Training Effectiveness

Training Methods/Modalities to Create Effective Learning & Retention
# Top Learning Priorities for 2014

<table>
<thead>
<tr>
<th>Priorities</th>
<th>2014 Priority</th>
<th>2013 Priority</th>
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<tbody>
<tr>
<td>Measuring training effectiveness</td>
<td>67%</td>
<td>56%</td>
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<tr>
<td>Collecting training data to support the organization's quality or compliance metrics</td>
<td>66%</td>
<td>59%</td>
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<tr>
<td>Responding to inspections from global regulatory agencies</td>
<td>51%</td>
<td>46%</td>
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<tr>
<td>Improving SOP and policy management</td>
<td>46%</td>
<td>52%</td>
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<tr>
<td>Adding risk-based approaches to training programs</td>
<td>46%</td>
<td>26%</td>
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Learning Maturity Model

Focusing on Training Methods/Modalities to Create Effective Learning & Retention
Levels of Training Effectiveness

- Reaction – What learners thought and felt about the training
- Learning – The resulting increase in knowledge or capability
- Behavior – Extent of behavior and capability improvement / implementation / application
- Results – The effects on the business of the resulting from the change in learner behavior.
Think about the best training . . .

. . .that you have taken as an Adult
Think about the best training . . .

. . .that you have taken as an Adult

Had clear objectives
Addressed “why” it was important to you
Contextualized
Allowed for opportunities to use the new knowledge and existing knowledge to solve problems
FDA’s View On Training Effectiveness

Effective Training Programs Include the Following (for both 21 CFR Part 211 and Part 820):

• Personnel must be trained in the particular operations that they perform.
• Personnel must be trained in the current good manufacturing practices (CGMP).
• This includes the regulations and the written procedures (SOPs) required by these regulations
• Training must be conducted on a continuing basis with sufficient frequency to assure that employees remain familiar with CGMP requirements
Effective Training Programs Include the Following (for both 21 CFR Part 211 and Part 820):

- Good documentation & reporting of the training is important (e.g. date, content of training, trainer, length of training, etc.).
- Qualified individuals must conduct training.
- Documentation is needed to demonstrate that employees are sufficiently trained to perform specific operations.
  - Reading an SOP is not always an effective training technique.
  - Must include methods to ensure employees can effectively demonstrate their understanding of the training (e.g. assessments, OJT, etc.)
Common Deficiencies

- Lack of CGMP knowledge
- Employees not trained on their specific job function prior to performing duties
  - Temporary employees
  - Contract employees
  - Employees performing “non-critical” functions
- CGMP training not tailored to the firm’s training needs
Common Deficiencies

- Employees not proficient in language in SOPs
- Employees are “trained” but do not follow SOPs
- Frequent deviations from SOPs
- Operators not familiar with SOPs
- Frequent operator error as the root cause of investigation
- Trainers not qualified to train
Common Deficiencies

- “Read and understand” as the most common training strategy
- No effectiveness or competency/skills checks, especially for technical duties
- No formal system to identify and track training needs for each employee
- Refresher CGMP training not conducted with sufficient frequency
- Personnel not trained when procedures are revised
Is This Important to My Firm?

YES!

Since January 2010, FDA has issued 66 compliance actions with failure to adequately train employees as one of the issues- at finished dosage sites alone!

This includes 28 Warning Letters, 3 injunctions, and 1 seizure.

Alicia M. Mozzachio, RPh, MPH - Branch Chief, ICB1
Center for Drug Evaluation and Research (CDER) - 5/8/2013
FDA 483 Example 1

There is no training and qualification program for new analysts assigned to conduct testing of raw materials and finished products. Training is limited to self-training without an evaluation of the analyst's understanding of the analytical methods and equipment.

Alicia M. Mozzachio, RPh, MPH - Branch Chief, ICB1
Center for Drug Evaluation and Research (CDER) - 5/8/2013
FDA 483 Example 2

There is no record of training of applicable written procedures (cleaning SOPs) for the contract personnel authorized for cleaning in the sterile injection (Class A-D) and tableting departments after regular duty hours. Furthermore, your firm delegated the training on these SOPs to the contracted cleaning company without adequate oversight to ensure the trainings are performed and employees are capable of adequately performing their cleaning duties without compromising the sterile manufacturing areas.

Alicia M. Mozzachio, RPh, MPH - Branch Chief, ICB1
Center for Drug Evaluation and Research (CDER) - 5/8/2013
Your firm failed to ensure that each person engaged in the manufacturing, processing, packing, or holding of a drug product has the education, training and experience, or any combination thereof, to enable that person to perform his or her assigned functions (21 CFR 211.25(a)).

For example, an employee examining microbial plates was unable to read and accurately record microbial counts. Additionally, our investigator observed employees functioning in roles supporting your sterile filling operations that were not following the procedures that govern their activities, such as glove change frequency, the handling of dropped objects, personnel monitoring, and sample acquisition.
Several other recent warning letters, to U.S. and non-U.S. firms, have discussed training deficiencies:

- Training for specific job functions
- Training for general CGMP
- Repeated failures of personnel to follow procedures
Best Practices – Training Effectiveness

- **COMPANY LEVEL**
  - HR, Legal, Corporate Policies

- **LOCATION LEVEL**
  - New Hire Orientation, Safety, Local Policies

- **DEPARTMENT LEVEL**
  - Functional Knowledge, Systems, Procedures

- **ROLE LEVEL**
  - Operational/Job-Specific SOPs
Best Practices – Training Effectiveness

- SOP Review with Assessments
- SOP Training with Read and Understand
- SOP Review with Qualified Trainer Oversight
- SOP Review with Assessments

High

Probabilty

Low

Severity

High

Low
Tools to Support Effective Training

- **Initial Evaluation**
  - Exam or Evaluation Form

- **Core Content**
  - SOP, CBT, or ILC

- **On-the-Job (OJT) Training**
  - Dual e-signature Form

- **Refresher (3 months)**
  - Read & Sign (Key Learning Objectives)

- **Post-Assessment (6 months)**
  - Exam or Evaluation Form

- **Annual Refresher**
  - CBT or Read & Sign (Key Learning Objectives)
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Core Content – Instructor Led Training

• Based on the Risk Level … training modality may need to be more robust
• Allows for learners to share ideas, work in groups, and debate/discuss with their peers
• Allows discussion on difficult concepts
• Explore the “gray areas” within the topics
• Can provide team building and be a Change Management tool
Core Content – Instructor Led Training

• Use the electronic Class Sign-in Sheet to reduce manual administration and eliminate processing delays.
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On-the-Job Evaluation – Forms Training Items

- Great for documenting evaluations based on demonstrated performance
  - When online assessments are difficult to construct/deliver or inadequate based on the material
- Perfect for higher risk processes that required more focused training and evaluation
- Required instructor and learner agreement to complete training
On-the-Job Evaluation – Forms Training Items

Measuring Progress via Online Forms

Build Baseline and Post-Training Forms:
Data is captured for analysis that demonstrate improvement

Capture Signatures from Both Employee and Trainer/Supervisor
Provides visibility for manager oversight

Auditble Format:
Record can be presented as part of Certification curricula within an employee transcript
On-the-Job Evaluation – Forms Training Items

Use Mobile Devices for Forms

Manufacturing Employees:  
Replaces PC’s for shop floor OJT Training

Sales Representatives  
Great for ride along activities

Customers:  
CW accessible from all types of devices
On-the-Job Evaluation – Forms Training Items

Smart Forms Automate Assignments

Pre-Assessment Determination of Training Requirements:
Automatically assign the appropriate training based on data collected in the form.

Failure on the OJT Evaluation can trigger additional training:
Automatically assign additional ILC training.

Post Assessment or Annual Recertification:
Automatically assign remediation training if a failure occurs at post assessment or recertification.
Case Study: OJT Training & Assessment

Operations/Manufacturing Case Study

• Role Based Curriculum includes:
  • Read & Sign SOP’s with a Quiz
  • On-the-Job Training (OJT)
  • Standard Behavioral Assessment (SBA)
  • Annual Retraining of SOP’s

• Program shows both a minimum level of knowledge (quiz) and a minimum level of job performance (assessment)
Opportunities to Improve:

- Ensure the SOP training includes an understanding of any pre or post steps including issues with defects.
- Include a three month re-assessment of newly qualified operators to show no decline in performance.
- Annual re-assessment of performance for all operators.
- Align with performance measurement (production, yield, scrap, etc.)
Case Study: Knowledge Assessment, Delivery & Reinforcement

CREATE Certification Process

Initial Evaluation
Annual Refresher

Core Content
Post-Assessment (6 months)

Course Feedback Analysis

Refresher (3 months)
Operational Training – Systems (optional)

Protocol-Specific Training (optional)
Opportunities to Improve:

- Align with performance measurement (audit findings, etc.)
Corporate Compliance Case Study
• Foreign Corrupt Practices Act (FCPA) Training:
  • Smart Form that asks about how the employee interacts with Foreign Government Officials
  • Based on the response it classifies them in three groups (High / Medium / Low Risk)
  • System automatically assigns corresponding training curriculum
• Program ensures that the right level of training is being received and taken by the employees based on their risk to the company
• Eliminates over and under training
Case Study: Targeted Training by Risk Level

Opportunities to Improve:

- Have the manager either approve the form submitted by the employee or fill it out in for the employee
- Have the form filled out annually to account for changes in role
Case Study: Blended Learning

Risk Management Case Study

- Educate the organization (over 3,200 trainees) on Risk Management (ISO 14971)
  - Foundational Computer Based Training (CBT) course on the basics of Risk Management (one of the most complex and least understood of the QSR’s)
  - Full day classroom session to discuss how to implement Risk Management in their organization
  - Class session includes customized/localized case studies/examples
  - Conducted Train-the-Trainer sessions to ensure enough qualified trainers were available to locally train employees
- Program ensured a consistent understanding of Risk Management requirements and more detailed training on how to apply those concepts to their organization