Train The Trainer

DCVMN Workshop
Hyderabad
April 2016
WHY DO ORGANIZATIONS TRAIN?
Training

2.8 The manufacturer should provide training for all the personnel whose duties take them into production areas or into control laboratories (including the technical, maintenance and cleaning personnel), and for other personnel whose activities could affect the quality of the product.

2.9 Besides the basic training on the theory and practice of Good Manufacturing Practice, newly recruited personnel should receive training appropriate to the duties assigned to them. Continuing training should also be given, and its practical effectiveness should be periodically assessed. Training programmes should be available, approved by either the head of Production or the head of Quality Control, as appropriate. Training records should be kept.

2.10 Personnel working in areas where contamination is a hazard, e.g. clean areas or areas where highly active, toxic, infectious or sensitising materials are handled, should be given specific training.

2.11 Visitors or untrained personnel should, preferably, not be taken into the production and quality control areas. If this is unavoidable, they should be given information in advance, particularly about personal hygiene and the prescribed protective clothing. They should be closely supervised.

2.12 The concept of Quality Assurance and all the measures capable of improving its understanding and implementation should be fully discussed during the training sessions.
A new study for the Manufacturing Institute shows that 82% percent of the companies surveyed plan to increase the number of skilled manufacturing roles in the next five years.

The study describes a growing skills gap in the industry as “storm clouds on the horizon that could dampen growth.”

Source: Accenture 2014 Manufacturing Skills and Training Study

cGMP AND FDA EXPECTATIONS

1. Review the current situation and people
2. Identify the needs and wants
3. Establish goals and objectives — set priorities
4. Develop a plan of action
5. Implement the plan (preferably on a small scale)
6. Evaluate and study the results
7. Take action—adopt, adjust, or abandon the plan
WHO SHOULD TRAIN?

Traffic regulator

Traffic sign

Car seller

Car mechanic

Car instructor

Car driver
Employees need to be trained on:

 Behaviours - rules, ethics, conduct

 Skills - competence, efficacy, accuracy

 Knowledge - development, insight, relevance

 Attitudes - teamwork, diligence, results
Training can be divided into several categories

- Induction
- Role transitions
- Business strategy alignment
- Process- or Equipment specific
- Compliance, Competence and Risk Management
- Policies and Procedures
Benefits of Training

- Employee Retention and Engagement
- Risk Management
- Increases Overall Skillset
- Increases OH&S Standards
- Change Management
- Intrinsic Unique Culture
- Compliance
WHAT DIFFERENTIATES LEARNING FOR CHILDREN AND TRAINING AND DEVELOPMENT FOR ADULTS?
INFORMATION TRANSACTION

CHILDREN
- Broad-based education
- Multi-subject learning
- Relevance to student not necessary
- Outcomes/Results focused on student
- Same progression pattern for student

ADULTS
- Specific modules
- Organizational/Workplace focused learning
- Relevance highly important
- Outcomes impact organization as a whole
- Develops individuals and groups to new frontiers
ATTITUDES

CHILDREN

► I HAVE TO PASS!!

► If i don’t go to school i won’t succeed

► Teachers are experts and i am a novice

► This is what i have to do

► I failed a test, will have to work harder next time

ADULTS

► How is this relevant to my job role/function?

► Will this improve my competency?

► Is this an opportunity for me to progress?

► What credentials does this trainer have?

► Why did my company think I needed training?
HOW DO PEOPLE LEARN?

Classic Model
Visual  -  Learn through seeing
Auditory  -  Learn through hearing
Tactile  -  Learn through touch
Practical  -  Learn through doing or teaching
Find it easy to learn through descriptions
Often use lists to keep up and organize thoughts
Remember faces but forget names
Have well developed imaginations
Easily distracted by movement
60% of people are visual learners
AUDITORY
(VERBAL INSTRUCTION/DISCUSSIONS/VIDEOS)

- Want the trainer to provide verbal instructions
- Find it easy to learn by listening
- Enjoy dialogues and discussions
- Do well working out solutions or problems by talking them out
- Often do best using recordings and webinars
TACTILE (GROUPWORK/DEMONSTRATION)

- Do best when they take notes either during a lecture or when reading something new or difficult
- Often like to draw or doodle to remember
- Do well with hands-on activities such as projects, demonstrations, or labs
PRACTICAL
(ON-THE-JOB/SIMULATIONS/PROJECTS)

- do best when they are involved or active
- Think and learn best while moving
- Lose much of what is said
- Have problems concentrating when asked to sit and read
- Prefer to do rather than watch or listen
POPULAR NOTION REGARDING LEARNING

Average Learning Retention Rates

- Teaching Others: 90%
- Practice By Doing: 75%
- Discussion Group: 50%
- Demonstration: 30%
- Audio Visual: 20%
- Reading: 10%
- Lecture: 5%

Source: National Training Laboratories, Bethel, Maine
SIMPLY PUT...

- Knows
- Knows How
- Shows
- Does
- Expert
THE NUMBER ONE TOOL IS...

ENGAGING YOUR AUDIENCE
Instructor-led training model is based upon educational model that has its roots in the 19th century . . . .
CREATING OBJECTIVES THAT ARE RELEVANT AND APPEALING TO YOUR TARGET AUDIENCE
THINK “MARKETING AND ADVERTISING...
SIMPLE IMAGERY IS KEY

WHAT DID YOU THINK WHEN LOOKING AT THIS ADVERT?

LET YOUR AUDIENCE DRAW CONCLUSIONS AND THEN GUIDE THEM TO THE MAIN POINTS
SIMPLE IMAGERY IS KEY

WHAT DID YOU THINK WHEN LOOKING AT THIS ADVERT?

LET YOUR AUDIENCE DRAW CONCLUSIONS AND THEN GUIDE THEM TO THE MAIN POINTS
Meet the world’s top destroyer of the environment...

‘emissions’ more damaging to planet than CO2 from cars... other forms of transport put together... A United Nations report has... the world’s rapidly growing herds of cattle as the greatest threat to the climate, forests & wildlife...” Independent.co.uk, 10 Dec 2006

See articles at www.cowspiracy.com/facts/ on:

- Test mass extinction in 65 million years
- Animal agriculture is responsible for up to Amazon destruction
- 130 times more animal waste than human waste is produced US
- 1/3 of the planet is desertified, with livestock as the leading driver
- Growing crops for livestock consumes 56% of water in the US
- Worldwide, at least 50% of food is fed to livestock
- Even without fossil fuels, we will exceed our 565 gigatones CO2 limit by 2030, all from raising animals
- 82% of starving children live in countries food is fed to animals, & the animals are eaten by western countries
- Each day, a person who eats a vegan diet saves 1,100 gallons of water, 45 pounds of grain, 30 sq ft of food land, 20 lbs CO2 equivalent... produces the equivalent of 50% less carbon dioxide, 1/11th oil, 1/13th water, & 1/18th land compared to a meat-lover for their food...
- & more

American Journal of Clinical Nutrition: “Scores of studies have documented... Vegetarians in affluent countries enjoy remarkably good health... a reduction of risk for many degenerative diseases... a significant... increase in life expectancy...” (AJCN 2003 Vol.78)

of the American Dietetic Association: “Well-planned vegan & other types of vegetarian are appropriate for all stages of the life cycle... are healthful, nutritionally adequate, & health benefits in the prevention & treatment of certain diseases...” (JADA 2003 Vol.103)
1-2 acres of rainforest are cleared every minute.

Animal agriculture is responsible for 91% of Amazon destruction.

1 hamburger = 660 gallons of water = Equivalent to showering for 2 months.

Waste from a farm of 2500 dairy cows = Waste from a city of 411000 people.

Global greenhouse gas emissions:
- 51% due to livestock and their byproducts
- 13% due to transport (road, rail, air & marine)
DIAGRAMS AND PROCESS FLOW CHARTS

TYPES OF VALIDATION:

- Analytical Method Validation
- Equipment Validation
- Process Validation
- Cleaning Validation

Validation Life Cycle

1. Design
2. Development
3. Product FMEA
   - Process Map
   - Process FMEA
   - Master Validation Plan
     - IQ
     - Attribute Test Method Qualification
     - Variable Test Method Qualification
     - OQ
     - PQ
       - Process Control
       - Master Validation Report
       - Process Monitoring

Sarika Kadam
DON'T BE AFRAID TO APPLY HUMOUR

QUALIFICATION

Here is why...

Y U TAKE SO LONG
UNDERSTANDING YOUR AUDIENCE AND THEIR SPECIFIC NEEDS
WHO AM I TRAINING???

- Basic GMP Training modules
  - For managers: Concise and direct
  - For operators: Focus on their target areas
  - For technicians: Relevance to their work
  - For validation: Protocols governing methodology
  - For cleaning staff: High priority areas per relevance
  - For admin: Empower them to understand the criticality
WHO AM I TRAINING???

- Specific focus areas (eg. Cleanroom Validation)

**WHO**
- Department?
- Personnel?

**WHAT**
- Content?
- Relevant Understanding?

**WHY**
- Validation Update, CAPA, Change?
- To up-skill, refresh, update?
FILTERING AND SEQUENCING OF INFORMATION
FILTERING OF INFORMATION

- Start with all information surrounding the topic
- Identify the key GMP aspects
- Consider your audience and cut out whatever information is not necessary for their job role
- Select specific details that are pertinent to comprehension and/or compliance
SEQUENCING OF INFORMATION

BEGIN WITH AN OVERVIEW

<table>
<thead>
<tr>
<th>Key Elements of a Quality Management System</th>
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<tbody>
<tr>
<td>1. Audit programs - internally and externally</td>
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<td>2. Qualification of vendors</td>
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<td>3. Quality Control testing (in-process and finished product testing)</td>
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<td>4. Complaint handling program</td>
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<td>5. Annual product reviews</td>
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<td>6. Stability Program</td>
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<td>7. Sample retention program</td>
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<tr>
<td>8. Documentation control/storage</td>
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<tr>
<td>9. Labeling and label control</td>
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<tr>
<td>10. Specification development</td>
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<tr>
<td>11. Generation and validation of analytical methods</td>
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</tbody>
</table>
SEQUENCING OF INFORMATION

THINK RECIPE

EGG CURRY
4 PEOPLE, MAIN DISH
SERVED WITH WHITE RICE & RED BEANS

8 eggs
boil 10'

2 onions
mince
brown

oil

1 hot pepper
salt
pepper
grind

1 piece
of ginger

4 ripe tomatoes
chop

thyme

saffron

stir 10'

simmer 5'

water

halve
SEQUENCING OF INFORMATION

PROCESS FLOW (RECIPE)

SEQUENCING OF INFORMATION

PROCESS FLOW (RECIPE)

SEQUENCING OF INFORMATION

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SEQUENCING OF INFORMATION

PROCESS FLOW (RECIPE)
BUILDING IN STRATEGIC QUESTIONS THAT ALLOW FOR GROUP DISCUSSION
STRATEGIC QUESTIONS ALLOW FOR:

- Audience engagement
- Self discovery
- Group discussions
- Reviews and summary
- Change of tone
- New topic introduction
- A break for the trainer
DIFFERENT TYPES OF QUESTIONS

CLOSED QUESTIONS

► IS HYGIENE IMPORTANT FOR ALL STAFF?
► WHICH DEPARTMENT HANDLES DOCUMENTATION?
► IF A PRODUCT HAS NOT UNDERGONE ALL NECESSARY TESTING, CAN WE RELEASE IT TO THE MARKET?

OPEN QUESTIONS

► WHY IS HYGIENE IMPORTANT FOR ALL STAFF?
► DOCUMENT CONTROL IS CENTRALIZED IN WHICH DEPARTMENT AND WHY?
► IF THERE IS A HIGHLY CONTAGIOUS PANDEMIC OUTBREAK, WOULD THE RISK OF RELEASING A PRODUCT THAT HAS NOT BEEN FULLY TESTED BE OVERLOOKED?
EVALUATION AND ASSESSMENT
WHAT ARE THE OBJECTIVES OF EVALUATION?

1. What did the participants think of the training?
2. What did the participants learn?
3. Is the knowledge being applied to the task/job role?
4. What was the company benefit of training?
WHAT DID THE PARTICIPANTS THINK OF THE TRAINING?

Measure or evaluate what the participant thinks about the program with "user friendly" evaluation forms

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Strongly agree</th>
<th>Agree</th>
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</thead>
<tbody>
<tr>
<td>Training was relevant to my needs</td>
<td>4</td>
<td>3</td>
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<tr>
<td>Materials provided were helpful</td>
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<tr>
<td>Length of training was sufficient</td>
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<tr>
<td>Content was well organised</td>
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<tr>
<td>Questions were encouraged</td>
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<tr>
<td>Instructions were clear and understandable</td>
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<tr>
<td>Training met my expectations</td>
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<td></td>
</tr>
<tr>
<td>The presenter and/or presentation was effective</td>
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WHAT DID THE PARTICIPANTS LEARN?

Written examinations are the most common assessment tool.

Multiple choice questions are common, but can be poorly constructed.

Written assessments are only one part of complete evaluation.
EXAMPLES

- Applying the correct torque to a fastener in assembling our medical device is important because:
  a. Over-tightening a fastener can damage or break the assembly.
  b. Under tightening a fastener can allow the assembly to malfunction.
  c. Both "a" and "b".
  d. Neither answer is correct.

- When making, GMP Amine, the blend time for raw materials in the Acme Blender:
  a. Is a broad guideline subject to individual employee interpretation.
  b. Can be ignored so long as the material is blended for approximately 30 minutes.
  c. If performed incorrectly, the mistake can be caught by QC testing.
  d. Should be followed exactly to avoid both under-blending and over-blending, either of which can result in a batch that is not homogeneous.
IS THE KNOWLEDGE BEING APPLIED TO THE TASK/JOB ROLE?

If production errors prompted the training session, are errors reduced after the training session? Be careful to quantify the types of errors previously made as compared to any errors made after the training.

Are errors of the types covered in training reduced after training? And, if errors still plague production, does training need to be directed at the prevention of other types of errors?

If employees "know" the correct procedure and aren't following it, the answer may not lie in training, but in supervision or management.
IS THE KNOWLEDGE BEING APPLIED TO THE TASK/JOB ROLE?

The role of training is to equip employees to perform tasks correctly on a consistent basis. This may not be achieved if their training is superseded by supervisory or management intervention.

Both managers and supervisors should receive training that is appropriate and related to their role in manufacturing and testing products.

Even under ideal working conditions, knowledge and adherence to established practices can erode over time without proper reinforcement. This is addressed in the cGMP regulations by the expectation that training must be done with sufficient frequency.
WHAT WAS THE COMPANY BENEFIT OF TRAINING?

- A reduction in manufacturing errors
- Higher output of correctly manufactured product or device
- Fewer documentation mistakes
HOW IS THIS MEASURED?

TRENDING ANALYSIS

FEWER PRODUCTION ERRORS

DOCUMENTATION REVIEW

PERSONAL TRAINING RECORDS PER EMPLOYEE REVIEWED BY SUPERVISORS AND MANAGERS
TRAINERS SPECIFIC SKILLS

REFINING
RE-DESIGNING
REAL RESULTS
UNDERSTANDING “DEATH BY POWERPOINT”
5 common errors

1. TYPING OUT EVERYTHING YOU WANT TO SAY IN A SENTENCE SO THAT WHEN YOU SPEAK YOU ARE JUST READING THE SENTENCE AND YOUR AUDIENCE WILL REMEMBER... NOTHING!!!
5 common errors

2. Placing a copy of a quality document up on the screen and reading off it
5 common errors

3. Having your text be too small
5 common errors

4. Using
   - Too
   - Many
   - Bullet
   - Points

   - On
   - A
   - Single
   - Slide
   - !!!
5 common errors

5. Assuming you **always** have to make a slideshow presentation
Does Your Presentation Stand Out?
UNIFYING YOUR KNOWLEDGE WITH YOUR PRESENTATION
HOW TO MAXIMIZE YOUR TRAINING

Perceive the value of your training
Envision the outcomes
Speed train yourself the key points
Record or type out the “story” of your training
Trim the excess
Use diagrams to summarize
Validation Project

Planning

Reporting

Specification

Verification

System Build / Implementation

VMP

URS

FS

DS/DQ

Final Report

Summary & Recommendations

PV/PQ

OQ

IQ

FAT

SAT
USE NOTES, HANDOUTS OR WORKBOOKS

Minimizes content on slides
Accommodates multiple learning styles
Audience can review during breaks
VERY IMPORTANT!!!

CREATE AND MAINTAIN A TRAINING MASTER FILE FOR ALL TRAINING

This should be encouraged site-wide
CONTENTS OF A TRAINING MODULE

Training agenda
GMP relevant chapter(s) and pre-reading material
Equipment list
Target departments / personnel
Outcomes
Copy of the slideshow / presentation with notes
Assessment and Memo
SHIFTING THE FOCUS FROM YOURSELF TO YOUR AUDIENCE
IT’S NOT ABOUT YOU...

Instil trust through credibility
Focus on their learning
Take time to clarify
Ensure comprehension
Repetition, questions and more repetition
Incorporate all learning styles
Thoughtfulness = Relevant
Economical = Clarity
Trustworthiness = Credible
Focus
Consensus = Agreement
Successful Decision
HANDLING DIFFICULT ATTENDEES / PROBLEMATIC SCENARIOS
THE TALKER

The Talker or Know-It-All has opinions on every subject and states them in a very authoritative manner. Other participants and the trainer find it hard to disagree with or to give help to this person.

Thank the person and move on to the next subject
Ask others to comment on his remarks
Thank the person for his participation and indicate it is time to hear from others
Tactfully ask the person to give someone else a chance
Use humor to invite others to speak up
Deliberately turn to others and ask for their opinions
Set rules: only the person who has the ball can speak, or there is a 2 minute limit per person
DO NOT

Compete with the person
Insult the person
Stifle the person’s enthusiasm
Get defensive
Express anger
Let the person control the discussion
THE ARGUER

The Fighter or Arguer is quick to find fault with the material or instructor. They pick apart statements in an inappropriate way. The Fighter often is angry, but will not come out and admit or explain the anger.

Keep your cool- you will never win the argument
Acknowledging the level of passion and ask for the reason behind it
Request that the person back up assertions. Ask for evidence
Determine whether the person is alone in his thinking, or if others feel the same way
Reframe an attack on you as an attack on the problem
DO NOT

Argue with the person
Insult the person
Get defensive
Express anger
Let the person control the discussion
Agree with the fighter just to end the argument, if that will mislead other participants
THE QUIET, DISTRACTED TRAINEE

The Quiet One or Withdrawer is non-participative and passive in the group. This individual does not make an effort to become part of the discussion, and is often on their phone or working on their laptop.

Treat the participant with respect
Build in time at the beginning of each interactive exercise for participants to read and work independently before they begin their group discussions
Engage the participant by posing a question that directly relates to her situation or concern
Subtly incorporate the person into the group by using her name in hypothetical examples or stories
Have participants pair off rather than working immediately in large or small groups. This will be more comfortable for the shy person
Always offer observer roles as options for role plays, games, or simulations
DO NOT

Assume that the participant is choosing to be difficult

Interpret the participant’s lack of verbal response as an indication of lack of interest

Get despondent

Focus all of his attention on trying to engage the quiet one

Ignore the participant.
THE UNCONSCIOUSLY INCOMPETENT

The Unconsciously Competent person thinks that he already has the correct knowledge, skills, and ability, when in truth he doesn’t. This person complains that attending the training session is a waste of time. He doesn’t feel the need to participate, since he is so certain he already knows everything.

In the introduction, mention that the collective expertise in the room far exceeds your own and request their input and assistance so that everyone can learn what they need to learn.

Begin with a focus question that will determine the extent of all of the participants’ knowledge of the topic.

Follow this with a questionnaire that asks questions regarding all of the key points to be covered.
DO NOT

Argue with the person
Insult the person
Get defensive
Express anger
Let the person control the discussion
THE POWER OF SELF-ACTUALIZATION FOR THE ATTENDEES
WHAT IS SELF-ACTUALIZATION?

Maslow’s Hierarchy of Needs Applied to Employee Engagement

1. HIGHLY ENGAGED
   - What can I do for others?
   - I inspire others to do their best
   - I love it working here
   - I’m a high flyer
   - On average less than 15% reach this level

2. ENGAGED
   - I’m a vital part of the business
   - I feel important at work
   - I’m really busy and very likely I’m highly stressed
   - I’m an achiever
   - I’ll leave if something much better comes along

3. ALMOST ENGAGED
   - I know I’m part of something bigger
   - I’m almost engaged but there are times when I’m not
   - I’m proud to work here but I wouldn’t necessarily shout it from the rooftops
   - I might leave if I’m tempted
   - There are no career development prospects here

4. NOT ENGAGED
   - I’m interested in overtime
   - I have more sick days than I should
   - I have poor working conditions
   - I don’t like my manager or working in my team
   - I don’t like my job much, but I get on with it.
   - I read job ads

5. DISENGAGED
   - I’m here for the money
   - I’m leaving when I can
   - I’m not satisfied with the job I do
   - My work doesn’t excite me
   - I’m a clock watcher
   - I’m a jobs-worth

2 and 3 have a direct impact on engagement and can be moved up by the 4 enablers of engagement
FOCUS ON INTRINSIC BENEFITS

According to "State of the Global Workplace" by Gallup, only 13% of employees are engaged.

Over the last few years, **intrinsic** rewards have risen in importance, and **extrinsic** rewards have declined in importance.

**Intrinsic rewards**
- Sense of meaningfulness
- Sense of choice
- Sense of competence
- Sense of progress

**Extrinsic rewards**
- Pay rises,
- Bonuses and
- Benefits.
THE MOST IMPORTANT SECRET TO BEING AN EFFECTIVE TRAINER
PERFORMANCE ART
PERFORMANCE ART

DOES NOT require you to be someone you are not

Find your style

Incorporate your 5 skills (from workshop)

Have fun