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by
David Gallup, Ed.D.
Katherine Beauchemin, Ed.D.
Marge Gillis, RN, MSN

Training and Communications Group, Inc.
1137 Lancaster Avenue
Berwyn, PA 19312
610-296-2171 (phone) · 610-296-2163 (fax)

The Road to Performance Excellence

Competency-based Training Program Design

DAVID GALLUP, KATHERINE BEAUCHEMIN and MARGE GILLIS

Training and Communications Group, Inc., Berwyn, Pennsylvania

Job Skills and Competency-Based Training

In the healthcare manufacturing industry each employee needs job-specific training in technical skills, SOPs, and awareness of the GMP regulations (see article A Comprehen*sive Approach to Compliance Training in a Pharmaceutical Manufacturing Facility* in the previous issue of this journal). To satisfy this requirement, companies must adopt a systematic approach to training design, development, and implementation.

FDA commentary suggests that training programs should be competency-based—that is, based on the knowledge and skills an employee must possess to perform successfully in the job. For example, if an employee needs to know how to perform each step in the operation of a certain machine, the steps are competencies the employee needs to demonstrate. Another definition of competency-based training is training in which required behaviors or competencies and performance standards are stated in advance of instruction.

Effective competency-based training programs do not just happen; rather, they are the result of applying a systematic process to training program design. This process involves following certain well-defined steps in a methodical way to develop a training program that meets both the trainee's and the organization's needs.

The Training Program Design Model

The most reliable method of training and qualifying employees in the safe and effective performance of technical skills is by using an instructional system design model. One such model, the Training Program Design Model (TPDM) developed by *Gallup and Griffin* is shown in Figure 1.

The use of this model in developing a competency-based training program is presented in a step-by-step discussion in the case study that follows:

A Case Study

This case study involves a single facility within a multi-facility pharmaceutical manufacturer (ABC Company). Management at a 350 employee facility wished to develop training to assist in achieving plant goals.

The ABC facility was the company leader in speed and in the number of new product introductions. Its goal was to broaden its manufacturing capabilities to accommodate more planned product launches to leverage their fast-track approach.

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Correspondence address: 1137 Lancaster Ave., Berwyn, PA 19312.

The plant had recently undergone a redesign that was not achieving the results anticipated. The achievement of this plant's corporate objective of increasing the speed and number of new product introductions was impacted by several critical factors.

- Planned product introductions required more complex processes than those currently in use.
- Highly skilled operators needed to be involved at the R&D level to speed the scale-up process from lab to pilot to production scale.
- Qualified operators were needed in numbers sufficient to continue operations through lunch and breaks on all shifts.
- One million dollars in nonconformances, 60% of which were operator-related, was inconsistent with plant goals.
- Facility-wide analysis showed a deficiency in technical training methodology. Training was based on the "buddy" system, "Follow Joe around until he feels you are capable of doing the job." Lack of cross-training meant skilled operators could not move between operations. This deficiency often meant a poor use of human resources and an inability to leverage existing technical skills within departments.

Using the Model

The facility followed these steps to address training issues:

I. Conducting a *Needs Analysis*

A training needs analysis is aimed at revealing the differences between the *current* situation and the *desired* situation—and whether training will correct the deficiency. For example, a team leader may state a problem this way:

"My group isn't meeting quality standards." During the needs analysis we learn what quality standards the group *is* meeting, the standards the group *should* be meeting and *why* the discrepancy exists. Then we decide whether training is required to correct the deficiency.

A needs analysis is typically conducted using one or more of the methods listed in Figure 2.

At the ABC facility, the needs analysis was based on key consultations with managers, reviewing production records and reports, evaluating recent changes in procedures and equipment, and group discussions with team leaders and operators that suggested procedures required standardization. Findings included: I) no competency-based training existed; 2) no qualified trainers existed; 3) some SOPs were

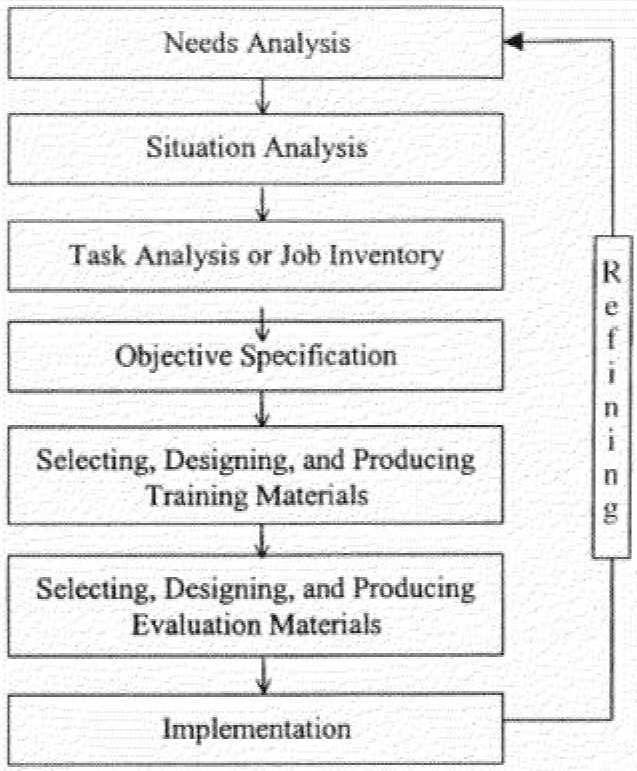

Figure 1—Sample instructional system design model.

not current in areas where the greatest amount of rework or lost product occurred.

The training needs analysis further revealed that granulation led in nonconformances. It was also the most complex technology. Training program design for operator certification began in this area.

Because of the time commitments and constraints on in-house resources, it was decided the project would require help from outside training professionals to work with in-house management to analyze operators' skills and knowledge, and develop the curriculum.

2. Situation Analysis

A situation analysis focuses on profiling the audience and the training resources within the facility. It determines who and how many will be trained, their level of education including previous job training, computer skills and other

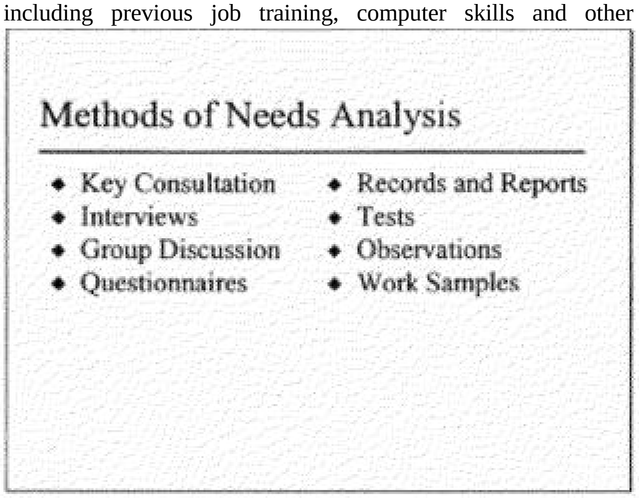

Figure 2—Typical needs analysis methods.

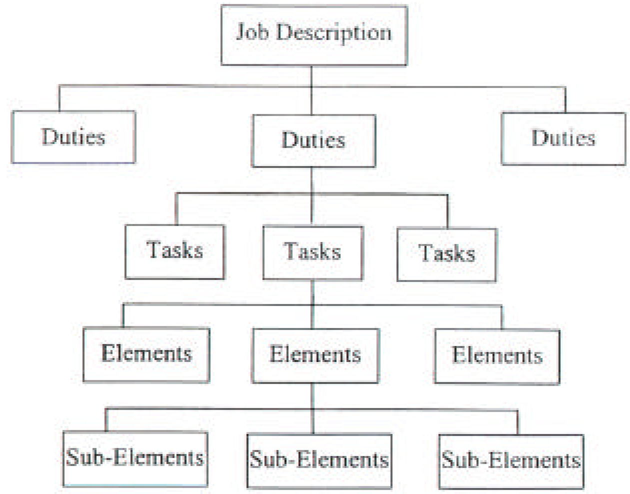

Figure 3—Methodology for conducting a Job Inventory Task Analysis.

characteristics that can affect how training should be designed.

It also identifies where the training will be conducted, availability of classroom space, personnel, the number of facilities involved, and available equipment—including access to the manufacturing suite and computer terminals.

The situation analysis at the ABC facility identified limited availability of equipment and qualified OJT instructors. Budgeting restraints and the need for quick and easy revision of materials were also limiting factors. Section 5 discusses how the situation analysis impacts the training program design process.

3. Job Inventory/Task Analysis

The next step in designing a training program is to identify job requirements in terms of skill and knowledge. This is done by conducting a job inventory or task analysis of each job.

This process involves studying ajob to subdivide or break it into discrete units to use as a basis for training program design. The job inventory helps identify the competencies (areas of skill and knowledge) needed to be focused on during the training. Figure 3 presents a methodology for conducting a Job Inventory/Task Analysis.

In the Task Analysis, all the departments in the organization and all the jobs within each department were identified. The training program design effort began with the Granulation Department, where a high number of operator-related errors were occurring.

Beginning with the Job Description—for example, "Perform steps in the granulation process," we identified major duties in the process operation. In this case one duty would be "set up the line." Then we broke each duty into tasks. For "set up the line," for example, a task might be "turn power on." The next step was to divide tasks into elements and sub-elements: "locate power switches on right side of machine; set switches to 'on' position."

To be sure all important aspects of a job are covered, each of the following duties were analyzed as to their task's elements and sub-elements:

- Process Overview
- Safety
- Set-Up
- Pre-Start-Up
- Start-Up
- Normal Operations
- Abnormal Operations
- Shutdown
- Cleaning in Place
- Completing Batch Records
- In-Process Product Testing

A brief description of what was included under each duty follows:

3.1 Process Overview: This describes the process or equipment with a tour highlighting features, purpose of equipment, and how it fits into the overall production process.

3.2 ***Safety:*** Covers general safety rules and requirements that may apply to the equipment or process, such as proper personal protective equipment. In addition, it includes safety issues pertinent to a specific process such as pinch points, guarding considerations, or lifting considerations. Safety issues are covered again in the modules that deal with specific process areas.

3.3 **Set-Up:** Covers getting the machine ready to operate or getting a process ready to run.

3.4 Pre-Start-Up: This module addresses all ancillary equipment necessary to a support process; e.g. bins are in place to collect product, and feed stocks ready.

3.5 Start-Up: This pertains to the first time the machine is turned on, and how to evaluate overall function of equipment before you move to normal operation.

3.6 Normal Operations: Covers tasks necessary to ensure that equipment is operating appropriately, including in-process testing. Testing is also covered under the In-Process Product Testing module.

3.7 Abnormal Operations: Addresses tasks involved in:

Responding to alarms specific to the process and/or equipment and equipment shutdowns.
Troubleshooting to correct problems.
Determining whether a mechanic needs to be called or if the problem is within scope of operator.

3.8 Shutdown (Partial and Total Shutdown): Includes all steps integral to the following scenarios:

Material or ingredient shortage or changeover.
Routine maintenance.
Complete changeover to different product or different size package.

3.9 Cleaning in **Place (CIP):** This involves complete cleaning, including shutdown and changeover.

3.10 Batch Records: This deals with how to read and follow the Batch Record requirements including in-process product testing results.

3.11 In-Process Product Testing: This covers tasks involved in product sampling and inspection required to ensure product is meeting specifications as to weight, size, quality, labeling, etc.

4. Specifying Behavioral Objectives

The next step is to develop behavioral objectives. They specify the exact competencies operators will demonstrate after completing the training program—that is, what they will know or be able to do. The program content trains to these objectives. Behavioral objectives also guide the development of evaluation instruments—the written tests and performance demonstration checklists used to determine whether operators acquired the competencies identified in the job inventory/task analysis.

The following objectives are examples from the Granulation System Overview Module.

1. Identify the major components of the Granulation System.
2. State the function of each component.
3. Describe how each component works to produce granulated product.
4. Define key terms related to topics covered in this unit.

5. Selecting, Designing and Producing Training Materials

Selecting, designing and producing training methods and materials is the next step in the TPDM.

5.1 Selecting Training Methods: Training methods are the ways in which training is delivered—classroom instruction, self-instruction, on-the-job instruction, or a combination of these methods. Training methods are chosen based on several factors included in the situation analysis such as, availability of classroom space, personnel, and equipment, as well as the subject matter and needs of the training audience. We chose some classroom instruction combined with a strong hands-on component to maximize effeciency in training program delivery.

These methods were judged best in terms of outlining outcomes, cost, and speed of development. Classroom instruction provides an environment for process experts to present information while participants take notes in their guidebooks. The participant is able to raise questions and gain additional insight through group interaction. Classroom training does not interfere with equipment scheduling. On-the-job training provides the hands-on experience necessary to gain the technical skills of the required granulation operator both through direct observation of an expert, and hands-on experience.

Experienced workers served as trainers because they could communicate and demonstrate correct procedures. Having a mentor to both observe and coach the trainees affords the learner hands-on experience in an actual work situation making it ideal for skill training. One limitation of on-the-job training is that mentors may not have formal training backgrounds and may require special training and program development. We addressed this by including a comprenensive train-me-trainer session for the technical trainers.

5.2 **Selecting Training Media:**

Training media can either support or deliver the training. Media can include:

- Printed Materials
- Flipcharts
- Overheads
- Videotapes
- Computer-Based Instruction
- Simulations
- Real Objects

To meet the objectives of a single training program, we "mix and match" training methods and media. This mixing and matching was based on adult learning theory, behavioral program objectives, and the results of the situation analysis. Technical skill objectives cannot be easily reached or evaluated without some type of hands-on experience. Also to be considered is cost, the size of the audience, the availability of hardware and software or other electronic equipment, and the development timetable.

A decision was made to use leader's guides and trainees' guides with overhead transparencies for classroom instruction and checklists for on-the-job training. These materials were the least expensive and quickest to produce, easy to edit and update. They were well-suited to reach audiences of 5—10 trainees who needed access to process experts, as well as hands-on experience with process equipment.

5.3 **Designing Training Materials:** The Job Inventory/ Task Analysis itself provided the basis for developing the comprehensive training program materials. The Job Description gave us the title of the training program: "Granulation Operator Training Course." The duties we identified in the task analysis formed the training topics, whereas the tasks, elements, and sub-elements gave us the content of the training program.

In our case, consultants created material that was reviewed by supervisors and expert operators serving as the Subject Matter Experts (SMEs). The development process also involved reaching consensus on best practices when disagreement arose among SMEs or when SOPs were too vague to be a deciding factor. As a result of the work done with SMEs, the SOPs were revised or updated.

5.4 **Producing Training Materials:** In this step the training materials were actually produced by the training program design team.

6. *Selecting, Designing, and Producing Evaluation Materials*

What is it exactly that we are evaluating when we collect data about training programs? Most specialist agree that we are evaluating three areas, all of which were assessed in the training.

6.1 Competencies: What competencies—areas of knowledge or skills—did trainees acquire as a result of the training? We usually evaluate what trainees learned by administering a written test or observing performance.

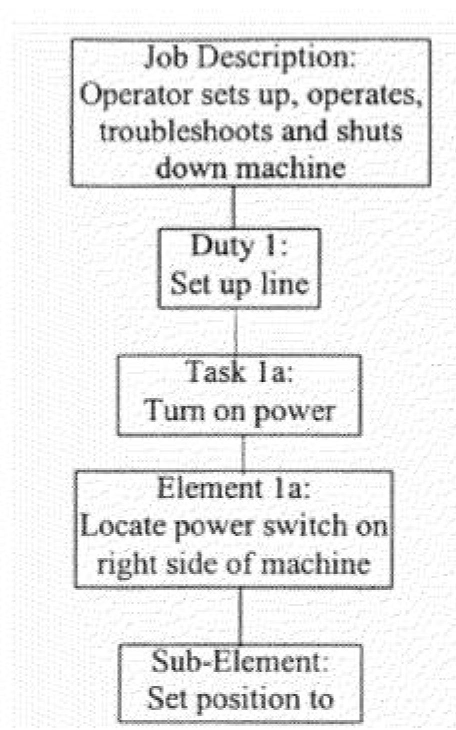

Figure 4—Basis for developing the comprehensive training program materials.

Evaluations must be based on program objectives, with each program objective tested. In competency-based training the trainee is required to demonstrate proficiency (competency) in an area, often by being observed performing a task and using a performance checklist, to verify successful demonstration of key competencies.

6.2 **Reaction:** What did the trainees feel about the program? Evaluation of trainees' reactions to training are usually conducted by questionnaires administered immediately after the program ends, although we can also measure reaction by observing trainees in class or interviewing them later.

This type of evaluation usually measures these areas:

- Were the objectives of the training program clear?
- Were the objectives appropriate?
- Were the objectives of the training program met?
- Did the program design support the objectives?
- How valuable was the program content in supporting the objectives of the program and the job need of the participants?

6.3 Results: Did the training pay off? Was the training valid—that is, did it do what it was supposed to do? We should never forget that a primary objective ofjob training is to ensure on-the-job results.

This type of evaluation can be difficult to design, administer and validate, which is why it is so seldom performed in industry. But it is wise to measure on-the-job behavior and productivity results to formulate a picture of the training and to build credibility for the training program.

- Did the trainees' peers, subordinates, or superiors notice changes in behavior? For example, application of new knowledge or use of new skills?
- Did the quality of the work change?

- did productivity or profits change in any of these ways?
  —Reduction in direct costs
  —Increased productivity of trained vs. untrained empl oyee s
  —Increased productivity after vs. before training
  —Improved quality of work
  —Fewer accidents
  —Reduced absenteeism
  —Lower turnover rates

Careful design of evaluation instruments is important; it is the only way to be sure that your training program is valid—that is, accomplishing its objectives.

7. *Implementation*

The first presentation of the program is usually referred to as the "pilot" program. This lets everyone know at least some program adjustments are expected. For this program that had a significant impact on operations; we engaged in true pilot testing—that is, testing on participants who actually need the training. For some programs, however, it is simply too expensive to put that time and effort into such testing. In these cases, you will be "piloting" the program on the first group to be ready for the training.

8. Refining

Even the best training programs can be made more effective if they are revised or modified. The pilot program evaluations will tell you where you can improve the training program.

Refining, the final stage in training program design, has two components:

- Analyzing the training program evaluations to see where revision is needed.
- Revising, re-implementing, and re-evaluating the training program to correct problems identified.

Revising the training program may mean incorporating new material to help the program meet its objectives, or it may mean revising the objectives themselves, based on input from trainees or managers. In any case, though, you will follow the steps you used to develop the training program as you refine it.

- First, make sure the revisions are designed to support specific, measurable objectives.
- Second, follow the appropriate steps to select, design or produce training materials to support those revisions.
- Finally, re-implement, reevaluate, and refine the revised program to see if further modifications are necessary.

In other words, you will follow the same process you used to design the program as you revised to meet the objectives you set.

In a sense, the refining process never ends because we are always looking for ways to update, revise, and modify the training programs we design. Developments in technology, changes in skills and knowledge among trainees, new marketplace demands, and a variety of other factors impact our training programs and make it critical that we improve training on an *ongoing* basis.

It is only by constant evaluation and revision that our training program—and therefore our employees—are the best that they can be.

8.1 The Case Study: How long did this process take in our case study? We spent 350—450 person hours per course in conducting the task analysis and developing the training materials. This included working with SMEs, revising SOPs as needed, establishing procedural agreement among operators, and piloting the program. One reason the number of hours was substantial was because this was groundbreaking work. Although revising SOPs is not considered part of actual training program development, in many cases SOPs need to be revisited to accommodate actual procedures and ensure the validity of training.

After 50-plus months of sustained effort, the ABC facility now has training programs that cover each operating process in their facility. Each training program takes trainees six to ten days to complete. They contain about 20% classroom training to ensure that trainees have the knowledge needed to begin working with equipment. The rest of the time is devoted to hands-on activities, including tours, demonstrations, and participating in training.

Each program contains the following:

Trainer's Guide. A comprehensive package designed for senior operators without training backgrounds. Included are professional objectives.

1. Detailed Outlines/Lesson Plans
2. Program Schedule
3. Support Materials
4. Pre-Test of Knowledge
5. Post-Test of Knowledge
6. Performance Checklists for use as pre- and posttraining. (Pre-Test can be used to test out of courses; post-tests are used for certification.)
7. Final Certification. Opportunity to demonstrate qualifi-cations for a specific job.
8. Performance Demonstration Guides. Steps necessary to perform a specific task. Each job may have multiple guides.
9. Support Materials:
   —Photographs
   —Slides
   —Video clips depicting important areas or processes

Trainee's Guide. All information required passing the written and performance-based tests. Included are copies of objectives, handouts, and diagrams with room for notes to serve as trainee's personal reference manuals.

Qualification and certification pathway for each job. Each program has individual modules that are associated with a list of knowledge and skills. Trainees are required to pass a knowledge test before they may complete a performance evaluation. Failure response is included in this document. If trainees arc unable to pass knowledge and performance tests after a certain number of exposures, then they are reassigned until able to satisfy knowledge and performance requirements.

Train-the-Trainer. Program designed for SMEs assigned to lead the training. Developed to train people without training backgrounds who are experts in the process on

equipment. Covers how to prepare to train in the classroom and OJT, as well as how to test and conduct performance observations.

9. *Operator Cert ifi cation/Qualification*

Competency-based training programs are designed to certify or qualify employees to ensure they are able to perform their assigned functions. Operator qualification or certification is the final step in completing competency-based training. This final step demonstrates that each trainee has acquired the competencies defined in the training program.

Certification means that someone—supervisor, senior operator, lead operator, trainer—has observed the employee performing the tasks associated with the job. The observer certifies the trainee through an observation checklist to demonstrate that the person performed the job correctly and produced a quality outcome. The formal certification process for any company should be part of the written Standard Operating Procedures.

Careful design of evaluation instruments is important; it is the only way to be sure that your training program is valid—that is, accomplishing its objectives.

Implementation Challenges

Before the ABC facility actually began training people, some issues had to be taken into account. For instance, because of production requirements, scheduling trainers and trainees was a challenge. Managers were understandably reluctant to release people for training when they were at full production. Added to this was the availability, or lack of availability of processing equipment and classrooms. Another challenge involved employees' perceptions of the large-scale curriculum. Experienced operators wondered whether they would be "tested" and perhaps found deficient in skills they had been using for decades.

To counter the first issues, the ABC facility worked hard to accommodate training to production schedules and classroom and equipment availability. This meant training was done only when release time could be justified and equipment was accessible. It also meant some false starts and not a few frustrations for schedulers and trainers alike. Fortunately, once managers began to see the benefits of training, they became more enthusiastic about sending employees to the session, and scheduling became less of a problem.

The next challenge involved reassuring employees that their jobs were not in jeopardy. This was done by ensuring experienced workers had input into both program development and pilot programs. Experienced employees were asked to help test the program, refine it, and validate evaluation instruments. The goal was to come up with the best possible programs, and the input of experienced operators and line tenders was essential to meeting that goal.

As time passed it became clear that training and certification were not being used as a means of downsizing personnel, and this issue resolved itself. In fact, once the element of anxiety was removed from the process, employees, like managers, became enthusiastic about participating in the training. As one experienced operator put it: "I've been doing things my way tor 20 years. Now b see there are better ways to do some of those things. And what we're doing is making the process more consistent. All in all, the training has been a plus for us."

The Outcome: Measurable Results

The effort that began with the needs analysis resulted in a competency-based, operator qualification program made up of classroom and on-the-job training. Trainers were selected from the plant's expert operators. The consultant conducted a train-the-trainer for the selected trainers to qualify them to perform the operator training for this facility. Training was implemented with cooperation from the entire facility. Results after 24 months and 95% of granulation operators trained were as follows:

Total Process-Related Destruct Order Costs

Year I, $692,000; Year 2, $325,000; Reduction, 53%. *Process*

Operator-Related Destruct Order Costs

Year 1, $215,000; Year 2, $160,000; Reduction, 74%. *Total*

Waste Costs

Year 1, $2,500,000; Year 2, $2,100,000; Reduction, 16%.

Additional highlights from this training program include the following one-year performance enhancements:

- 19% Reduction in Non-Conformances
- $50,000 Reduction in Landfill Costs
- 10%—15% Increase in Planning Values

Also reported were increases in employee moral and facility-wide recognition of the value of training in job performance.

The process used to develop the competency-based training programs begins with a needs analysis.

Perhaps the best endorsement of the program came from the Facility Manager, who noticed measurable increases in productivity in areas where training had been conducted. This resulted in continued organizational commitment.

ROI

Training is many times viewed as a cost of doing business. A principle incentive for approving training budgets in the past has been FDA regulations. As management experienced firsthand, the bottom-line benefits of competency-based training and the incentive to expand the training budget became an understanding of the ROI, which these expenses generate.

"A 10% increase in the book value of capital stock is associated with a 2.6% increase in manufacturing facilities' output compared to capital stock increase, the boost to productivity associated with increased years of schooling is more dramatic

In other words, a 10% increase in the amount of training workers within a manufacturing establishment results in a 6.2% increase in output—or greater than twice the improvement that would result from a similar increase in capital stock.