TRAINING FOR BIOTECH MANUFACTURING OPERATOR COMPETENCE

PRACTICES FOR STRUCTURING, CONDUCTING AND DOCUMENTING TRAINING TO ASSURE BIOTECH MANUFACTURING OPERATOR COMPETENCE
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BPOG Operator Competence: March 30, 2016

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Acknowledgement To The BPOG Operator Competence Work Stream
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EXECUTIVE SUMMARY

Are you realizing the desired value from your operations training efforts? Is your training system meeting compliance expectations, yet not delivering against performance goals? Are your associates struggling to keep up with reading document revisions?

This paper outlines a new approach to operations training that enhances proficiency and performance while maintaining a positive compliance position. Topics covered include

- What is a competency oriented approach?
- What is the link between document and training structures?
- How might you implement such an approach successfully?

Within operations there is limited time for learning and training efforts. It is imperative that the time spent on learning and training activities returns the greatest value. What is the current focus of the time your organization is spending on training? Answer the questions in the "What's Your Focus" box below to see whether a new approach may be what is needed to get the desired results from your operational training.

What's your focus?

1. Training assignments are primarily procedures and documents.
   Yes [ ] No [ ]

2. Emphasis is placed on being 100% up to date on document revisions.
   Yes [ ] No [ ]

3. The training function within your organization spends most of its time on system administration and maintenance.
   Yes [ ] No [ ]

4. Your primary metric for training is completion percentage.
   Yes [ ] No [ ]

5. Operations employees do not feel that their training adequately prepares them for successful performance.
   Yes [ ] No [ ]

If your answers are mostly "yes" – you have an opportunity for greater returns on your learning investment.
1. INTRODUCTION

Training within the biopharmaceutical industry for manufacturing operators often relies heavily on documents written for purposes other than training, such as procedures. A focus on being compliant with having read and understood procedures creates both a large volume of training requirements (both initial and revision training) and acts as a barrier to train for competence. Also, current training structures often lack clarity in what training is required to perform certain tasks.

The impact of this paradigm for training within the industry is that time is spent being “compliant” with non-value adding reading requirements rather than on learning and ensuring technical proficiency. Time is spent to maintain large numbers of read-only training requirements that focus on approaching training as a “check the box” activity rather than learning to competently perform the task. There is also the potential for insufficient and inconsistent technical training, as procedures do not (and should not) contain information required for a performer to learn. All of this leads to a potential for increased errors since focus is not placed on assuring the level of technical expertise required to operate in a dynamic and complex manufacturing environment. Beyond technical expertise, behavioral and cultural components of working effectively are also often insufficiently emphasized when procedural documents form the foundation of the learning program. “The training program that brings an individual into compliance does not provide the technical skills needed for his or her role” (A Tale of Two C’s: From Compliance to Competency, K.M. Kapp, 2015, uleduneering.com).

Our learnings on Human Performance have reinforced the critical importance of technical learning. In our dynamic and complex environments, people in their normal work are placed in positions in which they continually need to adapt and make decisions based on changing work conditions. How do we ensure they are prepared to make these decisions? By setting the expectation for and providing the opportunity for them to truly learn.

2. PURPOSE

The purpose of this paper is to describe practices for structuring, conducting, and documenting training to assure competence. These practices are recommended for adoption to shift the current “training for compliance” paradigm to a “training for competence” paradigm. It will also be demonstrated that a training for competence focus achieves compliance.

This paper is structured as follows. We begin by discussing the meaning of training to perform work and define competency based training. We then describe typical documentation structures within organizations for purposes of distinguishing their purpose from elements of a training system. We then describe training system elements to support a competency based training approach. The next section describes an effective competency based training process and describes how both the training system elements and document system components relate. We then discuss training assignment structure and provide considerations for learning management system requirements. An implementation roadmap is provided with suggestions for measuring effectiveness in the last sections.

3. SCOPE

Practices described within this report are focused on manufacturing operator training. Though these recommendations apply to other GxP areas, such as QC, QA, materials and maintenance, they were developed with focus on manufacturing operations.
4. TRAINING TO PERFORM WORK

Training to perform work is a different paradigm and mentality than training for compliance.

Training solely for compliance involves reading regulations and company procedures, resulting in a check the box process that does not demonstrate actual transfer of the knowledge needed to master a skill. This method allows tracking and managing of “training” but does not provide the knowledge needed to support performance nor does it affect behaviors, which ultimately result in success.

Training to perform work requires an integrated perspective including knowledge, skills and behaviors. In this paradigm, training focuses on ensuring the operator can perform in the actual work environment utilizing all documents, tools and equipment provided to complete that work. We refer to training that has this focus as competency based training.

A competency is a cluster of related knowledge, skills and behaviors that correlate with performance on the job. Competencies include specific work behaviors that distinguish high and low job performance. The competence to perform an activity or task can be defined by the integration of all pieces that make up that task or activity. Competencies are differentiated based on the role and responsibilities of each learner.

Competency based training is learner-focused and works naturally with independent study and with the instructor in the role of facilitator. The learning method allows the manufacturing operator to learn skills, which they find challenging, at their own pace. Performance can be measured against well-accepted standards and improved via training and development, which then serves as a platform for learning and organizational development.

In addition to being learner focused, competency based training is introduced in steps with each subsequent learning activity building on the previous. The skills may be grouped into unit operations, by the type of tasks or by skill levels.

Competency based training results in:

- appropriately trained/skilled and qualified operators who are prepared to perform and adapt to the complexities of day-to-day work
- improved individual and overall business performance

Competency based training is focused on the operator – not just on their development, but on their ability to work effectively in their work environment. Taking a competency based approach goes beyond teaching the step-by-step and also considers operating conditions that should be expected. Whitman highlights that the desire is to “implement an obsessive culture that strives to operate correctly” (reference “Process, People, Perfection: learning from the Pioneers in HuP”, PDA, Darren Whitman). The earlier you can engage manufacturing operators, the better performance will be (Kurt Lewin, 1943 – USA “T-Bones steaks”).

Competency and learning are cornerstones of Human Performance and foundational for Lean Manufacturing practices. Both Human Performance and Lean foundationally require that you do not have a “blame” culture, and seek to implement tools and system improvements to help manufacturing operators, such as Plan-Do-Check-Act (PDCA), Workplace Organization (5S), and standard work. Working within such an environment is foundational for competency based training.

<table>
<thead>
<tr>
<th>COMPETENCY COMPONENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Knowledge</strong></td>
</tr>
<tr>
<td>Context for how activities contribute to overall process; theoretical and practical understanding</td>
</tr>
<tr>
<td><strong>Skill</strong></td>
</tr>
<tr>
<td>Ability to do; application of knowledge</td>
</tr>
<tr>
<td><strong>Behaviour</strong></td>
</tr>
<tr>
<td>The way in which knowledge and skill is demonstrated</td>
</tr>
</tbody>
</table>

PAGE 6 – Training for Biotech Manufacturing Operator Competence
5. GMP REQUIREMENTS

Within industry, utilizing procedures as the base unit for training tends to be the standard approach. This has led to the thinking in some organizations that the compliance requirement is that you are trained specifically by reading and understanding documents. Figure 1 lists a summary of GMP expectations for training and performance. These expectations can be satisfied in a variety of ways, one of which is a competency based approach.

In addition, though not necessarily explicit in documented regulations, it is logical for a training program to be able to address questions such as "how do you know personnel are and remain competent to perform their jobs?", and "Is your learning system contributing to quality, compliance and knowledge management?" A training approach that emphasizes read and understand as a primary modality most likely will not provide sufficient evidence to address these questions.

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**SUMMARY: GMP EXPECTATIONS FOR TRAINING AND PERFORMANCE**

1. There are an adequate number of qualified people to safely and effectively perform the required tasks.
2. Tasks, roles and responsibilities are defined in job descriptions and organization charts.
3. Personnel are trained in the procedures and methods they use and in the tasks they perform.
4. Personnel are trained in the GMP concepts and regulations that apply to what they do.
5. Key personnel (including consultants and contractors) have the professional, educational and experiential credentials required.
6. Training is defined by a procedure and (an on-going) plan and it is documented; training effectiveness is evaluated.
7. Training is conducted by qualified personnel.
8. Supervisors and management have training that is appropriate to their functions.

*Source: GMP in Practice, 4th Edition, James Vesper*

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Figure 1. GMP Expectations for Training and Performance
6. DOCUMENT TYPES, DEFINITIONS & HIERARCHY

A distinction is made between documents to perform and documents to train. Documents to perform are those documents that are either referenced or in-hand while an activity is being done. Documents used for training are created to facilitate learning and are generally not used during activity performance.

6.1 Documents to Perform, Definitions and Hierarchy

Figure 2 illustrates a generic hierarchy of documents used to perform work activities.

![Generic Types of Documents](image)

6.1.1 Knowledge Documents

Knowledge documents describe policies, process overviews and often answer why things are done the way they are done. They can include roles and responsibilities, organization and decision governance, environment and regulatory constraints, and descriptions of strategies. Within biotech organizations these types of documents may include what are labeled Policies, Quality Manual components, Quality Directives, and Process Overviews. Job Descriptions that specify roles and responsibilities, for purposes of this paper, are considered knowledge documents.

6.1.2 Working Documents

Working documents describe how to do the work; how to perform activities. These documents will generally need to be in-hand at the time of performance. Within biotech organizations these types of documents may include what are labeled work instructions, standard operating procedures, specifications, guides, and job aids.

6.1.3 Data Collection Documents

Data Collection documents capture real-time evidence that can be referred to later to show that work was done per instruction. These documents are used during activities to record data, document equipment readings and perform calculations. Within biotech organizations these types of documents may include what are labeled forms, batch records, worksheets, and logbooks.

6.2 Documents and Materials used to Train, Definitions and Hierarchy

Documents and materials used to train establish the foundation for learning activities that assure competence. Learning activities involve transfer of knowledge, skills and behaviors that affect overall performance. Training on learning activities rather than relying on reading working documents for training provides for increased consistency in learning, more meaningful training and increased knowledge retention.

Figure 3 illustrates a typical training for competence progression. This training progression starts after an operator joins the organization. Though not discussed in detail in this paper, assessments of aptitudes and fit-for-role can be done as part of the recruitment and hiring process, ensuring a good start for new trainees. In application, a learner is considered independently capable to perform following the “Qualification to Perform” stage.

Training documentation and materials are created with different objectives than documents as described in section 6.1. Training materials are designed to summarize performance objectives and provide structure to enable learners to progress towards achieving them. Training materials do not describe how to perform, rather, they support learning the knowledge, skills and behaviors required for high levels of performance.

Training materials support learning the knowledge, skills and behaviors required for high levels of performance.
Skills and concepts are initially introduced to the trainee using methods such as seminar led, e-learning or one-on-one training. After the initial introduction, the trainee will be trained on basic steps, allowing them to perform in GMP conditions (operating equipment and performing basic steps) while gaining the experience to become proficient. More information, theory and the "whys" are provided as the trainee progresses through the steps toward being competent in the skill. As the learner continues to advance, he or she learns trouble shooting and advanced operations. Each of these trainings are defined by course plans and documented upon completion. Using this stepwise introduction to build towards competency not only leads to proficiency but also confidence.

6.2.1 Introductory Materials
Documentation and materials to support the introductory, novice phase generally include process overviews, unit operation descriptions, workbooks, and guides. Introductory training materials can be in document form, and are often developed and made available in e-learning formats or video.

6.2.2 Task Training
Task training is generally performed on the job and in some instances can be simulated in training facilities that are off-line from operations. During this phase of learning, the learner will be exposed to actual work activities. Training materials may be developed to support task training. These types of materials generally include training plans and documents that describe task standards. During the task training phase, learners practice task performance while utilizing the various tools and resources available. Training is conducted on-the-job with relevant working documents and data collection documents.

Task training, since conducted under operational conditions, is executed in phases. The extent to which each phase is completed or performed is dependent on learner prior experience and task complexity.

Phase 1: Observe and ask questions
In this phase, the learner observes others performing the task and asks questions to assure understanding of how the task is completed successfully.

Phase 2: Complete the task with direction, under supervision
In this phase, the learner completes the task under the supervision of a trained instructor. This phase is often repeated multiple times for a given task depending on learner proficiency and prior experience. It is acceptable for the trainee to be helped and/or prompted by the trainer during this phase.

Phase 3: Complete the task independently
In this final phase of task training, the learner practices independent performance of the task. Once both the learner and the trainer agree that the learner is ready to be assessed for qualification, a qualification assessment is done, as described in section 6.2.3. Independent completion without prompting from a trainer may be sufficient for completing qualification.

6.2.3 Qualification to Perform
Knowledge assessment and performance assessment is conducted on the job to verify that a learner can be qualified to perform. Training materials to support qualification may be labeled Performance Qualification Events, Performance Assessments, Observation Checklists or Standards Verification.
Though grouped within the general category of “training materials”, performance qualifications are assessments. As stated in section 6.2, a learner is considered independently capable following a performance qualification.

6.2.4 Reinforcement
Following qualification, reinforcement of working to established standards is important. This is done by conducting periodic observations, by providing feedback, and by providing refresher training and/or requalification. Formal refresher training and requalification is typically reserved for subsets of tasks deemed critical, where operator technique, in particular, is key to success, such as for aseptic practices.

6.2.5 Advanced Training and Skill Building
As an operator gains experience, he or she is prepared to progress towards advanced knowledge and skills. Advanced knowledge and skills include more complex theoretical process concepts and troubleshooting techniques. This type of training can be supported with working documents if they exist for troubleshooting, as an example. In general, it is good practice to leverage external resources for advanced scientific courses and enable informal learning processes to capture and share SME knowledge. Informal learning processes also enable learning from deviations and near misses that may not be readily available through formal documentation. This type of training is critical because it answers the why and helps the trainee respond to abnormal situations on the shop floor (instead of simply execute).

6.2.6 Training Progression for Temporary Employees
It is common to utilize temporary employees, either to provide a provisional period under which a new hire can be assessed for fit for job, or to augment staff resources for a short period of time. Is the training process different for a temporary employee? No. Temporary employees are task trained and qualified in the same manner as permanent employees. A difference, however, is the case of the shorter term assignment. Temporary workers on shorter term assignments will generally not progress past initial task training during their tenure. A general guideline for training investment for a shorter term assigned employee can be suggested at 10 to 20% of their expected tenure. For a temporary employee on a 4 month assignment, this would suggest the equivalent of 12 to 24 days of training. This is a guideline to support a balance between training investment and expected performance and is not suggested as a rule.

6.3 Relationship between Performance and Training Documents
The relationship between performance documents and training documents is described in Figure 4. This illustration depicts performance documents as inputs to the learning process.

Figure 4. Relationship between performance and training documents.
It is apparent from this illustration that documents contained within a typical document management system are insufficient to support a training for competence model. Knowledge documents provide background, and working documents provide “how to” instructions, but neither truly enable continuous learning.

Though performance documents are not designed for training and should not be used as the sole source for learning, the relationship between the two is critically important. Changes in work practice are captured in performance documents and the associated training materials need to be kept current with changes in the performance documents. This relationship is also important to the performer, as he or she needs to be able to easily determine what training is required to perform which tasks. In implementation of a competency model, changes may be required to the structure and hierarchy of an organization’s performance documents so that this relationship is clear.

The relationship between training materials and the related performance documents should also be explicit. When performance documents revise, a trigger needs to exist that ensures there is a review of related training materials. Revision processes need to align such that training material updates can be accommodated before new performance documents are released to manufacturing operators. A key aspect of the competency model is that all changes to work practice (as reflected in performance documents) are evaluated against whether or not the underlying competency requirements have changed in such a way as to require further training or re-qualification. In instances in which the training or re-qualification is not necessary, it may still be desirable to communicate the changes to operators. This can be accomplished in a variety of ways and should follow typical communication pathways within an organization. This type of communication, though important to support change management, is not formal training and should not be labeled as such so as to not be confused with the formal elements of a training for competence model.

Table 1 provides recommended guiding principles for types of training material that have proven to be generally effective for each phase of the training and learning process. For any training to be effective, it must be designed in direct relationship to performance and learning objectives. Before considering the recommendations provided in Table 1, the instructional designer would look at the performance objectives and then determine the delivery modality that is best suited to accomplish those objectives.

It is also recommended that training content not duplicate information already contained in performance documents. This creates an increased potential for inconsistency in documentation and an unnecessary redundancy. Where performance documents contain requirements and step by step instruction, training materials are designed to fill in context and background information that supports learning and successful performance.
<table>
<thead>
<tr>
<th>TYPE OF TRAINING</th>
<th>PRINCIPLES</th>
<th>RECOMMENDED TRAINING MATERIAL TYPES</th>
<th>INSTRUCTOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overview and introduction</td>
<td>• Content is appropriate for novice learner</td>
<td>e-learning with or without interactive quiz type activities, may include knowledge assessment</td>
<td>none</td>
</tr>
<tr>
<td></td>
<td>• Content provides context for application</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Task training on skill</td>
<td>• Focus is on learning to perform with resources that are available during regular task performance</td>
<td>Seminar / Instructor led, may include knowledge assessment</td>
<td>SME, possibly from external departments, such as technical development or engineering</td>
</tr>
<tr>
<td></td>
<td>• Information to support learning above what is contained in performance documents is housed in separate training materials</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Qualification to Perform</td>
<td>• Performance assessments capture task / activity standards so it is clear and objective how performance is assessed</td>
<td>Course plan with major tasks listed, may include verbal knowledge assessment</td>
<td>SME who is a qualified trainer</td>
</tr>
<tr>
<td></td>
<td>• Performance assessments are broken down based on how work is typically assigned so that operators can be qualified on activities that would be performed separately, e.g. being qualified to prepare a hood separately from performing a split</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reinforcement</td>
<td>• Training materials are formally established for specific events such as refresher training or requalification</td>
<td>Course plan checklist, Observation checklists</td>
<td>Peers, supervisors, area SMEs</td>
</tr>
<tr>
<td></td>
<td>• Observation and coaching programs establish more effective means of reinforcing performance to standards</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Advanced Training and Skill Building</td>
<td>• Content is more in-depth and takes into consideration that the audience is task qualified</td>
<td>Training materials could be workbooks, e-learning, or links to external content</td>
<td>SME who is a qualified trainer, Supervisors; both with coaching skills</td>
</tr>
<tr>
<td></td>
<td>• Often outsourced to local colleges, universities or vocational training centers</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Engages departments external to manufacturing to a greater extent, such as automation engineering</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
7. TRAINING ASSIGNMENT STRUCTURE

The key in structuring training assignments in a meaningful way for manufacturing operators is to make the link clear between what task or activity is being performed and what training is required. Also, since operators are often required to be qualified to perform a large collection of tasks, it is also considered a best practice to have these assigned in a manner that matches an operator’s typical training progression.

If training plans are created in the form of a single list, depending on the job, this may be several pages long. This particular structure makes it impossible for employees to accurately identify what training is crucial to their qualification, i.e. critical knowledge they must have in order to carry out their daily work. The end result is that employees, particularly those who are new, are frequently unable to make clear distinctions between critical and non-critical training, which may potentially, as is our concern, result in the mastery of neither.

Figure 5 depicts a logical training assignment structure that supports a competency based model.

Figure 6 provides guidance for the level of training required and type of training material to be developed for each assignment. Starting with the outermost ring, the area ‘Know About’, indicates training that an employee must be assigned but not necessarily know about in absolute detail. In essence, they must know the basics, understand the purpose, and be able to locate further information when needed. The second ring ‘Be Trained On’, indicates training that must be mastered in more detail, i.e. to be trained to a certain degree, to be able to understand and perform basic tasks, but not in quite as much detail as the final ring. In this final, innermost ‘Be Qualified On’ ring, the employee is expected to be qualified on this training in absolute detail and be able to display complete mastery of the specific job task or function.

Figure 5. Training Assignment Structure to support a competence based model.

Figure 6. Considerations for types of training assignments.
8. LEARNING MANAGEMENT SYSTEM (LMS) REQUIREMENTS TO ENABLE EFFECTIVE TRAINING PROCESSES

Learning Management Systems (LMS) are key enablers to provide visibility and control to training requirements, and linkages among inter-related training plans and other training support materials. Current LMS provide significant enhanced functionality that enable formal and informal learning processes, while also supporting advanced graphical reporting and analytics.

For manufacturing operator training in particular, there are several key needs a learning management system should meet in order to provide maximum utility and value. These are listed below.

- CFR 21 Part 11 compliant.
- Intuitive and easy to navigate user interface.
- Easy login process when a kiosk or shared computer / device is used.
- Ability to group training of various types into a plan that the system presents to the end-user in a simple and easy to interpret manner.
- Ability to prioritize learning and/or assign segments of learning based on training progression.
- Automated content updates and revisions when supporting documentation (such as SOPs, etc.) that might appear in a learning plan are changed. (Integration with Document Management System)
- Electronically enabled on-the-job performance assessments (often described as “observation checklists”) that allow for multiple observers and multiple approvals.
- Ability to manage approvers of observation checklists dynamically (based on a rule, such as train-the-trainer qualified and task qualified).
- Ability to conduct observation checklists on an ad-hoc basis (does not require scheduling).
- Graphical reporting that allows supervisors to tell at a glance who is qualified to perform what work.
- Collaboration and other knowledge management tools so general operating experience can be easily shared and stored (such as is described in section 6.2.5).
- Flexibility in security roles so that manufacturing training can be administered by a dedicated group.
- Ability to interface with other tools used to manage people and/or documentation.
- Support mobile learning on multiple devices.
- Ability for trainees to provide continuous improvement feedback on courses and training materials.
9. IMPLEMENTATION ROADMAP – TRANSITION TO A COMPETENCE MODEL

Table 2 describes an implementation roadmap to make a transition to a training for competence model. Activities for each stage along with outputs are provided. This is a significant undertaking and requires the partnership of several groups. Specific ownership for the activities and related approvals will be organization dependent, as training responsibilities are structured differently at different organizations. As an example, training material approval may be able to be performed by a central training unit, whereas in some organizations, it may be desirable or required to have the materials approved by Quality.

An additional important aspect of this model not yet explicitly discussed is the required competence of the supporting trainers, supervisors and managers. All play crucial roles in the success of a training for competence model.

- Trainers – need to be taught and evaluated against effective on-the-job training practices. Trainers also need to be internally qualified as trainers and need to keep their task qualifications current.
- Supervisors – need to reinforce the importance of technical learning and allocate time for training and learning as part of normal operations. Supervisors also have responsibility to observe their staff during work and provide coaching to performance standards.
- Managers – need to reinforce the importance of technical learning and ensure the training for competence model is executed and maintained as intended.

This roadmap describes activities through implementation. Following implementation, the new training system would need to be periodically evaluated, audited and continuously improved.
### Table 2. Implementation roadmap.

<table>
<thead>
<tr>
<th>COMMUNICATION AND ENROLMENT</th>
<th>ACTIVITIES</th>
<th>OUTPUTS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Identify impacted stakeholders</td>
<td>Broad agreement for change in training focus</td>
</tr>
<tr>
<td></td>
<td>Determine how each stakeholder is impacted</td>
<td>Broad awareness of change across impacted</td>
</tr>
<tr>
<td></td>
<td>Have dialog with impacted stakeholders to gain</td>
<td>groups</td>
</tr>
<tr>
<td></td>
<td>buy-in and support for the transition</td>
<td>Summarized stakeholder needs and concerns</td>
</tr>
<tr>
<td></td>
<td>Identify the effort required</td>
<td>Agreement to proceed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CREATE TASK STRUCTURE FOR TRAINING</th>
<th>ACTIVITIES</th>
<th>OUTPUTS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Identify manufacturing unit operations and their</td>
<td>Map of task-based training structure</td>
</tr>
<tr>
<td></td>
<td>underlying tasks</td>
<td>Relationship map of performance to training</td>
</tr>
<tr>
<td></td>
<td>Identify associations – which documents to perform are</td>
<td>documents / materials</td>
</tr>
<tr>
<td></td>
<td>utilized for each task</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DEFINE DETAILED TRAINING PROCESSES</th>
<th>ACTIVITIES</th>
<th>OUTPUTS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Identify specific training activities in alignment with</td>
<td>Plan for training materials that need to be</td>
</tr>
<tr>
<td></td>
<td>Figure 2</td>
<td>developed to support the new model</td>
</tr>
<tr>
<td></td>
<td>Determine how to structure training in LMS</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DEVELOP TRAINING MATERIALS</th>
<th>ACTIVITIES</th>
<th>OUTPUTS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Create training materials</td>
<td>Approved training materials for each</td>
</tr>
<tr>
<td></td>
<td></td>
<td>component of the new training structure</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IMPLEMENT</th>
<th>ACTIVITIES</th>
<th>OUTPUTS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Modify learning management system to incorporate new</td>
<td>Assigned training plans and materials</td>
</tr>
<tr>
<td></td>
<td>training materials</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Modify training plans, curricula and assignments based</td>
<td>Document / procedures reflect new training</td>
</tr>
<tr>
<td></td>
<td>on new structure</td>
<td>approach</td>
</tr>
<tr>
<td></td>
<td>Conduct change awareness and training sessions with</td>
<td></td>
</tr>
<tr>
<td></td>
<td>impacted stakeholder groups</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Update document management system as applicable</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Revise impacted documents</td>
<td></td>
</tr>
</tbody>
</table>
10. WAYS TO MEASURE THE RETURN

An effective training for competence model requires a greater investment than a typical training for compliance model. A question that may be raised is how to justify this investment, and how to measure whether the expected return is achieved. Measuring the return on training investments is a challenge, as many benefits are not easily quantified. Training and learning contribute to overall business performance result measurements.

It is not suggested to measure deviation rate reductions or human error rate reductions as a measure of effectiveness of the training program. Rather, the level of competence before and after program implementation could be measured, such as through pre and post-learning event assessments. Surveys could also be utilized to capture whether operators believe their ability to perform their jobs effectively increased following implementation. Another possible measurement is to quantify the number of operational near misses that were caught as a result of an increased level of technical competence. There are also possible efficiency metrics that can be calculated, as a shift to a training for competence model will often significantly reduce the overall training burden for operators through the elimination of read & understand training. Measurements to evaluate the return of a training for competence model should be established based on the specific performance results expected at the implementing organization.

11. CONCLUSION

This paper outlines the rationale for a training for competency approach and provides guidance for how to make this a reality in a biotech manufacturing environment. Benefits to a competency based approach are clear, as it naturally focuses on learning and providing assurance that when faced with the complexities of day-to-day work, operators are prepared to perform and adapt.

It also opens doors for learning to include the full range of system, behavioral and cultural elements that are impactful to success. Compliance requirements can be met in a variety of ways – organizations have the opportunity to define what this means. This paper outlines a pathway to a new interpretation of what it means to be qualified. Qualification is not being able to produce a report that shows that an operator completed training. Rather, qualification is demonstrating an ability to perform.
12. REFERENCES

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3  Kurt Lewin, 1943 – USA “T-Bones steaks”