GetReskilled

Validation Engineer Scenario - Facilitators Debrief Guide

Summary

Over the years, we see graduate validation engineers make the same mistakes mostly due to lack of experience. In response to that, we have tried to identify the more common missteps novices make and develop a decision-making scenario where they can practice making decisions in a fail safe environment.

The Facilitator

Ideally, someone with lots of relevant experience in this area so that they can talk authoritatively and share their experience and war stories from the front line with the class participants.

Subject Matter Experts

Try to bring in people with relevant experience to share with the class towards the end of the debrief.

Length

The session should take approx. 40 to 60 minutes.

Objective

Better prepare graduate validation engineers for their first days/weeks on the job so that they can make better decisions and hit the ground running.

Online Scenario

Assign the online scenario as homework. Encourage the learners to go through the scenario a few different times and explore all the various branches.

Class Debrief

Introduction

1/ Restate the purpose of the session i.e to help them get through the first days/weeks of work and explore the various challenges they may encounter and identity what steps they are going to take to deal with them.

Warm Up

Put the learners into groups of 3 to 4 people and have them ask each other these questions.

- Do you remember your first days on a new job?
- Looking back, what would you have done differently which could have helped you avoid some obvious mistakes?
- Do you think some pointed advice would have helped you avoid those mistakes?
- How would the advice need to have been given to you at that time for you to take heed of it (given your inexperience, enthusiasm and desire to impress and succeed at your new job)?
- How could you have been made more aware at that time of what's happening in the background (relationships between individuals and departments, etc) that could impact you in getting the job done?

Activity 1

Have each group outline (on a flip board or piece paper) the five key pieces of advice or takeaways from the scenario.

1/ Have someone on site show you around and introduce you to other people working there.
2/ Familiarize yourself with the site's GMP and documentation standards before getting started on any test protocols.
3/ Find and confirm the right templates to use for the job.
4/ Familiarize yourself with the responsibility matrix and organization chart to understand who is exactly responsible for what.
5/ Understand the health and safety principles for this site.

Note: Some learners may feel the situations don't sound so realistic or plausible in light of their own training or frame of reference and to be honest, that's a reasonable position to take from an individual perspective. But do bear in mind that cultural and working contexts can vary greatly across different countries, companies and work cultures and all the situations outlined in the scenarios are based on real world observations over many years.

Highlight any vital points or lessons that emerged out of the session.

Activity 2

Have each group brainstorm why it's usually a good idea to follow these pieces of advice and outline some specific and **painful** consequences of not following them.

Some suggestions

1/ Have someone on site show you around and introduce you to other people working there even if you are pressed for time.
Building back channel relationships with those people working on the project/site is crucial for your success and a few hours now spent getting to know people at the start will save you an enormous amount of time later on, as you get deeper into the project

2/ Familiarize yourself with the site's GMP and documentation standards before getting started on any test protocols
Attending an induction course on the site's GMP and documentation standards is essential if you are to correctly document the tests on the validation protocol on items such as data entry, date formats, initial format, signature, etc

3/ Find and confirm the right templates to use for the job
It is critical to double check that you are using the right template for that site and that you use the correct documentation protocols for data entry, date formats, initial format, e.g. do you use your full name; do you get assigned initials on a project, etc? You will need to find out all this information before you start testing.

4/ Familiarize yourself with the responsibility matrix and organization chart to understand who is exactly responsible for what.
This is essential for both on the site and with the contractor as it will help prevent job scope drift and help you make sure that you are working on your own specific tasks from Day-1 (rather than others landing their work on your plate, or the contractor looking to be paid for extra's).

5/ Understand the health and safety principles for this site
It's very important that you have familiarization training on the health and safety principles for this site relating to your validation task.

Have each group share their ideas with the class and highlight any vital points or lessons that emerged.

Activity 3

For each point, have the groups brainstorm some possible challenges to following each piece of advice and identify specific tactics and strategies they could use to overcome these challenges.

Have each group share their ideas with the class and highlight any vital points or lessons that emerged.

Activity 4

Q&A session at the end of the workshop with the subject matter expert.

If you feel the class might be quite reticent, you could have each group come up with a few different questions for the expert/s and you as the facilitator could ask them.

Wrap Up

Emphasize what the groups have learned or accomplished.

Congratulate the class for a job well done and tell them how much you enjoyed their involvement.

Encourage them to act or apply what they have learned on the job.

Ask for feedback and give participants a chance to evaluate the session.