

The Four Faces of Compliance Training

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John Constantine



Kent Malmros

ORCHESTRALL

John is a veteran of over 30 years in the life sciences industry, first at GlaxoSmithKline, then at Merck as Executive Director, Merck Polytechnic Institute in 2008, and joining Orchestrall, Inc. as Senior VP, Learning & Talent Solutions in 2016. His background includes Sales, Marketing, Corporate Staffs, Information Technology, Research and Development, and 25 years in Learning & Development.

VEEVA SYSTEMS

Kent has spent the majority of his career delivering technology-enabled training solutions to life sciences, holding leadership positions at industry leading companies such as AdMed, ClearPoint (Red Nucleus), UL EduNeering (UL), and now Veeva Systems.



The Industry Perspective

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A ComplianceLib!*



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One Problem, Three Perspectives



GxP Training

- SOP & Policy training (role-based)
- Part 11 compliant eSigs
- Qualification and Compliance
- Validation required
- Reporting emphasis
- First training adoption



Commercial Training

- Mobile friendly (includes offline)
- Engagement-focused
- Launch and field readiness
- Content-types expand
- Compliance burdens change
- Validation not necessary



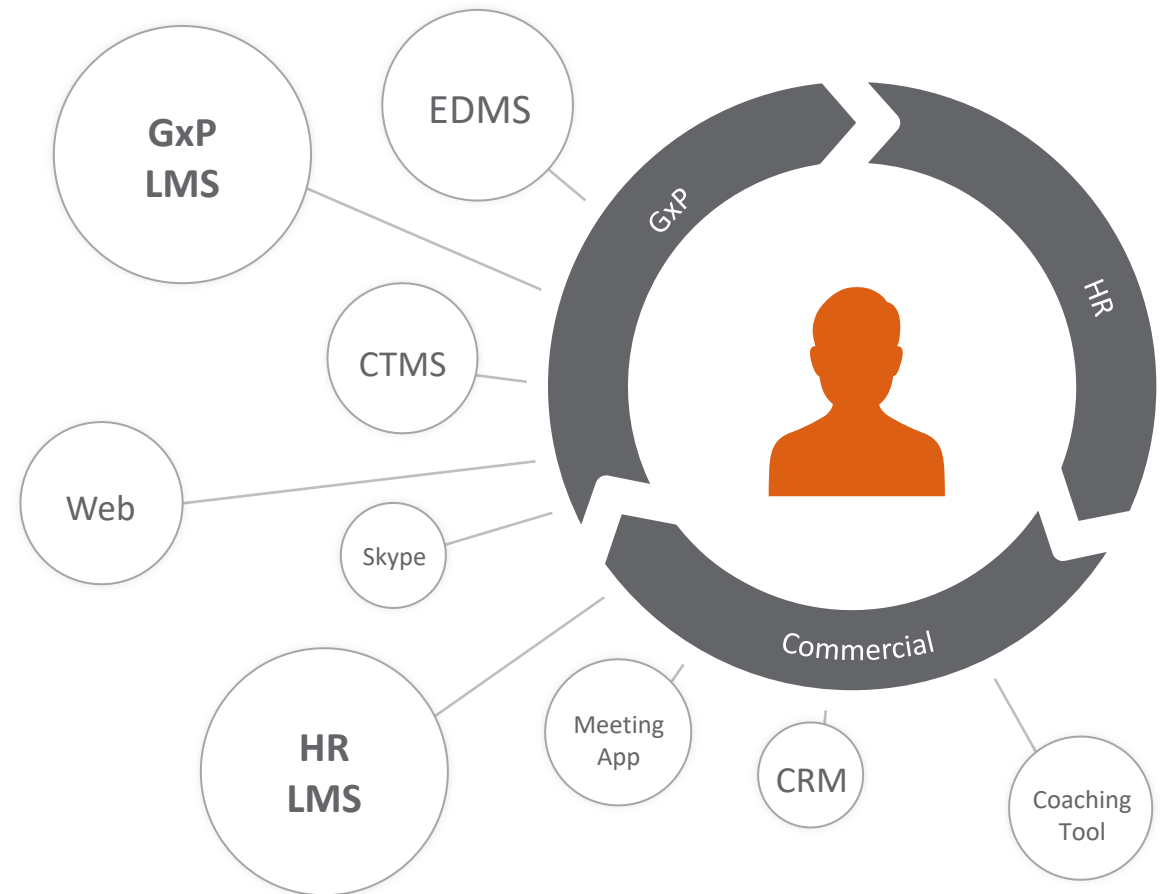
HR Training

- Learning paths and competency
- L&D orientation
- More aligned with commercial
- Overlap with compliance
- Often own eLMS
- HR-integration focus

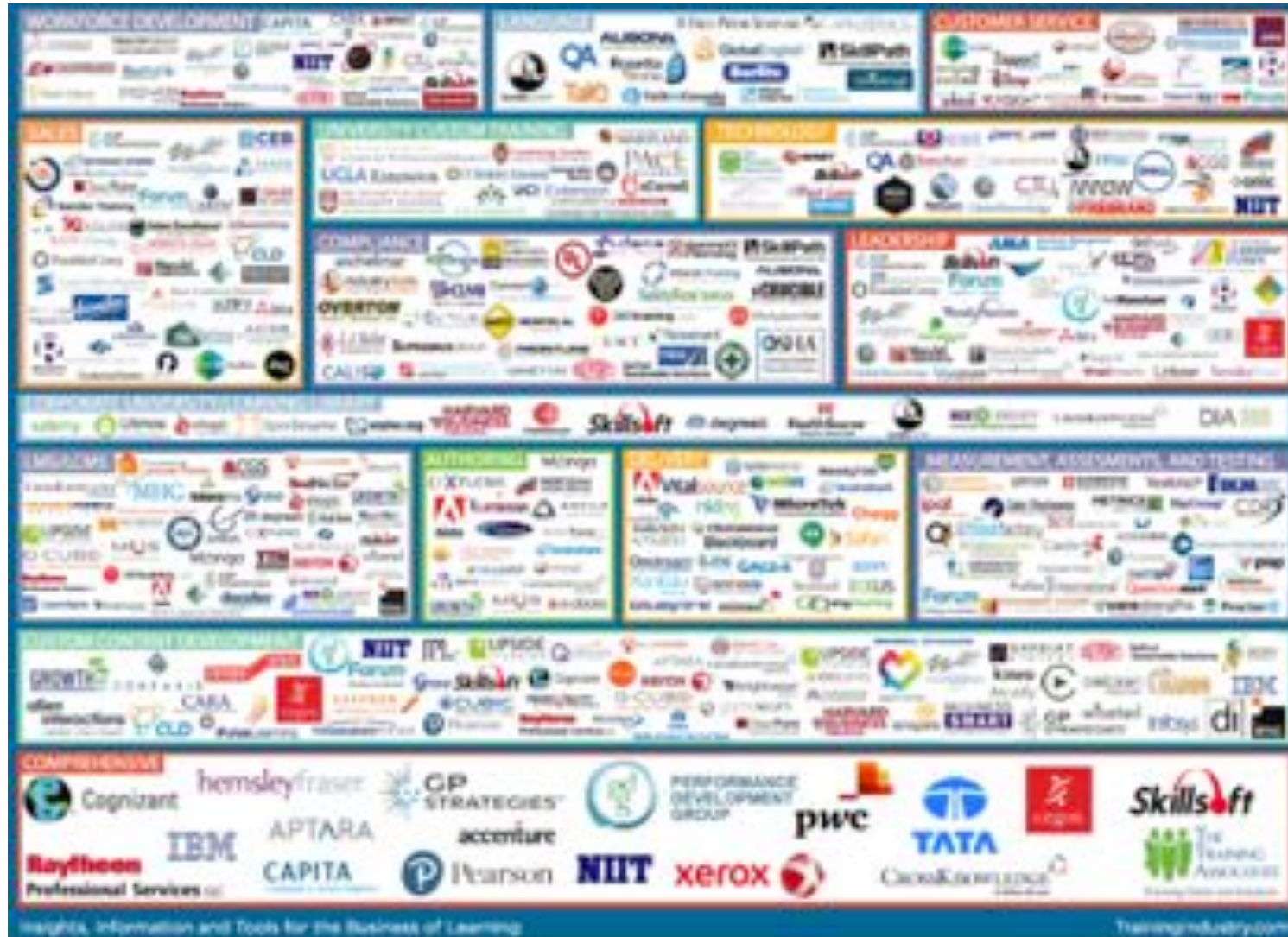
Enabling the Life Sciences Digital Ecosystem



Different content, delivered in different media types, organized by roles throughout different parts of the organization.



Corporate Training Landscape



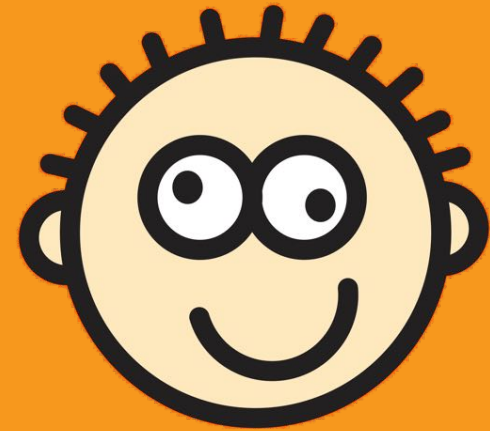


Training as a Part of Overall Compliance

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Training as Part of Overall Compliance Efforts



Why does it matter?

Training is the only way to demonstrate qualification



What does the FDA look for?

Gaps, oversight, overdue or general non-conformance



What's the impact of being out of compliance?

Poor performance, quality events, inspection findings.

Digging Deeper on Impact

Investigation Findings



- Internal quality events with training impact
- CAPA process oversight
- Chasing your tail

Warning Letters and 483s



- Inspections with training non-conformance lead to advisory actions by FDA
- 483 lists specific observations
- Easy to demonstrate compliance

Overall Impact



- Potential for large fines and business interruption
- Inefficient business processes
- Questionable product quality

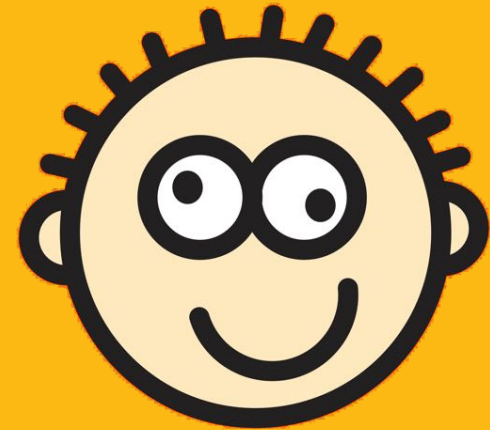


The Four Faces of Compliance Training

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The Four Faces of Compliance Training



Training Status

Validated Systems

Current and Correct Content

Qualification-driven Learner Roles

Key Takeaway:

It's not just about completing assignments on time

The Owners of Compliance Training



Training Status:

Learners, managers

Validated Systems:

Business process owners, IT

Current and Correct Content:

Subject matter experts, curriculum developers

Qualification-Driven Learner Roles:

Learning strategists, department heads, training

Key Takeaway:

It takes a village. Training is just the village chief



Digging Deeper: Each of the Four Faces

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Training Status

The Favorite Son



Training Status

The Favorite Son



KNOWN

Learners need to get the right stuff complete at the right time

UNKNOWN

Learner compliance can just as easily be derailed by lack of consumption clarity

MYTH

The definition of overdue.

INSIGHT

Status relative to job function is the key;

KEY TAKEAWAY: Status is critical relative to events. There's always a chance to get items completed and remediate.

Validated Systems

The Misunderstood Uncle



Validated Systems

The Misunderstood Uncle



KNOWN

GxP Training must be completed in a validated learning platform.

UNKNOWN

Any connected part that is not validated jeopardizes the entire ecosystem

MYTH

Any training content can be assigned through a validated learning platform

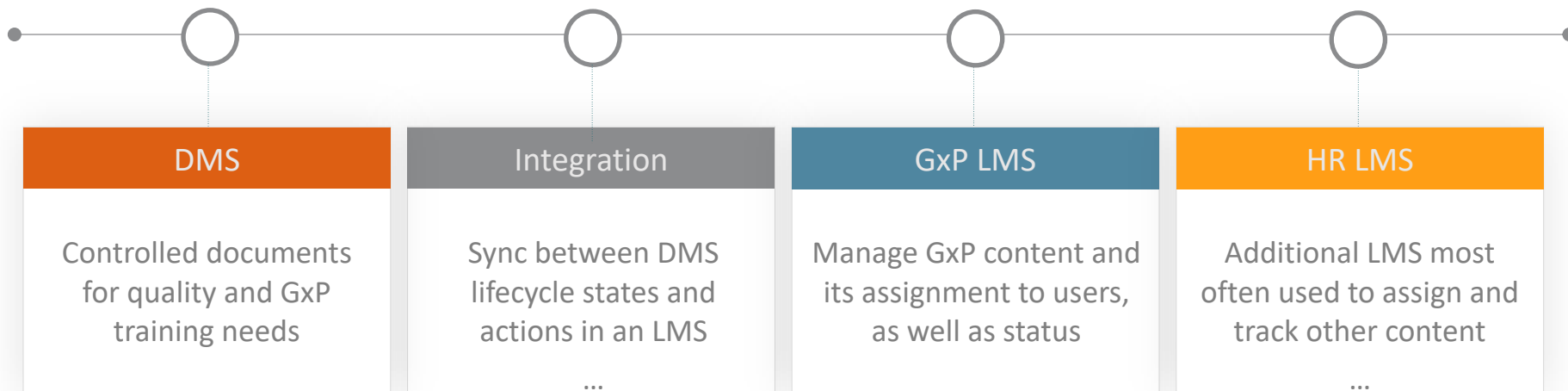
INSIGHT

Ensure any learning platform meets all critical components

KEY TAKEAWAY: Training system validation has tentacles; ensure you map the reach and identify any gaps.

Validated Systems

The Misunderstood Uncle



Current and Correct Content

The Fickle Grandparent

TIME
FOR!

NEW
CONTENT



Current and Correct Content

The Fickle Grandparent



KNOWN

Controlled documents
require retraining based on
critical revisions

UNKNOWN

Content changed based on
agency guidance updates
share the same burden

MYTH

Non-GxP doesn't share the
same burden of review and
currency

INSIGHT

Ensuring you have the right
content is a balance.

KEY TAKEAWAY: Training content and derivative plans require their own periodic review schedule, exclusive of reviews driving source document review cycles

Qualification-driven Learner Roles

The Millennial Nephew



KNOWN

We need to be concerned about under-training

UNKNOWN

The agency is increasingly concerned about over-training

MYTH

Learner roles are not necessarily linked strictly to someone's job description

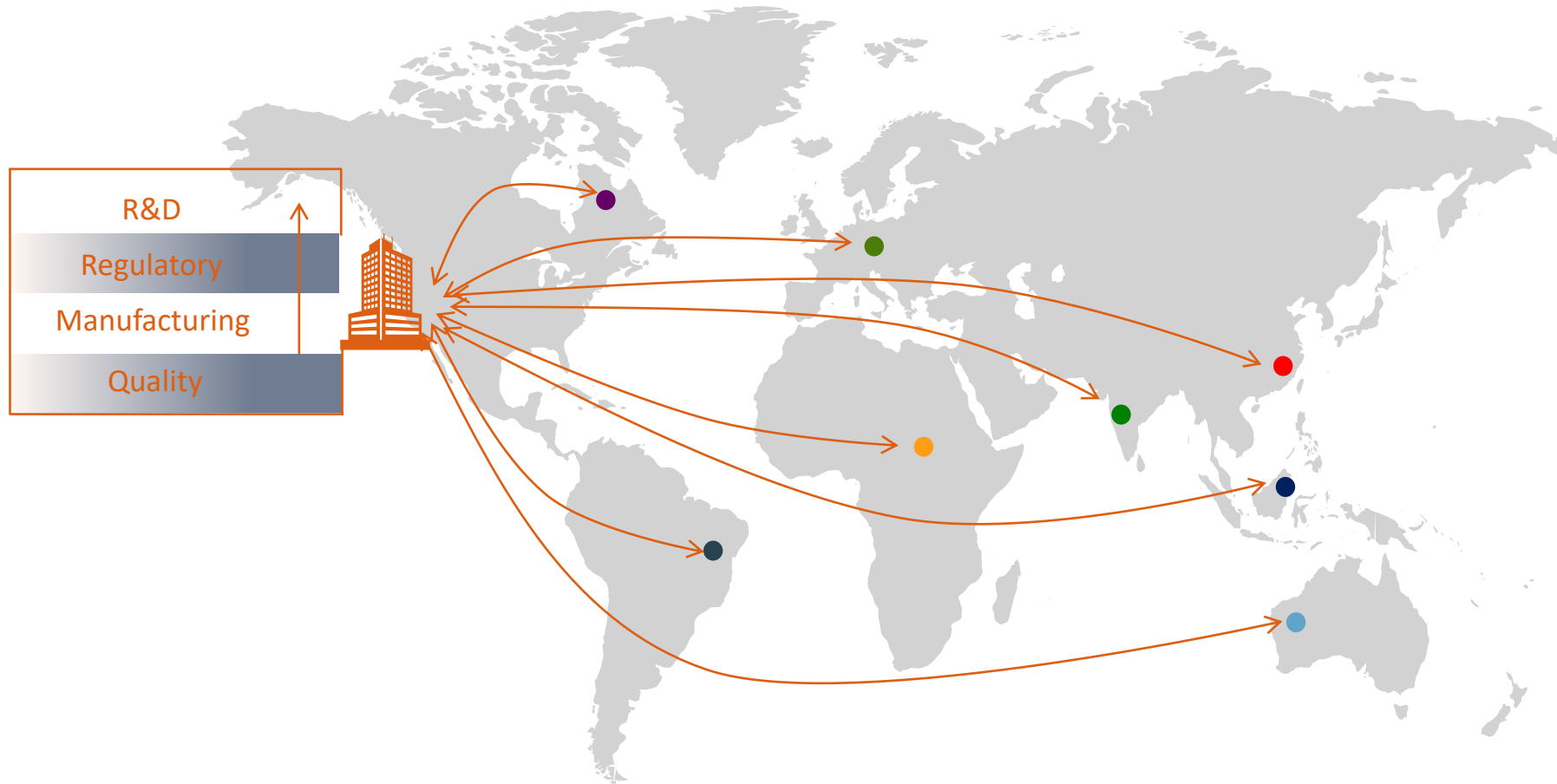
INSIGHT

Well-developed learner roles are the pivot point

KEY TAKEAWAY: Monitoring training status at a granular learner role level allows you to deliver the right content to the right people at the right time

Qualification-driven Learner Roles

The Millennial Nephew





Making the Family Less Dysfunctional

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Making the Family Less Dysfunctional



Making the Family Less Dysfunctional

Training Status:

Put status reports in the hands of managers

Validated Systems:

Move towards a single unified system

Current and Correct Content:

Coordinate periodic review of source and training content

Qualification-Driven Learner Roles:

Build learning path based on micro-curricula

Unifying Thought:

Choose one challenge at a time.





John Constantine
john.constantine@orchestrallinc.com



Kent Malmros
kent.malmros@veeva.com