"The 'Design' Phase of the ADDIE Model," Journal of GXP Compliance, Vol. 11, No. 4, July 2007, pp. 40-48 (Corrected version)

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The Design phase of the ADDIE model is where we address any performance gaps identified in the Analysis phase, complete the Training outline, and secure management approval.

INTRODUCTION

The ADDIE model is a generic instructional design model. It provides guidance at a fairly high level for instructional designers, software engineers, etc., as they author and revise learning products. The phases of the ADDIE model are Analyze, Design, Develop, Implement, and Evaluate. These phases are sequential – each depends upon the successful completion of the preceding phase (see *Figure 1*).

Moreover, the ADDIE model is an iterative feedback model, which means that the results of the Evaluation phase are returned to the origination point (fed back), closing the loop, facilitating further refinement of the learning product. If the evaluation shows that the module has shortcomings, for example, that the objectives of the module do not align with organizational objectives, those shortcomings are returned to be analyzed again. Further design and development efforts follow, until the module meets organizational needs.

In this article, we will examine the three components of the Design phase (*see Sidebar on p. 41*) in turn.

The Learning Product in the Larger Curriculum

Fitting the proposed learning product into the larger curriculum ensures the articulation of this product with all other learning products, and the alignment of this product with organizational goals. There are four aspects to this "fit" –

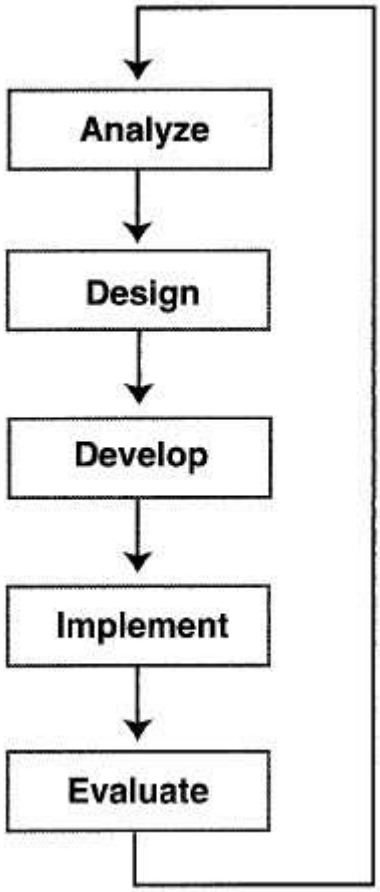

Figure 1
ADDIE Model Workflow

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• The structure of modules
• The relationship between the learning product and the associated SOP
• The learning product's reduction by consolidation of SOPs
• The relationship between learning product and the various regulatory requirements (e.g.: FDA, OSHA, EPA, DEA, etc.)

The Structure of Modules

The larger curriculum is comprised of a set of modules that focus the training effort on accomplishing organizational goals. The Design phase is where the fit between the proposed learning product and the larger curriculum is delineated. This means outlining the structure of the training module wherein the learning product will fit. Each module includes two types of learning product, an Overview Training element and one or more associated Skills Training elements.[1] A module is configured as shown in *Figure 2*:

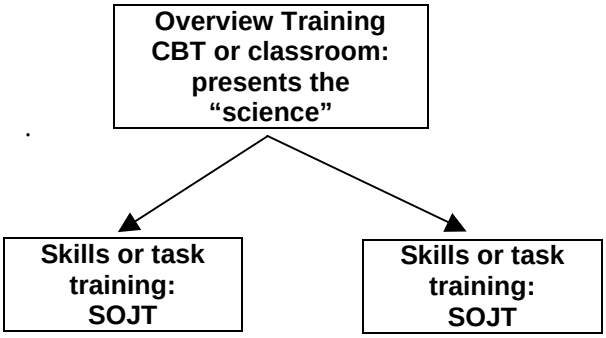

Figure 2
Structure of Training Module

In the Design phase, the precise location of the learning product – as an Overview Training element or a Skills Training element – is determined. To briefly review the difference between these two types of elements: the Overview Training is more conceptually focused, while Skills Training is more task or performance oriented. Concepts tell what a thing is, why it is important; tasks describe how to do something. Concepts provide the "science" for

ADDIE Model

- **ANALYSIS:**
The Analysis phase of the ADDIE model identifies a performance gap, a discrepancy between a standard stipulated in a standard operating procedure (SOP) and some employee performance. A performance gap can be addressed by a learning product, i.e.: a set of training and assessment materials.

- **DESIGN:**
The Design phase follows Analysis, where a planned approach to addressing the performance gap is outlined and approved. This planned approach has three components:
• Fitting the proposed learning product into the larger curriculum
• Outlining the proposed learning product
• Securing management approval of the outlined learning product

- **DEVELOP:**
If management approves the design, a Development phase comes next, where the learning product - the training materials and the assessment materials - is developed to address the performance gap.

- **IMPLEMENT:**
The Implementation phase follows, wherein the training materials and associated assessment materials are rolled out, on a provisional basis, to ascertain their real-world impact.

- **EVALUATE:**
Finally, an Evaluation phase of the ADDIE model either:
(a) documents aspects of the learning product that require further development, whereupon that documentation is fed back to be analyzed again, or
(b) documents that the product meets the organization's needs, whereupon it is finalized and rolled out.

task performance. For example, the tasks involved in sanitizing equipment might be conceptualized as "*Reducing the levels of microorganisms and particulates to acceptable limits*" thereby minimizing the risk of product contamination from the equipment.

The Overview Training element will typically be delivered by an instructor in a classroom; if a full-featured Learning Management System (LMS) is available, it may be delivered electronically. There will be an SOP for this Overview Training event. The Skills Training elements will usually be delivered, one-on-one, on the shop floor, by a subject matter expert (SME) who is also a trainer, as a Structured On-the-Job Training (SOJT) event.[2] There will be an SOP for each of the SOJTs in the module.

The Overview Training element includes an assessment of training effectiveness – a Knowledge Transfer Assessment (KTA), for example. The training event is documented in a Training Record where the trainer and trainee concur that the trainee has, or has not, successfully concluded the event. In the case of classroom instruction, this training record is entered into the training tracking system and the entry is verified. In the case of a validated LMS, the training record will be an integral part of the learning product and will be electronically entered into the trainee's training history.

The precise fit of each of these modules into the larger curriculum is determined in the Design phase.

Once that Overview Training event is successfully concluded, the trainee goes on to the SOJT events. The several SOJTs are documented in Skill Demonstration Assessments (SDAs), where the trainee's ability to independently perform the task is documented. The results of the SDA are then entered into the training tracking system, and the entry is verified. After all the relevant SDAs are successfully completed, the trainee is qualified, meaning the trainee is ready to perform that module's tasks independently.

Let us consider several examples (*see Figure 3*).

The Relationship between the Learning Product and the Associated SOP

A second aspect of the fit between learning products and the larger curriculum is the relationship between the learning product and the associated procedure. That, too, will be delineated in the Design phase.

There are two ways that a learning product can be related to a procedure. The first is directly, where the product trains to the procedure; this is sometimes called "document based training." The second is indirectly, where the learning product is mandated in the procedure, but the product does not train to the procedure; this is called "non-document based training." An example of the latter is training in current Good Manufacturing Practices (GMPs), a Food and Drug Administration (FDA) requirement. The FDA requires that this training be both "*current*" and "*conducted on a continuing basis*." [3] These requirements are typically met by training on courseware that is repeatedly offered, say on a quarterly basis, and is also frequently revised to ensure current technological methods are included in training. The SOP that provides guidance for the

Module	Overview element	SoJT element
Central Weigh Module	Material Management	• Storage of Raw Materials • Dispensing Raw Materials
1st Cleaning Module	Cleaning and Sanitizing I	• Facility Cleaning
Preparation of Solutions and Buffers	Media and Buffer Preparation	• pH Measurement • Preparing Media • Preparing Buffers
2nd Cleaning Module	Cleaning and Sanitizing II	• CIP (Clean-in-Place) • SIP (Sterilize-in-Place)

Figure 3
Example Overview and SOJT Elements for Training Modules

GMP regulatory training is, by contrast, relatively fixed.

In the diagram seen in *Figure 4*, the procedure is on the left and the learning product is on the right. In the case of a procedure such as Management Notification, which identifies the routine as well as exceptional situations where employees must notify their management, the product trains directly to the procedure.

In the case of a procedure such as Train-The-Trainer (TTT), by contrast, there are several learning products; one trains to the management of the TTT program; another is the courseware for the TTT classroom sessions; and a third is the courseware for the subsequent TTT qualification session. These learning products have different training audiences; the first product – the program management product – has the organization's training unit as its audience; the second and third products have the prospective qualified trainers as their audience.

Document based training and non- document based training must carefully be distinguished in the Design phase; if not, there is the possibility that all the learning products in non-document based training will be named after the same procedure. The author is aware of instances where a several-hour classroom session of mandated training had the same name and course number as a one-hour program management course, causing confusion in the training tracking system and among the several training audiences.

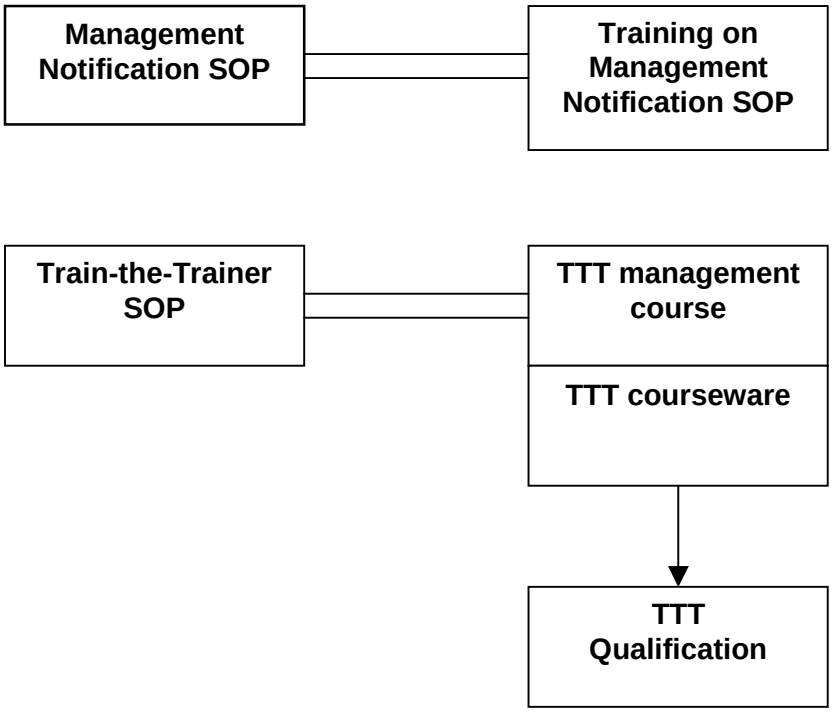

Figure 4
Document Based Training

It is better to delineate clearly the more complex relationship between learning products and the associated procedure. The next diagram, shown in *Figure 5*, more clearly displays the non-document based training structure; it is now viewed as similar to a GMP regulatory procedure, where there is training to the procedure and also (a different thing) training on courseware that is mandated by the procedure.

Now the one-hour training on the management of the TTT program will have its own name in the training tracking system, and the several-hour long TTT classroom course will have a different name, as will the subsequent TTT qualification session. The two different training audiences can clearly recognize the relevant learning products.

The clear statement of the relation between the learning product(s) and the associated procedure should take place during the Design phase of the ADDIE model, and will be an important contribution to the ultimate success of the learning product
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The Learning Product's Reduction by Consolidation of SOPs

Several learning products can be associated, directly or indirectly, with a single procedure. This suggests that a straightforward means of reducing training time within a training system might be to consolidate SOPs, thereby reducing the number of learning products. However, consolidation (or "streamlining") of SOPs should be logical and be done to eliminate redundancies, not simply to reduce the number of SOPs. We will clarify this point.

Consider four examples that illustrate the issue:
1) The FDA requires gowning procedures.[4] Department A has a gowning procedure. Department B has a different gowning procedure. Consolidation of SOPs would remove the redundancies here; Departments A and B would work together toward a single gowning procedure.

2) Department C has a protocol on the use of Equipment Specific Instructions (ESIs), say involving equipment maintenance manuals. Department D has a different protocol on the same kind of ESIs. Again, streamlining

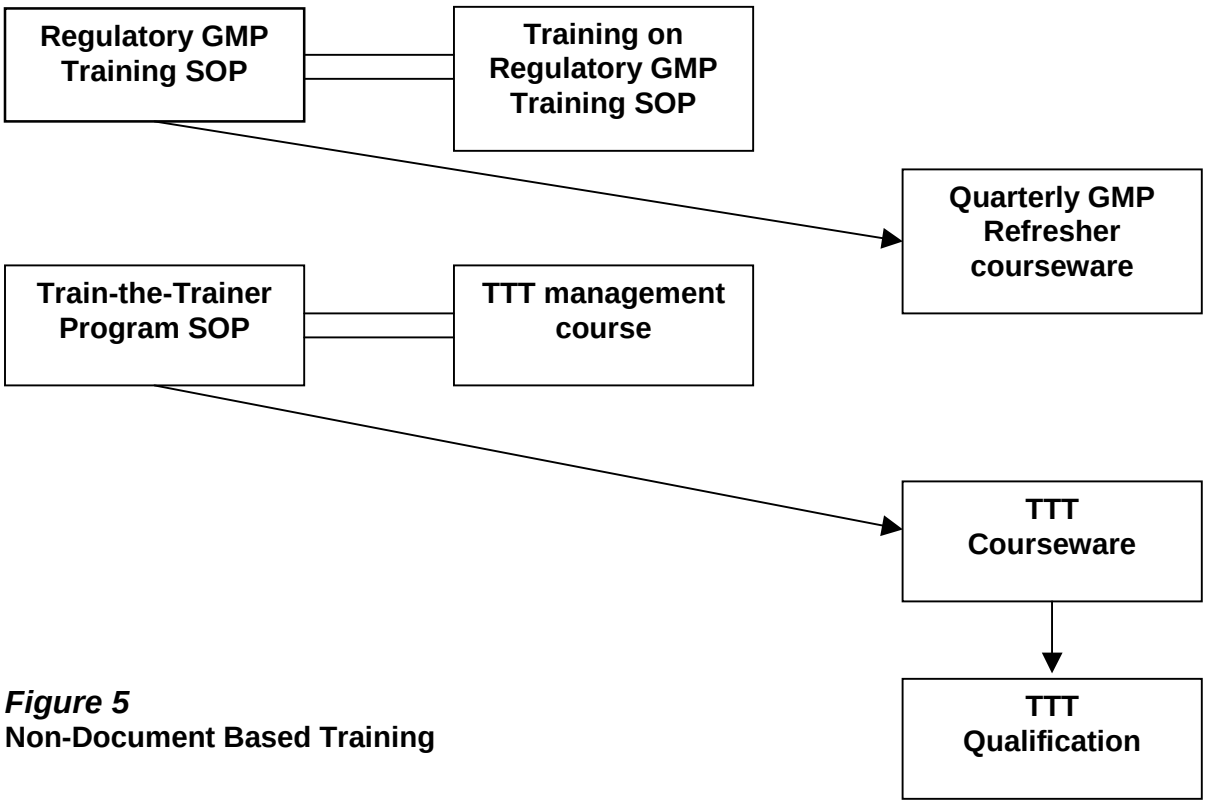

Figure 5
Non-Document Based Training

procedures would remove the redundancies; Departments C and D would work together toward a single protocol on the use of ESIs.

3) Department E has an SOP for operating an autoclave, and another SOP for operating a capping machine. There is no redundancy here; it would be counterproductive to consolidate the two procedures, since they deal with two distinctly different types of machines.

4) Department F has three SOPs and three packaging lines, one procedure for the operation of each line; each includes a brief section on equipment maintenance. There is redundancy here, but unlike that in examples one and two. The redundancy here is in the sections on maintenance. Consolidation of the procedures would remove the sections on maintenance and put them in a maintenance procedure of their own. [We will return to this issue in the next section.]

Consolidation of SOPs is essentially an issue of the correct writing of procedures. Very briefly, procedure writing has six steps, all but the last involving the collaboration of a procedure author (usually a technical writer) and one or more SMEs.

• First, the SME(s) and the author identify the process to be captured in this SOP.

• Second, they identify the audience for this SOP.

• Third, they develop the process map for this process. The process map breaks down the process into its elements and displays the logical interconnections between the elements.

• Fourth, the SME(s) and the author "chunk" the process. The chunks are developed from the process map, putting like elements together, and pulling unlike elements apart.

• Fifth, the text of the SOP will be written from the chunks. The author writes this up and the SME(s) reviews the text in light of the intended audience.

• Finally, the text will be revised by the author of the procedure into the standard format for SOPs.

Consequently, if procedures are correctly written, they will need little streamlining in the future, and will facilitate consolidation whenever new processes come online and procedures need to be created. Of course, if procedures have been poorly written, poorly chunked, or if there is a great deal of redundancy, then they must be revised along the lines sketched out above.

The Relationship between Learning Product and the Various Regulatory Requirements

A fourth aspect of the fit between learning products and the larger curriculum is the relationship between the learning product and the various regulatory requirements. This aspect is also delineated in the Design phase. There are a number of regulatory regimes that impact on the training environment. These regimes include such agencies as the FDA, OSHA, EPA, DOT, DEA, and others, each with its own set of regulations.[5]

On the one hand, the number of regimes means that there are simply more regulations to be taken into account. On the other hand, the various regimes can present the problem of regulatory overlap, where different agencies have differing regulations covering the same situation.[6] We will consider how this impacts the design of the learning product.

If we conceptualize the manufacturing cycle where each process has a Setup Period, a Startup Period, followed by an Operate Period, and then a Shutdown Period, operating under GMP procedures, this cycle can be disrupted at any time by a malfunction or abnormal end event (Abend). The process is interrupted by a breakdown, jam, or some other malfunction. An initial question is, How do we deal with these Abends consistently, as a procedure? There seem to be two options: they can be captured in the same GMP procedures that cover the process, or they can be captured in procedures of their own.

In either case, when we create a procedure to deal with an Abend, we must include a troubleshooting process, the original equipment manufacturer (OEM) technical manuals or other instructions that are specific to the equipment, a set of corrective and preventive actions, follow-up monitoring, and any safety or other relevant concerns.

The author has witnessed instances where the process of dealing with Abends is captured in the same GMP procedures that cover the routines of the manufacturing cycle. There are several problems with this approach. First, it overlooks the very abnormality of the Abend. After all, this is called an Abend because, in important ways, it is abnormal. Second, it overlooks the distinct division of labor between operators who enact the routine steps of the manufacturing cycle and the mechanics who address the abnormal events. This has substantial training implications; the procedures tend to be much longer, and both groups must train on the whole GMP procedure. Third, it confounds the "operational" level of detail in the routine situations with the more fine-grained level of detail in the abnormal situations, a level of detail that can only be addressed by reference to technical manuals. Fourth, it blurs regulatory requirements that differ between normal situations and exceptional situations, e.g.: OSHA safety regulations.

For these reasons, among others, it seems more appropriate to create a procedure dealing with Abends by having separate procedures; an illustration will clarify this.

If we represent the manufacturing cycle in a vertical process map, consisting of the Setup Period, followed by the Startup Period, then the Operate Period, and finally the Shutdown Period, abnormal events can be represented in a horizontal process map that intersects the manufacturing cycle at the point of the disruption. This horizontal map lays out the process of trouble- shooting, reviewing service or maintenance instructions that are specific to the equipment, implementing a set of corrective and preventive actions, conducting follow-up monitoring, as well as addressing safety or other relevant regulatory concerns.

At the point of an abnormal event, the GMP requirements of the manufacturing cycle are suspended, temporarily, by an OSHA-mandated Lockout/ Tagout (LOTO).[7] That is where the mechanics or engineers (in OSHA terms, the "LOTO authorized employees") intervene with their Troubleshooting SOP and associated Equipment-Specific Instructions (ESI) to troubleshoot and maintain or repair the equipment.

These troubleshooting procedures and ESI protocols make up the horizontal process map. Its training module will include a Troubleshooting SOP that would be delivered by an instructor in a classroom, or electronically; the ESI protocols would be SOJTs. These would appear on the curriculum of the mechanics (see *Figure 6).*

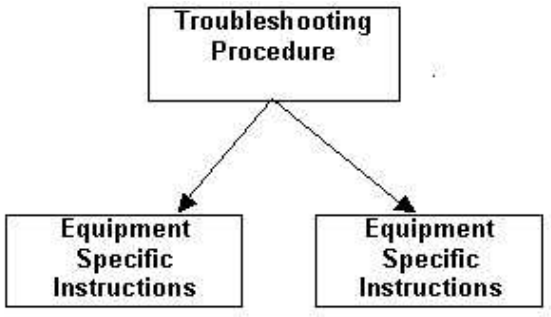

Figure 6
Troubleshooting Procedure Structure

After the abnormal event is under control, the LOTO is removed and the LOTO affected employees (the operators) resume the manufacturing process, under the guidance of the GMP procedures.

Back in the GMP realm, and depending on the specifics of the abnormal event - for instance, the impact on the product – a Management Notification is prepared (a Notification of Event, NOE) that could lead to an investigation, corrective and preventive action, and follow-up monitoring.[8]

By keeping these processes separated (vertically and horizontally), the operators would have training on the GMP procedures on their curricula, and would qualify on these modules. The mechanics would have training on the troubleshooting SOPs on their curricula, and would qualify on those modules. Thus the operators would not need to train on the troubleshooting modules and the mechanics would not need to train on the operational modules. Of course, this would require that the SOPs would be written in a focused fashion.

We have seen how the proposed learning product is fit into the larger curriculum in the Design phase of the ADDIE model. The learning product

FIELDS	INSTRUCTIONS
1. COURSE TITLE:	Enter the title of the document or course.
2. COURSE NUMBER and VERSION:	Enter the number and version of the procedure, protocol, or document.
3. TRAINING AUDIENCE	Those required job positions included in the scope of the learning product. Identify the areas, departments, and positions. For example, a training audience may consist of: • All managers in a department • All managers and supervisors in an area • All employees in a department • All employees who operate the bottler on Packaging Line 84.
4. CURRICULUM FIT	Identify the training module; other associated courses
5. PREREQUISITE COURSES/ REQUIRED SKILLS	List any prerequisite courses; any required skills
6. TRAINERS:	All qualified trainers who have been identified as SMEs on the course, including the Originator and Business Owner, if they are qualified trainers.
7. BEHAVIORAL OBJECTIVES:	Specify the observable competencies that trainees will demonstrate upon completing the training. For example, "At the end of this training session, the trainee will be able to demonstrate the following skills or perform the following tasks…"
8. TRAINING DELIVERY METHOD:	Check as appropriate: • Classroom • Structured On-the-Job Training • Computer Based Training, etc.
9. COURSE LENGTH:	Enter the approximate time required to deliver the training session. This information is for planning purposes only.
10. SPECIAL INSTRUCTIONS:	Instructions to facilitate the preparation and execution of the event (e.g. safety issues, logistical requirements, pre-work, handouts, etc.)
11. MEASURES of EFFECTIVENESS:	The KTA (and Answer Sheet) or SDA should be attached. The content of the KTA or SDA is derived from the Behavioral Objectives.
12. APPROVAL:	Includes signatures from • Originator • Department Management and/or Business Owner • Quality Unit.

Figure 7
Training Outline Template

thereby aligns with other learning products, and with organizational goals. We reviewed four aspects to this "fit" –

• The structure of training modules
• The relationship between learning product and SOP
• The reduction of training time by consolidating SOPs
• The relationship between learning products and various regulatory requirements

Now we will consider how the proposed learning product is outlined in the Design phase.

Outlining The Proposed Learning Product

Outlining the proposed learning product will usually consist of completing a Training Outline template (see *Figure 7*). We will first display an illustrative template, with twelve fields and instructions for completing each field. This will be followed by comments on several of the fields.

Training Audience: The personnel included in the learning product's training audience must be negotiated. Many times a learning product will impact not only the business unit of the business owner of the SOP, but will impact other units as well. Personnel in those impacted units will be listed on the Scope Statement of the SOP, and also in the list of Task Responsibilities within the SOP itself. Unfortunately, these two lists of personnel do not always coincide.

Precisely defining the training audience becomes critical because those are the personnel who must be trained on the learning product associated with the new or revised SOP. After a new or revised SOP has been approved, there is a "training window" before the procedure goes into effect within which the impacted personnel can be trained on the SOP. This window is typically a week or two in length. It is critical that the training audience be defined before that window opens – before the SOP is approved – so that all the training will be completed before the effective date. Thus, the risk of untrained personnel "touching" the regulated product will be minimized.

When the learning product is in the Design phase, the author of the product can provisionally prepare a Training Audience List based on a review of the SOP Scope Statement as well as the Task Responsibilities. When the Training Outline is circulated for approval, the Training Audience List can be circulated as well. Management of each impacted unit reviews the list and recommends limiting it or expanding it, based on their direct responsibility for the task assignments of the impacted personnel. The author of the learning product can then take those recommendations into account as the product is finalized. Moreover, management in the impacted areas are alerted for the approval and implementation dates of the SOP, and can accordingly schedule personnel for necessary training.

As an additional comment, it is important to recognize the different kinds of personnel that may be included in the training audience for a given SOP: (1) employees (in the strict sense), (2) independent contractors, (3) contract company (third-party) workers, and (4) temporary agency workers.[9] These four types of employees are cross-cut by several levels or ranks: (a) subordinates, (b) supervisors (i.e., managers, directors, etc.), and (c) executives. The finalized Training Audience List must identify impacted (and non-impacted) personnel from each of these groups.

Behavioral Objectives: There is a strong case to be made for behavioral objectives, sometimes called S.M.A.R.T. (Specific, Measurable, Achievable, Relevant, and Time-based) objectives, in training.[10] On the one hand, behavioral objectives permit the alignment of the intended training outcomes with organizational objectives. Anyone who advocates cognitive (i.e., non-behavioral) objectives for training must be prepared to explain how these objectives are to be aligned with those of the organization. On the other hand, behavioral objectives permit the trainee to have clear expectations of the trainer's (and the organization's) intended training outcomes.[11] These clear expectations play a critical role in effective adult learning.

Many academics reject the role of behavioral objectives in the university classroom; this highlights the difference between training in industry, on the one hand, and higher education on the other. In higher education, accredited institutions award diplomas to students on the basis of a series of learning experiences over an extended period of time. The organizational objectives include (a) awarding the diplomas and (b) maintaining the accreditation. This has very little to do with training in industry, where the organizational objectives include (a) improving employees' task performance on-the-job, and (b) addressing the requirements of various regulatory regimes.[12]

Training Effectiveness: Assessment of training effectiveness must be distinguished from evaluation of training programs. There is a difference in kind – trainees are human individuals; training programs are organizational entities. Of course trainees participate in training programs, but the difference in kind means that the measures are different. For instance, trainee reactions (Donald Kirkpatrick's Level One, [13]) are perhaps useful in evaluating training programs – favorable trainee reactions may factor in decisions about program continuity. Trainee reactions are much less useful in assessing training effectiveness, which involves assessing performance improvement that will impact on-the-job – a supervisor's reactions are much more relevant.[14]

In the present context, training effectiveness is assessed by one of two types of measures – a KTA or an SDA. The KTA in particular need not be validated in terms of the task(s) at hand. If the KTA is validated, then performance improvement on-the-job can be predicted from trainee performance on the KTA. If the KTA has not been validated, the measure can still be included in the learning product, as an interactive element of the courseware, and as a promissory note of future validation, if you will. The training event will be concluded in this case by the trainee (and trainer) concurrence that the trainee was trained on this courseware, and thereby on the SOP.

An SDA, by contrast, directly and validly documents the trainee's ability to independently perform the task(s). Furthermore, once the relevant SDAs for a process are completed, the trainee is qualified, able to independently perform the tasks in that process.

Once the template is completed , it is ready for management signoff, which concludes the Design phase of the ADDIE model.

Securing Management Approval Of The Outlined Learning Product

The final component of the Design phase is management approval of the proposed learning product. This approval is important for at least three reasons. First, this ensures that resources allocated to the subsequent phases, Development, Implementation, and Evaluation, have approval at the appropriate organizational level. The investment of resources - particularly in the Development phase - will be substantial, and knowledge workers, be they instructional designers, software engineers, or whomever, are in no position to make the management decision about resource allocation. Second, Quality Unit approval ensures that the proposed learning product meets the organization's quality criteria. Finally, there are a number of points where training implications of the proposed learning product - the training audience, the course length, etc. – can have a profound impact on business lines, and again, this impact must have managerial approval. The signatures on the Training Outline satisfy these needs.

CONCLUSION

The Design phase of the ADDIE model is the occasion for a planned approach to addressing a performance gap identified in the Analysis phase. This planned approach includes fitting the proposed learning product into the larger curriculum; it involves outlining the learning product in terms of a systematic template, the Training Outline; and, it includes the need for securing management approval of the outlined product. When the proposed learning product has moved through the Design phase, it is ready for the Development phase where training materials and assessment materials are developed to address the performance gap.

ABOUT THE AUTHOR

Gordon Welty, PhD has been designing, developing, facilitating, evaluating and managing technical and regulatory training programs in the healthcare and pharmaceutical industries for more than twenty years. This article is the second in a series on the ADDIE model; the first appeared as "Strategy and Tactics of Task Analysis," *Journal of GxP Compliance* (April 2007), Vol. 11, No. 3, pp. 26-34. Contact Gordon at gwelty@wright.edu

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1. See D. Zielinski's discussion of "blended learning models" in "A Closer Look," *Training* (Nov 2005), Vol. 42, No. 11, p. 21; also Harvey Singh "Building Effective Blended Learning Programs," Educational Technology (Nov. 2003), Vol. 43, No. 6, pp. 51-54. As B. Hall and J. LeCavalier put it in their "E-Learning across the Enterprise: The Benchmarking Study of Best Practices," Sunnyvale, CA: BrandonHall.com (2000), p. 6: across a range of industries, the emerging best practices model *"is a highly compatible 'ménage à trois' uniting online learning for information transfer and procedural skill acquisition (often this constitutes pre-work for the next tier of the model), classroom or other site-based learning for higher order competencies, and structured on*

the-job learning, integrated with knowledge management and competency evaluation."

2. On SOJT, see William Rothwell and H C Kazanas, *Improving On-The-Job Training: How to Establish and Operate A Comprehensive OJT Program*, San Francisco: Pfeiffer (2004); also Ronald L Jacobs, *Structured On-The-Job Training*, San Francisco: Berrett-Koehler Publishers (2003).

3. See 21 CFR Part 211.25, "Personnel Qualifications."

4. See 21 CFR Part 211.28, "Personnel Responsibilities." Also Jan Eudy, "Clean Manufacturing," *Controlled Environments* (March 2004), Vol. 7, No. 3.

5. See for example Lawrence Bierlein, "Who Has Responsibility for Employee Hazmat Training?" *Transportation and Distribution* (Nov. 1998), Vol. 39, No. 11, page 123; also L. Bierlein "Conduct a Hazmat Review before the DOT Comes Calling," *Logistics Today* (July 2005), Vol. 46, No. 7, page 16; and Shadid Jamil, H. L. Floyd, and D. Pace, "Implementing Electrical Safety Regulations and Standards," *IEEE Industry Applications Magazine* (Jan 1999), Vol. 5, No. 1, pp. 16-21, esp. pp. 20-21. There are also state laws and regulations that must be taken to account; see A. Bender, N. Shannon, and J. Braun-Davis, "Orchestrating Compliance," *Pharmaceutical Executive* (Oct 2005), Vol. IV, pp. 17-18.

6. For instance, the chain of custody required by DEA's 21 CFR Part 1301.73, "Physical Security Controls…" and the evacuation requirements of OSHA's 29 CFR §1910.38(c), "Emergency Action Plans." See also National Academy of Sciences/ Institute of Medicine *Ensuring Safe Food: From Production to Consumption* Washington, DC: National Academy Press (1998); Society of the Plastics Industry, *Food, Drug, and Cosmetic Packaging Materials Committee Newsletter* (08 June 1998): "over the years, the food packaging industry has been subjected to an undue burden as a result of the regulatory overlap among FDA, USDA, and the Bureau of Alcohol, Tobacco, and Firearms (BATF);" and "FDA Cancels Part 11 Meeting," *Part 11 Compliance Report* (09 June 2004), Vol. 4, No. 12, p. 2, for a discussion of the regulatory overlap between 21 CFR Part 11 and other regulations affecting life science companies, such as HIPAA and Sarbanes-Oxley. For an overview, see Robert W. Hahn, "Government Analysis of the Benefits and Costs of Regulation," *Journal of Economic Perspectives* (Fall 1998), Volume 12, Number 4, pp. 201-210.

7. See 29 CFR §1910.147, "Control of Hazardous Energy." This standard mandates that each workplace, with few exceptions, must develop a program to "disable machinery or equipment and prevent the release of potentially hazardous energy while maintenance and servicing are being performed." Hazardous energy includes electrical, mechanical, hydraulic, pneumatic, and other energy sources. The mandated LOTO program will have three components: (a) a set of written procedures for the control of hazardous energy, (b) an employee training program to ensure that the procedures are implemented, and (c) an annual inspection to ensure that the procedures continue to be followed. See also Federal Register (Nov. 06, 1989), Vol. 54, No. 213, p. 46610; and Danny P. Liggett, "Training and Qualifying your Employees," Petroleum and Chemical Industry Conference, 2005. Industry Applications Society 52nd Annual Conference (Sept. 2005), pp. 327-332.

8. The corrective and preventive actions (CAPA) may, in the event, be the same for the troubleshooting process and the manufacturing process.

9. See John Garen "Use of Employees and Alternative Work Arrangements in the United States," *Labour Economics* (February 2006), Vol. 13, No. 1, pp. 107 ff.

10. D. D. Ely "Training by Objectives, a Systems Approach to Instruction," *Training & Development Journal* (June 1975), Vol. 29, No. 6, pp. 23-24.

11. As Craig Cochran has stated, "People have trouble contributing to fuzzy, undefined objectives;" "Creating and Meeting Objectives," *Quality Digest* (September 2004), Vol. 24, No. 9, p. 56.

12. As Harry Moser, "The ROI for Manufacturing Training," *Modern Machine Shop*, (May, 2005), Vol. 77, No. 12, p. 98 ff. points out, higher education is not incompatible with training in industry - just different. See also E.J. Rice-Munro and R. A. Munro "Continual Improvement of Training," *Quality Digest* (August 2004), Vol. 24, No. 8, pp. 43-53.

13. Donald Kirkpatrick, *Evaluating Training Programs*, San Francisco: Berrett-Koehler (1994); also James Kirkpatrick, "Transferring Learning to Behavior," *Training & Development Journal* (April 2005), pp. 19-20.

14. R. K. Mahapatra and V. Lai, "Evaluating End-User Training Programs," *Communications of the ACM* (Jan 2005), Vol. 48, No. 1, pp. 67-70.