

Bringing cGMP regulations alive at the work floor

A best practice guide
to implement cGMP guidelines

Patrick Maetens
Senior Specialist Training
Oktober 2006



Johnson & Johnson
PHARMACEUTICAL RESEARCH
& DEVELOPMENT
DIVISION OF JANSSEN PHARMACEUTICA N.V.

Sounds familiar?

- Employees don't implement what's been told after a training?
- Should the employee need a re-training?
- How many hours of training were provided?
- How many trainees have participated the GMP training?
- Training records shows that all employees are trained, so we are compliant?



Exercise 1

- Read and try to memorize the following number:

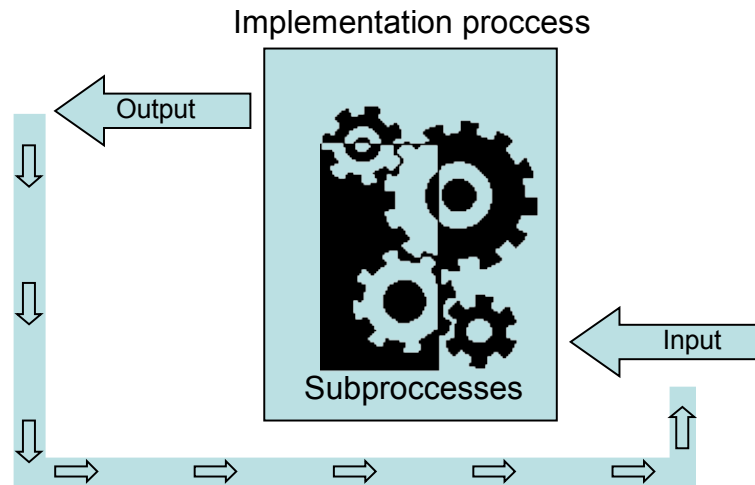
7332091952800476523470

Got it?



Introduction

- Implementing GMP guidelines at the work floor is a continuing process
- Different sub processes are part of the implementation process
- To have the highest output, all sub processes need to run synchronized



Process



People



Learning Process

Bringing cGMP regulations
alive at the workflow



Training process



Learning Process

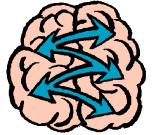


People



Learning Process

Short and long term memory



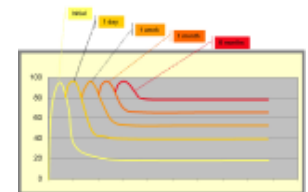
V-A-K



Kolb



Ebbinghouse



Bringing cGMP regulations alive at the workflow



Training process



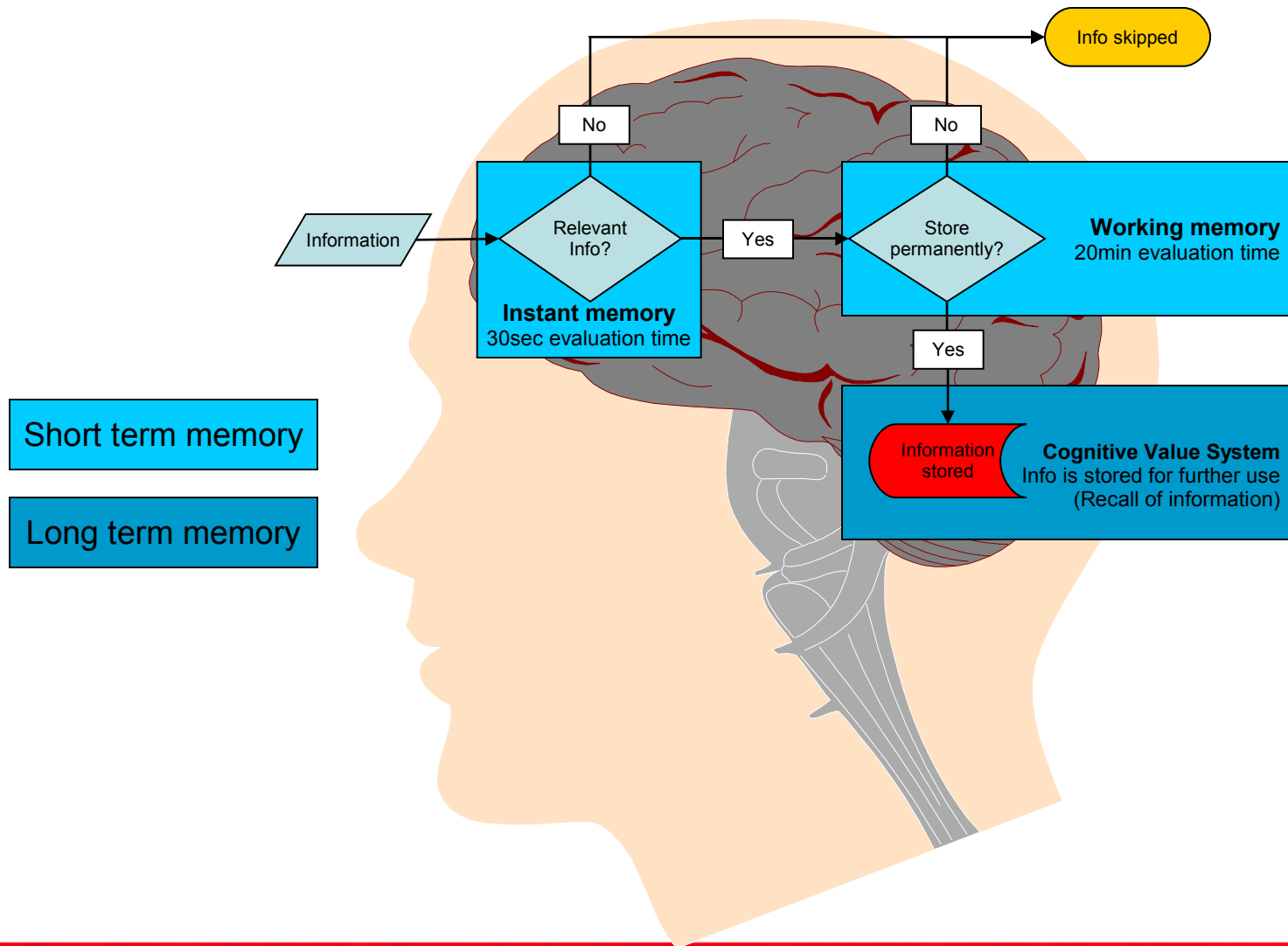
Learning Process - Long and short term memory

- Can you memorize the number from the exercise 1?

7332091952800476523470



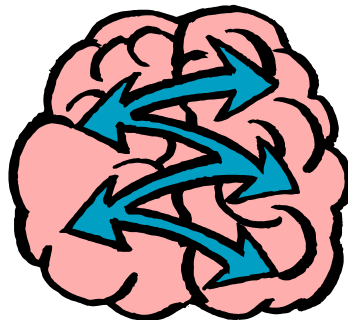
Learning Process - Long and short term memory



Learning Process - Long and short term memory

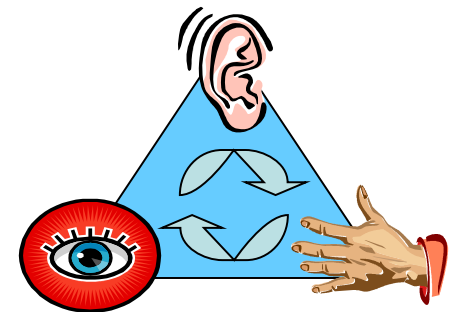
Criteria to store info in the Long Term Memory	
Information	Questions raised by the individu
Data influencing SURVIVING	Do I have to react to survive?
Data influencing EMOTIONS	Does this touch my emotions?
Data who seems LOGICAL	Do I understand this?
Data which are RELEVANT for the individu	Can I do something with this?

**The more information is linked in different ways,
the easier the recall of information is done.**



Learning Process - V A K cycle

- Capturing information is done using our senses.
- Most of the people has a dominant sense:
 - **V**isual: I see things different, See it my way, ... (appr. 80%)
 - **A**uditive: Explain me, I understand, Tell me, ... (appr. 15%)
 - **K**inestatic: I feel it this way, Can I try it?, ... (appr. 5%)
- It's important to stimulate ALL these different types during training every 15 min.



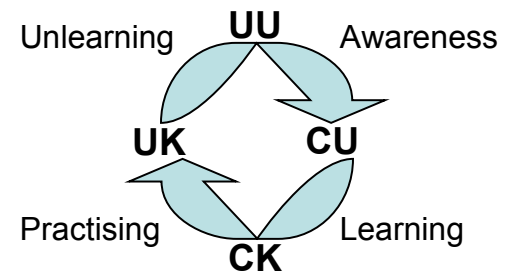
Learning Process - Exercise 2

- Jugglin balls???

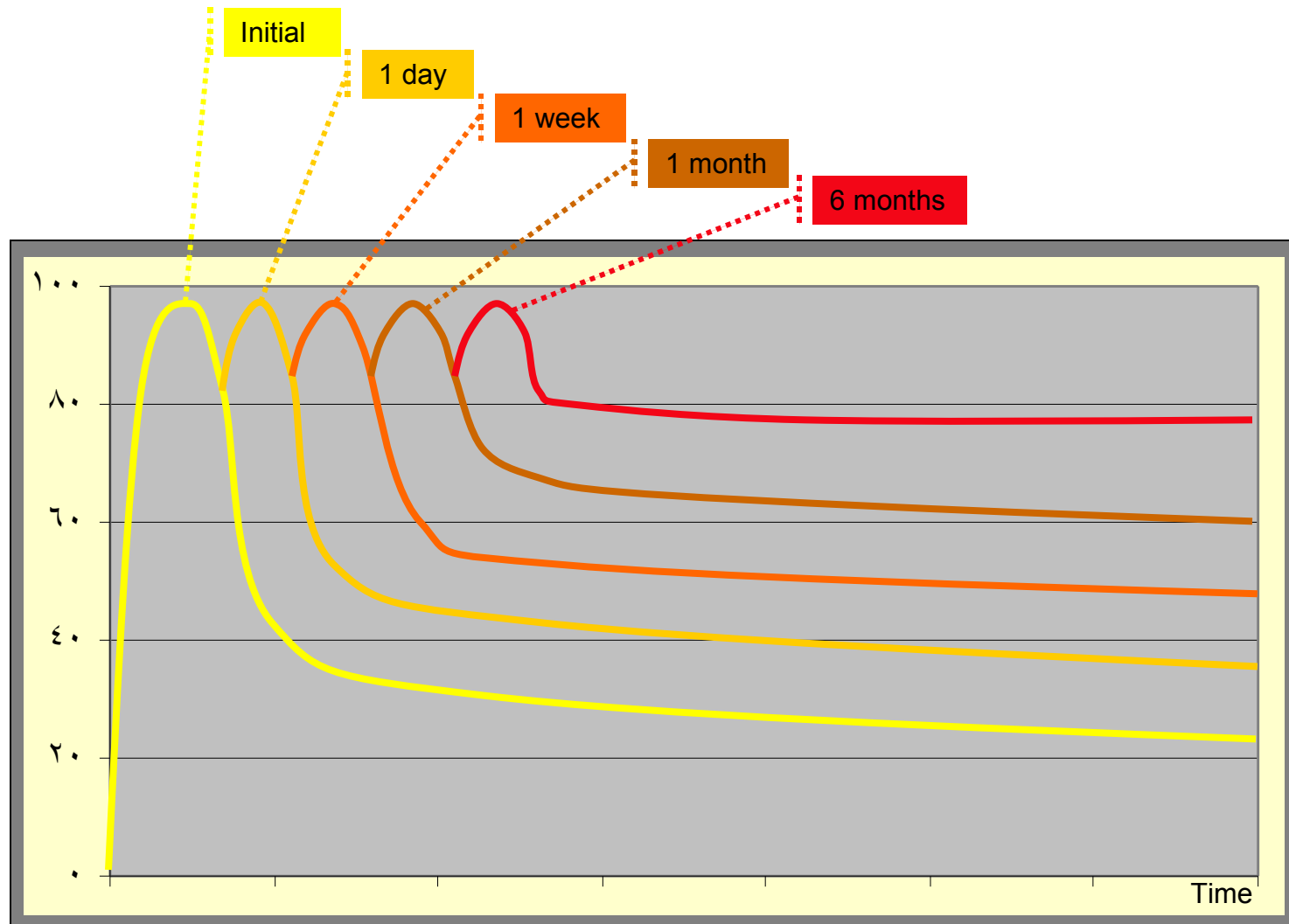


Learning Process - Kolb's learning cycle

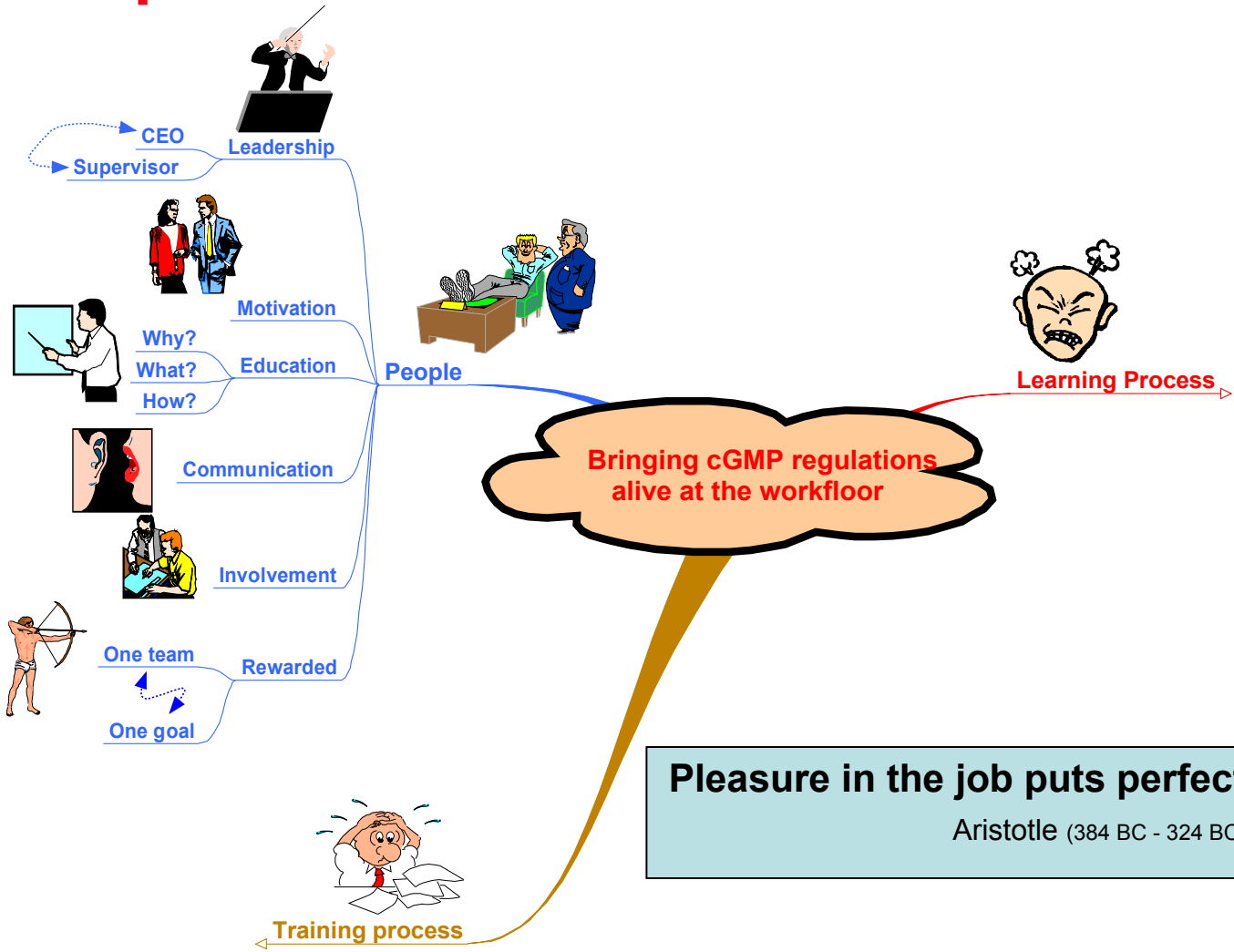
- According to Kolb, learning is a 4 phase process.
- To have the highest learning effect, each phase should be passed.
- Learning therefore is cyclic model, to be seen as a spiral due to the increase of knowledge level
- These 4 levels are:
 - Unconsciously Unknown: UU
 - Consciously Unknown: CU
 - Consciously Known: CK
 - Unconsciously Known: UK



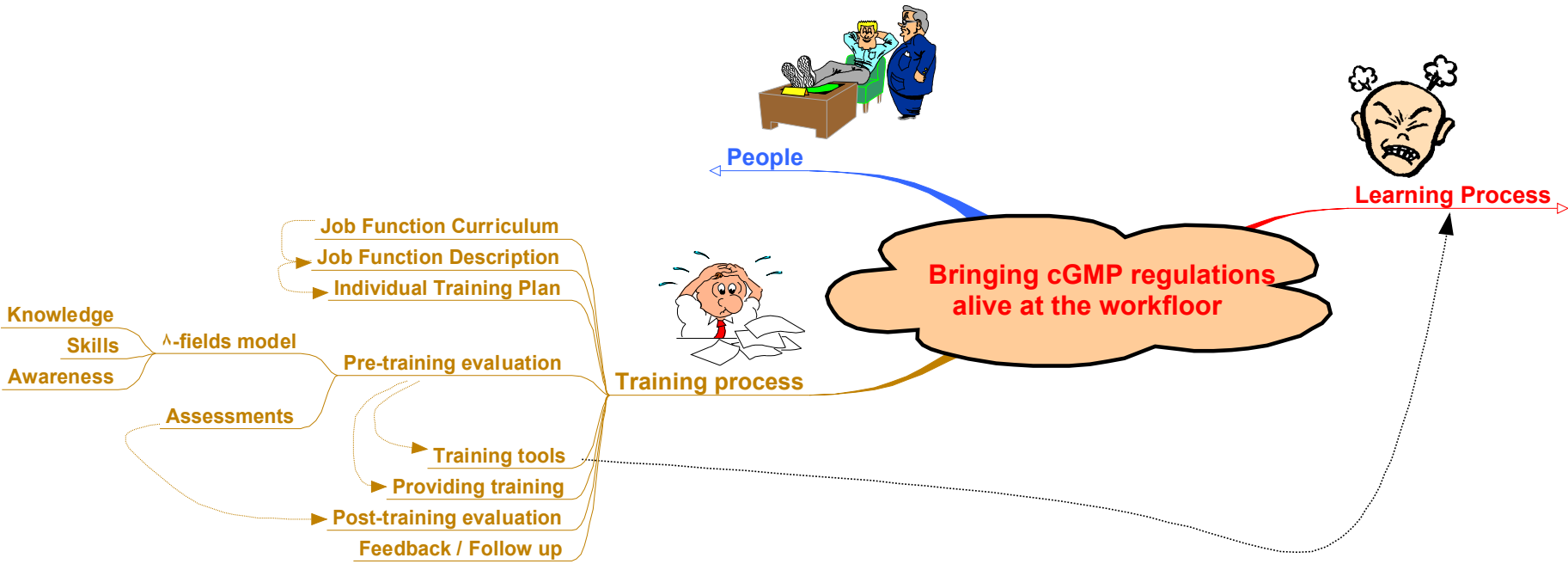
Learning Process - Ebbinghouse Memory Recall chart



People



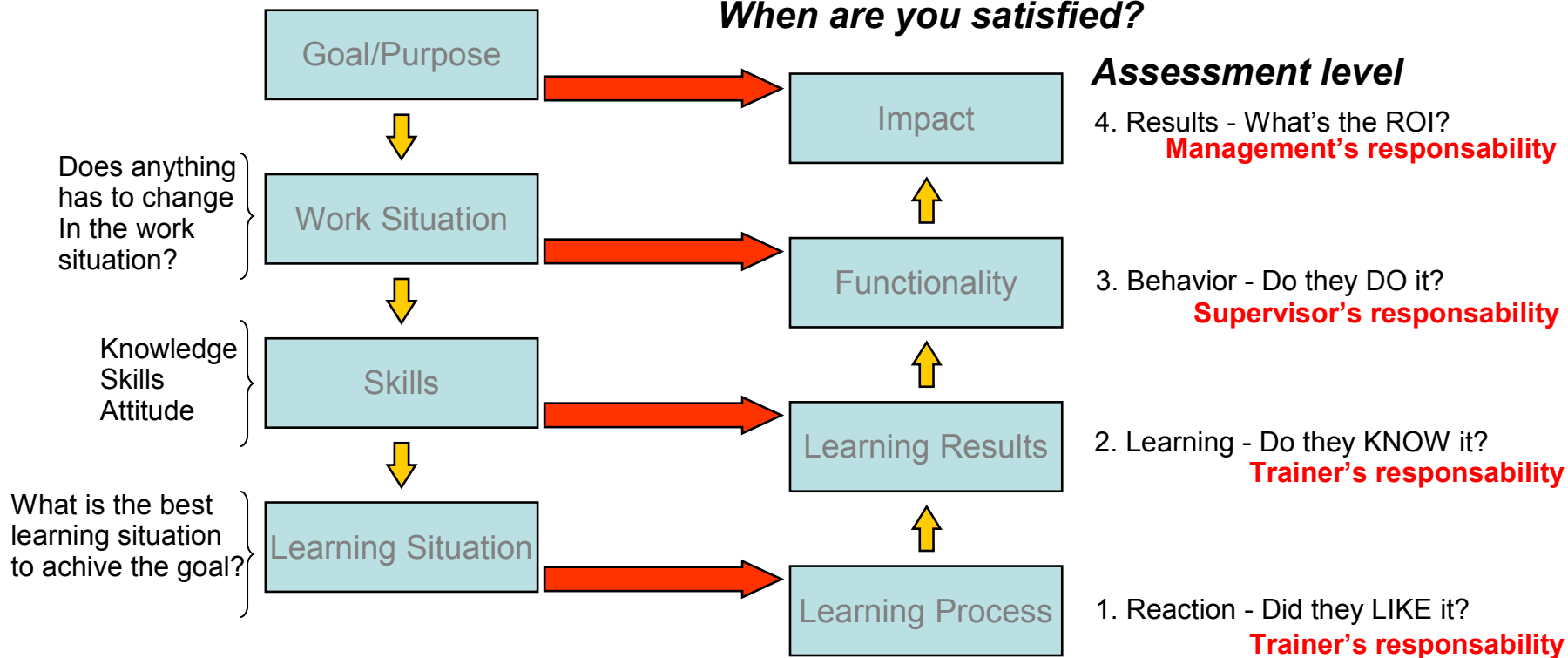
Training Process



Training Process - 8 fields model (Kessels & Smit)

What do you want to achieve?

When are you satisfied?

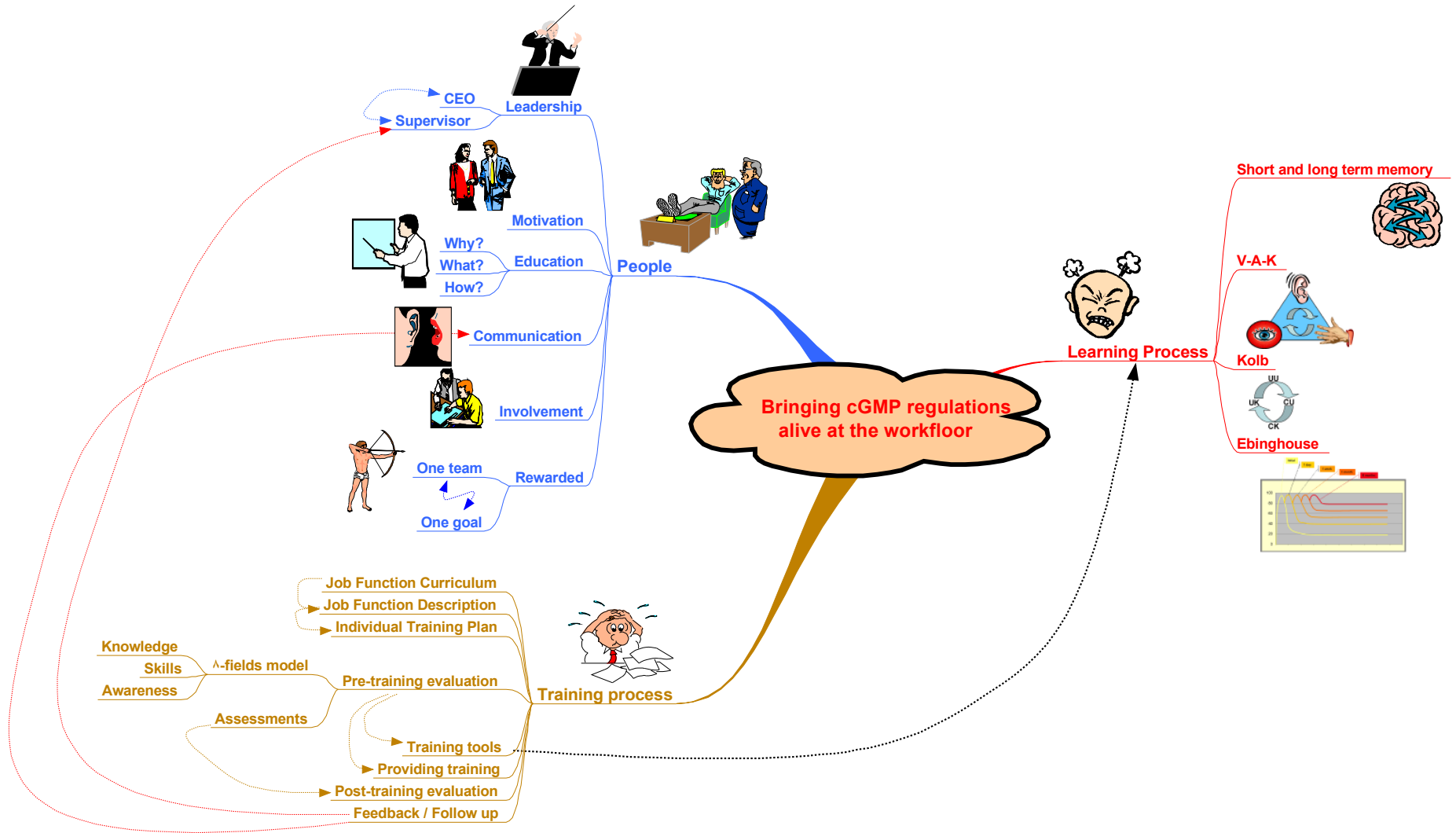


Training Process - Post-Training Evaluation / follow-up

- If no actions are taken after assessments why measure?
- **Follow-up by supervisors/managers to see if the GMP guidelines are implemented at the work floor is critical!!**
- Actions should be taken if GMP guidelines are not implemented:
 - Check if the employee understood what was trained;
 - Check if the employee shows the right attitude;
 - Did changes took place in the work situation, if applicable?
 - Re-training is the easiest way, but not the most effective!
- **Walk the talk! Give the right example!**



Process overview



**Freedom is not worth having,
if it does not include the freedom to make mistakes.**

Mahatma Gandhi (1869-1948)

