

# Train The Trainer

DCVMN Workshop

Hyderabad

April 2016

# WHY DO ORGANIZATIONS TRAIN?

# IT IS A GMP REQUIREMENT

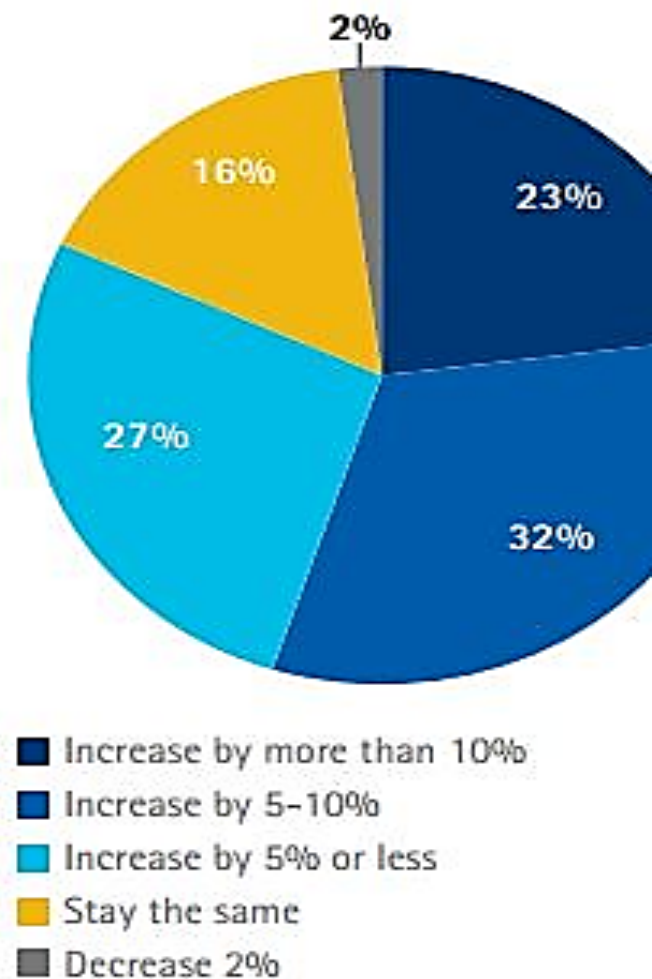
## Training

- 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.

# Training Programs Alleviate Skills Gap

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

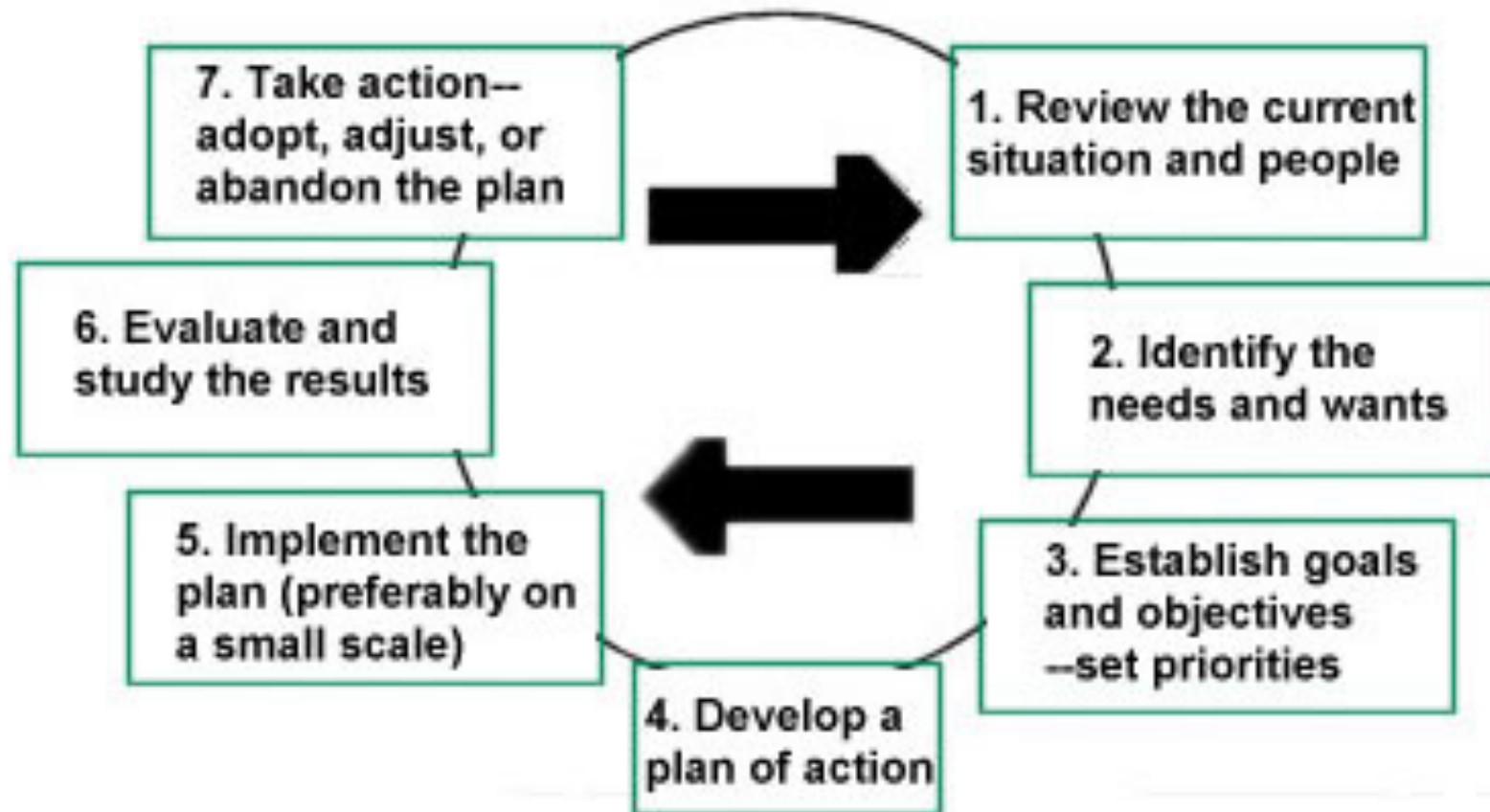
The study describes a growing skills gap in the industry as “storm clouds on the horizon that could dampen growth.”



Source: Accenture 2014 Manufacturing Skills and Training Study



# cGMP AND FDA EXPECTATIONS



# WHO SHOULD TRAIN?



Traffic regulator



Traffic sign



Car seller



Car instructor



Car mechanic



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

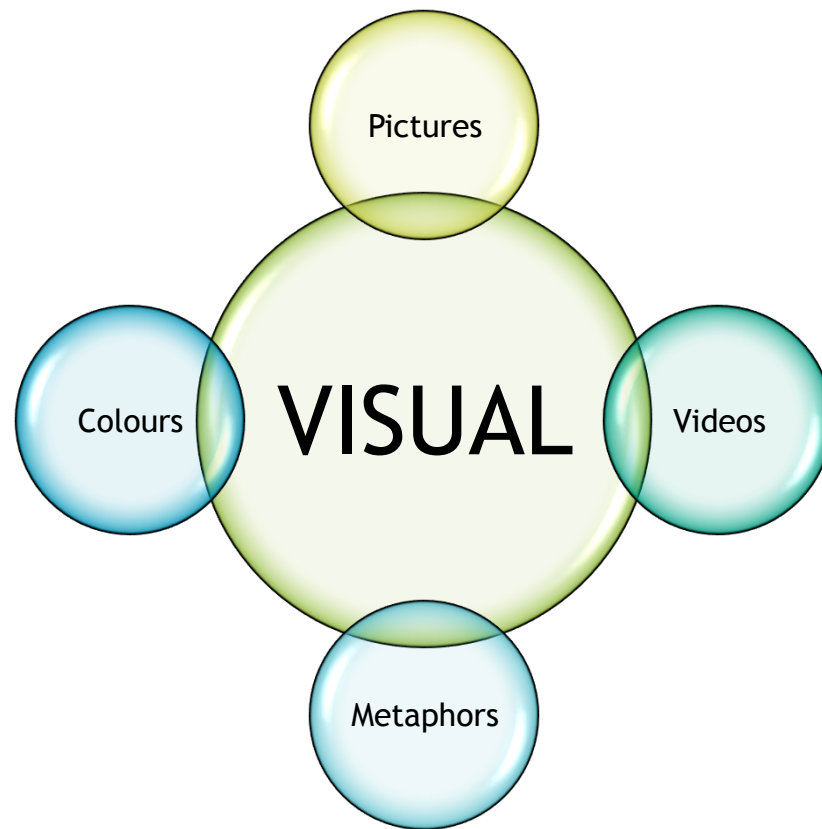
**Auditory** - Learn through hearing

**Tactile** - Learn through touch

**Practical** - Learn through doing or teaching

# VISUAL (PRESENTATIONS/DIAGRAMS/ILLUSTRATIONS)

- ▶ 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)

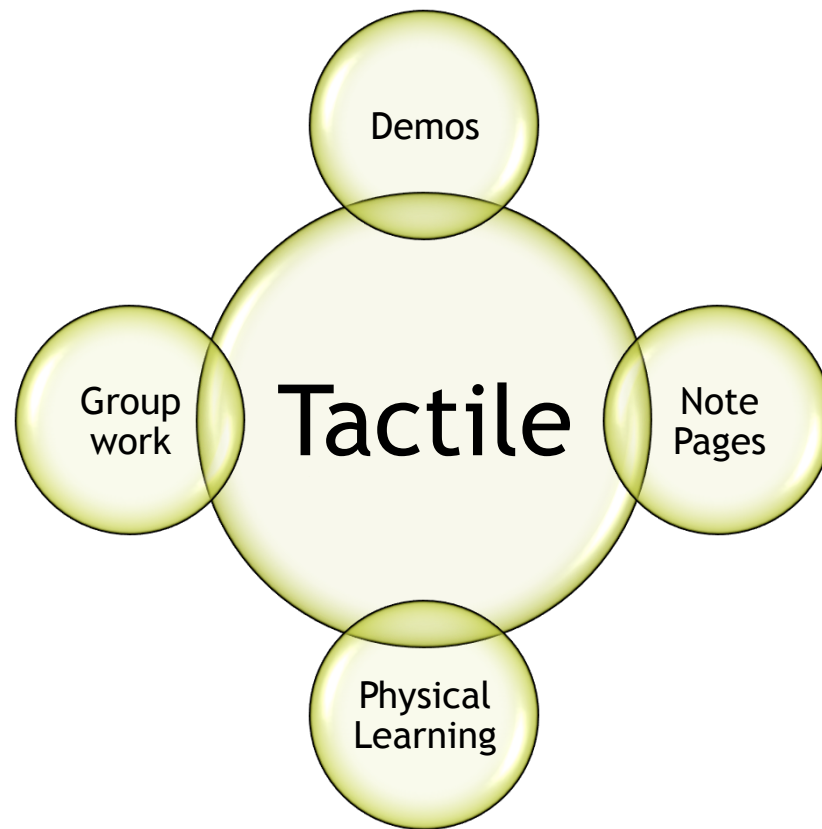
- ▶ Want the trainer to provide verbal instructions
- ▶ Find it easy to learn by listening
- ▶ Enjoy dialogues and discussions
- ▶ Do well working out solutions or problems by talking them out
- ▶ Often do best using recordings and webinars





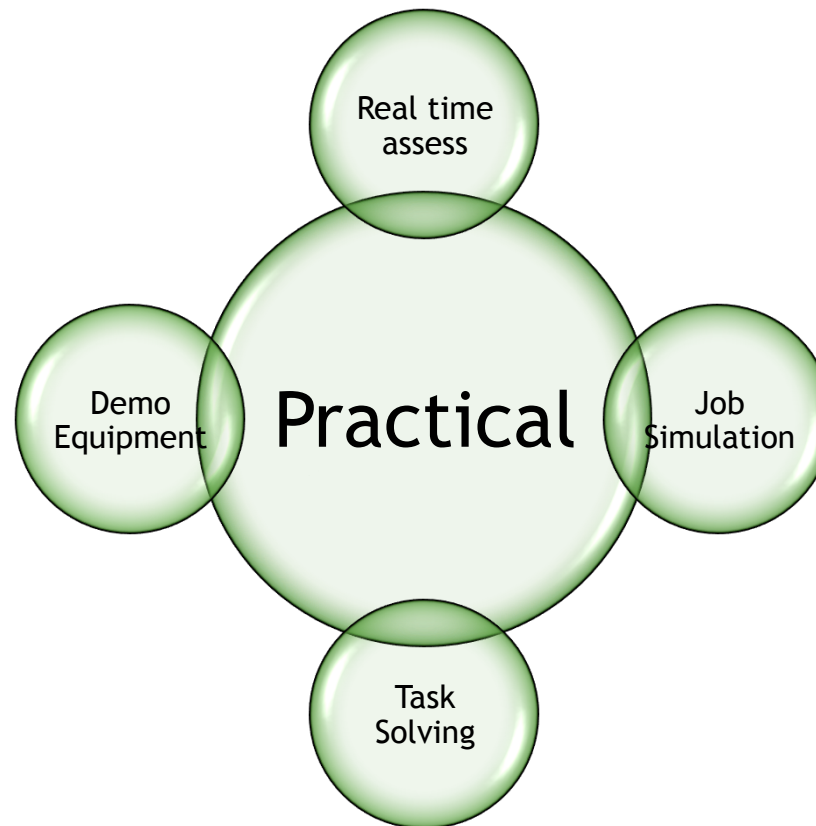
# TACTILE (GROUPWORK/DEMONSTRATION)

- ▶ 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

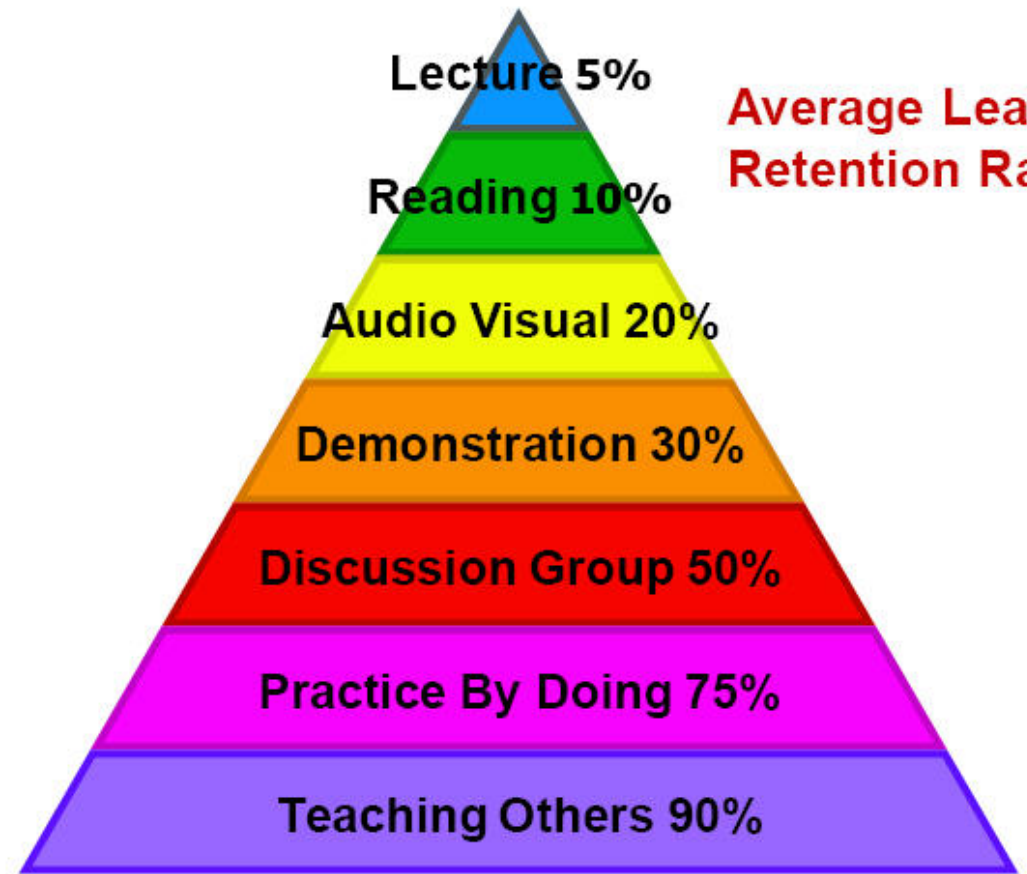


# PRACTICAL (ON-THE-JOB/SIMULATIONS/PROJECTS)

- ▶ 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

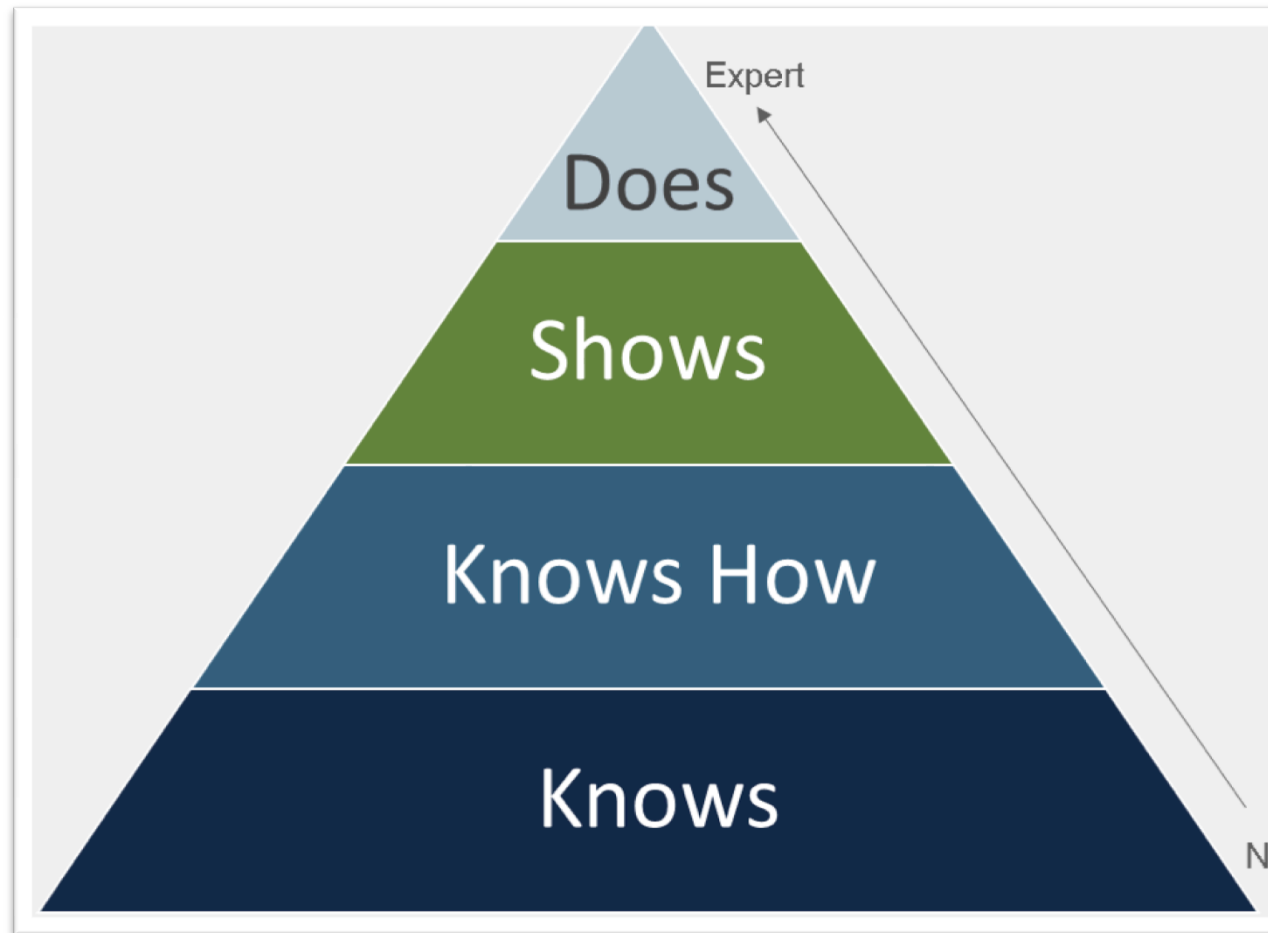


# POPULAR NOTION REGARDING LEARNING



Source: National Training Laboratories, Bethel, Maine

## SIMPLY PUT...





E 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  
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THEM TO THE MAIN POINTS

# Meet the world's top destroyer of the environment...



'emissions' more damaging to planet than CO<sub>2</sub> from cars... other forms of transport put together... A United Nations report has identified 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/](http://www.cowspiracy.com/facts/) on:

Fastest mass extinction in 65 million years" - "Animal agriculture is responsible for up to 130 times more animal waste than human waste is produced in the 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 gigatonnes CO<sub>2</sub> limit by 2030, all from raising animals" - "82% of starving children live in countries where 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 farmland, 20 lbs CO<sub>2</sub> 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

British Medical Journal: "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)

Journal of the American Dietetic Association: "Well-planned vegan & other types of vegetarian diets are appropriate for all stages of the life cycle... are healthful, nutritionally adequate, & have health benefits in the prevention & treatment of certain diseases..." (JADA 2003 Vol.103)

AVOID CLUTTERING YOUR  
SLIDES WITH INFORMATION



## DEFORESTATION

**1-2** ACRES RAINFOREST  
ARE CLEARED  
EVERY MINUTE

ANIMAL AGRICULTURE  
IS RESPONSIBLE FOR


**91%**  
OF AMAZON DESTRUCTION



## CLIMATE CHANGE

GLOBAL  
GREENHOUSE  
GAS EMISSIONS

**51%**  DUE TO LIVESTOCK AND  
THEIR BYPRODUCTS

**13%**  DUE TO TRANSPORT (ROAD,  
RAIL, AIR & MARINE)

## WASTE



## WATER USE



  
WASTE FROM A FARM  
OF 2500 DAIRY COWS

— WASTE FROM A CITY  
OF 411000 PEOPLE

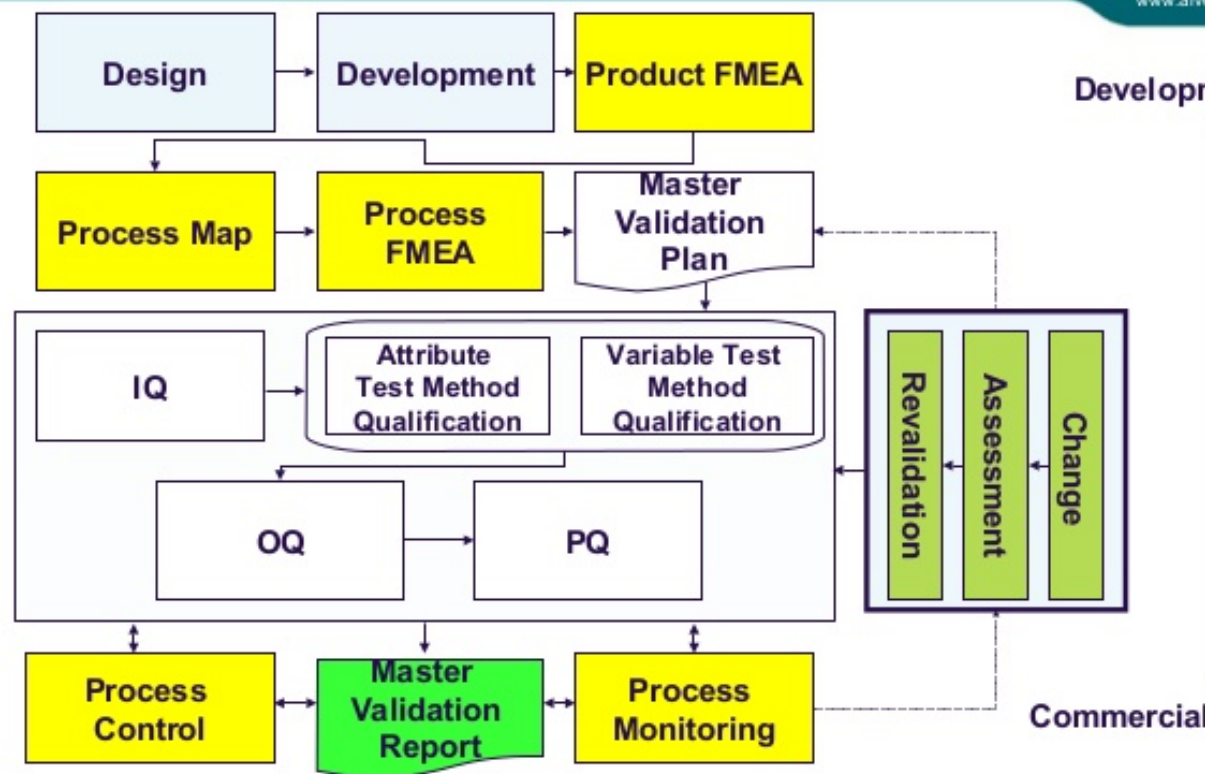
# DIAGRAMS AND PROCESS FLOW CHARTS

## TYPES OF VALIDATION:



Sarika Kadam

## Validation Life Cycle



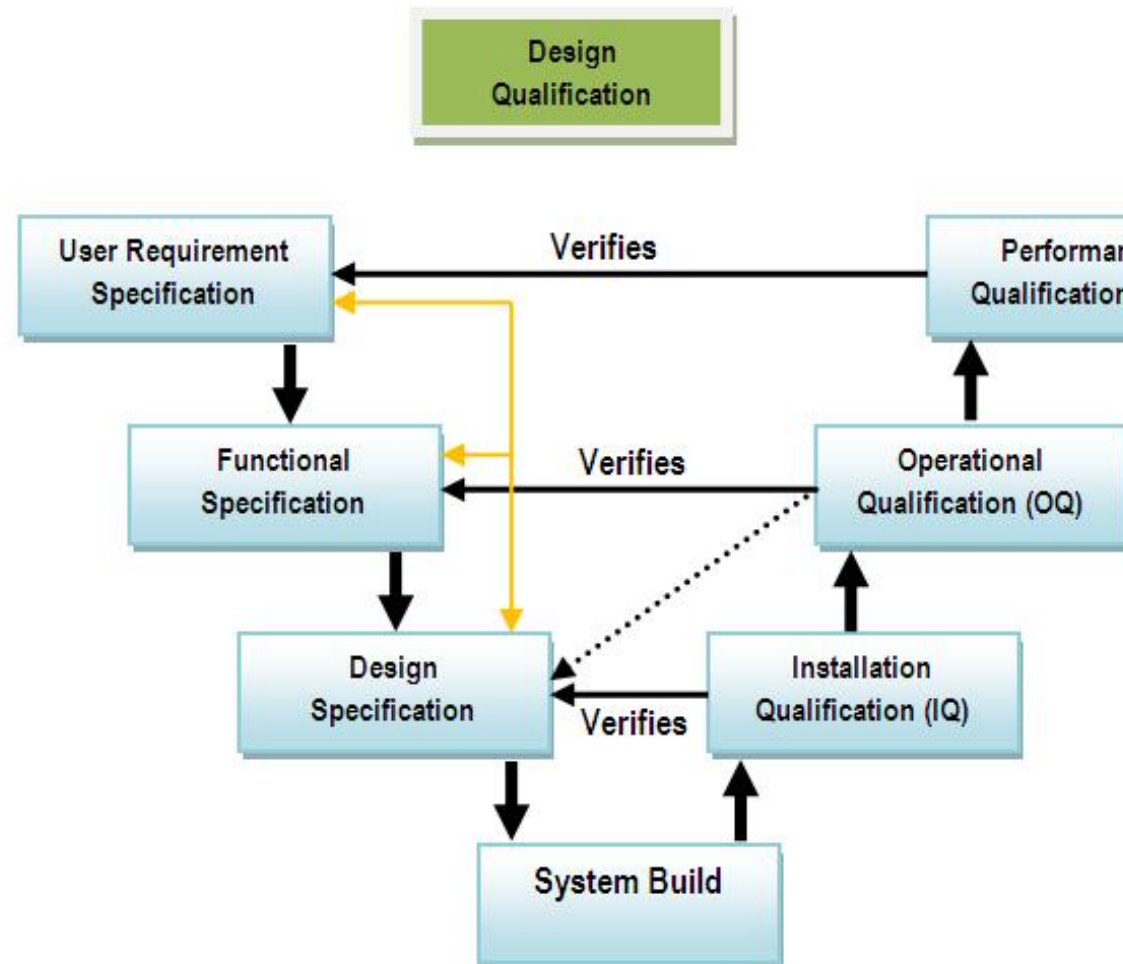


## QUALIFICATION

# Here is why...

# Y U TAKE SO LONG

**DIYLOL.COM**

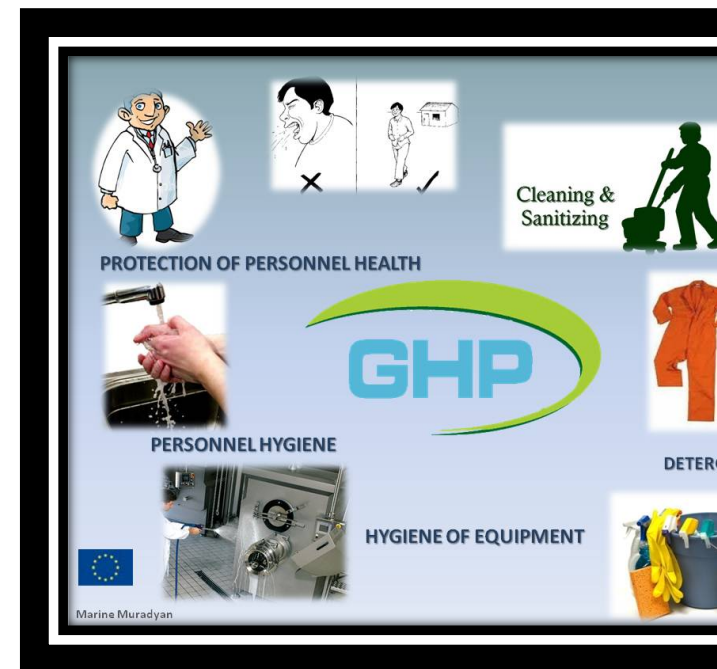




# UNDERSTANDING YOUR AUDIENCE AND THEIR SPECIFIC NEEDS

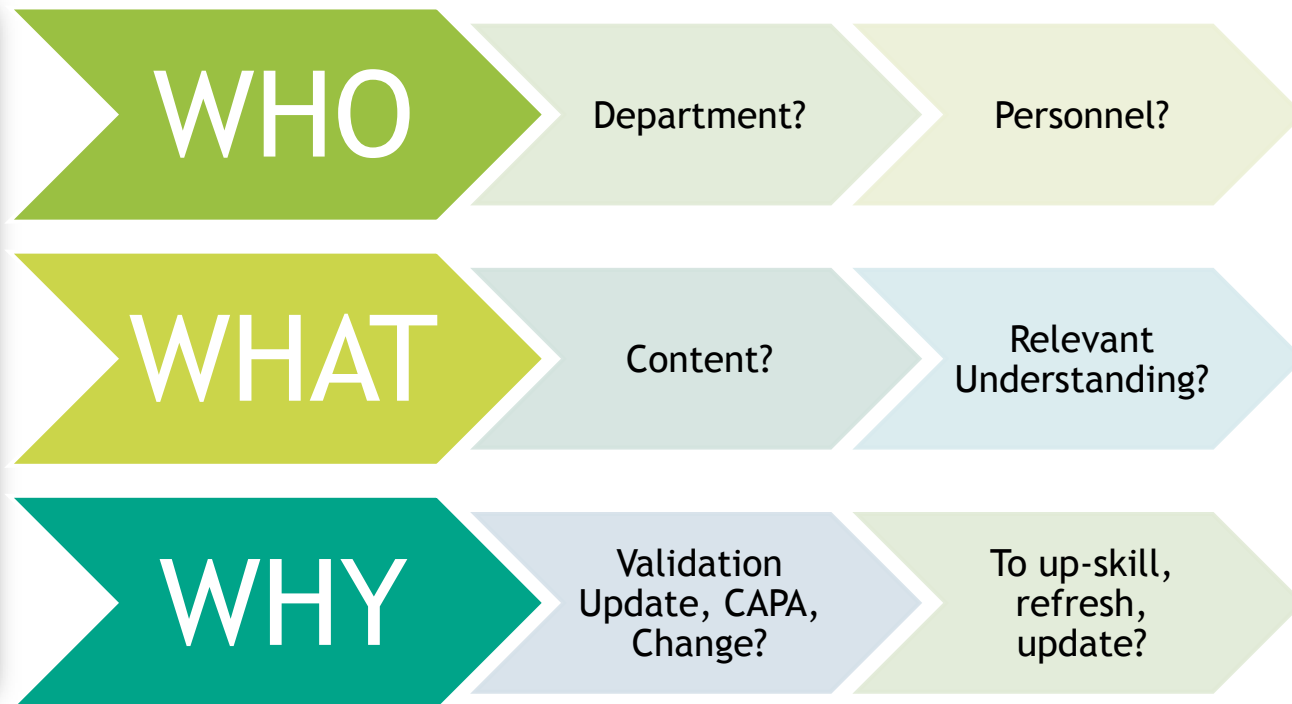
# WHO AM I TRAINING???

- ▶ 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)





# 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



Icons by <http://lab.liroja.com>



# SEQUENCING OF INFORMATION

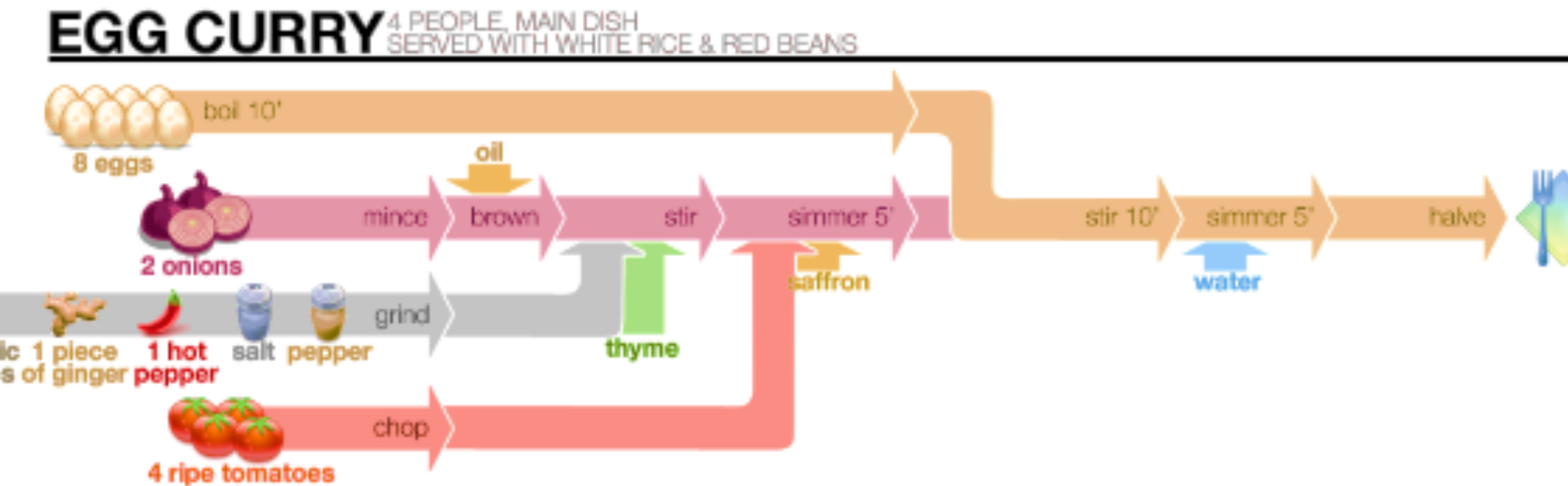
BEGIN WITH AN OVERVIEW

## Key Elements of a Quality Man

1. Audit programs - internally and externally
2. Qualification of vendors
3. Quality Control testing (in-process and finished product testing)
4. Complaint handling program
5. Annual product reviews
6. Stability Program
7. Sample retention program
8. Documentation control/storage
9. Labeling and label control
10. Specification development
11. Generation and validation of analytical methods

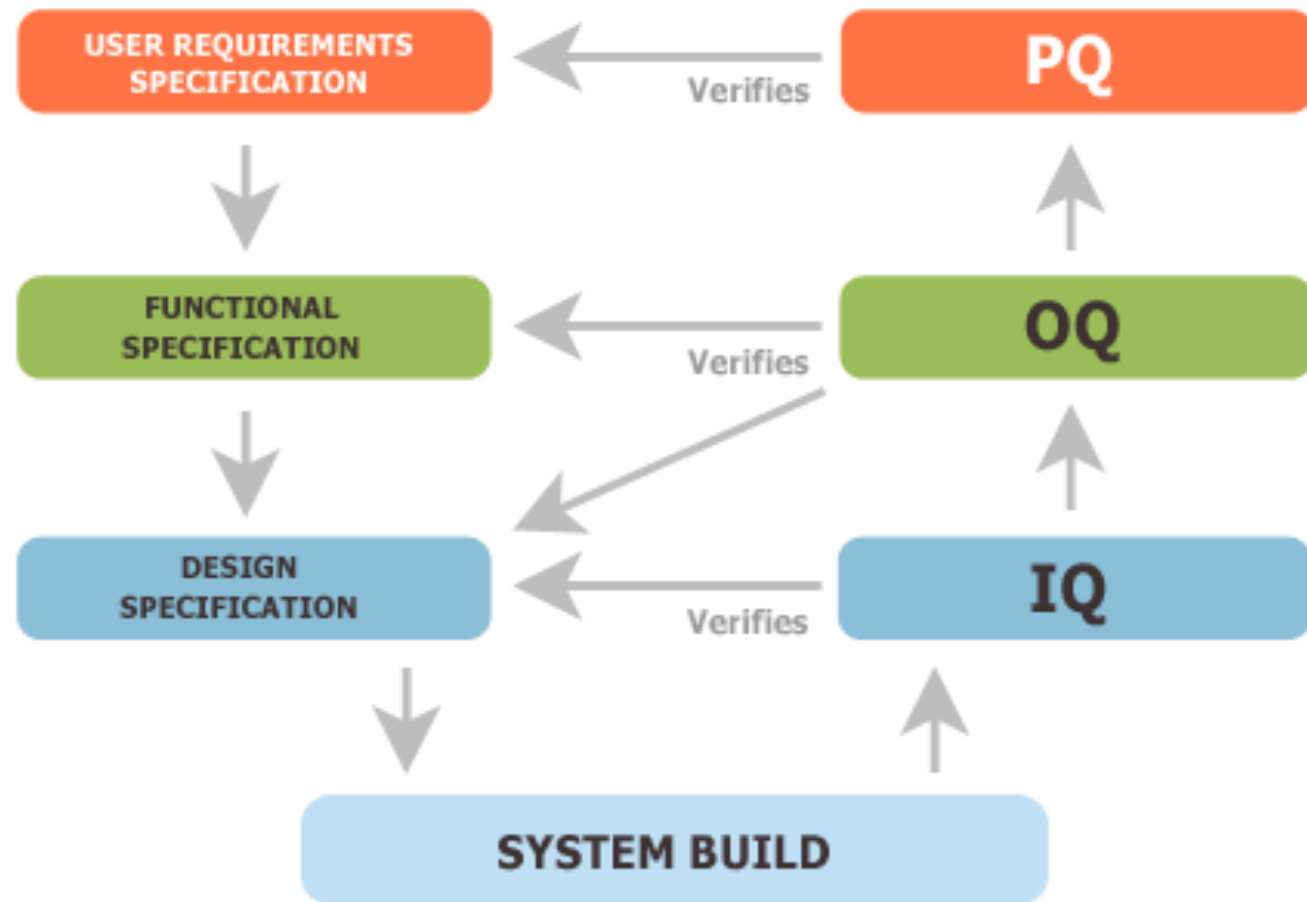
# SEQUENCING OF INFORMATION

THINK RECIPE

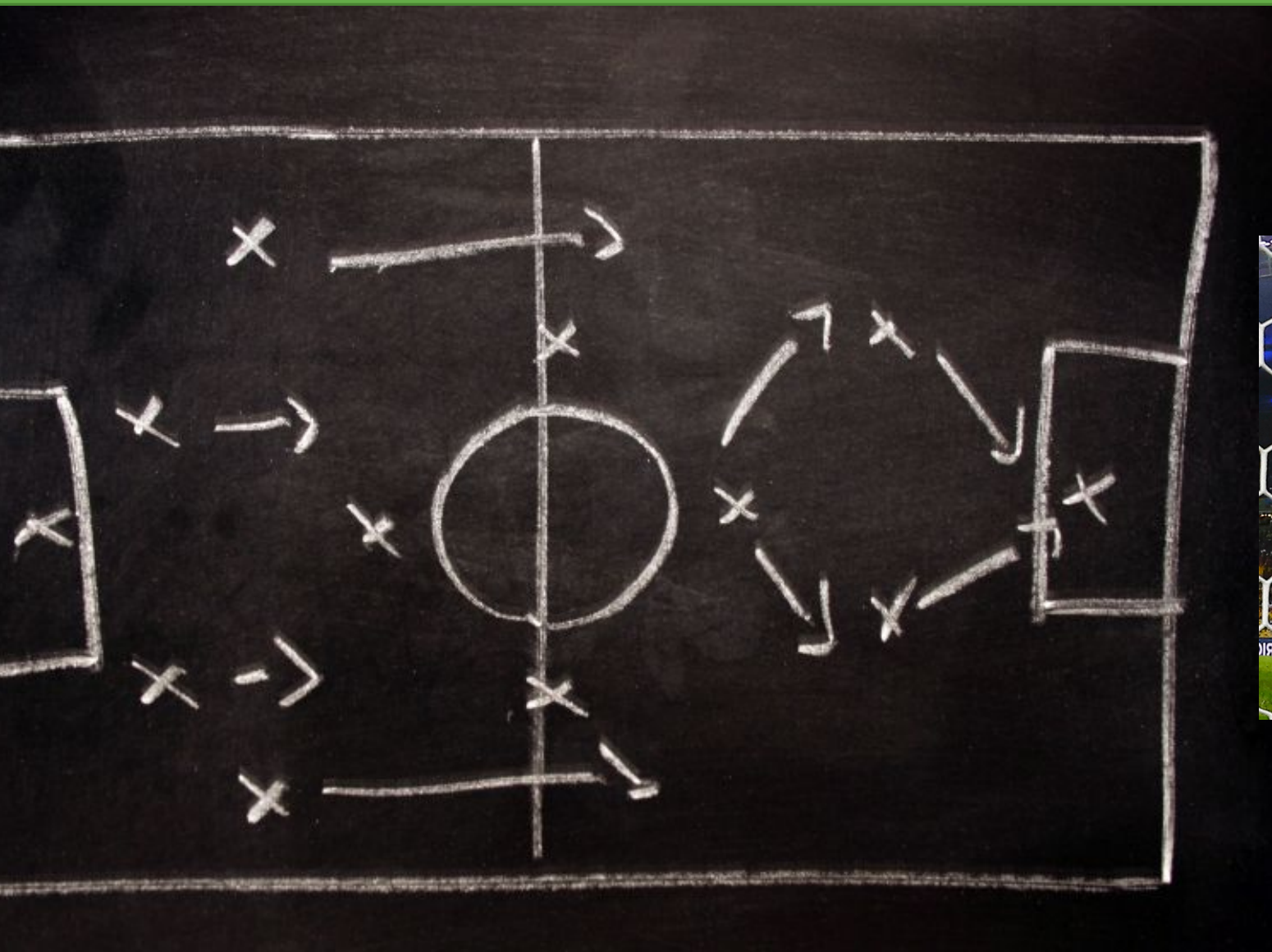


# SEQUENCING OF INFORMATION

## 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

## Training Evaluation Form

*Date of Presentation:*

*Presenter's Name:*

*Topic or Session:*

*Please complete the evaluation for today's training session – your feedback  
AusDBF is committed to continual improvement and suggestions will be*

Criteria	Strongly agree 4	Agree 3	
Training was relevant to my needs			
Materials provided were helpful			
Length of training was sufficient			
Content was well organised			
Questions were encouraged			
Instructions were clear and understandable			
Training met my expectations			
The presenter and / or presentation was effective			

# 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



# TRAINER 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

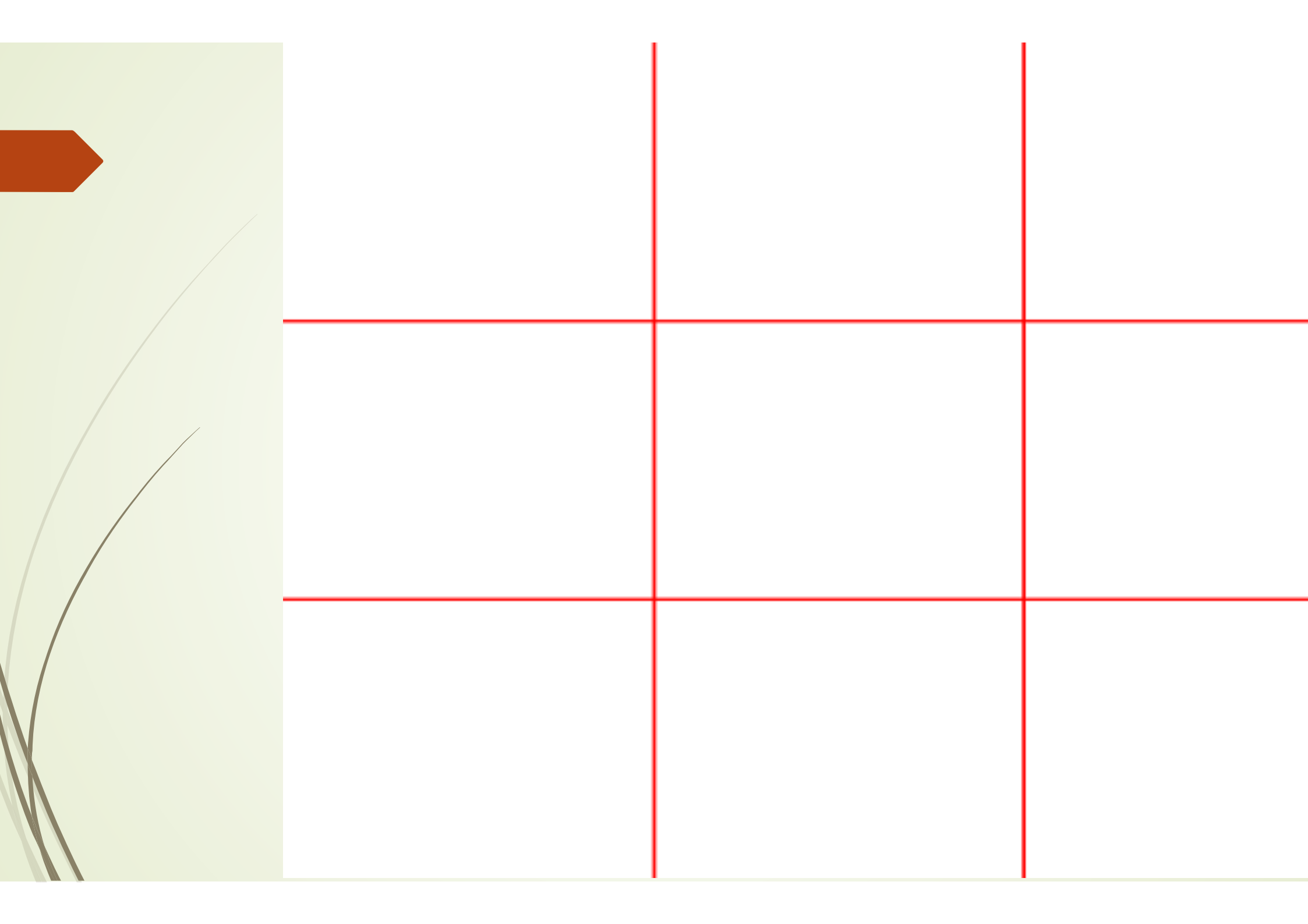
- Too
- Many
- Bullet
- Points

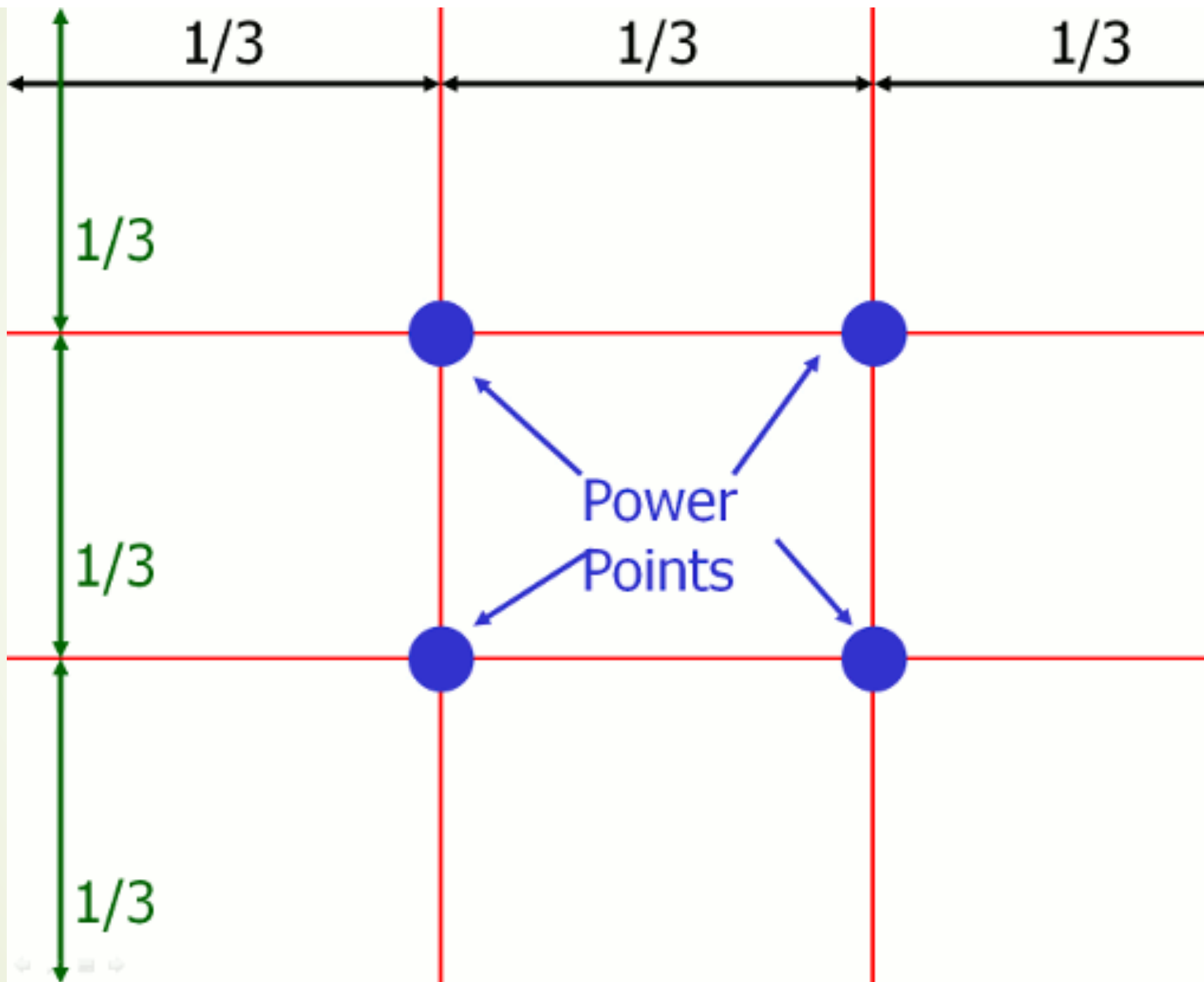
- On
- A
- Single
- Slide
- !!!



## 5 common errors

5. Assuming you always have to make a slideshow presentation

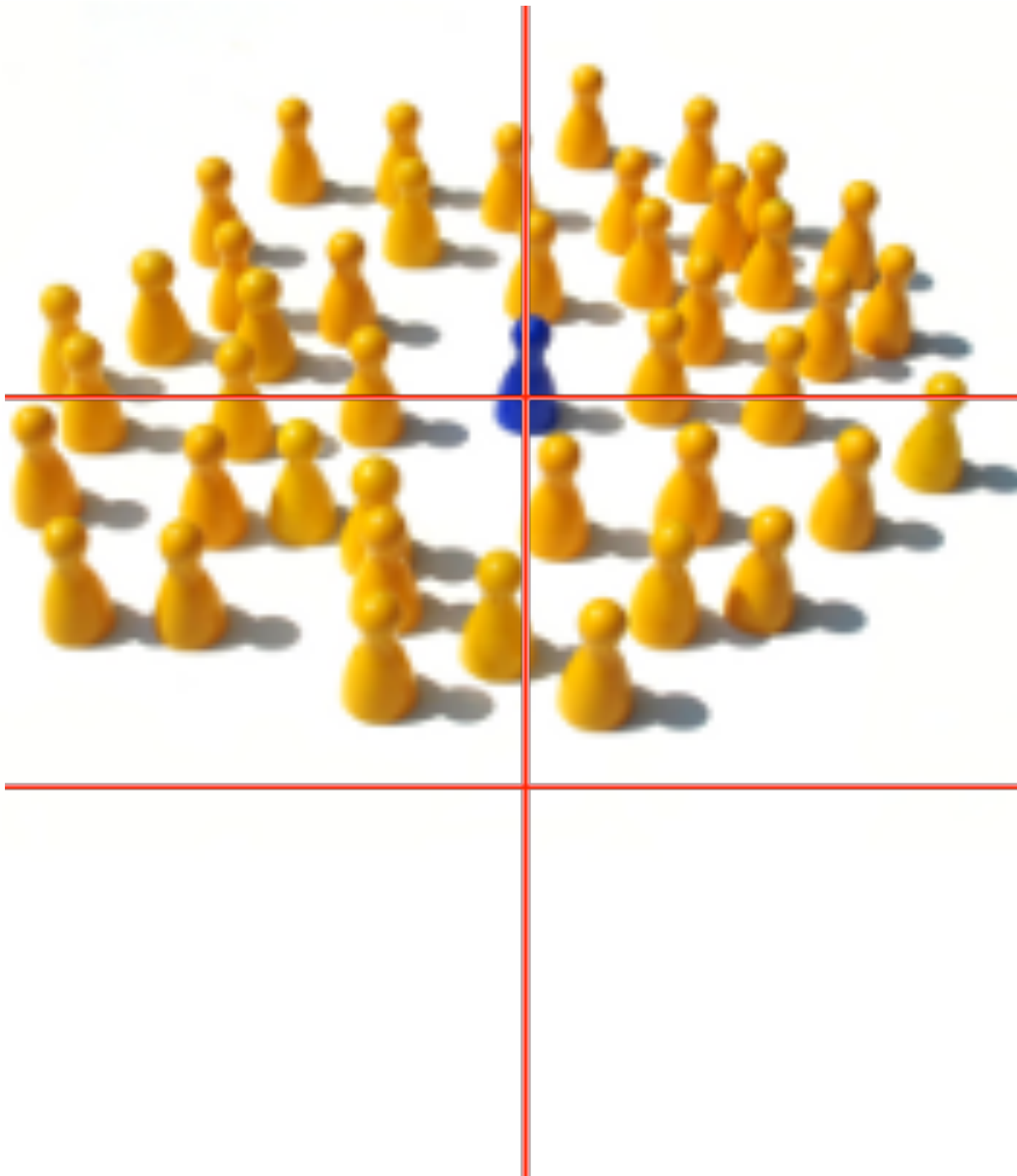








**Does Your  
Presentation  
Stand Out?**



**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

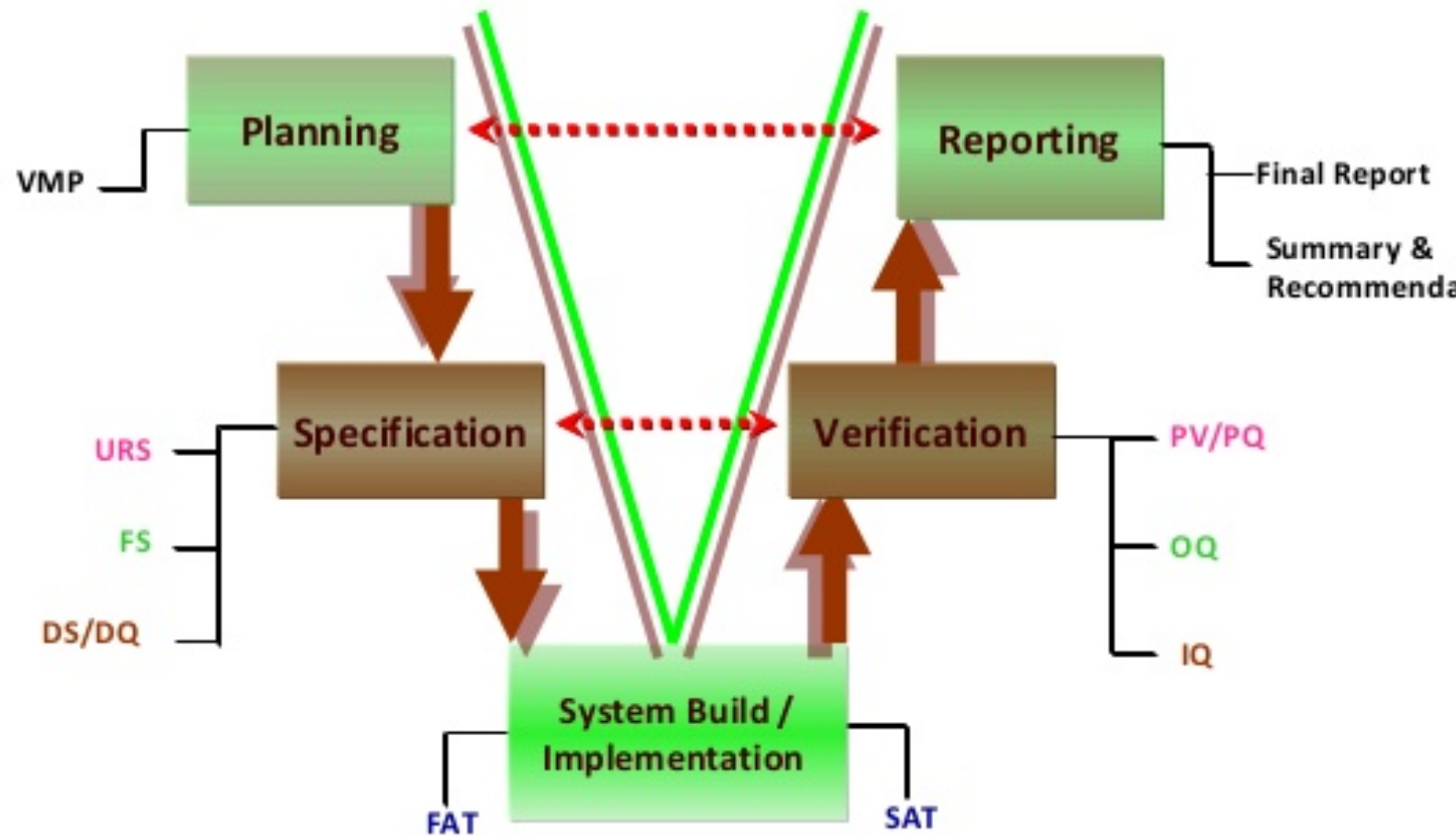
Record or type out the “story” of your training

Trim the excess

Use diagrams to summarize



# Validation Project





## 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

**Version controlled**





# 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



Presenter's Attributes

---

Outcome

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

Acknowledge 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

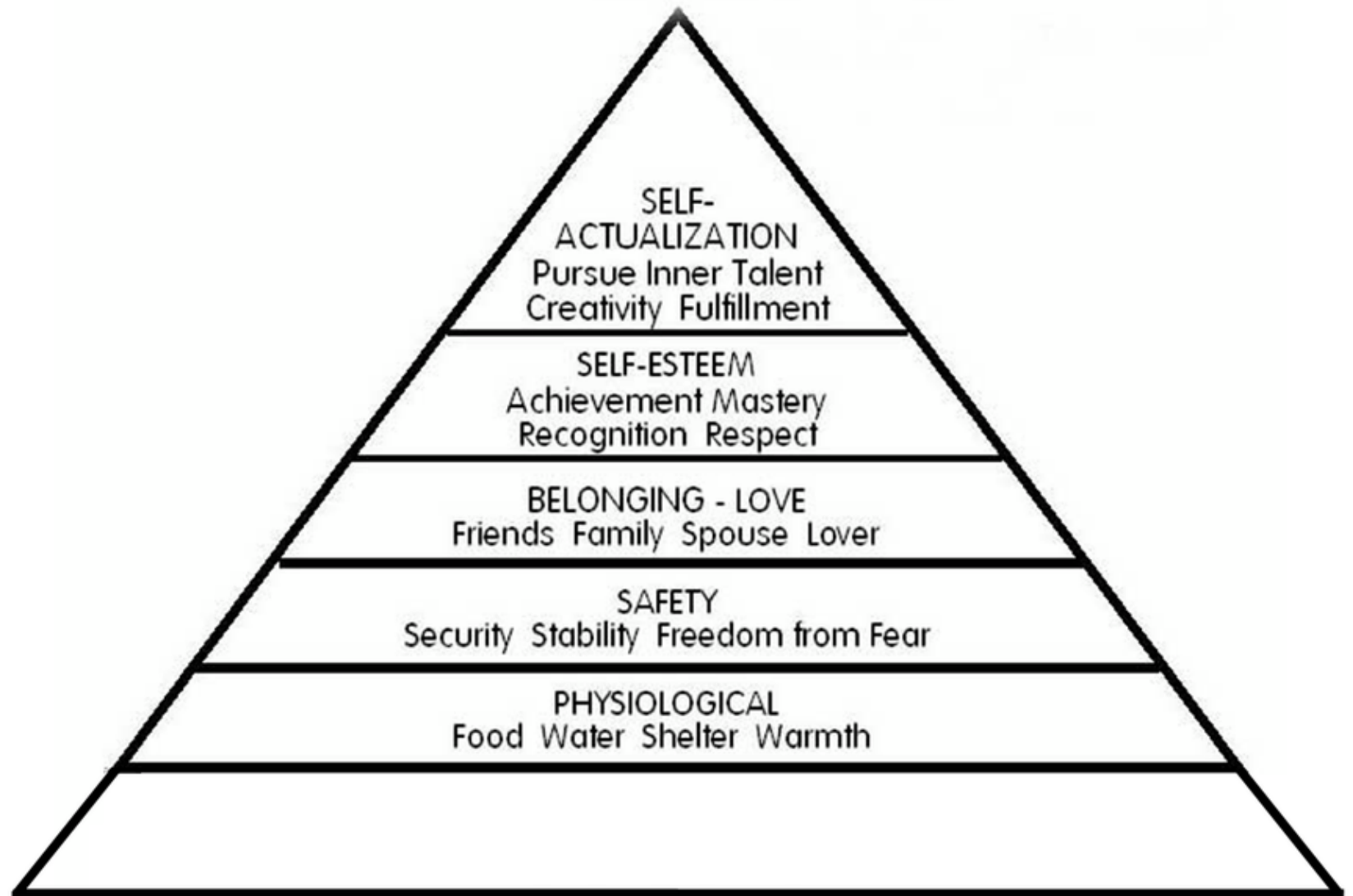
Let the person control the discussion





# THE POWER OF SELF-ACTUALIZATION FOR THE ATTENDEES





# MASLOW'S HIERARCHY OF NEEDS APPLIED TO EMPLOYEE ENGAGEMENT

## 1 HIGHLY ENGAGED

On average less than 15% reach this level

HIGH FLYER

- What can I do for others?
- I inspire others to do their best
- I love it working here
- I'm a high flyer

## 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



SELF  
ACTUALISATION

IMPORTANCE

BELONGING

SECURITY

SURVIVAL

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



De-m

# FOCUS ON INTRINSIC BENEFITS

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



13%

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



Source: BSC Designer  
[www.bscdesigner.com](http://www.bscdesigner.com)

## Extrinsic rewards

- Pay rises,
- Bonuses and
- Benefits.



## Intrinsic rewards

- Sense of meaningfulness
- Sense of choice
- Sense of competence
- Sense of progress



# 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