

## Medical device training validation audit worksheet

### *Is your training verified, validated, or just completed?*

**Purpose:** Use this worksheet to review one medical device training program and identify whether it is internally aligned, connected to real-world outcomes, or relying too heavily on completion data.

**How to use it:** Choose one training program. Complete the snapshot first, then rate each verification and validation item using the 4-point scale. Use the gap analysis and next-best-action section to decide what should be improved first.

### Rating scale

1 = Not yet	2 = Weakly	3 = Mostly	4 = Clearly
Not present or not defined.	Present only in a limited or inconsistent way.	Mostly present, but could be clearer or stronger.	Clearly present, documented, and useful.

### Training program snapshot

Complete this section before rating the course. The goal is to name the training and the result it is supposed to support.

Field	Response
Training name	
Device or product	
Target users	
Primary training purpose	
Required user behavior after training	
Current evaluation method	
Current completion or pass requirement	
Primary business outcome expected	

### Verification check: Did we build the training right?

**Verification** focuses on internal alignment: objectives, content, methods, practice, resources, and evaluation. A verified course can show that the pieces fit together and support the stated purpose.

Item	Rating	Notes or evidence
The learning objectives describe what users must be able to do after training.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
The content directly supports the stated objectives.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
The practice activities prepare users for realistic device-use situations.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
The post-test or knowledge check measures the stated objectives.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
The course includes realistic examples, scenarios, or decisions users are likely to face.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
The course materials are accurate, complete, and consistent across slides, manuals, job aids, and evaluation tools.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
The course can show documented alignment between objectives, content, practice, and evaluation.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	

**Verification score:** \_\_\_\_\_ out of 28

### Validation check: Did the training get the right result?

**Validation** focuses on real-world impact: performance, safety, adoption, support issues, customer success, and business outcomes. Medical device training validation looks for evidence that training changed something that matters after users returned to practice.

Item	Rating	Notes or evidence
We know what users should do differently after training.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
We have identified the errors, workarounds, or support issues the training is meant to reduce.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
We collect evidence after training that shows whether users are applying what they learned.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
We can tell whether users are using the device more correctly, consistently, or confidently.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
We can tell whether training reduced repeated support questions or common mistakes.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
We can connect training to at least one clinical, operational, adoption, customer success, or revenue-related outcome.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	

We review validation evidence and use it to improve the training.	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	
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Validation score: \_\_\_\_\_ out of 28

### Gap analysis

Use these prompts to identify the difference between what the course can currently prove and what the business, customer, or clinical team actually needs to know.

Prompt	Notes
What can we currently prove about this training?	
What are we assuming but cannot yet prove?	
Where are we relying too heavily on completion, attendance, or test scores?	
What real-world evidence would help us know whether the training worked?	
What business or customer outcome does this training need to support?	

### 5. Score interpretation

Pattern	What it may mean
Mostly 1s and 2s in verification	The course may not be defensible yet. Start by strengthening alignment among objectives, content, practice, resources, and evaluation.
Mostly 3s and 4s in verification, but 1s and 2s in validation	The course may be well built, but you cannot yet show whether it worked in practice.
Mostly 3s and 4s in both verification and validation	The course is more defensible because it is both internally aligned and connected to real-world outcomes.
High validation claims with weak verification	Be careful. You may be claiming impact without a strong design foundation.

## 6. Next best action

Based on this audit, the next best action is:

- Strengthen course alignment
- Rewrite objectives
- Improve practice activities
- Rebuild the post-test
- Define validation evidence
- Connect training to adoption, safety, customer success, or revenue outcomes
- Conduct a deeper course alignment audit

### Notes for the next revision cycle:


**Soft next step:** Want a second set of eyes on this? A course alignment audit can help identify whether your training is verified, validated, or relying too heavily on completion data.