Objectives for this session:

- Establish the value of role-based curricula
- Share FDA and investigator expectations
- ID industry best practices
- Share a compliance model for role-based qualifications
FDA Expectations for Training

• Each employee shall have the education, training, and experience (21 CFR211.25)
• Training shall be in the operations the person performs
  - Regulations related to their function
  - Written procedures
• Establish procedures for identifying training needs and assuring all personnel are adequately trained to perform responsibilities
• Trainers shall be qualified
• Training is conducted on a continuing basis
  - Refresher – assure employees remained trained
  - Continuous – new/revised regulations and procedures
• Training shall be evaluated and documented

Industry Best Practices

• Training is curriculum – driven
  - Each GMP job position (Role) has a Qualification curriculum
  - Courses are sequential (order is important)
  - Completion progress is tracked
• Qualified trainer’s
  - Supervisor
  - Subject matter expert with documented skills
  - Specific curriculum for trainers on “how to train others”
• Written training instructions – stepwise TTT- OJT
• Learning assessment
  - Comprehension
  - Demonstration
• Retraining: refresher vs ongoing
  - Procedures change
  - Process changes
  - Deviations happen
Qualification by – Job Role

- ID Critical job tasks
- Performance-based curriculum
- Identify when Qualification Achieved (endpoint)
- Independence achieved when Qualified
- Consider periodic re-qualification (recurring assignment)
- Consider Disqualification

Curriculum Architecture Process

Analysis Phase
- Identify Goals & Expectations
- Analyze Work Flow & Resource Needs
- Identify Job Positions
- Identify Competencies

Design Phase
- Define Required Training
- Define Required Qualifications
- Map Training & Qualifications
- Define Learning Progression

Development Phase
- Identify Training & Qualification Gaps
- Assess Adequacy of Training & Qualifications
- Fill Gaps with Recommended Training & Qualifications
- Develop Curriculum Architecture

Implementation Phase
- Load Architecture into LMS
- Assign Employees in LMS
- Track & Monitor Training Completion in LMS
- Track & Monitor Qualification Completion in LMS
Process Steps

• Consider Fundamental Questions

• 1. Identify the Target Audiences – Work Flow/Job Roles
• 2. Identify Critical Tasks (functions) for each Role
• 3. Write Learning Objectives (what is expected)

4. Define the Learning Progression

• Hierarchy may be multi-level – Basic to Advanced
• Sequence learning activities
• Start with Core/Basics and move towards specifics
5. Gather available training materials

- Examples: Corporate Policies, Quality Standards, job aids, SOPs, training checklists, classroom courses, online learning, etc.
- Plug what you have available into each role
- Begin creating matrices

6. Notice the numerous “Gaps”

- Gaps = compare what is expected vs available training
  - No learning activity
  - Poorly developed learning activity (most SOPs)
  - SOP – Add knowledge test, and skill assessment
7. Fill in the Gaps

- Add new courses
- Augment existing materials with tests
- Add performance evaluation
- Identify preferred learning approach

8. Finalize the learning architecture

- Gain agreement among stakeholders
  - Supervision
  - The learners
- Suggestion: form project teams in each area
  - Curriculum building is not for training staff alone
- Check again for correct sequencing
9. Load the courses into the LMS

- Load courses into CWire
- Critical to use consistent course numbering
- Develop a course numbering convention system
- Tremendously aids report generation

Example: CO0713571 SOP for Training or SOPQC13571 (version#)

9a. Create the Curriculum Hierarchy

- Master Curriculum
  - Sub-Curriculum
  - Sub Curriculum

  Core GMP Knowledge (Applies to everyone)
  Manufacturing GMP (Applies to all Mfg. employees)
  Specific Job Qualification (Applies only to specific function)
Role-Based Curricula: Applied Learning

OJT Specifics
1. Job related SOPs
2. Skills demonstrated
3. Qualifications achieved

Compliance/Quality Knowledge by Job Function
1. Operating Technician
2. Validation Engineer
3. Warehouse Operator

Core Compliance/Quality Knowledge
1. Corporate Policies & SOPs
2. Basic GMP/QSR Courses

Tier III
1. Role-based Qualification Curriculum Assigned
2. Internal SOPs, Batch Records, Mentoring, OJT
3. Demonstrated Knowledge and Skills Evaluated
4. Qualifications by Functions Achieved
5. Cross-training to other Functions
6. Additional Qualifications Achieved
7. Annual GMP Refresher (Tier I review)
8. Continuous Learning (Compliance trends/Issues)

Tier II
1. Orientation to GMP Compliance
2. Understanding GMPs for Facilities and Equipment
3. GMP Principles for SOPs
4. GMP Principles for Batch Records
5. Principles of Good Documentation
6. Part 11: Electronic Records; Electronic Signatures
7. Awareness of FDA Inspections

Tier I
1. Orientation to GMP Compliance
2. Understanding GMPs for Facilities and Equipment
3. GMP Principles for SOPs
4. GMP Principles for Batch Records
5. Principles of Good Documentation
6. Part 11: Electronic Records; Electronic Signatures
7. Awareness of FDA Inspections

Role-Based Curriculum

TIER III – OJT, Role Specific Knowledge/Skills Qualification
1. Role-based Qualification Curriculum Assigned
2. Internal SOPs, Batch Records, Mentoring, OJT
3. Demonstrated Knowledge and Skills Evaluated
4. Qualifications by Functions Achieved
5. Cross-training to other Functions
6. Additional Qualifications Achieved
7. Annual GMP Refresher (Tier I review)
8. Continuous Learning (Compliance trends/Issues)

TIER II – Intermediate GMP Manufacturing Curriculum
1. Care and Handling of Drug Product Components, Containers and Closures
2. Maintenance and Cleaning of Drug Manufacturing Equipment
3. Principles of Process Controls
4. Concepts of Process Validation
5. Implementing an Equipment Qualification Program
6. Essentials of an Effective Calibration Program
7. Change Control
8. Failure Investigations for Pharmaceutical Manufacturers

TIER I – Core Manufacturing GMP Curriculum
1. Orientation to GMP Compliance
2. Understanding GMPs for Facilities and Equipment
3. GMP Principles for SOPs
4. GMP Principles for Batch Records
5. Principles of Good Documentation
6. Part 11: Electronic Records; Electronic Signatures
7. Awareness of FDA Inspections
10. Assure learning evaluation

- Use the best measurement approach
- One course can have more than one measure – SOPs
- Minimum: acknowledgement of reading
- Maximum: Task performance and skill assessment
Process Steps to Curriculum Mapping

1. Identify GMP job roles
2. Identify Job Functions for each Role
3. Write Learning Objectives for each Function; Identify competencies
4. Review existing training and link to job functions and learning objectives
5. Look for GAPS
6. Search for courses, SOPs, online learning, etc. or create new learning materials needed
7. Evaluate the Learning
8. Curriculum Map

Final Thoughts

Remember to Be
• patient
• thorough
• collaborative
• consistent
• effective – measure success