Quality Education (Training)

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What are your biggest challenges with Training (System)?

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What are your biggest challenges with Training Systems?

For me:
Too much time on “tick list”
Not enough on real education

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"Training is a powerful tool. It plays an important role. But using it inappropriately is a waste of time, money and opportunity."

WHO GMP Part 3: Training (2006)

*https://www.google.co.za/#q=WHO+GMP+Part+3:+Training+(2006)&**

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Requirements

EU GMP Chapter 2 (2013): 5 paragraphs.

- **Who?** Personnel whose activities can affect quality of the product, visitors.
- **What?** QMS, GMP, job requirements (sampling, cleaning), specialist (e.g. biosafety, aseptic)
- **When?** New and continued. Practical effectiveness assessed periodically.

- Training programmes should be available, approved by either the head of Production or the head of Quality
- Training records.
- Consultants qualifications *added.*

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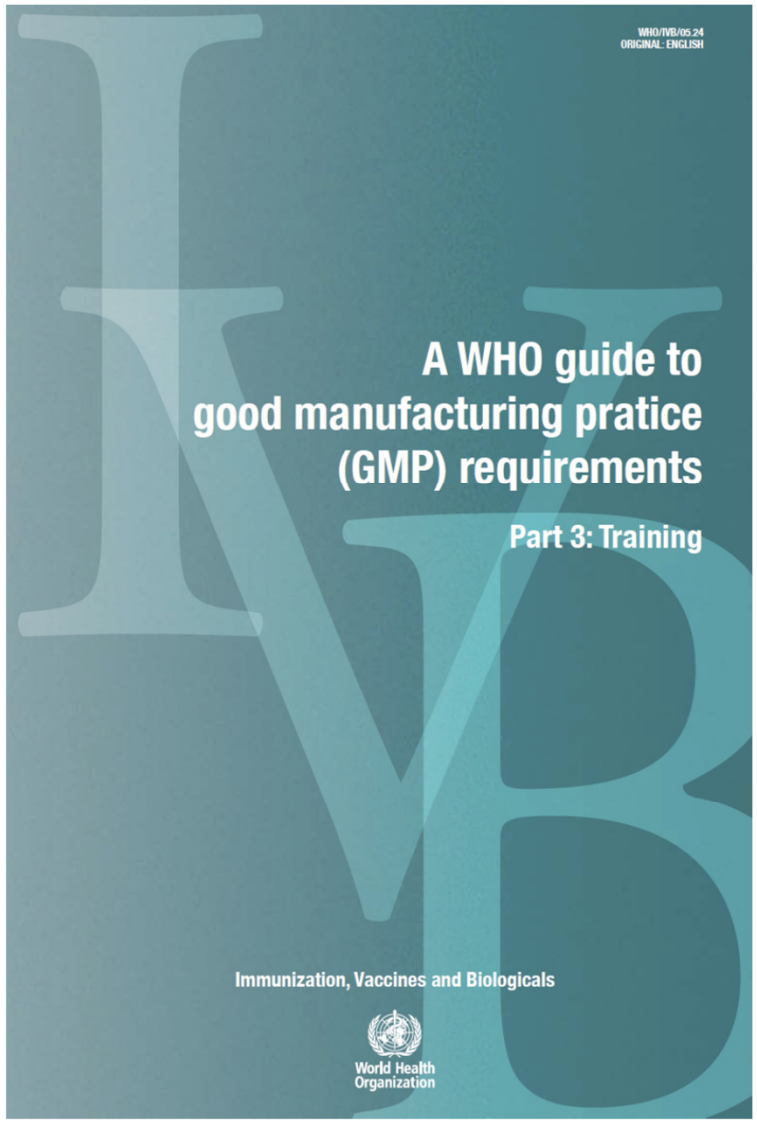
2006



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- Training Programmes

EU GMP Chapter 2 (2013)
https://ec.europa.eu/health/documents/eudralex/vol-4_en

- Training Curriculum (roles) – SOP, other
- Training Plan (annual)

WHO GMP Part 3: Training (2006)
http://apps.who.int/iris/bitstream/10665/69396/1/WHO_IVB_05.24_eng.pdf

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Training System Responsibilities

System coordinator	• Define and manage the Training System • Maintain learning materials (versions) • Qualify instructors
Instructors	• Deliver training using approved training materials.
Trainee	• Complete or Attend & Participate • Manage own training compliance
Supervisors	• Learning programme and plans for staff • Ensure staff are qualified to do their job
Quality	• Compliance oversight (review metrics) • Approval of learning programme, materials, qualified instructors

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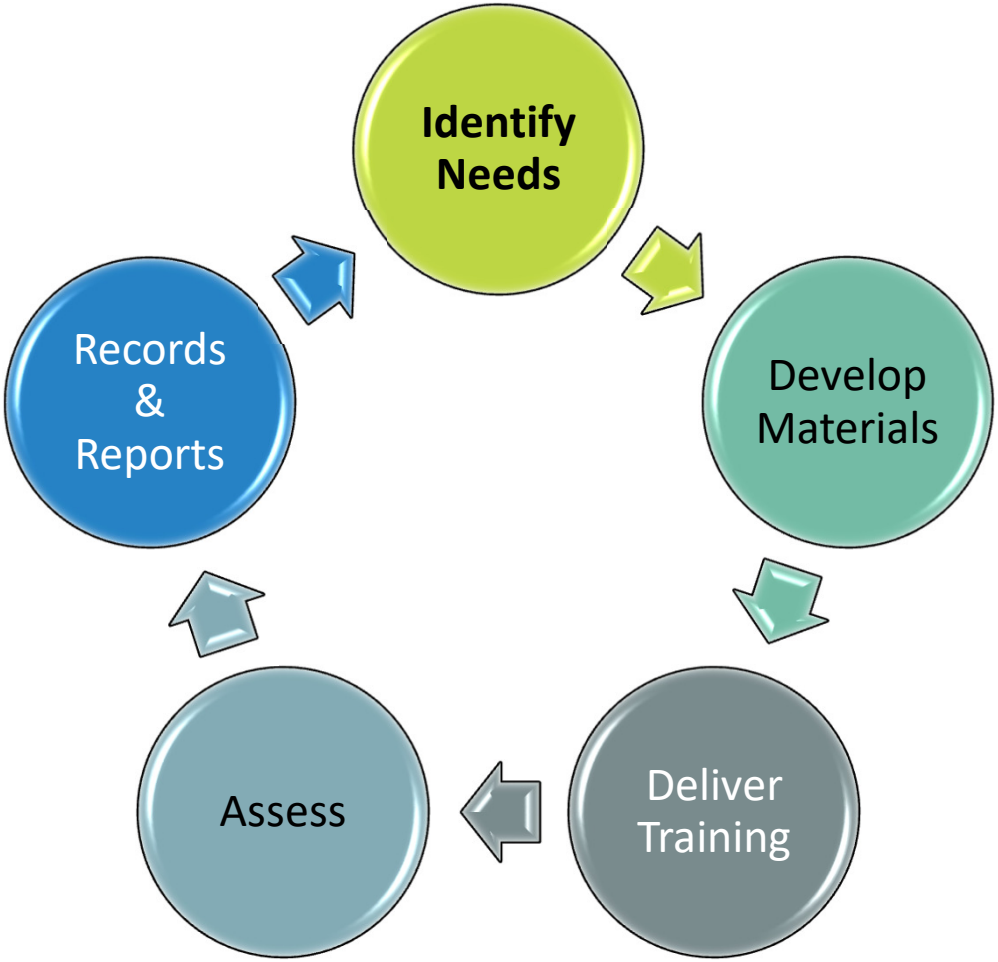
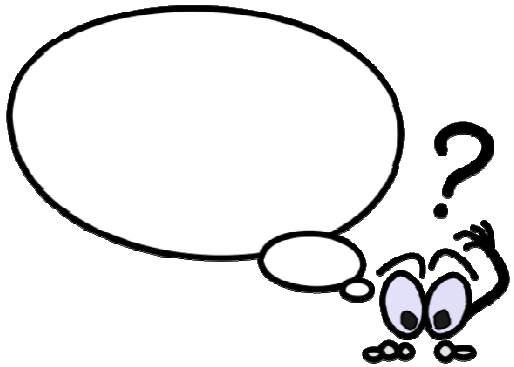
Training System



Needs

- Basic induction
- GMP - levels
- QMS - levels
- Specialized (e.g. lab)
- Competency licensing



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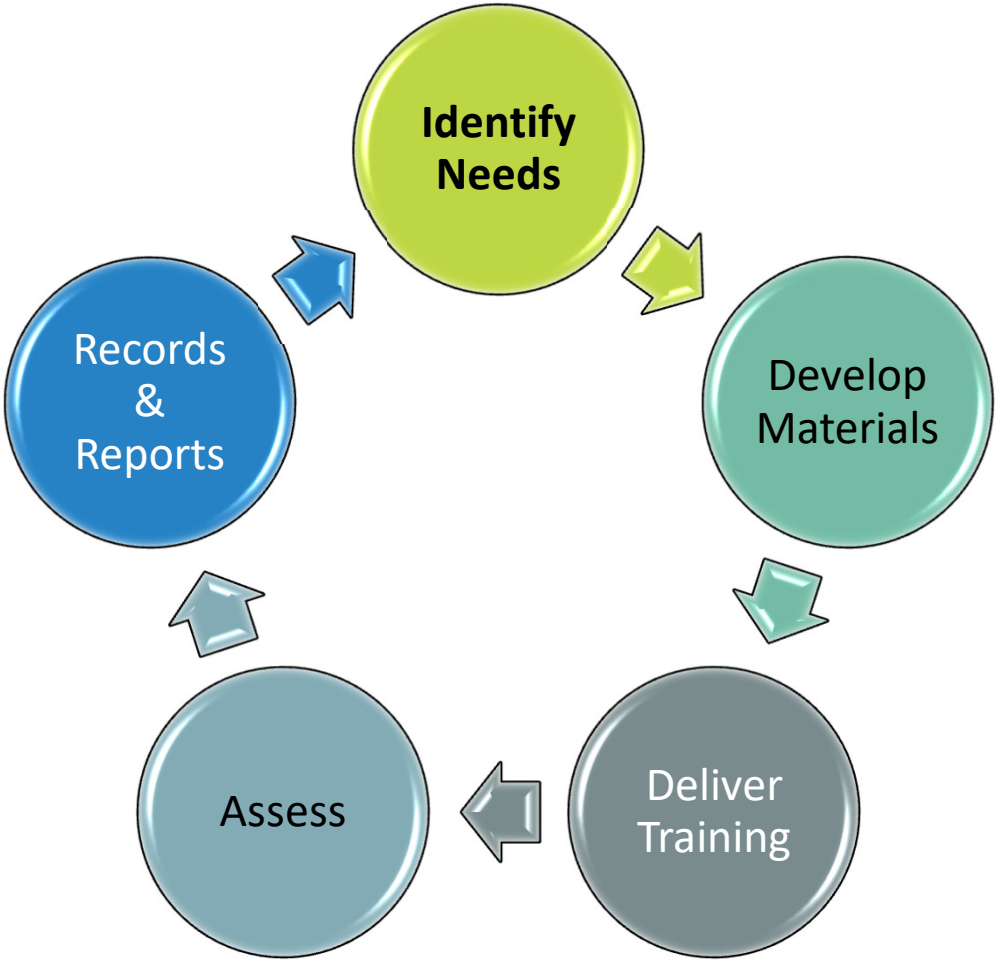
Training System



Needs

- Basic induction
- GMP - levels
- QMS - levels
- Specialized (e.g. lab)
- Competency licensing

(e.g. gowning, sterility testing, media fill, visual inspection).

Attach license to batch records or enter expiry date

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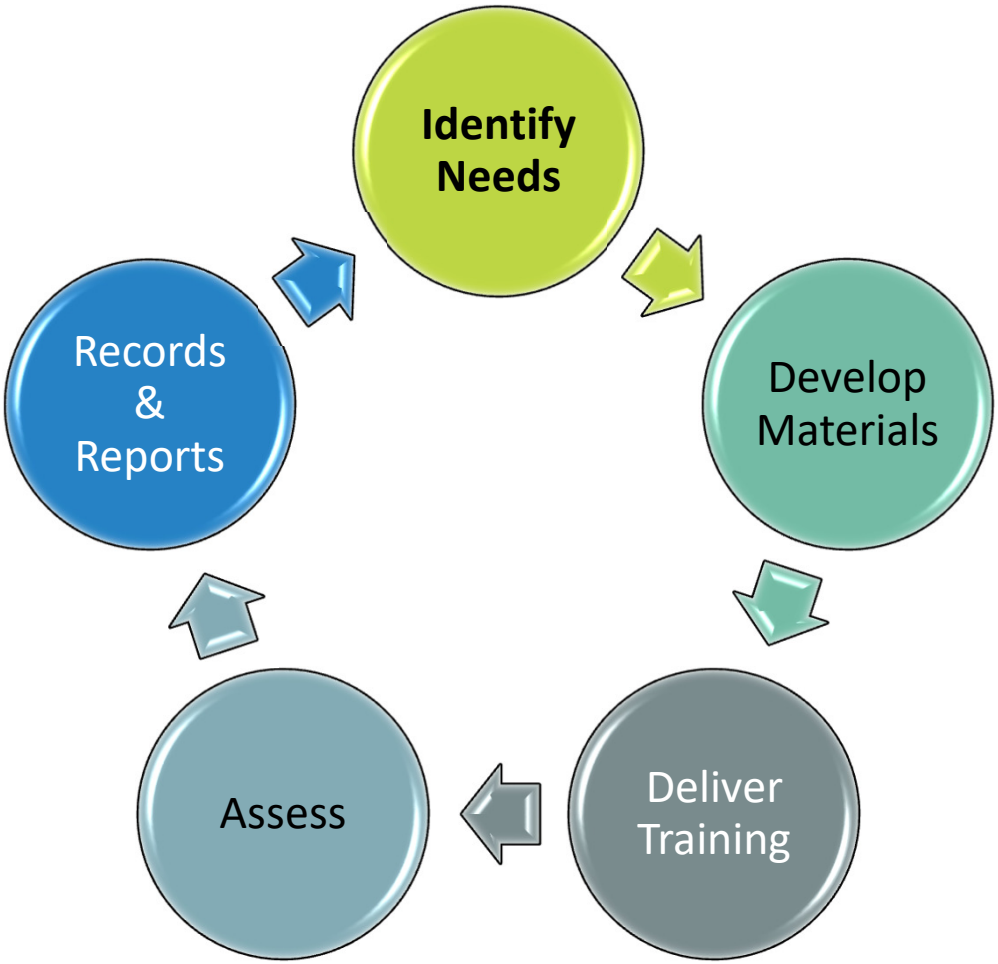
Training System



Needs

- Basic induction
- GMP - levels
- QMS - levels
- Specialized (e.g. lab)
- Competency licensing

Learning Programme per role / person

- Courses
- Reading (Chapters)
- SOPs
- External courses (key staff) – up to date

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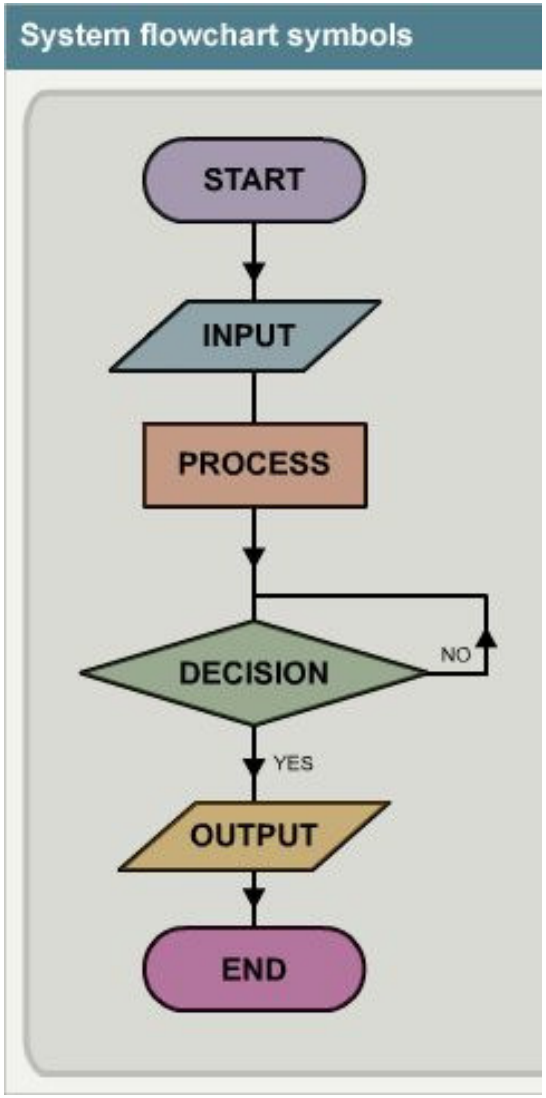
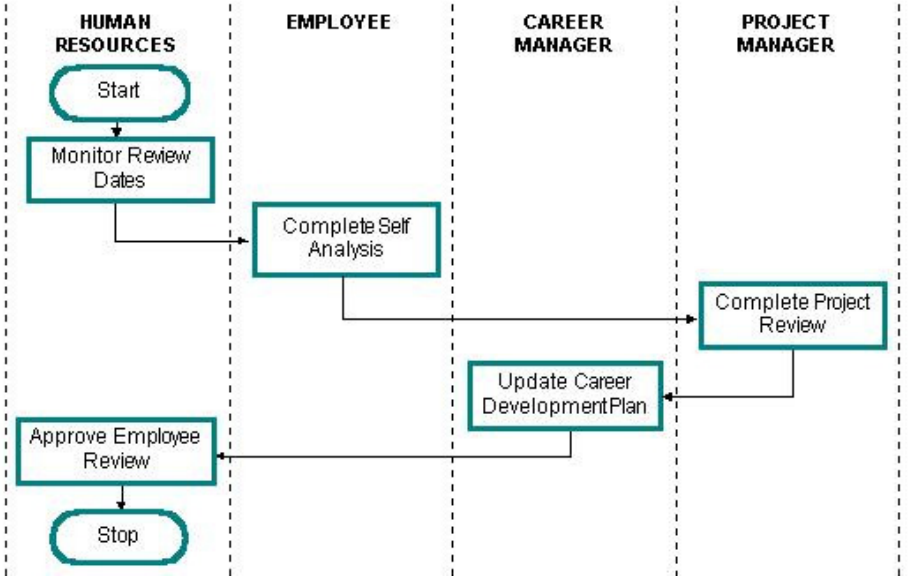


FUNCTIONAL FLOWCHART SAMPLE FOR EMPLOYEE REVIEW PROCESS



COURSE #	SOP REF.	Rev	Proposed Training Date	DESCRIPTION	JOB TITLE NAME	JOB TITLE NAME	JOB TITLE NAME
				Conducting Root Cause Analysis			
				Managing Regulatory Inspections			
				Risk Management			
				Internal Auditing			
				Change Control			

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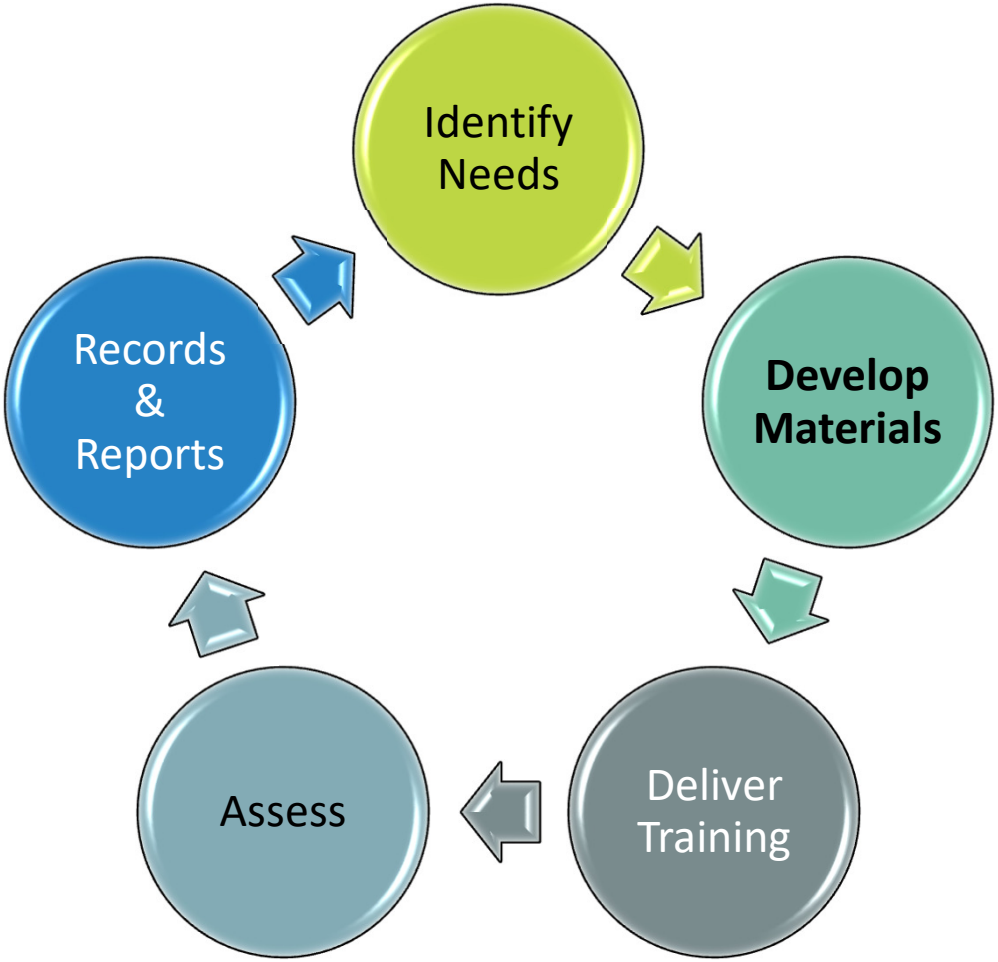
Training System



Training materials
- Objectives, methods
- QA Approval (except SOP training)
- Version control

E-Learning is ideal for courses with a large target audience

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Training Material Design Worksheet

- Topic
- Learning Objectives
- Essential Questions
- Participant Activities
- Training resources / references
- Assessment
- Course Evaluation

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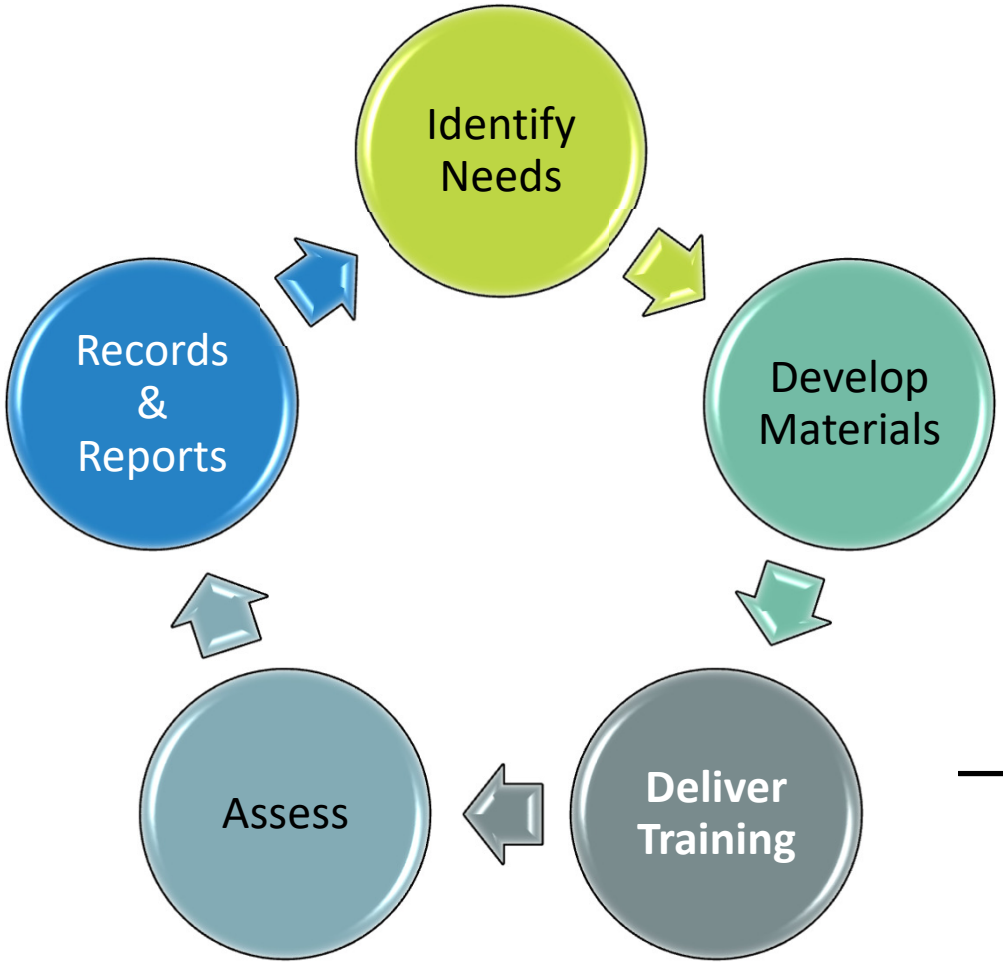
Training System



Self-directed

- Read & Understand
- E-learning

Instructor-led

- Classroom e.g. Induction
- OTJ: **Watch 1, Do 1, Teach 1**

Separate training from product testing

Qualified Trainers (QA oversight)

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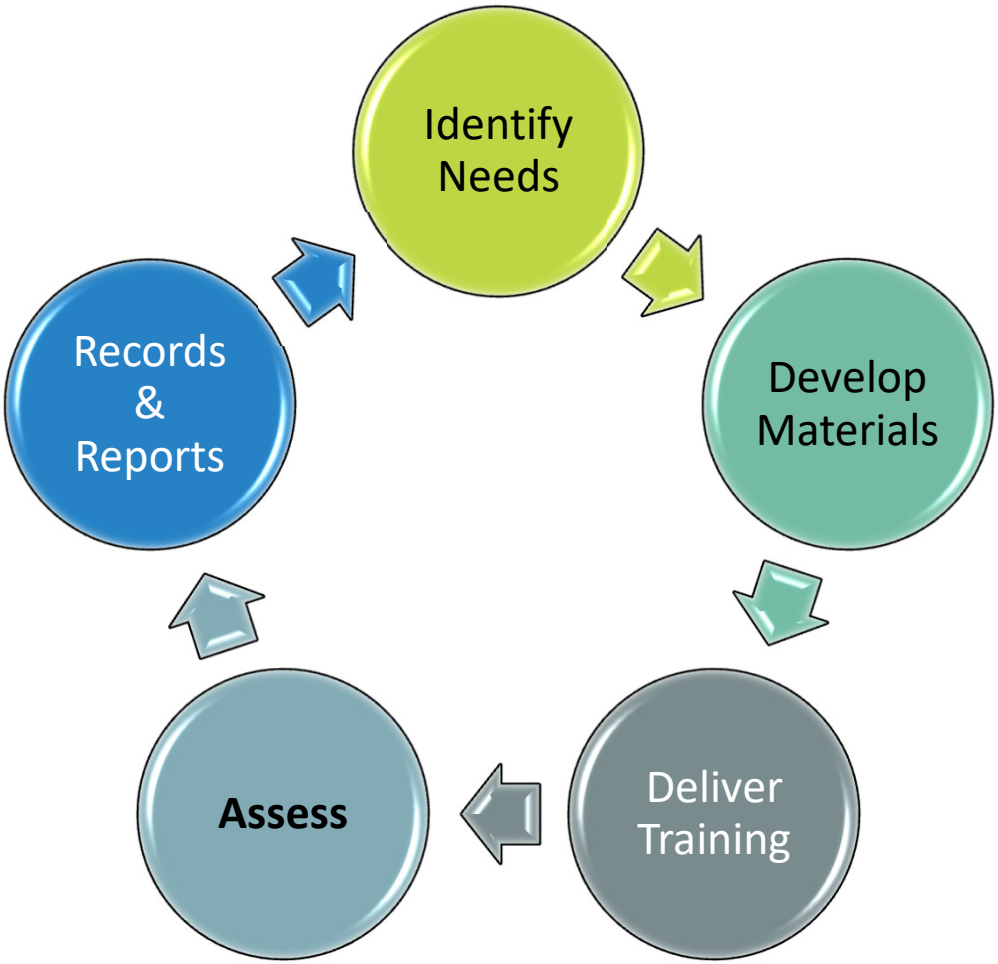
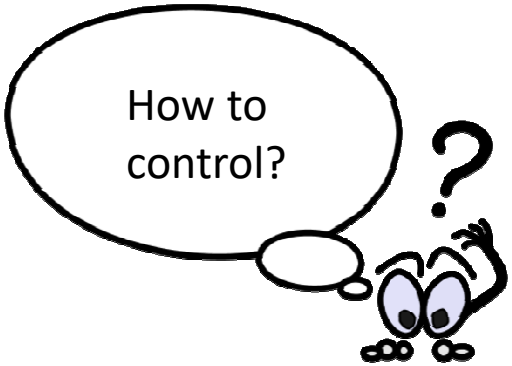
Training System





- Performance-based or written
- No work without results
- Competency license / expiry system
- What if fail?
- Automated assessment?

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Test Paper 8 – GMP Training
Section – Personnel

There are 18 questions to be answered in 20 minutes. Circle clearly the correct answer(s). In case of a mistake draw a line through the incorrect answer and circle the correct one. There may be more than one correct answer for some questions.

1. Establishment and maintenance of a satisfactory system of quality assurance:
   - (A) Relies upon people.
   - (B) Needs good systems with just a few good people in charge.
   - (C) Just needs one or two good people at the top.
   - (D) Can be done by one good person.

2. The manufacturer:
   - (A) Can make one individual responsible for all GMP issues.
   - (B) Need have only a limited number of people who look after all GMP matters.
   - (C) Should have an adequate number of people who are well qualified but may lack pharmaceutical manufacturing experience.
   - (D) Should have an adequate number of people who have both the necessary qualifications and experience.

WHO GMP Training Modules – Questionnaires

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FDFPHDRM2A: Dispense pharmaceutical raw materials

Unit Sector

Pharmaceutical

National Training Information Service
Comprehensive information for the training sector specialist

https://training.gov.au/Training/Details/FDFPH2009A

Performance criteria

Element	Performance criteria
1. Prepare to dispense raw materials	1.1 Materials are inspected to confirm type, quality clearance, quantities and identify any obvious contamination or non-compliance
	1.2 Measuring and weighing equipment is selected appropriate to dispensing requirements and checked to confirm readiness for use
	1.3 Containers/bags and labels are available as required
	1.4 Pre-start checks are carried out as required by workplace requirements
2. Measure and/or weigh raw materials	2.1 Non-bulk ingredients and additives are weighed/measured to meet production requirements
	2.2 Dispensed ingredients are labelled according to workplace procedure
	2.3 Accuracy of measuring/dispensing equipment is monitored to identify variation in operating conditions
	2.4 Variation in equipment operation is identified and maintenance requirements are reported according to workplace reporting requirements
	2.5 Workplace housekeeping standards are maintained
3. Shut down the dispensing process	3.1 Dispensing equipment is cleaned according to workplace procedure
	3.2 Unacceptable equipment/utensil condition is identified and reported
	3.3 Dispensed materials are recorded and reconciled
	3.4 Maintenance requirements are identified and reported

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Competency Record

FDFZPRCR2A Work in a clean room environment

Name: _____ I.D: _____

Company:

Work area: _____

The purpose of this document is to provide a record of the assessment activities ur... the participant and the outcomes of the assessment process. This document is ...pleted b... the trainer/assessor and can be maintained/archived by the particip...

Assessment Methods

The participant has demonstrated their competency in all of the p... rmanc... teria... and associated abilities and knowledge from the Evidence Guide, u... a numb... assessment methods including verbal questions, writte... ent tas... nd observation of tasks in the workplace. The results of ...ese ass... ents is ...orded below.

Elements	Performance Criteria	...sult (...NYC, ...RPL)	Assessor Signature & Date
1.0 Prepare to enter a clean room environment	1.1 Appropriate clothi... and footwe... identified and av...		
	1.2 Clothing ... ootwear is c... tly fitted and inspected prior to ...ering a clean room		
	...3 Hand ... g and d... infecting procedures ...e follo...d ac...ing to workplace procedure		
2.0 W...rk in a c... n ro... en... ...ent	2.1 ...ow w...rkplace procedures to enter a clean ... vironment		
	2... Conduct work activities so as to minimise ...k of contamination		

Key: C – Competent NYC - Not Yet Competent RA – Recognition Assessment

https://training.gov.au/Training/Details/FDFPH2009A

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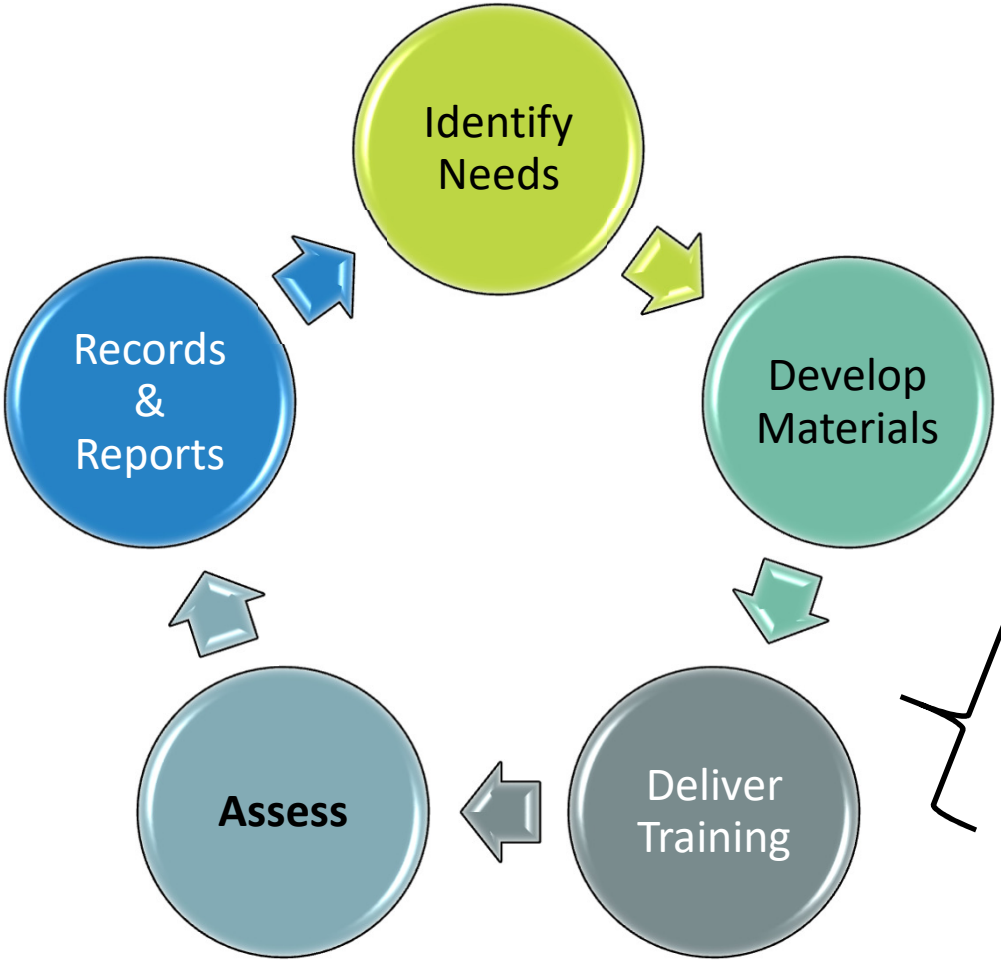
Training System



Management data e.g.

- % overdue
- % first time right

- Trainees check, and manage own compliance?

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Remedial Training / Re-Training

"Retraining is an easy but usually invalid corrective action that is used when the real root cause of the problem in not obvious."

WHO GMP Part 3: Training (2006)

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Root Cause Analysis Tool 3 (Example of Format): Personnel Error Questionnaire

	Question	Response
System Design:	Are SOPs / instructions clear, logical, accurate, in order?	
	Are there sufficient materials, equipment, facilities to perform the task?	
	Are there sufficient personnel for all required tasks?	
	Is there standardised training for the task?	
System Implementation:	Are SOPs or instructions available in work area?	
	Are correct materials and equipment immediately available?	
	Was there time pressure?	
	Were all tasks performed in sequence, documented at the time?	
	Is there someone available to answer questions?	
	Is there documented training for individual performing the task?	
	Does the individual understand the reason for the controls?	

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Root Cause Analysis Tool 3 (Example of Format): Personnel Error Questionnaire

Individual Performance?	How long has the individual been in their current role?
	Has the individual successfully performed the task before, but did not do so in this situation?
	Is there appropriate fit between the individual's qualifications, training or education and the particular task?
	Was the individual unable to apply existing knowledge to a novel situation?

Further Comments:

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Starting at the top ….

Training programme for SENIOR MANAGEMENT / DIRECTORS:

Do they affect product quality?

Do they have a training programme?
Is it signed off by Quality?

- What?
- How?
- Who?
- How often?

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Training plan for SENIOR MANAGEMENT:

- What? ⟷
  - Quality philosophy, costs, risks
  - Measuring effectiveness of outputs
  - Changes in GMPs, Medicines Regulations
  - Management Responsibilities (GMP Ch1)
  - Management Review (ICH Q10)

QUALITY COSTS	
Preventative costs	Vendor approval, Training, Procedures, Metrics, Validation, CpK, Maintenance
Appraisal	Inspection, Testing, Auditing, Reviews, Approvals
Internal Failure	Waste, rework / retest costs, investigations, downtime
External Failure	Complaints, recalls, returns

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Training plan for SENIOR MANAGEMENT:

- How? / Who?

Self-directed

- Read & Understand
- E-learning

Instructor-led

- Classroom
- Outside courses

- Site Master File
- Quality Manual
- Management Responsibilities
- Management Review
- Induction
- GMP / Regulatory updates

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Starting at the top ….

Training programme for
TECHNICAL STAFF:

Do they have a training programme?
Is it signed off by Quality?

- What?
- How?
- Who?
- How often?

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Training for TECHNICAL Staff:

- GMP: induction, at least annual refresher, updates, specialist
- QMS / QA
- SOPs / On-the-job
- Competency licensing: methods - sterility, gowning, media fill, visual inspection

- *GMP Chapters, guidance documents*
- *WHO Training Modules*
- *Other training materials*

- *Attach license to batch records or enter expiry date*

Self-directed

- Read & Understand
- E-learning

Instructor-led

- Classroom e.g. Induction
- OTJ: **Watch 1, Do 1, Teach 1**

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Failure to establish **procedures for identifying training needs**, ensure that all personnel are trained to adequately perform their assigned responsibilities, and document training, as required by 21 CFR 820.25(b).

For example:

"a. Training records for a sterilizer operator and packager were requested at your xxxxx facility during the 2007 FDA inspection. Out of five (5) training records requested for the sterilizer operator, only two (2) were available. Two (2) training records were requested for the packager and only one (1) record was available."

"b. A number of documents were collected demonstrating that employees were not adequately trained, at your xxxx facility.

FDA Warning Letter on Training, 2007
https://www.fda.gov/iceci/enforcementactions/warningletters/2006/ucm076532.htm

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Failure to ensure that all employees have the necessary training and experience to perform their jobs, as required by 21 CFR 820.25 (b). Specifically employees who manage, perform, and assess work affecting quality have not been adequately trained as members of your firm's quality unit. **Quality Assurance employees have not performed effectively in conducting complaint investigations, corrective/preventive action activities, design activities, internal audits, risk analysis and/or document reviews.**

Your October response is inadequate in that there were no commitments to improve employee training. You December response appears adequate. We will evaluate the adequacy and effectiveness of your employee training during our next inspection.

FDA Warning Letter on Training, 2008
http://www.ofnisystems.com/media/s6660c.pdf