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Application of Validation Principles to Training: Part 2 - Training Modules

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ABSTRACT

This discussion continues a multipart series of discussions in which well-accepted concepts in manufacturing and validation are proposed for application to the training quality system. It proposes application of the process validation lifecycle approach to technical training modules. Technical training modules comprise information content, delivery methods, and trainee verification requirements. Options in each of these componets are described. Components are evaluated, selected, and integrated to form an appropriate final technical training module based on risk to patient, product, and organization. Training modules should be managed utilizing the three stages of the validation lifecycle approach to provide a structured approach including design and development; execution, and follow-up monitoring and maintenance. Just as with pharmaceutical products, serious effort expended in Stage 1 design and development will result in successful Stage 2 training execution and Stage 3 verification of ongoing performance. Case studies that describe problems with training modules volunteered by multiple quality and validation managers from multiple companies are described. Application of validation lifecycle stage concepts to training modules should identify gaps, deficiencies, and omissions and ultimately strengthen the site training quality system.

INTRODUCTION

This discussion continues a series of discussions addressing the application of validation principles and concepts to the training quality system (1). The site training program is a critical component of the quality program in pharmaceutical, medical device, and other regulated manufacturing industries. Training modules containing training content are the most important element in training programs. Training modules comprise a range of content, method of delivery, method of verification, and other considerations. At a minimum, training modules are documents containing written content of a topic requiring reading by the trainee. At the other extreme are complex and lengthy procedures requiring multiple individual on-the-job training (OJT) sessions with actual demonstrated performance competence by the trainee.

This discussion addresses the application of validation principles and concepts – primarily the lifecycle approach to validation -- to the topic of technical training modules. Specific topics for discussion include:

- Training module considerations – the broad scope of training module content, delivery methods, and verification of trainee competence
- Validation lifecycle approach description
- Application of the validation lifecycle approach to training modules

- Case studies and problems solved.

Training and product manufacturing are analogous. In training, trainees are transformed through multiple training module content, delivery, and integration thereof to yield competent trained workers. In manufacturing, raw materials are processed through multiple unit operation process parameters to form pharmaceutical products. Validation principles and practices provide structure and organization to the manufacturing effort and should do similarly for training. Application of lifecycle validation concepts to training modules should identify gaps, deficiencies, and omissions and ultimately strengthen the site training program.

Site training programs comprise both technical and non-technical training. This discussion focuses on technical training modules for GMP-related topics.

This series of discussions was suggested by quality and validation managers in response to problems experienced at their respective sites. Approaches and problems described include comments from multiple managers from several companies.

TECHNICAL TRAINING MODULE OVERVIEW

Technical training modules in a site training program comprise a range of content, delivery methods, and trainee verification requirements. These components are then appropriately integrated to form the final complete training module.

- Information content. These include general categories of training information, technical level of information, and risk analysis – risk to patient, product, and organization. Training modules comprise multiple categories of information and a range of technical content complexity within categories appropriate to accomplish a particular task.
- Delivery methods. These include the method of information delivery such as hardcopy, electronic, human interaction, on-the job training (OJT) with equipment, and combinations thereof. Qualified trainers are part of several of these methods.
- Verification of trainee competence. These include trainee signature, written testing, skills demonstration, other methods, and combinations of same.
- Component integration. Most important to the creation of the final training module are the evaluation, selection, integration, and specifics of the above for the final training module. Re-training frequency for the module is determined based on risk analysis. The finalized module is then executed for actual employee training.

Non-Technical Training

Non-technical training on topics such as company policies, company-required training, and company/site news and announcements may be integrated into site training functions in some organizations. Company policies are often presented to new employees during the first few days after being hired by the company. Examples of information in this category includes new employee policies, working hours, dress code, company holidays, vacation policy, company management, benefits, and similar information. Company-required training includes policies that all employees must know and to which they must comply. It includes ethics policies, anti-harassment policies, confidentiality requirements, and other important non-technical or non-product related information. These trainings may be legally required. Company news and announcements comprises optional information available to all company employees available on bulletin boards, electronic messaging, and informational meetings. These non-technical trainings may be administered by the corporate or site business function and/or Human Resources (HR) in group meetings.

Non-technical training topics are not addressed in this discussion, but are acknowledged because their recording/documentation, re-training notification, and other requirements may be the responsibility of the site training quality system.

Information Content

The following describes a range of technical content information in training modules available to employees in the pharmaceutical organizations. Each of these comprises a range of technical complexity and associated risk in performance. These factors are considered in the ultimate design and development of the training module. Four categories of technical training are identified:

- Function policies and procedures
- Application procedures
- Job skills performance – On-the-Job (OTJ) training
- External continuing education.

Function policies and procedures. This category comprises policies, procedures, SOPs, and practices that are critical to the employee's job responsibilities in respective site technical functions in the manufacturing facility. For example, manufacturing personnel must be training on manufacturing policies and procedures, documentation practices, safety policies, quality policies, technical process theory, cleaning theory, and so on. Analytical lab personnel must be trained on laboratory policies, instrument operation, sample handling, data integrity, and so on.

Application procedures. This category comprises specific information used in conjunction with function policies and procedures. Function policies described above enable actual performance of all procedures. Application procedures may be bulleted lists of operational parameters that provide details of performance for specific situations, i.e., they are considered in conjunction with function policies. For example, specific conditions for HPLC testing for potency testing of a specific product to be used in conjunction with an HPLC operational policy, or specific conditions for moisture testing of a specific product to be used in conjunction with a gravimetric instrument operational policy are procedures in this category.

Job skills performance – On the job training (OJT). This category includes activities that require demonstration of manual skills to accomplish a specific task. The content of this training for future use in actual delivery should be available in procedures or otherwise written for reference. For example, a manufacturing operator must assemble equipment, operate equipment according to batch record parameters, adjust parameters if needed, disassemble equipment, clean equipment, and then reassemble equipment for subsequent manufacturing. Training on the operation of a tablet compressing machine should enable compressing of all products on that machine. Training on an HPLC system should enable all specific procedures and the corresponding techniques to be performed on the HPLC systems. This training would be provided by designated Subject Matter Experts (SME's) or experienced personnel within the function. It might be accomplished in multiple joint sessions of trainer and trainee culminating in the trainee demonstrating competence to accomplish the assigned task.

External continuing education. This category comprises information obtained from organization outside the company that support organizational training. It includes external seminars, professional meetings, courses, forums, and other events focused on specific training and education otherwise not available within the company. For example, seminars attended by SME's to further their knowledge of a technical area, green/black belt statistics training, ASQ certifications, or training of operators at an equipment manufacturing site are examples of this category of information. This category includes training by outside organizations who present training at the company with minimal site involvement other than providing site facilities.

Content Delivery Methods

Information delivery describes the method of presenting information to industry personnel being trained. The method of delivery is related to the complexity of the information and risk or impact if the information if not understood. There are numerous learning models used in educational settings (2). These models are useful for delivery of training to individuals or groups such as in discussion groups, team activities, role playing, and other variations. Human factors are an important consideration in the delivery of training content. Basic categories of content delivery identified are the following:

- Individual delivery – Individual person reading or listening by hardcopy, computer, or video
- Interactive delivery – Individual person or group interactions with human trainer such as in a classroom setting
- Skill performance activities with a human trainer.

Trainer qualification is a significant consideration in both interactive delivery methods and skill performance training – human communication skills are vital in delivery of these training modules. Trainer qualification considerations will be addressed in a future discussion in this series.

Methods associated with external training delivered to trainees are determined by the contracted organization.

Individual delivery – reading or listening by computer or video. Individual delivery describes information provided directly to the trainee – "one-way" -- without any interaction with the provider. The recipient individually simply reads information, or listens or observes information being presented by video, computer, or other means. There is no communication between provider and recipient. Virtual reality is also being used, with or without response feedback. Individual delivery must consider the reading and comprehension skills or the trainees. Pictures, diagrams, videos, and graphs are recommended, especially for complex content such as for operation of complex machinery.

Interactive delivery – individual or group. Interactive delivery comprises information presented by an individual that enables discussion between trainee and trainer. Interactive delivery may include delivery between individual trainer and trainee with opportunity for Q&A and discussions. Interactive delivery may include classroom sessions with a group of individuals, again with opportunity for Q&A and discussion. These sessions do not include actual performance of technical skills. Group sessions may include lectures, group activities, team activities, role-playing, and other interactive exercises – human factors considerations. Communication between trainer and trainee is the key element in this category of information delivery.

Skill performance. Skill performance delivery is On-the-Job (OJT) training whereby a Subject Matter Expert (SME) trains a trainee in a technical skill including actual performance of the skill. For example, an SME manufacturing operator will train a new operator in the disassembly and cleaning of manufacturing equipment, or an SME analytical chemist will train a new chemist on techniques in the potency determination of a pharmaceutical product. Depending on the complexity of the skill and the risk involved in performance, multiple training sessions may be required. In these sessions, the trainee will demonstrate increasing levels of competence until successful performance of the entire skill activity will be demonstrated, i.e., the trainee will successfully perform the activity without help from the SME. Human factors considerations are important in the delivery of this training.

Verification of Trainee Competence

Methods to verify information delivery describe the method of proving that training content has been successfully provided to the personnel being trained, and that the trainee has demonstrated an appropriate level of competence regarding the information. The method of verification is related to the complexity of the information and risk or impact if the information if not understood. Basic categories of methods to verify information delivery are the following:

- Attendance record – Signature verification
- Competency test
- Skills demonstration

A responsible trainer or training manager must approve and document the trainee completion of training when appropriate requirements are achieved.

Attendance record – signature verification Certain information provided to employees requires only signature verification that the specified information has been read by the trainee, or that the individual has attended a group training session. For example, dress policy for GMP-manufacturing areas, or SDS labeling and safety policy for chemicals. This category of training is routinely termed "read and sign" training. A better term that emphasizes the intent of this training would be "read and understand" – the key objective being content understanding.

Competency test. Other information provided to employees requires a written competency test to confirm successful delivery of information. For example, an online training will require correct answering of multiple-choice questions at the completion of the course to demonstrate understanding of content. A minimum percent correct will be specified for acceptability (pass / fail). For example, 80% correct answers on 20 multiple-choice questions are required for successful completion of training.

Skills demonstration. Certain activities require demonstration of technical skills beyond technical "book" knowledge about a given topic. In these sessions, trainee and trainer meet to effect training on a specific technical skill. The trainee will demonstrate increasing levels of competence until successful performance of the entire skill activity will be demonstrated, i.e., the trainee will successfully perform the activity without help from the SME. After successful training, the newly trained person is competent and expected perform the subject task without specific task supervision. The trainer must document that training was successfully completed.

Component Integration

Assembly of the training module for a specific training topic and information category requires evaluation and identification of the training content, selection of appropriate delivery method, and inclusion of the appropriate training verification. Risk analysis for the topic is critical to these selections. The retraining frequency for the training module is also based on the risk analysis.

Evaluation, selection of applicable training parameters, and integration. Preparation and integration of the training module content, method of delivery, and trainee verification must be a deliberate activity based on risk to patient, product, and the organization. A simple and straightforward policy may be read by the trainee at his computer. In contrast, a GMP documentation policy may best be delivered in a classroom setting conducted by an SME with example documents, example errors, and a written test to verify trainee understanding. Training topics must be evaluated, risks assessed, appropriate method of delivery chosen, details of delivery considered, and testing to demonstrate competency determined. Key information to be delivered must be appropriately identified and emphasized. Key delivery parameters must be determined – what delivery skills are needed. Content verification must be consistent with training content and delivery emphasis. The completed training module must integrate appropriate categories of components and identify the specifics necessary for successful training.

Module re-training frequency. The frequency of retraining is based on risk analysis of the specific training

topic. For example, retraining for topics associated with aseptic techniques must be more frequent than retraining on “read and understand” policies. Managers explained multiple experiences in which training was never repeated in their sites. If activities are not part of routine job performance, retraining is necessary. Training someone as a backup person, and then expecting competence when asked for an emergency performance years later is unrealistic.

Technical training module summary. Table 1 provides a summary of training information categories, delivery methods, and competency verification for typical information categories. Combinations such as signature verification for a job skills module are irrational. If a job skill is demonstrated for training, the trainee must actually demonstrate performance to corm training.

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TECHNICAL TRAINING MODULE COMPONENTS

INFORMATION CONTENT	DELIVERY METHODS	TRAINING VERIFICATIO
Function policies and procedures • Equipment operating procedures • Instrument operating procedures	**Trainee reading** • Read hardcopy • Read from computer **Interactive session with trainer/SME**	**Signature** **Written test** **Computer interactive test**
Application procedures • Manufacturing process variables • Dissolution test variables • Moisture test variables	**Trainee reading** • Read hardcopy • Read from computer	**Signature**
Job skills • Equipment disassembly/cleaning • Equipment setup/operation • Analytical instrument operation	**Interactive session with trainer/SME**	**Skill demonstration to SME**
External continuing education • ASQ courses • Green or black belt statistics courses • Professional meeting CE seminars	**Trainee seminar/project** • Read hardcopy • Read from computer **Interactive session with trainer/SME**	**Certificate - External agency**

Table I. Technical Training Module Components Summary

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LIFECYCLE APPROACH TO PROCESS VALIDATION

The lifecycle approach to process validation was initially introduced in 2004 and formalized in a final FDA guidance in 2011 (3). FDA defined validation in this guidance as follows:

“Process validation is defined as the collection and evaluation of data, from the process design stage through commercial production, which establishes scientific evidence that a process is capable of consistently

delivering quality product. Process validation involves a series of activities taking place over the lifecycle of the product and process."

Three stages are identified in the lifecycle approach. In brief:

- Stage 1 – Process Design comprises all work conducted in advance of traditional validation. This includes R&D, development, pilot-scale trials, scale-up, and all other work to understand the formulation and process. Stage 1 activities may be simply described as process understanding.
- Stage 2 – Process Qualification incudes actual performance of the commercial process by means of conformance lots. This stage confirms – note this key word -- the work of development. Stage 2 may be simply described as process demonstration.
- Stage 3 – Continued Process Verification comprises ongoing monitoring and maintenance of the manufacturing process throughout the entire product manufacturing life until product expiration. Stage 3 may be simply described as process monitoring.

The lifecycle approach to process validation emphasizes Stage 1 and Stage 3 relative to Stage 2 traditional process validation – better planning, design, and development and better follow-up, monitoring, and maintenance. This approach differs significantly from the previous validation approach, i.e., emphasis on Stage 2 based on the 1987 FDA Guidance (4) in which successful manufacturing of three validation lots was essentially the complete story on validation.

Part 1 of this series provided more details on the lifecycle approach to process validation and other applicable validation concepts.

LIFECYCLE APPROACH APPLICATION TO TRAINING MODULES

Training modules should be managed utilizing an approach equivalent to the three stages of the lifecycle approach to process validation. The lifecycle approach provides a structured approach to training modules – Stage 1 design and development, Stage 2 execution, and Stage 3 follow-up monitoring and maintenance. Stage 3 monitoring of training module performance should lead to corrections or improvement projects on training modules. Just as with manufacturing and validation of pharmaceutical products, serious effort expended in Stage 1 design and development and Stage 3 ongoing verification of performance will result in improved Stage 2 training. Serious planning, design, and development of training modules prior to training, and follow-up monitoring of training efficacy post training is equivalent to the lifecycle approach to manufacturing and validation of commercial pharmaceutical products.

Stage 1. Training Module Design and Development

Stage 1 training module design and development provides the foundation for the training module. Training modules must be designed and developed considering the technical content, objectives, and desired attributes of future trained personnel. Important points to be trained must be emphasized in the integrated module. Training module design must also consider the risk level associated with module objectives. Risk to patient, product, and organization must be considered. The more critical the training objective and impact on patient, product, and organization, the greater the intensity of required training process parameters in the training module. Past trainees should also have input into training design -- trainees are the customers of the training program – and will "buy-in" to content if they have contribution into development. This buy-in is very important if not critical to the success of the training program. The better the effort in Stage 1, the better will be Stage 2 actual training and results in Stage 3 post-training monitoring. After training module design is completed, it should be evaluated by the requesting function and appropriate SME's to confirm accomplishment of design requirements. The better the planning, the more careful the design, and more thorough the development --- the better will be the training module.

The following describes a general approach to Stage 1 training module design and development.

Training module initiation. This activity comprises basic training module considerations prior to actual

design of the training module. This is analogous to the Quality Target Product Profile (QTPP), the initial Quality by Design (QbD) consideration in pharmaceutical product development.

- Training topic
  - What is the technical topic and content of the training?
  - What organizational function is requiring this training?
  - Does new training overlap or continue other training in this function?
- Training objective and quality attributes
  - What are the training objectives?
  - What is the basis for these objectives?
  - What are key points that trainees must learn, understand, and remember in training to accomplish successful training? What will be required of trainees?
  - What functions will trainees be required to understand and perform?
  - What performance will trainees before required to demonstrate to confirm competence?
- Risk analysis
  - What are the risks to patient, product, or organization if training is not effective? The training module content, process, and testing effort should reflect the risk level. The greater the risk, the more intense the training — More personal involvement, more prolonged review of content, more difficult testing of trainees to demonstrate understanding, and more frequent re-training.

Training information category. After initiation and basic training requirements are identified and understood, the appropriate training information category and associated considerations can be addressed. After assessment of the training content and requirements, delivery method and skills assessment may be addressed.

- Training content
  - What is the technical content of the training module? Policies, procedures, safety, or documentation, other major content; associated supportive lists, manual operational skills, or advanced level training.
  - Are procedures or other detailed written content available to support and document training module content? These documents must reflect the key training points to be learned.
- Training variables. What factors may impact a successful training session?
  - Is preliminary education needed for trainee before initiation of training? For example, are basic math, reading and comprehension skills required for training content? Are basic lab skills required to perform an analytical assay method? Is preliminary equipment experience or mechanical skills needed?
  - Language. In what language will training be delivered? Is there need for multiple languages to be provided for training?

<u>Delivery method.</u> The training module delivery method is often critical to training efficacy. Substandard training delivery may weaken a well-designed and developed training module. Training module design and development must include requirements for trainers and prerequisites for trainees before acceptance into training. Some training is adequately delivered by trainee reading. Others require significant and repeated personal interaction between trainer and trainee. Individual training differs from group training. An activity requiring “hands-on” activity cannot be taught in a lecture format.

- Training content
  - Is content something that can be read and understood, or is a higher level of personal interaction needed to understand the content? For example, operational setup of technical manufacturing equipment.
- Trainee reading
  - How should the reader training be delivered — Hardcopy or computer?
  - If “read and sign” training, how will reading be controlled to ensure actual trainee reading?
- Trainee interactive training

    - If interactive training is needed, what interactive methods should be used?
    - Do trainees require certain skills prior to beginning training?
    - Have human factors been considered in content delivery?
- Trainer requirements
    - Do trainers require specialized skills to present training modules?
    - What visual aids or demonstrations are needed?
    - Will trainers present training to individuals, or to a classroom of 100 people?

Training verification. What evaluation methods should be used at conclusion of training to verify training delivery and evaluate trainee understanding and competency?

- Trainee reading
    - Is "read and sign" adequate to demonstrate content understanding?
    - Should correctly answering test questions be required to demonstrate understanding, either by written test or computer-assisted testing?
- Interactive training
    - How will "hands-on competence" be demonstrated by trainee?
- External training
    - How will external training be verified?
    - How will this be documented in the internal training system?

Re-training frequency. Critical training on high risk activities should be repeated at an appropriate frequency depending on the level of risk.

- How often should employees be required to re-take the training session?

Stage 2. Training Module Delivery

After completion of Stage 1 design and development considerations, the training module is delivered to trainees according to the methods previously determined. Training content is presented (electronic, human interaction, on-the-job skills, external training, or combinations thereof) by trainers to trainees. Trainees who have identified pre-requisite education or skills receive training from qualified trainers or trainer systems. Appropriate testing of training content is accomplished according to module design.

Trainer considerations will be more thoroughly discussed in a subsequent discussion in this series. Trainee considerations will be more thoroughly discussed in a subsequent discussion in this series.

Trainees who have completed training should provide immediate feedback on the training sessions – trainees are the customers of training. Session improvements (module and trainer) should be initiated based on trainee feedback. Future training sessions will be more successful through contributions of trainee employees.

Training module delivery is equivalent to Stage 2 commercial product manufacturing in the lifecycle approach to process validation. Stage 2 training module delivery is the execution of Stage 1 planning, design, and development of the training module.

Stage 3. Continued Training Verification -- Maintenance and Monitoring

Training modules must also be routinely maintained. Modules must be updated as need for consistency with equipment operation or other changes. Training module delivery may also need to be modified as need for consistency with changes. Trainers may need additional training to update or improve their skills based on monitoring data. Trainee requirements prior to training may also need to be updated.

Training modules and delivery methods should also be monitored and evaluated for efficacy over the long term. Deviations, non-conformances, and other negative events indicating substandard trainee performance

on the trained activity should be correlated to the training module including trainer delivery. For example, if there are repeated machine set-up problems with new operators, specific areas of training may need to be revised to emphasize deficient areas. Increased frequency of re-training sessions may be recommended. Responses to identified deficiencies should result in training module improvements.

Training module continues training verification is equivalent to Stage 3 commercial product monitoring and maintenance in the lifecycle approach to process validation. Reviewing training performance and correlating performance to training module design and delivery will ultimately improve the entire site training program.

Summary

Figure 1 summarizes the lifecycle approach to technical training modules. This figure demonstrates emphasis on Stage 1 planning and Stage 3 monitoring as part of the lifecycle approach relative to actual training occurring in Stage 2.

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LIFECYCLE APPROACH TO TRAINING MODULES

STAGE 1. TRAINING MODULE DESIGN AND DEVELOPMENT

- Identify training module objectives and quality attributes of successful training
- Evaluate risk
- Design the training module content
- Design training module delivery method
- Consider human factors in training delivery
- Determine specific requirements for trainers
- Determine trainee prerequisites for training
- Design training module verification method and testing
- Determine re-training frequency
- Documentation

STAGE 2. TRAINING PERFORMANCE

- Train trainees using training module and method of delivery designed in Stage 1
- Test comprehension by method of verification
- Training session evaluation
- Training improvements (module and trainer) based on training session evaluation
- Documentation

STAGE 3. TRAINING CONTINUED PROCESS VERIFICATION

- Monitor the trained activity
- Update training module as needed based on content changes or new information
- Correlate trained activity performance to training module, delivery method, and verification method.
- Training module improvements (module and trainer) based on monitoring results
- Documentation

Figure 1. Training Module Lifecycle Approach

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TECHNICAL TRAINING MODULE LIFECYCLE APPROACH – PROBLEMS SOLVED

The following describe actual training-related events from validation and quality managers. A structured and comprehensive approach to training modules as described above would likely have prevented the described problems.

Case Study #1. Trainees with English as Second Language

A manufactured tablet product lot failed potency and content uniformity specifications. Investigation indicated perfectly-executed manufacturing documentation. The manufacturing operator was questioned by technical support personnel. It was determined that significant processes were incorrectly performed. The operator had signed all manufacturing documents, but could not read or understand the procedures required. He operated equipment from memory. The manufacturing records were written in English, but English was a second language for the operator whose English skills were minimal. FDA cited the site in a 483 observation. Multiple managers from different companies reported this same problem.

Investigation and CAPA. This deficiency should have been identified for the site training program – training was delivered in English but was not completely understood by the operator. Design of training modules, SOP's, and manufacturing records should have required appropriate language to be read and understood by trainees. The site implemented bilingual training and bilingual manufacturing records to support the language demographics of their work force.

Case Study #2. Documentation Practices

A two-hour training session on GMP documentation practices in the site auditorium was conducted for 200+ attendees. The session lasted approximately two hours. The session was held to fulfill a regulatory observation commitment. The session discussed data recording in laboratory notebooks, error corrections, signature/date verification, "white-out" use, date requirements, black ink requirements, and numerous other topics.

Three days after the session a site engineer was observed recording original data on scrap paper for later transfer to his notebook. His supervisor observed his actions. When confronted about his data recording, the engineer had no recollection of the applicable GMP documentation practices described at the training session. Another manager reported seeing technicians writing data on their hands or on "Post-It" notes and then transferring data to batch records.

Investigation and CAPA. Site management discussed the training session as result of the above violation. Deficiencies were obvious -- Too many people in the room, too lengthy the session, too hot in the room, too many detailed requirements, no handouts for subsequent review, and inadequate trainee attention. This training was poorly designed – perhaps due to management lack of interest and support for training. New sessions with smaller groups and less content per session and other improvements were planned. Annual retraining was also required.

Case Study #3. Training Overload

An engineering technician was assigned to write and execute equipment IQ's, OQ's, and PQ's on new equipment at the site. He completed the task. Multiple significant errors were noted in his work. He had completed all applicable training, but training was obviously inadequate. When questioned, the technician admitted that he did not read all training documents because he was pressured by management to complete training and "get to work." His department required completed training -- more than 50 training modules – to be completed before allowing GMP work.

Investigation and CAPA. Departments must not require excessive numbers of procedures for training within a limited amount of time. The engineering requirements were reorganized to contain smaller numbers of related topics to facilitate integrated learning. For example, all validation training was grouped by employee function rather than being combined with numerous other training on unrelated topics. Management was

also counseled to allow adequate time for review of training modules. One manager commented that their site limited training to no more than eight procedures per day to limit information overload.

Case Study # 4. Re-training Frequency and Interval

An internal audit was conducted observing manufacturing operators who were expected to use "clean" techniques in non-sterile processing. Numerous violations of expected performance were observed. Applicable training records of operators were consulted. The most relevant training module was designed to be a single "read and sign" presentation when new employees were hired into the manufacturing work center. No re-training was required. One operator had worked in the area for 17 years, i.e., his only training on the topic was 17 years ago! There was no documentation to justify these previous re-training frequency judgments.

Investigation and CAPA. The site changed their internal policy to require re-training on this module at a frequency appropriate for job performance based on risk analysis – annual for sterile product operators and less frequent for non-sterile operators. New training modules were also developed to address handwashing, garbing, and other activities applicable to microbial contamination.

SUMMARY AND FINAL THOUGHTS

The following briefly summarizes validation concepts proposed for application to the technical training module processes:

- Concepts in the lifecycle approach to process validation are proposed for application to technical training modules. In brief, plan, design, and develop; execute based on planning; and monitor trained performance.
- Training module approach, i.e., content, delivery, testing, and frequency of repetition, should be designed with consideration for technical information complexity and risk analysis. Training module design is analogous to manufactured product design and development – Stage 1 of the lifecycle approach to process validation. The better the effort in planning, design, and development of the training module, the better will be the module.
- Training module administration to trainees is analogous to manufacturing processing – Stage 2 of the lifecycle approach to process validation. Training module administration sessions should be evaluated by trainees to provide immediate feedback on the training module content and delivery process. Actual training is the execution of training design and development.
- Ongoing performance deviations and non-conformances should be evaluated relative to training content and delivery – Stage 3 of the lifecycle approach to process validation. Review and evaluation of training performance will identify desirable improvements in the training module or delivery performance.

This discussion is offered as a logical, organized, structured, and documented approach to training module design, delivery, and monitoring – a lifecycle approach. This lifecycle approach has been well-received and effectively used in commercial product process validation for several years. Validation concepts described are an expectation of regulatory auditors when auditing the validation function.

Key points of this proposal for technical training modules is greater emphasis on both the planning stage in training module design and post-training monitoring of trained activities to confirm ongoing acceptable performance. Training modules must also be routinely reviewed and updated. Case studies relating training module problems are described that illustrate significant training deficiencies, many of which could have been prevented with reasonable conscientious effort in training module design, delivery, and monitoring. Application of lifecycle validation concepts described to technical training modules should identify gaps, deficiencies, and omissions and ultimately strengthen the site training program.

FUTURE DISCUSSIONS

Basic descriptions provided in this discussion will be utilized in future training topic discussions. Future discussions will provide detailed application various validation approaches to specific aspects of the training quality system. Topics to be addressed in following discussions:

- Training personnel (trainers) qualification. Trainers should be qualified according to a deliberate qualification process including ongoing monitoring.
- Training recipients (trainees) screening, training, and monitoring. Trainees should be screened for training, and then trained and monitored to verify continued acceptable performance.
- Training function management. The site training function should be designed, executed, and monitored according to the lifecycle approach to process validation to ensure training quality system performance.
- Training Master Plan. Training documentation may be organized and structured in the same manner as the Validation Master Plan.
- Training self-audit. Questions about the training program process to be used in a site self-audit are discussed.

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Paul Pluta, Ph.D, has extensive pharmaceutical industry and university academic experience, and has been involved with the Journal of Validation Technology and Journal of GXP Compliance as a writer and editor-in-chief...
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