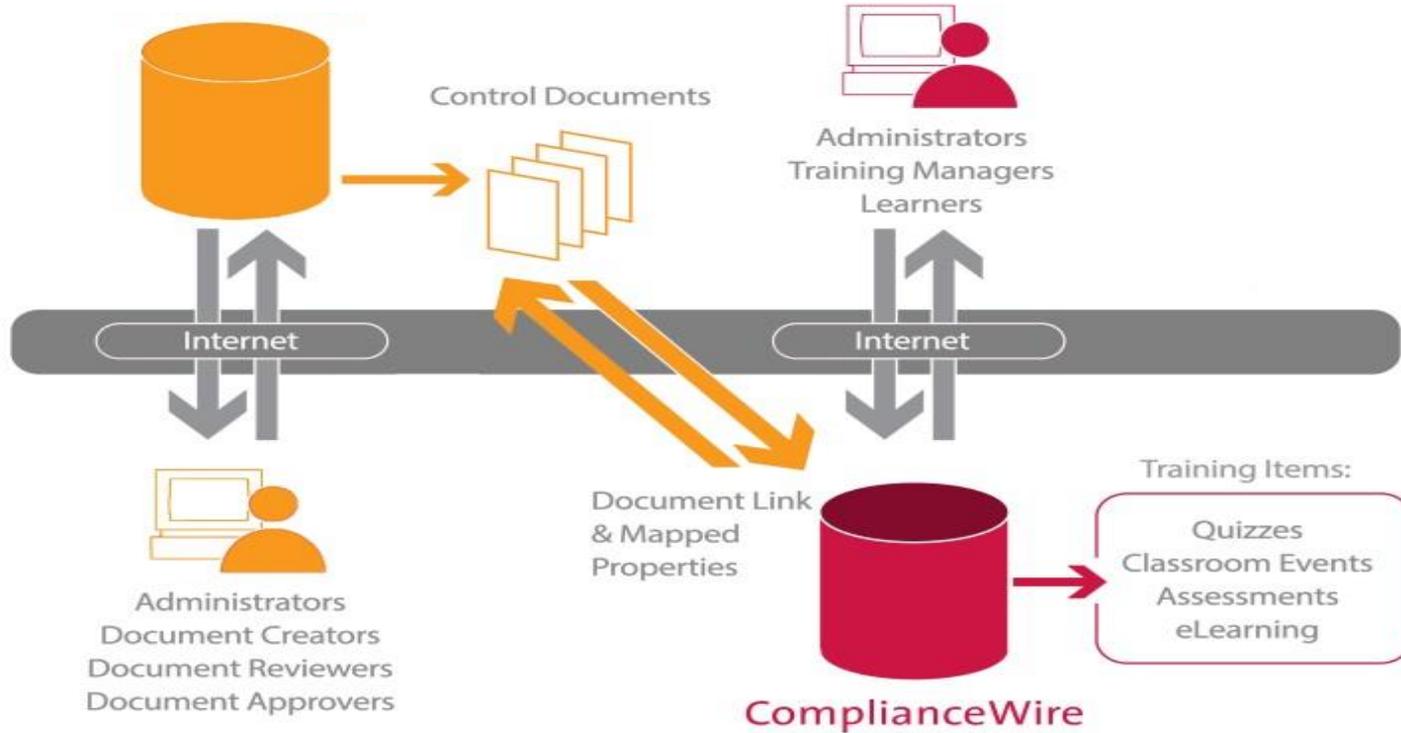
- Training Strategy
- Governance
- Automation of Compliance & Competency Management
- **Integrated Technology Infrastructure**
- Rapid Content Development, Localization & Delivery
- Metrics to Measure, Monitor, & Manage Compliance, Effectiveness, & Performance



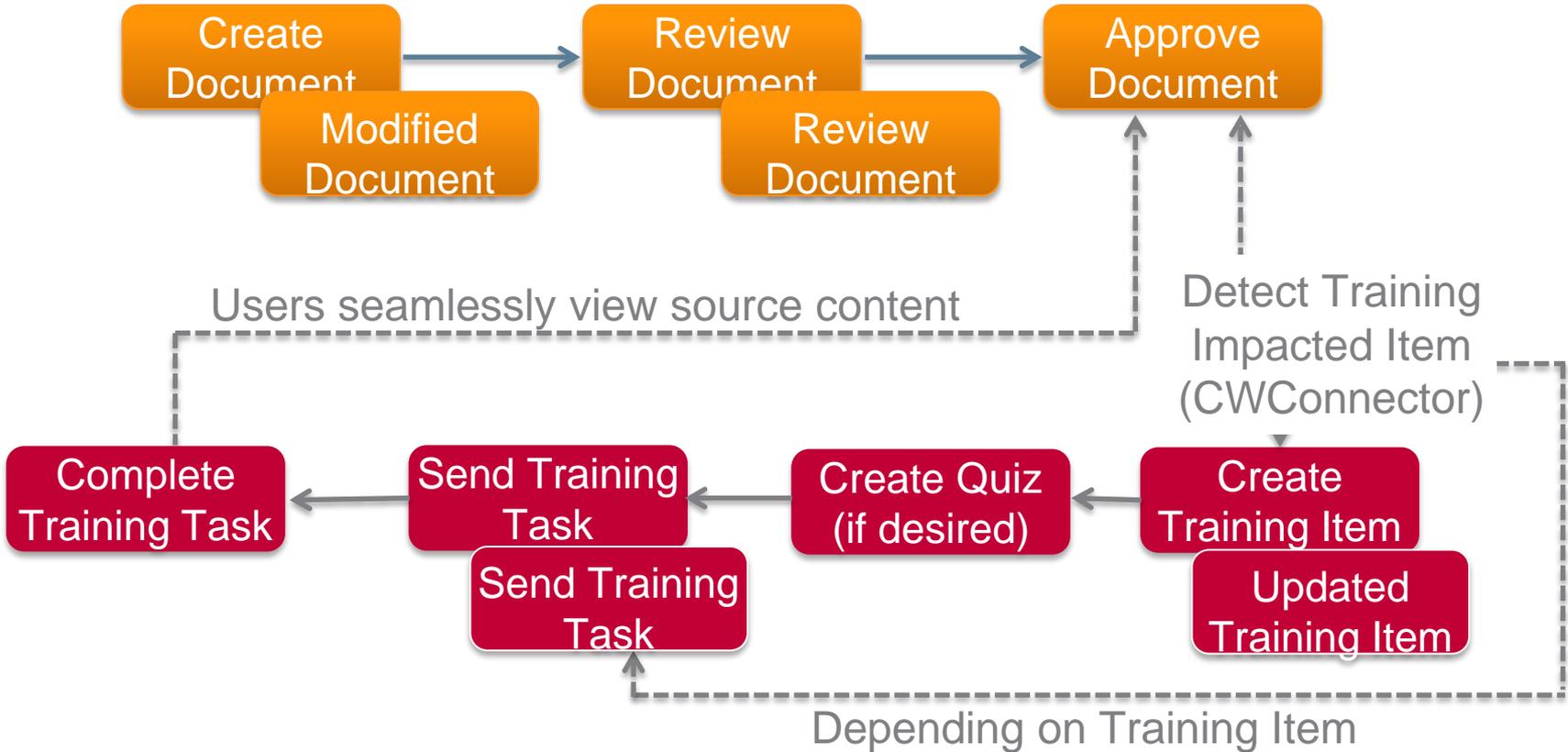
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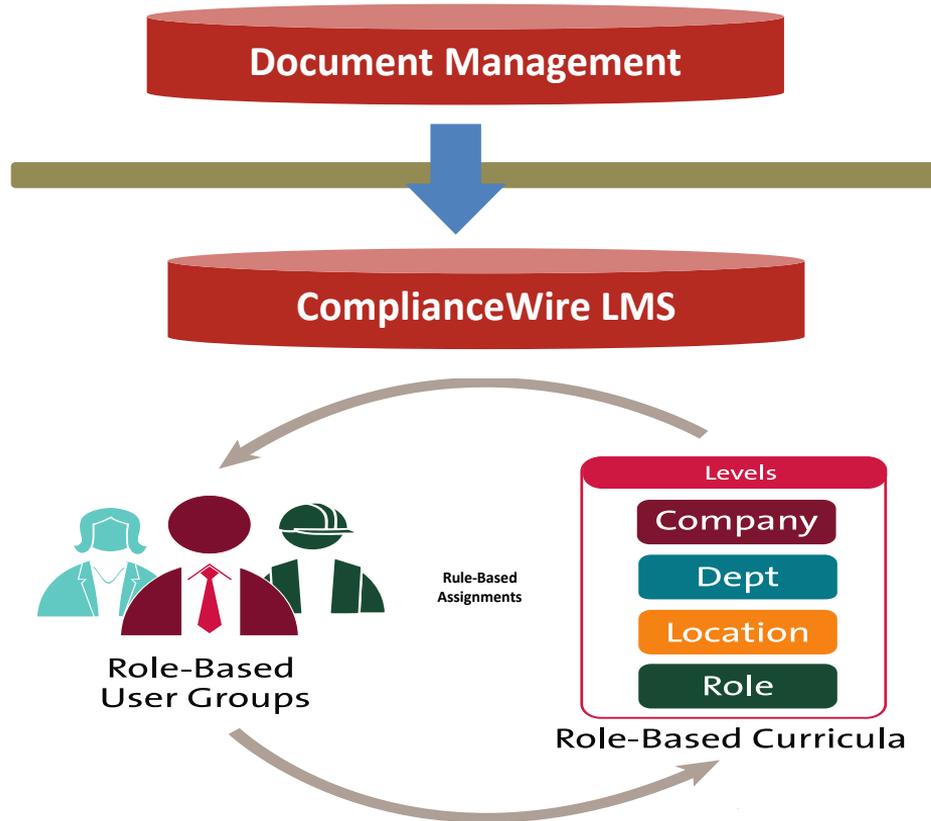
DMS Integration



DMS Integration



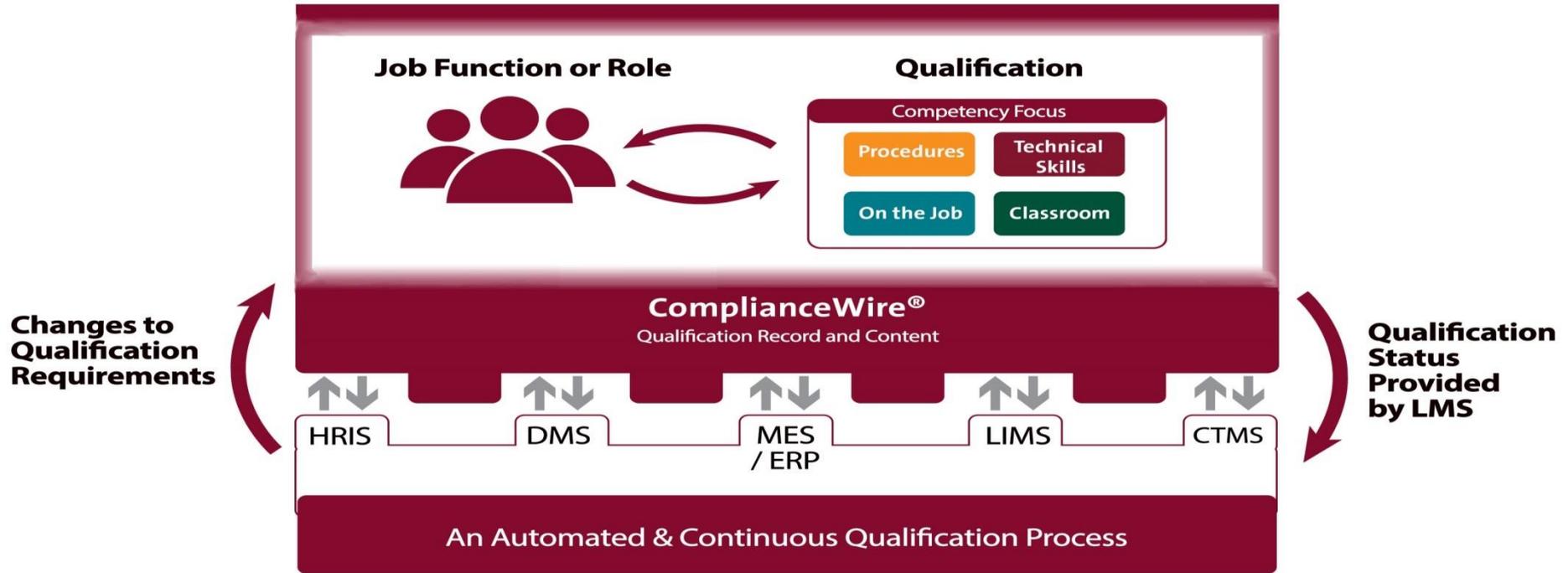
DMS Integration



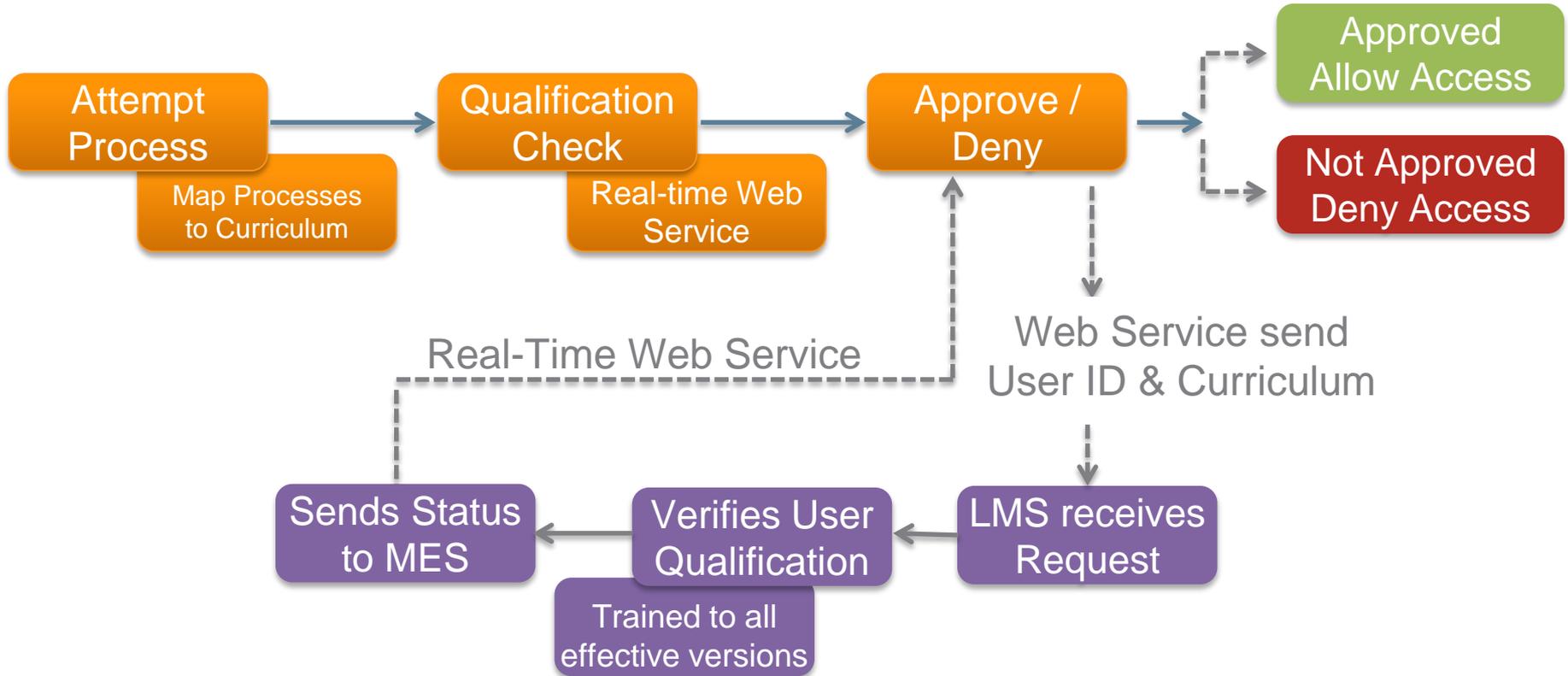
- Create new documents
- Revise existing documents
- The connector sends real-time metadata from DMS to the LMS
- Creates new training items
- Revises existing training items

- LMS automatically pushes out required training
- Ensures the Right People get the Right Training at the Right Time

Imbedding Qualification Into Process



Operator Certification Integration



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Benefits of an Integrated Infrastructure



Seamless Processes



Real-time Integration



Automated Training
Workflows



Eliminate Human
Element

Accelerated Compliance



Faster Validation



Detailed Audit Trails



Ensure Compliance –
Focus on Performance



Questions?

