QUDOS
For a quality future

Learning Effectiveness Framework

Product Development Quality (PDQ) Training

This document provides a comprehensive plan for evaluating the effectiveness of training and learning interventions within PDQ.

Learning Effectiveness Framework

Product Development Quality (PDQ) Training

Goals

Quality Management System (QMS), QUDOS and procedural training aims to result in several outcomes:

- Increased compliance with regulatory authority requirements and standard operating procedures (SOPs)
- Improved quality of patient outcomes
- Better efficiency in executing regulated activities

PDQ Training supports these goals by designing learning events and providing information about the results.

Scope

PDQ Training assesses effectiveness at two points:

1. Completion of training
   - **Training satisfaction** – participants complete a survey regarding the relevance, level of engagement in training and motivation to apply the new skills on the job.
   - **Qualification** – participants must achieve 80% on a skill and knowledge test to "qualify" on the procedure.
   - **Compliance** –completion status will be tracked.
2. 30 and 60 days following training
   - **On-the-job adoption** – participants indicate whether they have had the opportunity and whether they have applied *key practices*.

This Plan describes how PDQ Training will provide information about the results and outcomes of training.

Focus of Learning Effectiveness

For the purposes of PDQ Training, learning effectiveness is the degree to which training results in *a consistent base of applied knowledge and skill*. There are three parts:

- Are participants motivated to try out what they learn? ("Like")
- Did they learn the key concepts and skills? ("Learn")
- Are they applying key practices on the job? ("Leverage")

"Like," "Learn" and "Leverage" are all necessary to achieve compliance.

Contents

Learning Effectiveness and the Implementation Process

Learning fits into the landscape of implementing new practices and behaviors. Discovering best practices, breaking old habits and ingraining new ones is very challenging. In this context, what is learning effectiveness? PDQ Training defines learning effectiveness as:

1. Training itself is relevant to participants' roles, engaging and motivational
2. Participants achieve the expected level of expertise through training
3. Participants apply certain key practices on the job
4. Business processes achieve a target level of quality (beyond the scope of PDQ Training)

The implementation effort typically consists of eight major steps, aligned with effectiveness indicators.

Implementation Step	**Effectiveness Assessment**
1. Define the *goals* of the program, procedure, system or change	
2. Define the desired impact of the program on *individual outcomes,* responsibilities and behaviors	
3. Plan for the change – implementation Plan, Training Alignment Plan	
4. *Assign responsibilities* and qualification requirements	
5. *Qualify* on the program, procedure, system or change	■ Training satisfaction survey ■ Skills and knowledge qualification ■ Training compliance metrics
6. *Apply* new practices on the job	■ Key practice application assessment
7. *Monitor* progress against goals at the individual, unit and organization levels	■ Business process quality metrics ■ Audit findings
8. *Modify* implementation and training plans	

The effectiveness of any step builds on the previous steps. For example, changes, procedures or new systems must be understood at the level of individual outcomes, responsibilities and behaviors for training to be effective.

Training Satisfaction

PDQ Training assesses training satisfaction immediately following training using a voluntary, online survey. The survey assesses whether the course or module itself is relevant to participants' roles, engaging and motivational. A Training Satisfaction dashboard compares results to a baseline.

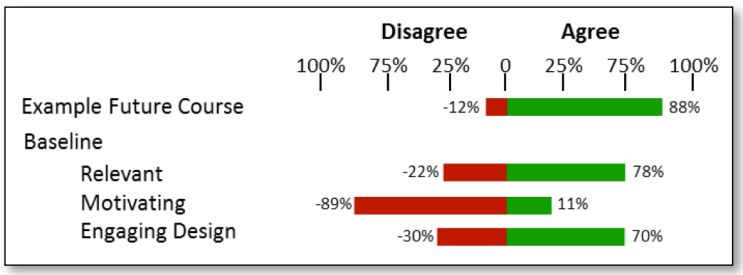
Baseline

In July 2013, PDQ Training commissioned a PD Training Compliance Survey. 276 people responded worldwide (GMA, PDB, PDS, PDG, PDG-CCO, PDP, PDQ, PDR, Affiliates).

Overall results showed general acceptance of the need for compliance training, but concern about relevance, time required, lack of value and tedium.

When mandatory training has been assigned to me, the following thoughts come to mind		
Option	Count	Percent
1. A great learning experience	37	13.7
2. A waste of my time	38	14.0
3. I already have too much training	79	**29.2**
4. I have to do it. It is a goal and will affect my bonus	86	**31.7**
5. I know I have to complete it but I won't learn anything	77	**28.4**
6. My line manager does not care so why should I	3	1.1
7. Not relevant to my job	80	**29.5**
8. Something I look forward to doing	23	8.5
9. Technically difficult to access	29	10.7
10. This is going to be boring	90	**33.2**
11. This training is needed for me to be able to do my job	169	**62.4**

We grouped numerical and content responses into three categories to create a baseline. The chart at right shows an example future course (fictitious data) and the baseline with data from the PD Training Compliance Survey.



The three factors are measured by eight survey questions:

Relevance

- The knowledge and skills that I learned are either frequently useful or critical to my role.
- The examples, cases and exercises were realistic and sufficient to put the procedural document into practice.
- This training was needed to learn the required skills and knowledge to comply with the procedure.

Motivating

- I am confident that I can put this procedural document into practice as intended.

- This training provided me with new and/or valuable insights about quality and compliance in this area.

Engaging Design

- The materials were concise, clear and well organized.
- The course content (video, graphics, text) kept me engaged.
- The amount of time given and the pacing of the material was appropriate to learn the knowledge and skills required to comply with the procedural document in my role.

See Appendix A for the survey questions for both procedural and non-procedural courses.

Satisfaction Scorecard

Each course has a satisfaction scorecard posted on the PDQ Learning Portal showing the scorecard for the course. The scorecard is updated quarterly during the life of the course.

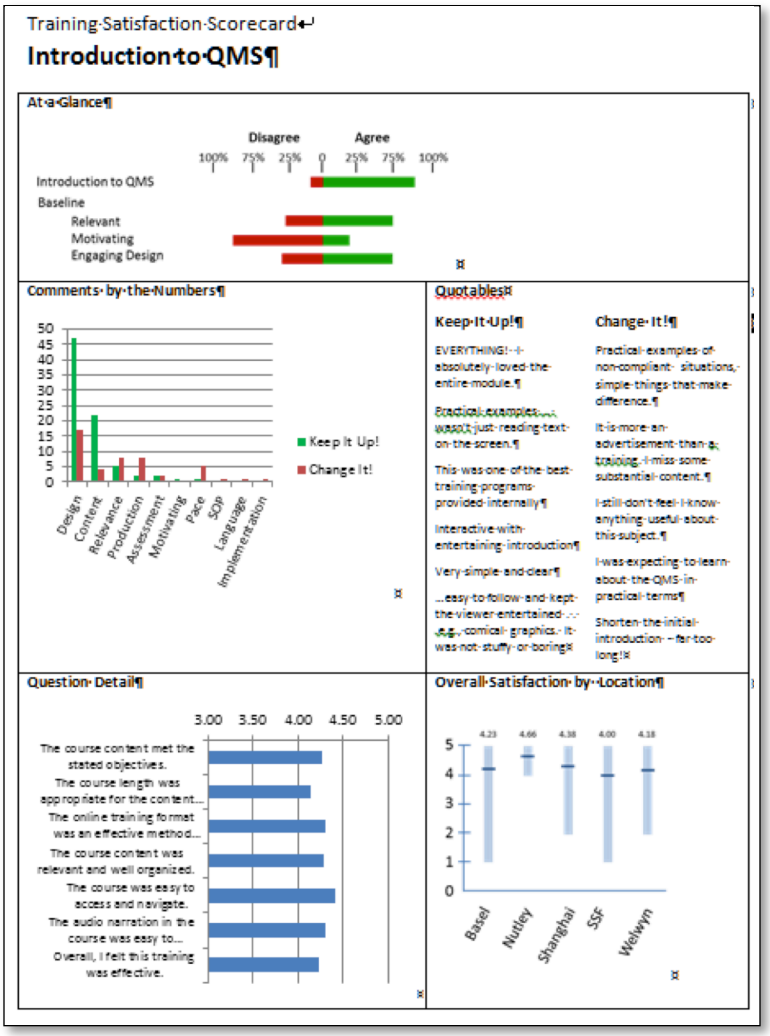
At-a-Glance shows the course compared to baseline

Comments by the Numbers displays a Pareto analysis of the comments.

Quotables lists typical positive and corrective comments.

Question Detail displays results for each question.

Overall Satisfaction by Location compares overall ranges by location.



Data Collection

Data will be collected via online survey (SurveyMonkey) set up for each course before it is published.

Qualification Assessment

Qualification assessment ensures that participants achieve an expected level of expertise through training.

Method

At the end of each course, participants take a quiz to qualify on the procedure or pass the course. The quiz consists of at least 5 questions drawn from the procedure (if applicable) and the training material. Participants must achieve 80% to pass.

Questions assess each learning objective at the appropriate skill level

- **Recall** – Remember a concept or fact from the training or procedure, for example who is responsible for which tasks, the sequence of tasks, requirements, etc.
- **Comprehension** – Put in your own words, recognize an example, distinguish between related concepts or other indications that the participant understands a concept, process, responsibility or rule.
- **Ability to apply** – Accurately recognize compliance risks in a realistic scenario and recommend ways to prevent or mitigate the risk.

Each qualification assessment for procedural training must contain at least one scenario and two application-level questions.

Instructional designers, in collaboration with the assigned subject matter expert, are responsible to define learning objectives and create assessment questions. They create a pool of questions so that if a participant does not achieve 80% correct the first time, they will be presented with different questions on subsequent quizzes.

See the guidelines for writing assessment questions in Appendix B.

Report

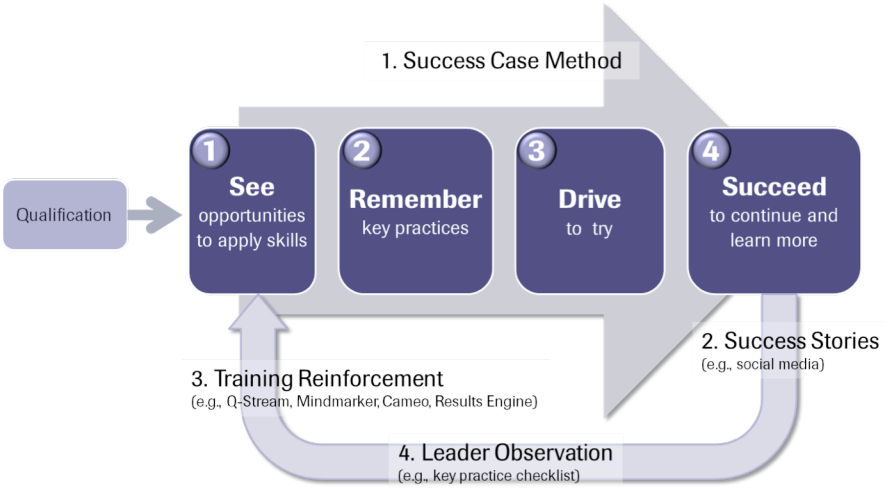
See the following page for reporting of qualification results together with training completions.

On-the-Job Adoption of Key Practices

Assessment of adoption on the job applies only to procedural training.

For learning to be effective, skills and knowledge cannot remain latent potential. Skills and knowledge must be applied at the right time in an appropriate way. Many times, people will apply a new skill or concept if they have the intention to do so. Other times, habits must be broken, changed and re-formed for a new practice to take root.

Learning is part of this landscape. But several "disruptions" in everyday tasks are usually required, as shown in this figure.



1. Success Case Method

At 30 and 60 days following training completion, participants receive an online survey concerning key practices from the procedure. Key practices are indicator tasks pulled from the SOP that are likely to happen frequently and indicate whether other practices will be implemented.

Participants are asked whether:

- This practice is relevant to their job.
- They have had the opportunity to use it yet.
- They tried it but can't yet point to positive results.
- They tried it and it led to positive results.

See Appendix C for a survey and impact report templates.

Responses are randomized. A sample of positive (practice tried) and negative (practice not attempted) is contacted briefly for follow up.

Results are compiled into a training impact report for the course.

Implementation Steps

Task	R	A	C	I	Completion
Agree on key practices	ID	BPO			
Create survey (from template)	ID	TM			
Send survey to all participants at 30 and 60 days	TC	ID			
Sample the participants by organization, location, SOP	ID	TM	BPO		
Conduct follow-up phone interviews with sample (using 7 min protocol)	ID	TM			
Compile responses into an impact report (using template)	ID	TM			

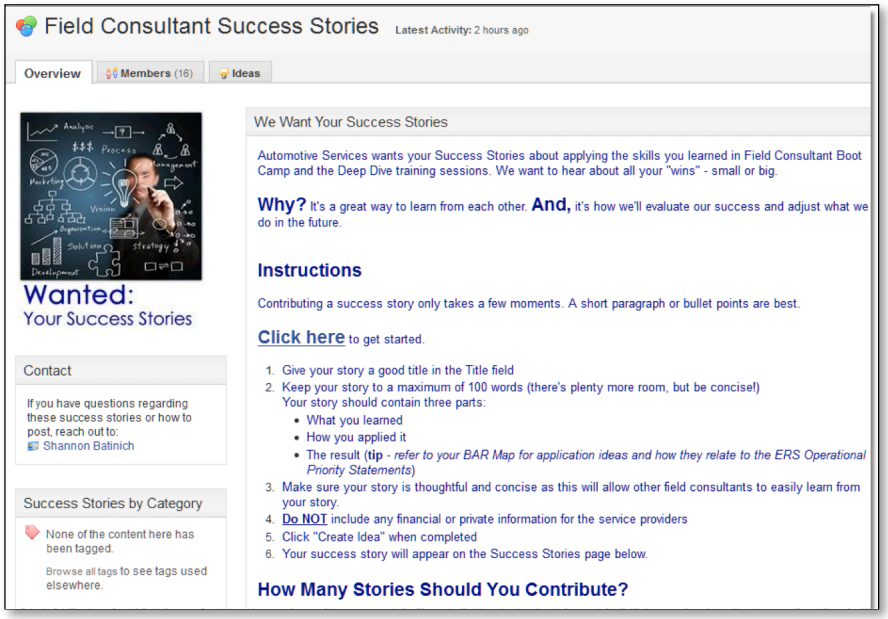
2. Success Stories

Success stories create recognition for participants who have achieved good results practicing what they've learned in training. Participants post stories directly on an "idea" page in the PDQ web portal.

Success Stories are short, fast and easy to write. They have three elements:

- What they learned
- How they applied it
- Result they got

Other participants can vote on stories they find useful so stories are sorted by usefulness. Stories can also be categorized and browsed by category.



Implementation Steps

Task	R	A	C	I	Completion
Align with QUDOS project leadership	TM	PDQ			
Determine web tool	ID	TM			
Develop and author web page	TC	ID			
Gather "starter set" of success stories via interview and post	TC ID	BPO			
Release, announce, showcase the site	ID	TM			

3. Leader Observation

Leader observation will happen whether or not it is structured. To make the data comparable and more objective, observation should be structured using a checklist or "rubric" of key practices. This checklist is the same as the Success Case Method survey questionnaire.

Checklist

Implementation Steps

Task	R	A	C	I	Completion
Align plan with QUDOS project leadership and BPOs	TM	PDQ BPO			
Identify leaders to observe for the SOP	BPO	PDQ			
Train the leaders on the checklist and data collection process	ID	TM			
Gather observations (completed checklists)	O	BPO			
Collect observations at 30 and 60 days. Compare observations. Publish report.	ID	TM			

4. Training Reinforcement

Two SOPs will be selected on a pilot basis for training reinforcement. The purpose of this pilot is to establish value for pull-through activities following training.

A random sample of the training audience will be selected for the two SOPs. The sample will be divided into an experimental group and a control. The total number of participants will be about 100.

Control Group

The control group will participate in the Success Case Method, success stories and leader observation only.

Training Reinforcement Group

Approximately 6 weeks of scenario-based questions will be developed for each SOP in multiple choice/multiple response format. Scenarios will be additional to the qualification assessment.

Using Mindmarker or Q-Stream,

Appendix 1. Training Satisfaction Surveys

Survey for Procedural Training

SOP-123456 V1.0 – Title Here

3. Please review the questions below and select the best response.

	Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree
The knowledge and skills that I learned are either frequently useful or critical to my role.					
I am confident that I can put this procedural document into practice as intended.					
The materials were concise, clear and well organized.					
The examples, cases and exercises were realistic and sufficient to put the procedural document into practice.					
The course content (video, graphics, text) kept me engaged.					
The amount of time given and the pacing of the material was appropriate to learn the knowledge and skills required to comply with the procedural document in my role.					
This training provided me with new and/or valuable insights about quality and compliance in this area.					
This training was needed to learn the required skills and knowledge to comply with the procedure. Simply reading the procedural document by itself is NOT enough.					

4. What did you like about the course?

5. What changes would you recommend to improve this course?

Survey for Non-Procedural Training

Course Evaluation

Please take a few minutes to help us make this course better. As context, think about how you will be able to put the knowledge and skill you learned into practice in your role.

Thank you in advance!

1. What is your Organization

Other (please specify)

2. Where is your office located?

Other (please specify)

3. Please review the questions below and select the best response.

	Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree
The knowledge and skills that I learned are either frequently useful or critical to my role.					
I am confident that I can put the course content into practice as intended.					
The materials were concise, clear and well organized.					
The examples, cases and exercises were realistic and sufficient to put the course content into practice.					
The course content (video, graphics, text) kept me engaged.					
The amount of time given and the pacing of the material was appropriate to learn the knowledge and skills required to comply with the course content in my role.					
This training provided me with new and/or valuable insights about quality and compliance in this area.					

4. What did you like about the course?

5. What changes would you recommend to improve this course?

Appendix 2. Guidelines for Skill & Knowledge Assessment

The purpose of the skill and knowledge assessment is to promote the development of the learner. It determines whether the desired behavior changes have occurred following the training activities. It also performs this by evaluating the learner's ability to accomplish the learning objectives. The following document provides guidelines for writing skill and knowledge assessments. Prior to writing your assessment, please read the following guidelines

General Guidelines FOR WRITING QUESTIONS

- **Number of questions**. Skill & knowledge assessments should have as many questions as required to assess competence on the objectives.
    - A single assessment must have a minimum of **5** questions.
    - There is no upper limit on the number of questions. Ideally the number of assessment questions should be in multiples of 5 (for example, 5, 10, 15).
- **Assessment pool**. You must create a pool of questions so that the learning software (Captivate, Storyline) can draw questions at random.
    - A pool allows participants to take the assessment multiple times without seeing exactly the same questions in the same order.
    - The number of questions needed in the pool is double the number needed to display on one assessment. For example, if the number of questions to display on an assessment is 5, you will need two pools of five questions. If your skill and knowledge assessment will display 10 questions, you will need two pools of ten questions.
- **Scope of questions**. Questions should cover the content in the SOP and the course. The questions should not cover supplemental information outside of course materials.
- **Assess learning objectives**. There should be at least two assessment questions in the pool for each major learning objective. This ensures that each major objective will be assessed when questions are drawn at random from the pool.
- **Cover learning levels**. Questions should assess the learning level of the objective to which it applies. Identify the learning level of the objective to ensure questions are written to that level. For example:
    - **Knowledge**-level objectives: The question should assess recall or recognition of definitions, facts, lists or sequences.
    - **Comprehension**-level objectives: If the objective is to “describe” a process, questions should assess whether a participant can interpret the process, distinguish between examples and non-examples, classifying, summarizing, comparing or explaining.
    - **Application**-level objectives: Most courses aim for application of a policy, procedure or skill. The assessment pool should have at least two questions that assess the participants’ ability to apply a skill. Application-level questions should present scenarios or problems for participants to show or simulate a job-related action or decision.

- **Types of questions**. We recommend you write the following types of questions. Templates exist for each of these question types.
    - Multiple choice (one answer).
    - Multiple response (more than one answer).
    - Matching or sequencing.
    - Fill in the blank.
    - We do not recommend True/False. As they are easy to guess, if you must include a True or False question, only include 1 in the assessment.

WRITING MULTIPLE CHOICE QUESTIONS

- Aim for 4 – 6 choices total (which includes correct answers and distractors).
- You can use 2 distractors (wrong choices) if you cannot create a credible 3th distractor.
- For multiple choice (single answer) questions use 'Select the best answer.'
- Place as much wording as possible in the stem [the question], rather than in the choices.
- Write the stem [the question] as a question, not an incomplete sentence.
- Avoid absolute terms such as *all, always, never*, and *only*.
- Avoid "*All of the above"* & "*None of the above,"* "a and b" as options. Instead, use the "multiple response" question type.
- Word the stem positively; avoid negatives such as "not" or "except." If negative words must be used, use the negative word cautiously and capitalize and bold it [e.g., **NOT**, **NO**, **NONE**]
- Cautiously use imprecise probability terms such as *often*, *frequently*, *rarely*, and *occasionally.*
- For "multiple response" (more than one answer) questions, do not use "*Choose all that apply."* Instead state the number of choices that are needed to supply a complete answer. For example: "Select two answers." Ensure there are an equal amount of correct answers and distractors. For example, if the question says select 3 answers. You would have 6 total choices. Doing this ensures a consistent level of difficulty.
- Refer to the assessment checklist for a summary of question-writing do's and don't's (see page 3).

ASSESSMENT CHECKLIST

	1. Avoid True/False questions.
	2. Question types besides multiple choice (multiple response, drag and drop, matching, fill the blank) are used when relevant and meaningful.
	3. All questions directly relate to the trainee's job tasks and performance.
	4. Each course that aims for applying a skill or procedure should have at least two application-level questions in the assessment pool.
	5. Determine the number of questions for an objective based on "frequency" and "criticality." For example, the more frequent or critical the job task, the more assessment questions to create.
	6. Each question tests the right Bloom level of each learning objective Refer to the Verb List.
	7. Ensure there are an equal amount of correct answers and distractors.
	8. Ensure assessment questions follow the rules of valid question writing: ▪ One piece of Information per question ▪ All information should appear in the stem ▪ Answer choices should be grammatically parallel ▪ Do not use double negatives ▪ Avoid "All of the above" (use multiple response questions instead) ▪ If there is a logical order, arrange choices in logical order (and indicate sequence on the storyboard template) ▪ Correct choice and distractors should be of the same length ▪ All choices should be in subject/verb agreement with the stem ▪ All choices must be plausible
	9. Test the assessment with a SME to ensure that an 80% score shows the learner has mastered the content.
	10. Set the level of question difficulty so that a novice is likely to reach an 80% score after taking the course.
	11. Each question has feedback for both correct and incorrect responses.
	12. Correct and wrong answers have a reference back to the material to support the answer.

Appendix 3. Guidelines for Assessing Application on the Job (Level 3)