THE TRAINING PROCESS

PRESENTED BY

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OBJECTIVES OF THIS COURSE

1. To create an effective training process
2. To train the process owner
3. To train the trainers

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yù玉bù不zhuó琢bù不chéng成qì器， rén人bù不xué学bù不chéng成cái才

Jade must be carved and polished before it becomes an ornament, man must be educated before he can achieve great things.

Despise learning and make everyone pay for your ignorance.
Chinese Proverb

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授之以鱼不如授之以渔

Shou(4) Zhi(1) Yi(3) Yu(2) Bu(4) Ru(2) Shou(4) Zhi(1) Yi(3) Yu(2)

Teach him how to fish is better than just giving him a fish.

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Ignorance is worst case.

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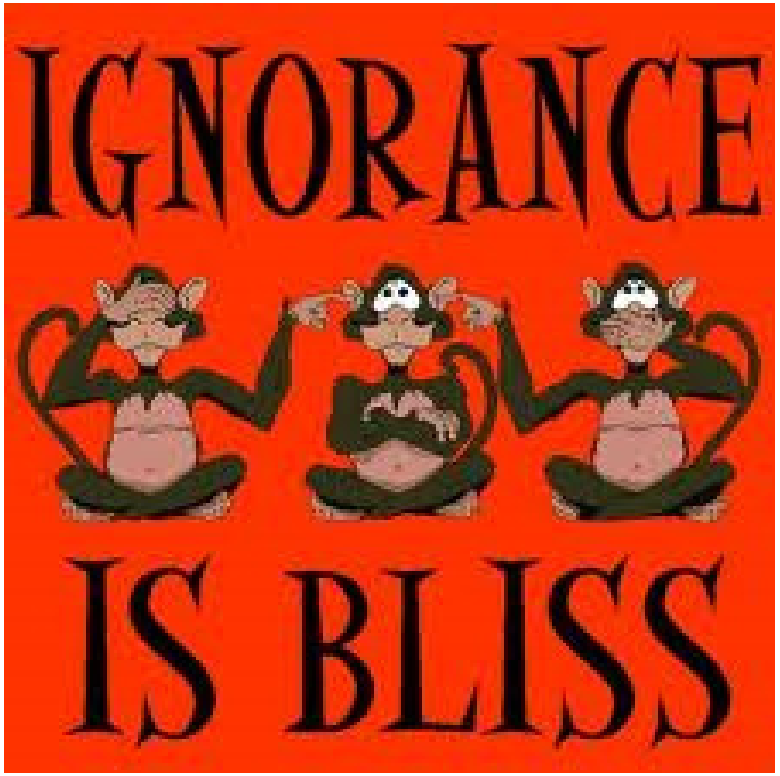

Ignorance is worst case.

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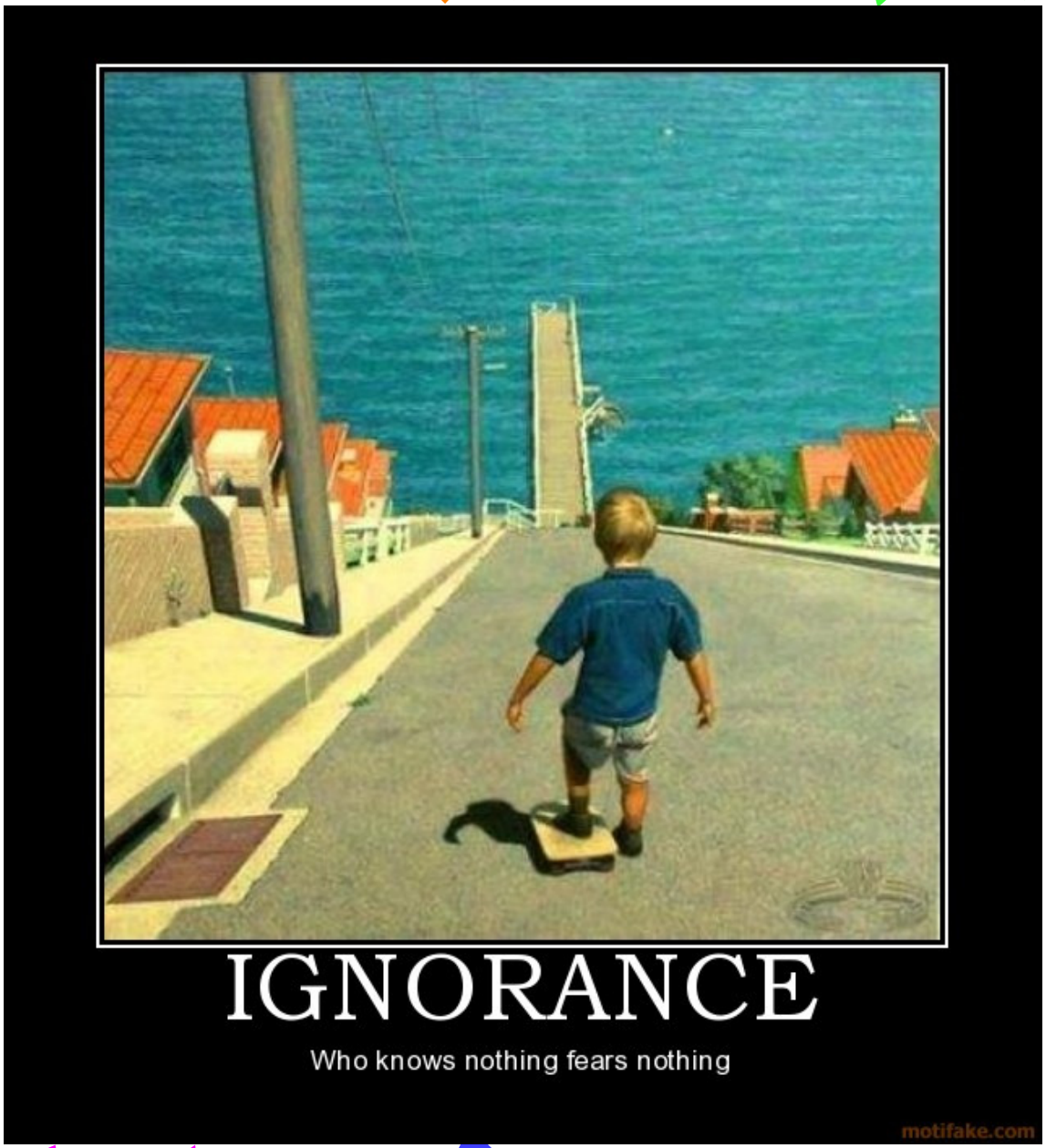

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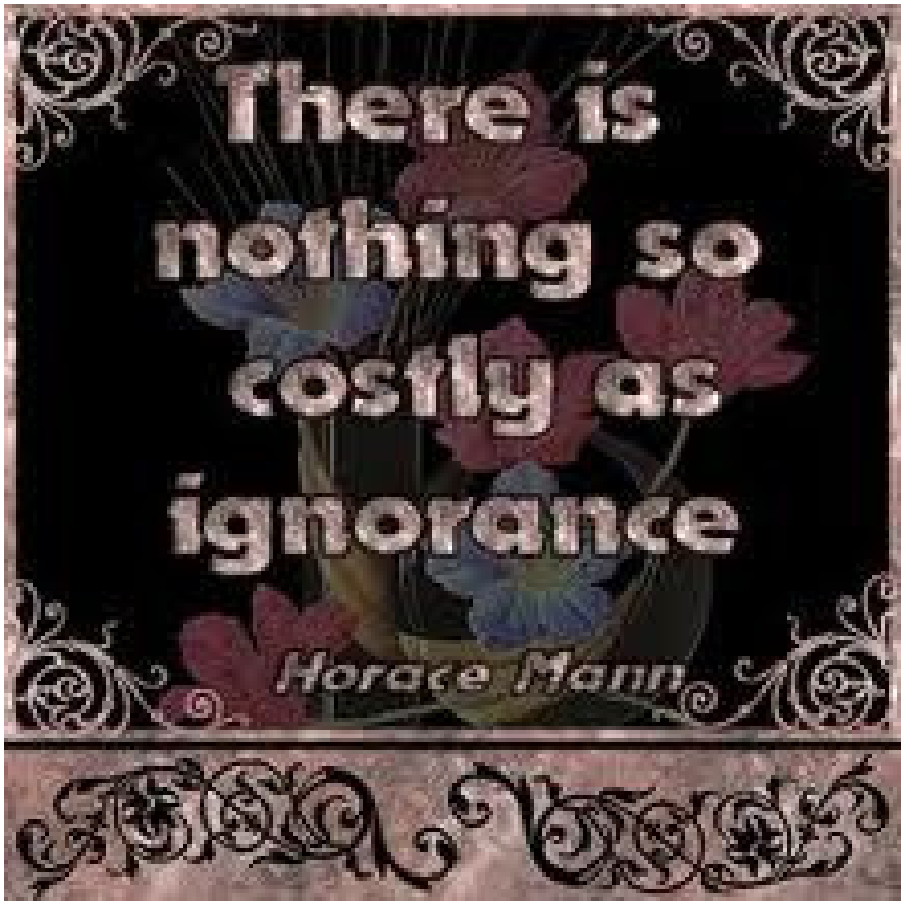

Why does the pharmaceutical industry invest so little in training?

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OUTLINE

1. Introduction
   - Purpose and importance
   - Return on investment (ROI)

2. A qualified person

3. GMP requirement

4. Prerequisites

5. Principles of adult learning (Androgogy)

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OUTLINE

6. Process
   - Knowledge and Skills (K&S) requirements
   - Current K&S
   - Gap Analysis and Prioritization
   - Execution, lesson plan
   - Qualification of trainer. Train the trainer
   - Evaluation of effectiveness

7. Coaching and mentoring

8. Measures

9. GMP training

10. References

11. Appendices
    - Inductive vs deductive reasoning

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PURPOSE

To create qualified people.

Qualified people have the necessary skills to perform their work safely, effectively and efficiently; and are motivated to do so.

They understand what is important and why.

They know the total flow of their processes, their role in them, the performance of their processes and how to control or adjust them when necessary.

They know how to identify and resolve problems and how to improve their processes

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Purpose

- **Understand and follow a procedure or to think?**

“A thought which does not result in an action is nothing much, and an action which does not proceed from a thought is nothing at all.” (*George Bernanos*)

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LEARNING IS UNCOMFORTABLE

TRAINING IS ABOUT CHANGE

At which level in the organization are there the greatest training needs?

Top Management

Middle Management

Supervisors

Workers/analysts

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TRAINING EFFECTIVENESS?

- Read an SOP
- Read a professional article
- A course like this with representatives from different companies
- A course like this within your company
- One on one coaching (mentoring)
- Attend a professional meeting
- On-line, computer-based

1 = not effective
5 = very effective

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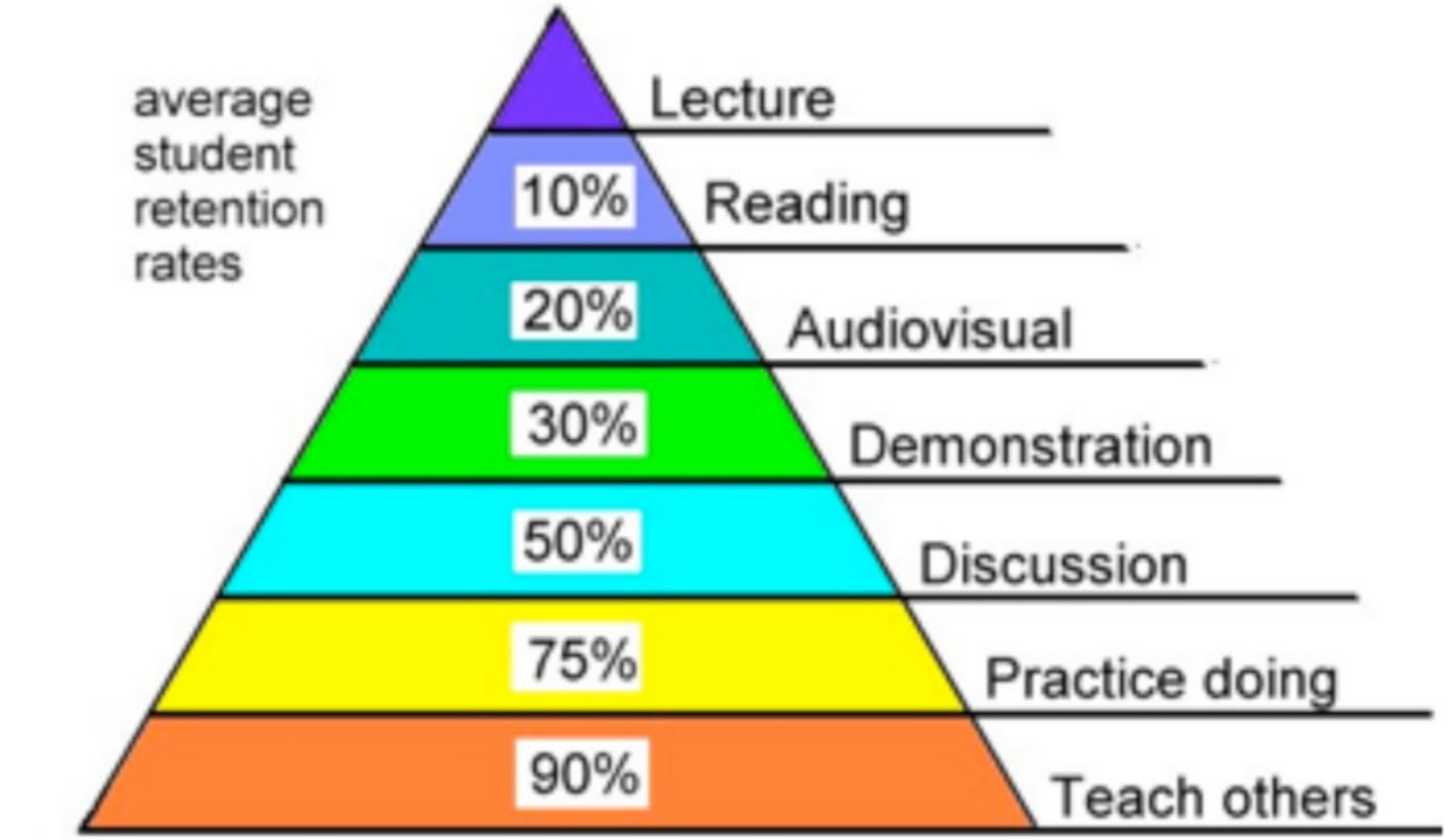
Learning Pyramid



Source: National Training Laboratories, Bethel, Maine

Training - Investment or Cost?

Benefits:

- **Increased job satisfaction and morale among employees**
- **Increased employee motivation**
- **Increased efficiencies in processes, resulting in financial gain (reduction in errors)**
- **Increased capacity to adopt new technologies and methods**
- **Increased innovation in strategies and products**
- **Reduced employee turnover (40% of employees who get poor training leave their positions within 1 year.)**

How can one expect continuous improvement without continuous learning?

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Training - investment or cost?

Example:

Bob is paid $50,000/year

Bob wastes 1 hour /day

The cost to the company is $6,250/year

Waste in our industry is at least 25%

Why does the pharmaceutical industry invest so little in training?

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ROI = Benefits/Costs

How does one measure the benefits of training?

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Why does the pharmaceutical industry invest so little in training?

- **We don't know the cost of poor quality.**

- **Studies show that 80% of training dollars are a waste. *(Dr. Rob Brinkerhoff)***

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TIME DEVOTED TO TRAINING, TO LEARNING?

New hire or new person in job?

On-going:
Hours per week – 1 hour, 2 hours, 4 hours?

Professionals, Management:
Hours per day – ½ hour, 1 hour, 2 hours?

Where are the largest training gaps, at the top or bottom of the organization?

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Table 1: Amount of training required

More training is required when...	Less training is required when...
• The workforce is relatively new to the job	• The workforce is experienced
• There is a high, rapid employee turnover rate	• There is a low employee turnover rate
• New products are being added	• No new products are being added
• There are some/many worker performance issues	• There are few worker performance issues
• The technology, equipment, or process is new or changing	• The technology, equipment, or process is stable
• New personnel are added; the firm is expanding	• Few new personnel are added; the firm is staying the same size
• The facility operates 24 hours a day using multiple shifts	• The firm operates on one shift
• There are gaps between what a person can do when hired and what he is required to do.	• There is a close match between knowledge and skills of personnel and what is required of them

"In firms with skilled, experienced personnel, training could be reduced to 3-5% of available time."

WHO

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KEY PERSONNEL (WHO)

“The scientific education and practical experience of experts should be such as to enable them to exercise independent professional judgement, based on the application of scientific principles and understanding to the practical problems encountered in the manufacture and quality control of pharmaceutical products.”

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WHAT IS THE CONNECTION BETWEEN TRAINING AND MOTIVATION?

Motivation – a person's desire to do certain things, to achieve certain goals.

Is training motivating?

What other things motivate an employee?

What are some things that are demotivating?

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TRAINING IS ABOUT CHANGE

If there is no improvement in performance – safety, effectiveness and/or efficiency – training is waste.

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GMP REQUIREMENT

"Each person….shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions."

Training:

- **particular operations person performs**
- **regulations and procedures "as they relate to the employee's functions."**
- **training by qualified individuals**
- **training on a continuous basis**

The training of supervisors

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TRAINING PREREQUISITES

Factors that influence training effectiveness:

1. **Capability of trainee**
2. **Time available to trainee to put the learning into practice**
3. **Trainee has coach/mentor available to help in implementing the learning**
4. **Management/supervision support and encouragement**
5. **Well-designed, fail-safe processes (procedures)**

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PRINCIPLES OF ADULT LEARNING
(Andragogy, M. Knowles)

Adults require more control over their learning than children.

1. **Adults have a need to know why they should learn something.**
2. **Adults have a deep need to be self-directing.**
3. **Adults have a great diversity and volume of experience.**
4. **Adults become ready to learn when they experience in their life situation a need to know in order to perform more effectively and satisfyingly.**
5. **Adults enter into a learning experience with a task-centered or problem-centered orientation to learning.**

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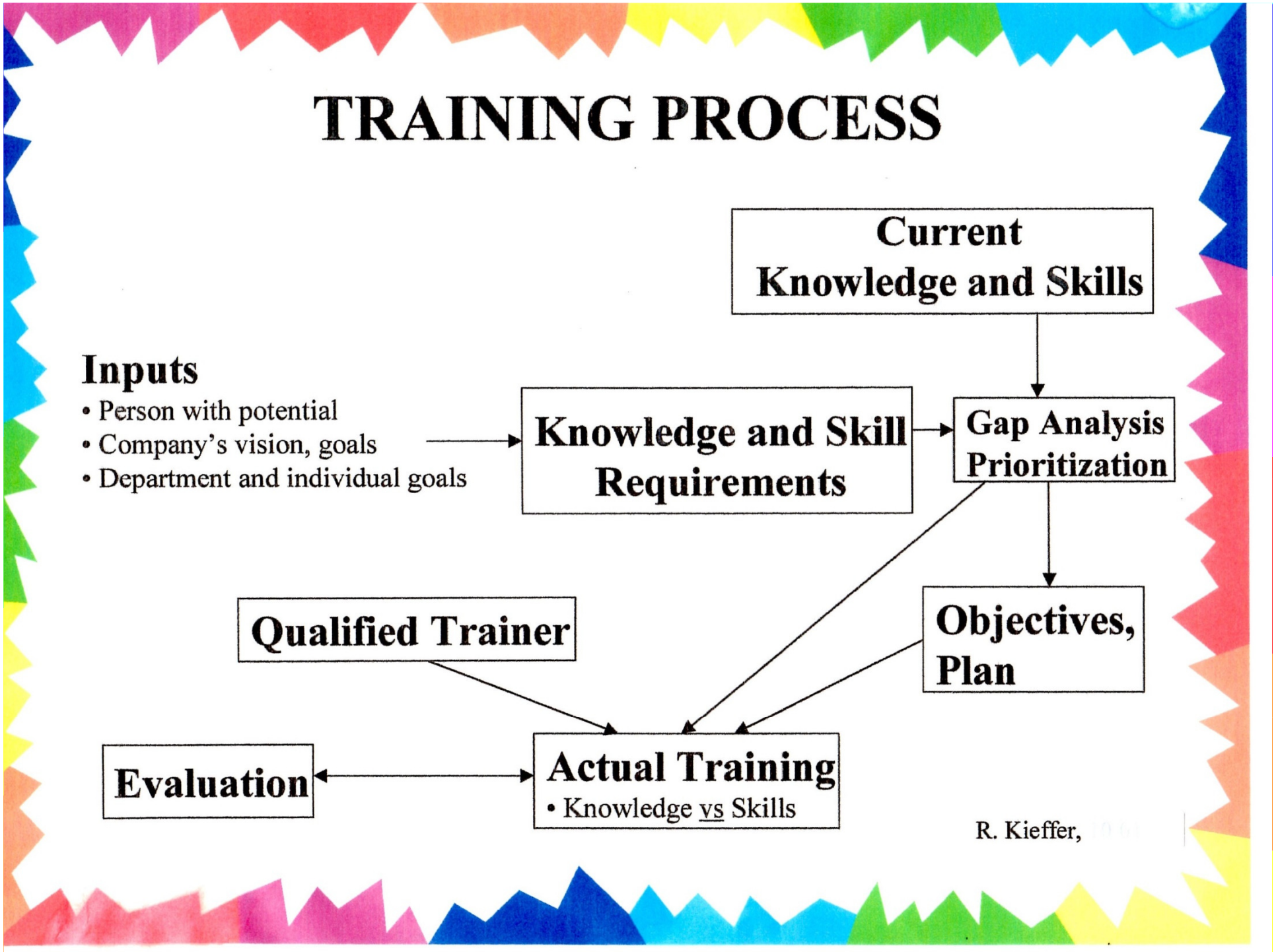
TRAINING PROCESS



KNOWLEDGE AND SKILL REQUIREMENTS

Let's use the quality professional as an example.

Reference: Kieffer et al., "The Knowledge and Skills of the Successful QA/QC Manager"

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SKILLS OF QUALITY PROFESSIONAL

KNOWLEDGE and SKILLS LIST

SCOPE: Quality, Cost, Service, People, Culture

Skills to run a business, a work center: leadership/management, capacity planning, scheduling, productivity

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QUALITY KNOWLEDGE AND SKILLS

(partial list)

Business

- **supply chain**
- **quality models and theories**

Customers

- **internal and external**

Leadership and Management

- **performance management**
- **change management**

Manufacturing

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KNOWLEDGE AND SKILLS

(partial list)

Processes and Systems

Risk Management

Quality Tools
- **root cause analysis**
- **statistical**

Validation

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KNOWLEDGE AND SKILLS

(partial list)

Laboratory

Documentation

- **procedures and records**

Audits, Inspections

- **process assessments**

Suppliers and Third Party Manufacturers

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Table I: Competency assessment.

Skill Level	
E = Expert	High level of knowledge and experience on the subject with the capability of readily educating others.
C = Competent	Good basic understanding and working knowledge of the subject with the capability of applying the principles in the workplace.
N = Needed	Some to little knowledge, experience, or understanding of the subject. Training and experience would be necessary to apply the skill in the workplace.
Priority Rating	
1	Skill necessary to perform current job
2	Skill necessary to perform future job
3	Development needed to improve flexibility/ capability
4	Not required/low priority

Obviously an item that scores N and Priority 1 should get the most urgent attention in a personal development plan.

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SIX LEVELS OF COGNITION

Remember:
Recall or recognize terms, definitions, facts, ideas, materials, patterns, sequences, methods, principles, etc.

Understand:
Read and understand descriptions, communications, reports, tables, diagrams, directions, regulations, etc.

Apply:
Know when and how to use ideas, procedures, methods, formulas, principles, theories, etc.

Analyze:
Break down information into its constituent parts and recognize their relationship to one another and how they are organized; identify sublevel factors or salient data from a complex scenario.

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Evaluate:

Make judgments about the value of proposed ideas, solutions, by comparing the proposal to specific criteria or standards.

Create:

Put parts or elements together in such a way as to show a pattern or structure not clearly there before; identify which data or information from a complex set is appropriate to examine further or from which supported conclusions can be drawn.

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TRAINING/DEVELOPMENT

Desired skills (boss)

Current skills (subordinate)

Prioritization and Plan (boss and subordinate)

Subordinate needs to take initiative

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TRAINING/DEVELOPMENT
Planning Tool

1. **Develop skills list (boss)**
2. **Current skill level (subordinate)**
   - **none, competent, expert**
3. **Need – unimportant, long-term, now (boss)**
4. **Prioritization (boss and subordinate)**
5. **Develop plan (subordinate)**

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QA Department Skills Development Matrix

	Business	Customers	Mgn/Lead	Manuf.	Process	Risk Mgn	Root Cause	Statistics	Validation	Laboratory	Documen.
Bill Mathews	L C	C	C E	L C	C	L C	L C	L	L	L C	C
Bob Smith											
Dan Miller											
Mary Kane											
Jane Harmon											
Marty Campbell											

L = low skill level C = competent skill level E = expert skill level

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What are your development needs?

Short term (1 year)

Long term

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TRAINING PLAN

1. Set measureable objectives

2. Define method:
   - internal course
   - external course
   - on-the-job
   - self study, reading

3. Trainees

4. Duration of training

5. When?

6. Define method(s) of evaluation

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LESSON PLAN

1. Measurable objectives
2. Outline
3. Materials
4. Processes, procedures involved
5. Exercises – individual, team
6. In-process evaluations
7. Trainee involvement (4:1 rule)
8. Performance recognition
9. Make it fun!
10. Course and trainer evaluation

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EXECUTION OF TRAINING

1. **Make it fun**

2. **Don’t lecture. Involve the trainees. Exercises.**

3. **On-going evaluation to assure that trainees are learning.**

4. **Post training exercises to put into practice the learning, to develop skill.**

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ON THE JOB TRAINING

1. **Tell them.**
2. **Show them.**
3. **Have them show you.**
4. **Repeat until the performance is satisfactory**

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QUALIFIED TRAINER

1. Subject expert
2. Understands the trainees
3. Can present concepts at trainees' level, simple
4. Can involve the trainees
5. Can evaluate during the training if the trainees are understanding what is taught
5. Can make it fun
6. Can create visuals and interesting training materials
7. Understands the learning process, the psychology of learning
8. Is very well prepared and organized

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Train the Trainer

HINTS FOR GOOD INSTRUCTION

1. **Introduction:**
   - Tell the students what will be learned. Stress importance to the individual. Tell them how it is to be used.
   - Let the students know what is coming and what is expected of them.

2. **The Delivery:**
   - Speak clearly. No slang.
   - Speak directly to students.
   - Adjust to the level of the students.
   - Vary rate, pitch, intensity.
   - Convince yourself of the value of your message.
   - Prepare your questions and answers.

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HINTS FOR GOOD INSTRUCTION

3. The Summary:
   - Summarize frequently as each major point is made.

4. Classroom Management:
   - Prepare
   - Don't let class get out of hand.
   - Continually check class reaction.
   - Direct questions to inattentive students.

5. Demonstrations:
   - Rehearse. Follow a written lesson plan.
   - Use realistic aids.
   - Leave out unnecessary information.
   - Set high standards.

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HINTS FOR GOOD INSTRUCTION

6. Application - Practical Exercises:
   - Doing is the most effective form of learning.
   - Observe performance so that you can give constructive criticism.
   - Take time to assist students. Things which seem easy to you may not be easy to them.
   - Developing a competitive spirit will increase interest and learning.

7. Evaluations:
   - Informal testing should be continuous.
   - On-the-job performance is the best test of learning.

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How did I do?

+	-

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SECTION 8.0 QUICK LIST OF HINTS FOR GOOD INSTRUCTION

	The Introduction
Motivate	Create interest. Make the individual want to learn.
Brevity	Make your introduction brief, clear and convincing.
Why	Tell students what will be learned. Stress importance to individual. Tell them how it is to be used.
Associate	Relate to previous instruction and to what follows.
How	Outline the method of presentation. Let the students know what is coming and what is expected of them.
	The Delivery
Attention	Be sure you have your students' full attention before starting.
Volume	Adjust to the size of your audience. Be sure that you can be heard.
Enunciation	Speak clearly and distinctly.
Pronunciation	Be sure you are correct. Get the "dictionary habit."
Avoid	Use of localisms, slang, profanity and monotonous connectives should be avoided.
Contact	Look directly at and speak directly to students.
Excuses	Prepare yourself. You won't have to make excuses.
Vocabulary	Adjust to the level of the students. Define new terms.
Emphasis, Repetition	Gain emphasis by forceful presentation, repetition, gestures, pauses, and variation in rate, pitch and intensity.
Sell Your Subject	Convince yourself of its value. The rest is easy.
Prepare	Have your questions and expected answers ready prior to class. Be sure questions are clear and concise and answers definite.
Kind	Be specific. Each question should contribute to the instruction. Be certain that each point of the instruction is covered.
Stimulate Thinking	Phrase your questions to bring out the WHY and HOW. Don't let your students guess.
Rotate Questions	Cover the entire class. Recognize and evaluate student's responses.
	The Summary
Essential	Summarize frequently as each major point is made. Conclude each period, course, or phase of instruction with a summary.
What	Restate major points.

Classroom Management

Preparation	There is no substitute for preparation. Know your subject and lesson plan. Check on seating, lighting, ventilation, instructional materials, equipment, training aids, and assistant instructors before class.
Exercise Control	Remember, you are the instructor. Don't let a class get out of hand, don't argue, and keep the lesson moving toward objectives.
Timing	Cover all material. Prepare a schedule and stick to it.
Be Alert	Continually check class reaction.
Question	Direct questions to inattentive students. Question students frequently to keep class alert and to check their understanding.

Demonstrations

When	If it will contribute to student learning or understanding.
Preparation	Plan every detail. Train personnel. Rehearse. Follow a written lesson plan.
Introduce	Carefully outline the procedure to be followed.
Realism	Make the situation genuine. Use realistic aids.
Explain	Cover every detail. Demonstrate only one thing at a time. Be sure that each is understood before proceeding. Leave out unnecessary information.
Safety	Emphasize safety factors.
Standards	Set high standards.
Summary	Review what the demonstration has shown.

Application - Practical Exercises

Why	Doing is the most effective form of learning.
Introduce	Carefully outline the procedure to be followed.
Phase	Work step-by-step. Complete each one before preceding to the next.
Standards	Set high standards. Continue work until they are met.
Supervision	Observe performance so that you can furnish constructive criticism. Correct errors on the spot. Don't permit practice of incorrect methods.
Be Patient	Take time to assist students. Things which seem easy to you may not be so easy to them.
Competition	Developing a competitive spirit will increase interest, motivation and learning.

Evaluations

When	Informal testing should be continuous.
Performance	On the job performance is the best test of learning. Use it to check instruction when ever practical.
Oral	Good for informal testing. Limited to small groups.
Written	Good for testing large group.

EVALUATION

1. During the training

2. Immediately at end of training

3. Later on-the-job
   - review documents
   - failure investigations
   - audits
   - presentations
   - others?

Depends very much on the objectives of the training. The objectives must be clear and measureable from the beginning.

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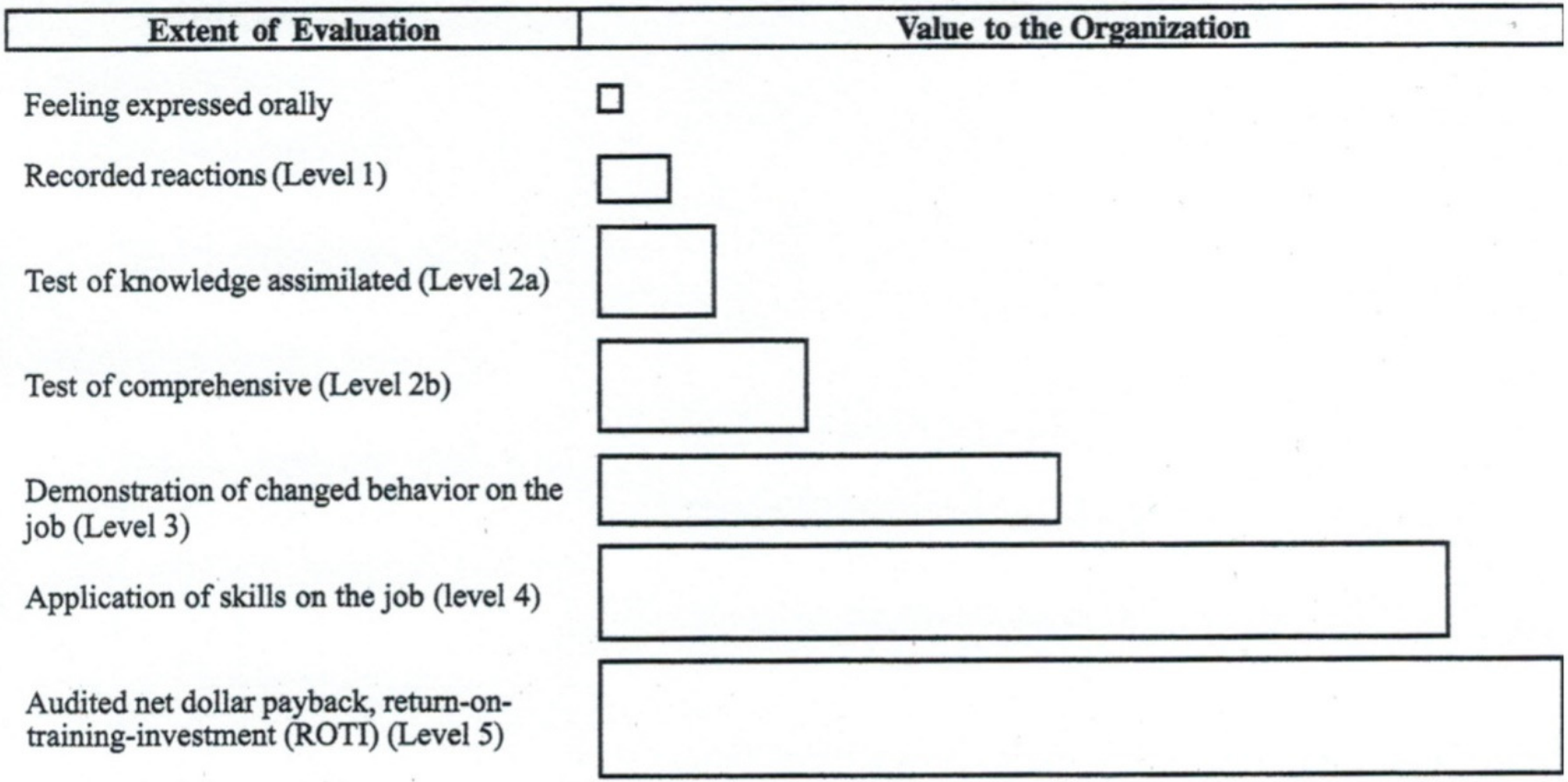

Figure 17.5 Conceptual view of the relative value of evaluated training.
Reprinted with permission of R. T. Westcott & Associates.

ON-GOING SUPPORT IS ESSENTIAL

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Just in time training, followed by immediate implementation.

PRACTICE, PRACTICE, PRACTICE….

The learner needs feedback

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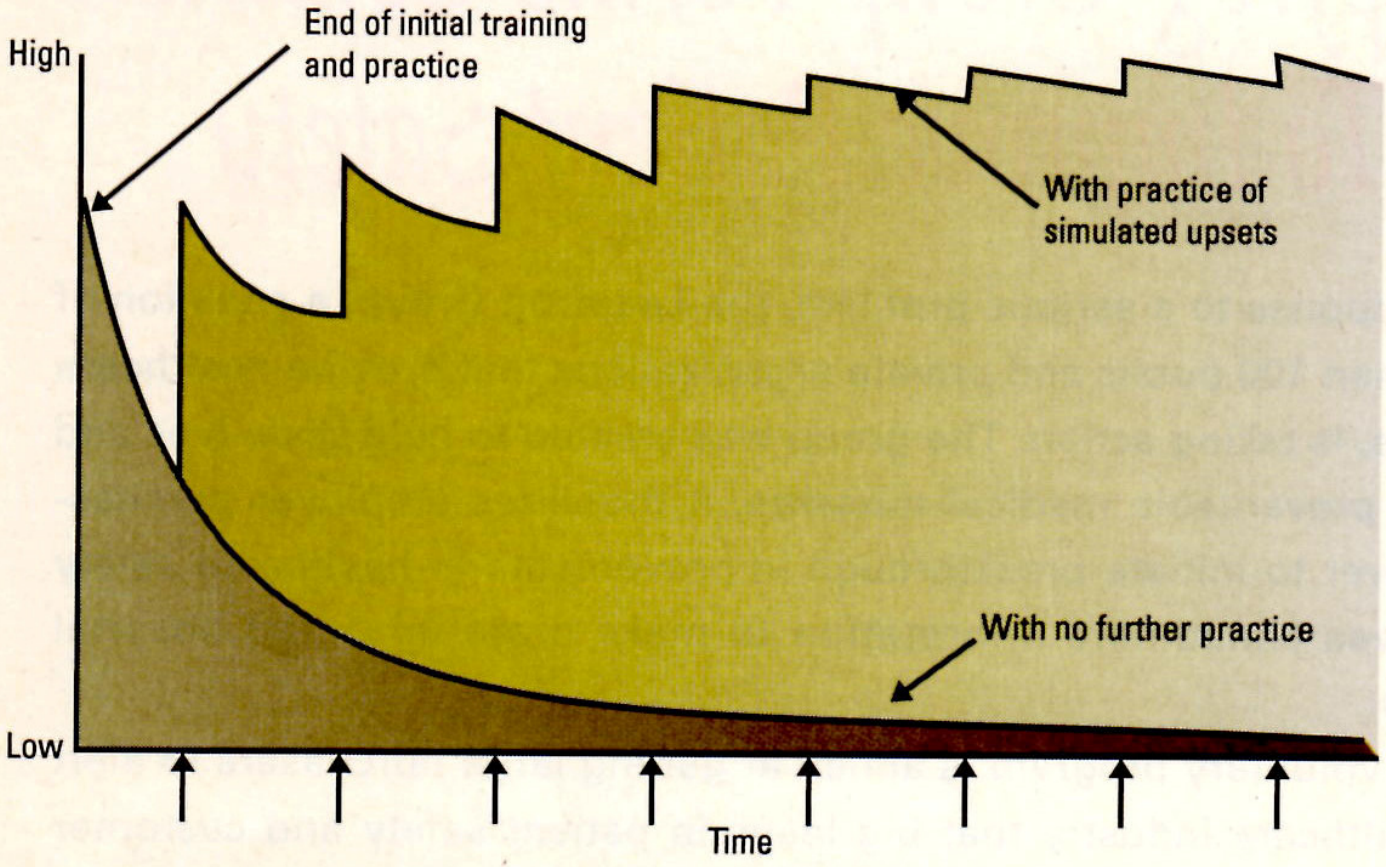
FIGURE 5 Conversion of Knowledge to Skill



Vertical arrows represent practice sessions such as drills, talk-throughs, what-if challenges and simulator training.

JUST IN TIME TRAINING

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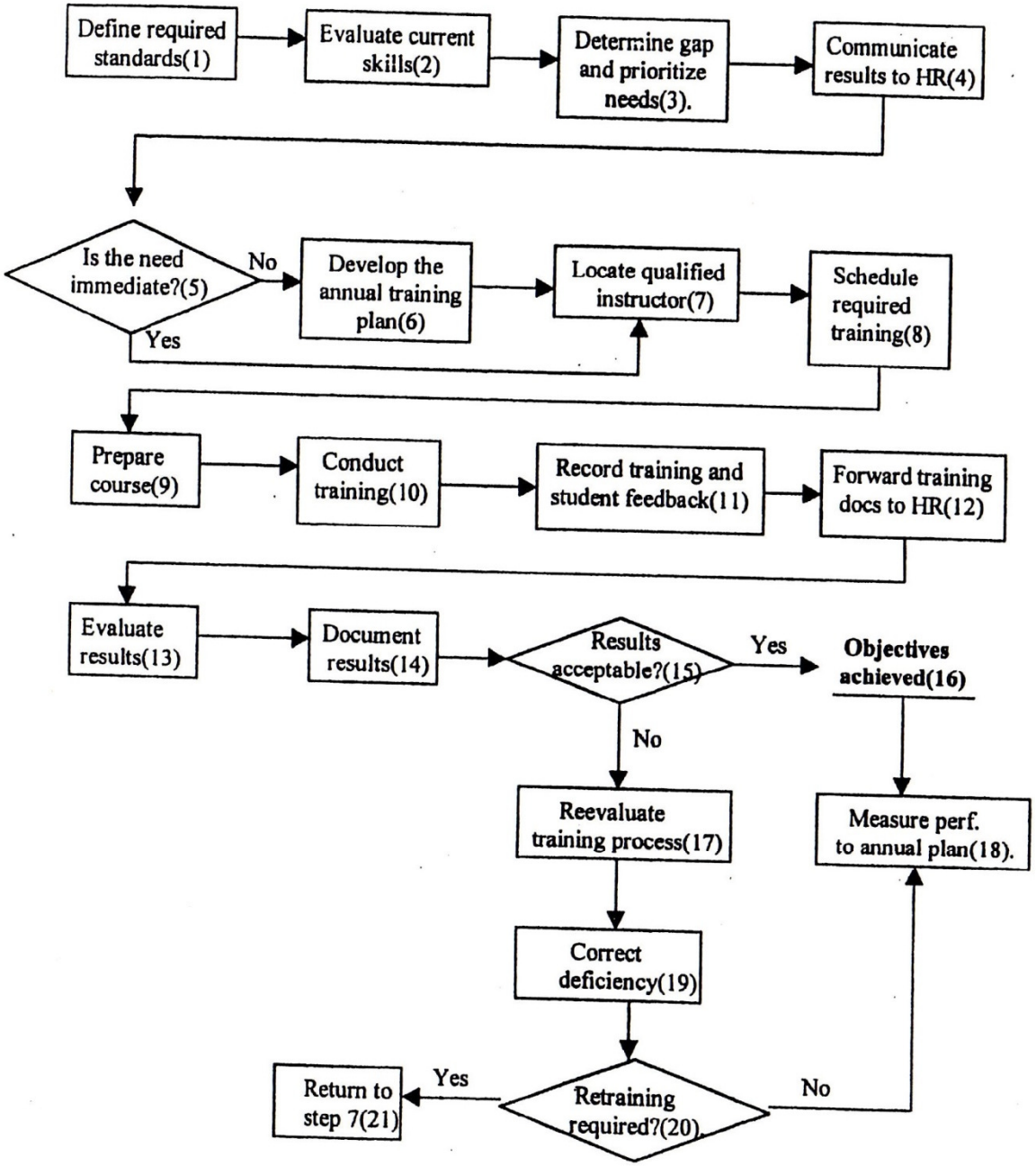
Inputs	Responsibilities
Job Desc. Product Specs Process req Quality/Business Plan Goals/Objectives	Department Mgr.
Needs Assessment and Priorities	HR
	Instructor
Training records Curricula Student feedback	HR
Training records Annual training plan	HR and Department Mgrs
	HR and Department Mgrs.
	HR and Department Mgrs



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“As with any skill, practice and feedback are essential for learning.” (McGregor)

The biggest challenge today is not getting an education, it’s keeping one.

It takes 3-5 years for 50% of our skills to become outdated.

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TRAINING PROCESS MEASURES

1. Number of hours per week devoted to training
2. Number of qualified trainers
3. % of trainees whose on-the-job performance improves after training

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FACTORS THAT IMPACT TRAINING EFFECTIVENESS

1. Intrinsic capability of the trainee.
2. Trainee has the time available to put training into practice.
3. Trainee has a coach/mentor to help with the implementation of the training.
4. Management support and encouragement.
5. The quality of the process to be used.

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GMP TRAINING

How much of what has been presented earlier applies to GMP training?

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GMP REQUIREMENT

"Each person….shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions."

Training:

- **particular operations person performs**
- **regulations and procedures "as they relate to the employee's functions."**
- **training by qualified individuals**
- **training on a continuous basis**

The training of supervisors

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CONTENT

1. Why GMPs – the patient

2. Safety, efficacy

3. Essence of GMPs
   - validated and controlled processes
   - qualified people
   - documentation: procedures and records

4. Quality is the responsibility of everyone, not just the quality department.

5. All have the responsibility to inform upper management of quality problems/risks.

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CONTENT

6. Everyone needs to understand the total process, both production and control. (Plant tour)

7. Products made in the plant and their use.

8. Emphasize the importance of cleanliness and personal hygiene.

Finally job specific responsibilities.

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Outline of Program Content

I. GMPs
- A. Introduction and overview of program
- B. Overview of the pharmaceutical industry
  1. Dosage forms
  2. Regulatory atmosphere
  3. Industry safeguards
- C. Introduction to Sterling International
  1. History, product lines, and plant locations
  2. Sterling quality philosophy and standards
- D. General concepts of GMPs
  1. Hygiene
  2. Housekeeping
  3. Standard operating procedures
  4. Documentation
  5. Validation
  6. In-process testing
  7. Quality of workmanship

II. The production cycle
- A. Introduction and overview of program
- B. The pharmaceutical manufacturing production cycle
  1. Receipt of raw materials and packaging components
  2. QA quarantine and testing
  3. Warehousing and storage
  4. Dispensing
  5. Product manufacturing
  6. In-process testing
  7. Packaging
  8. QA finished goods testing and release
  9. Warehousing and distribution
- C. Key design and implementation considerations
  1. Process design
  2. Validation
  3. Documentation
  4. Dealing with specific problems
- D. Commentary for Specific Dosage Forms

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Let's design a GMP training plan for a specific job using the principles presented in this course.

How do we make it interesting and meaningful?

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5. Kieffer et al., "The Knowledge and Skills of the Successful QA/QC Manager"
6. Kieffer et al., "Designing and Implementing an International GMP Training Program"
7. "Train the Trainer Guide", www.au.af.mil/au/awc/awcgate/edref/traingde.htm
8. "A WHO guide to good manufacturing practice (GMP) requirements, Part 3: Training"
9. "The Certified Quality Manager Handbook", Okes and Wescott Editors, asq.org. (Training chapter)

Appendix 1, Inductive vs deductive

Deductive starts with a general statement → particular examples

Inductive starts with specific observations, or examples, → broad generalization.

Applications:

- **change control**

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