

Compliance Training In
Pharmaceutical Research & Development

Dawn Antonis,
Associate Director
Global Compliance Training

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- ❖ We work in a highly regulated industry, complex world of statutes & regulations, GLPs, GCPs, GMPs
- ❖ Need to enable employees to understand expectations

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❖ Why do we train in Compliance?

- Do we do it to just tick a box and say we've covered our tracks?
- No, we do it to better develop our culture
 - ✓ “Commitment” rather than “compliant”
 - ✓ Gaining and keeping the competitive edge
 - ✓ Doing it right the first time, eliminate re-work
 - ✓ Establish the right culture

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- ❖ How do we train in compliance in a research environment?
- ❖ We don't just TRAIN
- ❖ We must first set up a Compliant training Infrastructure
- ❖ Then we must identify our needs—
 - Content
 - Delivery
 - Audience
- ❖ Then we must decide whether to buy or build training

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❖ So, your baseline before content delivery

➤ Technical Infrastructure in Place

➤ Learning Objectives Identified

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To accomplish this:

❖ **A 5 Step Model:**

- 1) Understand your Audience**
- 2) Understand your Environment**
- 3) Understand your Obligations (regulatory & otherwise)**
- 4) Understand your Limitations (staffing, technology, remote users, etc)**
- 5) Understand your Learning Objectives & Desired Outcomes**

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1) Understand your audience

- Are they IT savvy?
- What is their baseline subject knowledge
- Culture

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❖ Leaner Styles in Research

➤ Science & Learning

- ✓ Highly intelligent & educated
- ✓ No time for this!
- ✓ Practical, pragmatic & EFFECTIVE!
- ✓ WIIFMs are critical
- ✓ Resistant to new knowledge
- ✓ Scientists depend upon physical senses for “proof positive” –
vague, non tactile training can be difficult

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2) Understand your Environment

- Lab worker and/or administrator environments
- Telecommuters or road warriors?
- Shift work

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3) Understand your obligations (regulatory & otherwise)

- GMP Concerns:
 - ✓ Annual Refreshers
 - ✓ New Hire Training
 - ✓ Documentation & Tracking
- Other Regulatory Obligations

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4) Understand your limitations (staffing, technology, remote users, etc)

- Limitation and creative approaches to learning in a research environment:
 - ✓ Classroom
 - ✓ e-Learning
 - ✓ Hybrid systems
- Standardized Curriculum:
 - ✓ Saves money
 - ✓ Delivers consistent messages
 - ✓ Balances training delivery – all courses not just dumped at once

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5) Understand your Learning Objectives & desired outcomes

- ❖ Synchronous or Asynchronous?
- ❖ Measurement and ROI
 - ✓ Testing required?
 - ✓ Attestations?
 - ✓ How will you know you've met your goals?

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❖ Therefore, training in research must be:

- quick hits
- perceived as valuable
- available JIT
- available in various formats and locations (labs, etc)
- creative, but not too creative!
- not too touchy feely
- relevant – make them see the value, whether it's related to science or not. If it's saving time by less rework, say so. If it's saving time for science, by having fewer audit exceptions because notebooks are better documented, say so.
- focus on quality in the workplace with real examples

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❖ Closing:

- Training Industry Best Practices and Standards will work in research environments, with just a little extra massaging and discussion to ease the scientific minds.
- Commitment rather than Compliant!