NEW GMP FOR IMPS IN THE EU

Click the Start button to begin! START

CHOOSE YOUR LEARNING PATH!

Regulatory context - Until 31 Jan 2022

Notes:

- Brief Overview: About the regulatory context until Jan 2022. For example, we can include 4-5 multiple-choice or True/False questions related to basic GMP principles or prior knowledge of IMP manufacturing which comes under regulatory context until Jan 2022.
- Target Audience: Would like to revise this regulatory context.

Regulatory context - As from 01 Feb 2022

Notes:

- Detailed Information: About the regulatory context to be effective from Feb 2022.
- Target Audience: Already mastered/aware of the regulatory context until Jan 2022.

OBJECTIVES

By the end of this module, you will be able to:

01

Understand
how the last four regulatory contexts have impacted the development and manufacturing of IMPs in the EU.

02

Gain
a comprehensive understanding of the revised regulatory context

03

Explain
the key changes in the IMP manufacturing regulations (Feb 2022).

04

Identify
the specific areas of your QMS affected by the revised regulations.

05

Develop and implement
a plan to adapt your development QMS to comply with the new regulations.

06

Apply the revised regulations
within your development QMS, ensuring a smooth and compliant transition.

IMP MANUFACTURING REGULATIONS

DID YOU KNOW?

How it all started!

Notes:

- Showcase a timeline depicting the history of the last four regulatory contexts, highlight the difference, the impact it had on IMPs.
- Learners will click each timeline to know how it started and the difference between each regulatory contexts.
- It could be either short videos about each regulatory contexts Or brief description about each regulatory contexts in bullet points Or open a flowchart that gives an overview about each regulatory contexts.
- The last timeline will be the one to be effective from Feb 2022 and it will take the learners to the next screen to cover more in detail. Include the zoom in effect here.

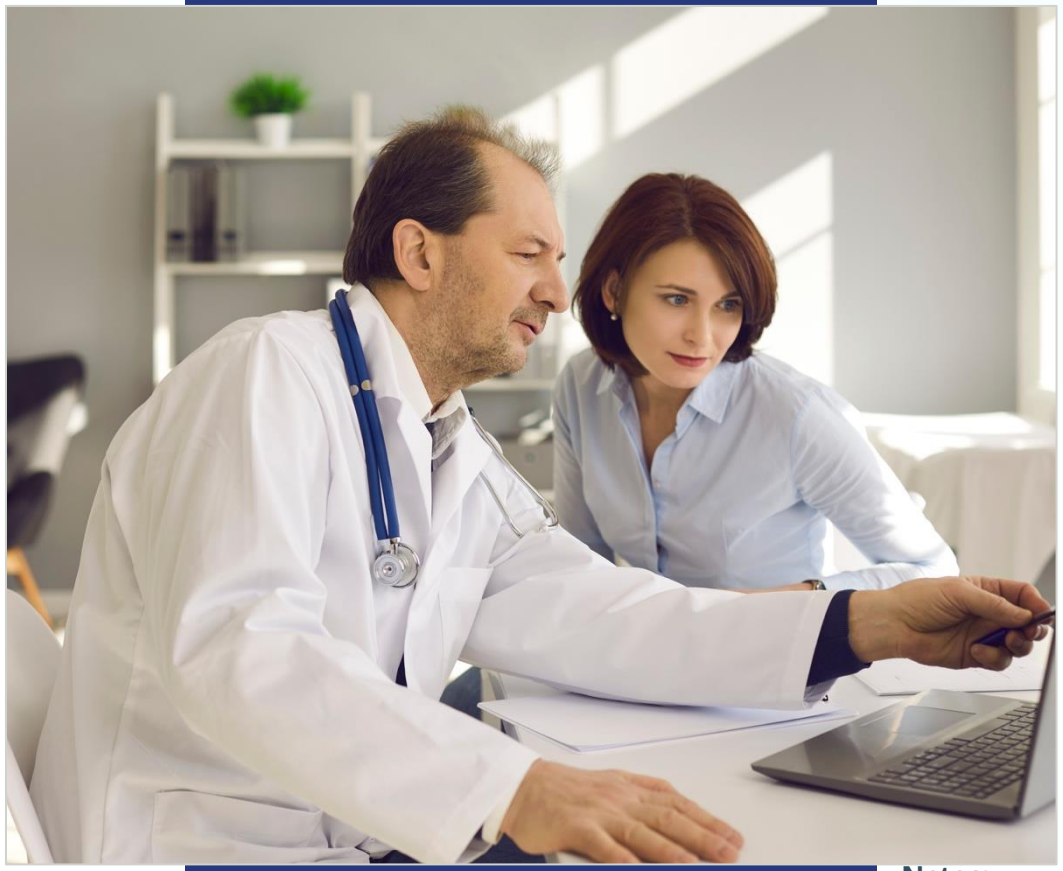
Dr. Sarah

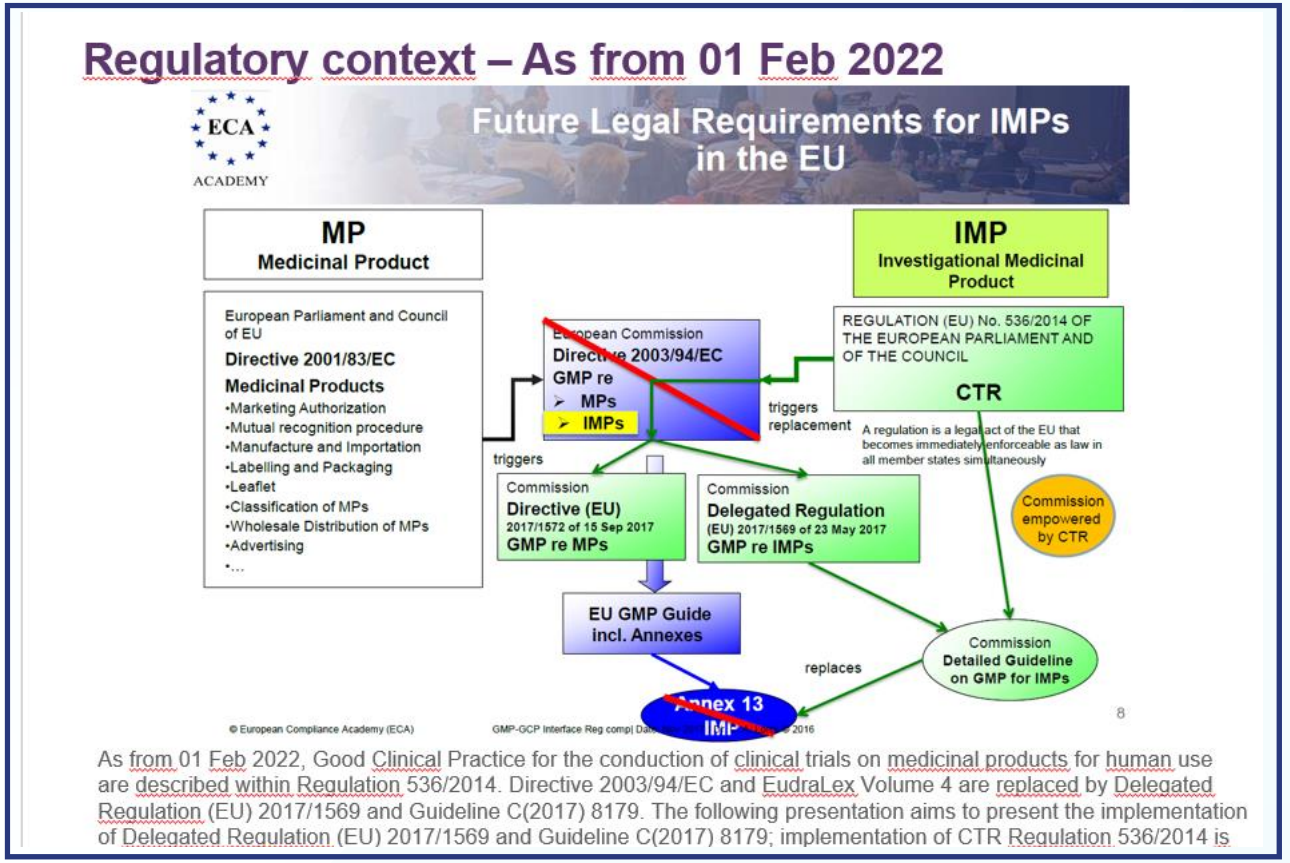
Dr. Pierre

Notes:

- Show 2 researchers - Dr. Sarah is developing a new drug in a lab and tells Dr. Pierre about the challenges she faced for drug approvals under the current regulations (Jan 2022).
- Dr. Pierre mentions about the new regulations coming into effect from Feb 2022.
- Discussion continues on the next screen .

REGULATORY CONTEXT – AS FROM FEB 2022





Notes:

- Split this screen into two parts. On the left side, Dr. Pierre opens the regulations document and both the doctors looking at the screen.
- On the right side, there would be the new regulations page.
- This would be a hotspot activity with clickable elements to explore the different aspects of the new regulations. Add an instructional line for the learners (Click the hotspot to learn more).
- Learners will click on each hotspot to learn more. It shall open a text box with explanation about the respective clicked element.
- P.S: We need to recreate this diagram for better clarity and understanding. Right now it is purely used as a reference to explain the approach.

Dr. Sarah

Dr. Pierre

Notes:

- They both conclude their discussion by discussing - for example, the purpose, how the new regulation is more streamlined, how it would impact their choices, behaviour, challenges at work.

PRACTICE TIME!

Remember, it is not about right or wrong but all about practicing what you've learned.

Imagine you are a working on a new treatment for a rare disease. You've been working tirelessly to get your Investigational Medicinal Product (IMP) approved for clinical trials. However, the current regulatory process feels overwhelming and complex.

1. Based on what you learned about the new IMP regulations, which of the following benefits would most help you get your IMP approved faster and with less hassle?

- [ ] More streamlined and efficient approval process (Most apt. choice)
- [ ] Stricter quality control measures for IMP manufacturing (This is important, but doesn't directly address speeding up approval)
- [ ] Increased focus on post-marketing surveillance (This is important, but not relevant to initial approval)

SUBMIT

Notes:

- This is one example of a scenario-based question that would make the learner analyse and help them efficiently react to a situation like this in their workplace.
- Add layers to show the feedback. The one in the bracket is the feedback that would appear in a separate layer.
- We can create a few more questions to make them feel confident about the content.

IMPLEMENTING NEW REGULATIONS IN QMS

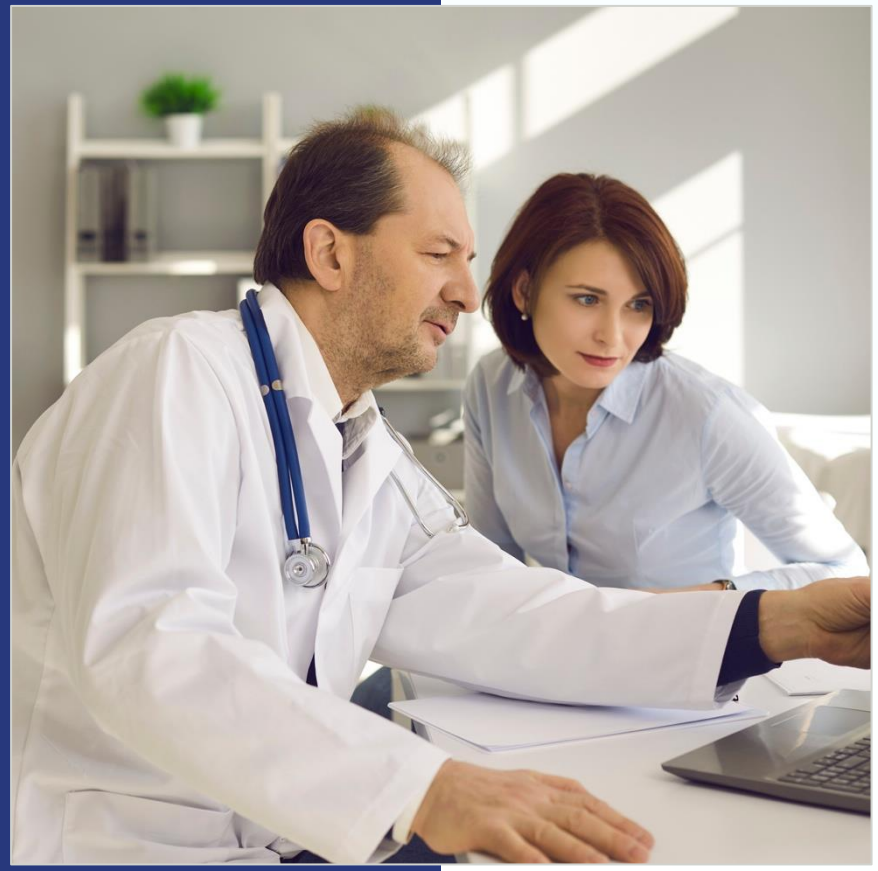
Dr. Sarah

Dr. Pierre

Notes:

- Both the characters are having coffee in the breakroom and start conversing about the new changes and implementing them within their Quality Management System (QMS).
- Dr. Sarah says - Dr. Pierre, these new regulations are a lot to take in but the best part is that it will ultimately improve patient safety and efficiency.
- Dr. Pierre nods and says - Absolutely, Dr. Sarah! Now let's deep dive into the changes we need to implement within our QMS.
- Dr. Sarah - Of course, Dr. Pierre!
- Show the next screen.

CHANGES AND IMPLEMENTATION WITHIN QMS



Notes:

- Split this screen into two parts. On the left side, Dr. Sarah and Dr. Pierre are back at their desk and looking at the screen.
- On the right side, there would be a video about Expiry date must appear on the primary packaging component and New guideline detailing roles and responsibilities between sponsor and manufacturer.
- Add an instructional line for the learners (Click the video button to learn more about the new changes related to expiry dates and sponsor-manufacturer responsibilities).

PRACTICE TIME!

Carefully look at both the images. Which IMP packaging complies with the new regulations? Select the correct one.

Notes:

- Present two images side-by-side:
  - One image of an IMP with a missing expiry date.
  - Another image with the expiry date clearly displayed on the primary packaging.
- This would be a flip card activity. Flipping the card would show the answer along with the feedback.

CHANGES AND IMPLEMENTATION WITHIN QMS

Click each tab to learn more about it!

- PSF Requirements
- Applicable Section of the Product Specification File
- New Retention Period for Documents
- IMP Specificity Training
- Changes are Inherent

Notes:

- This will be a Tab interactivity that can be done using triggers and layers.

Dr. Sarah

Dr. Pierre

Notes:

- Both of them are done reviewing the regulatory expectations to be reflected within their QMS.
- Either of them add a closing line by saying that they need to align on this with their team.
- To which the other one agrees.

LET'S SUM UP!

Check each box to revise and reinforce learning!

- [ ] Statement 1
- [ ] Statement 2
- [ ] Statement 3
- [ ] Statement 4
- [ ] Statement 5
- [ ] Statement 6

Notes:

- This will be an interactive screen wherein checking in the boxes would add a tick mark inside the box.
- Making the learners check each box would gain their attention and involve them in a quick revision.
- Each statement will be aligned with the learning objectives included in the beginning of the module.

ASSESSMENT

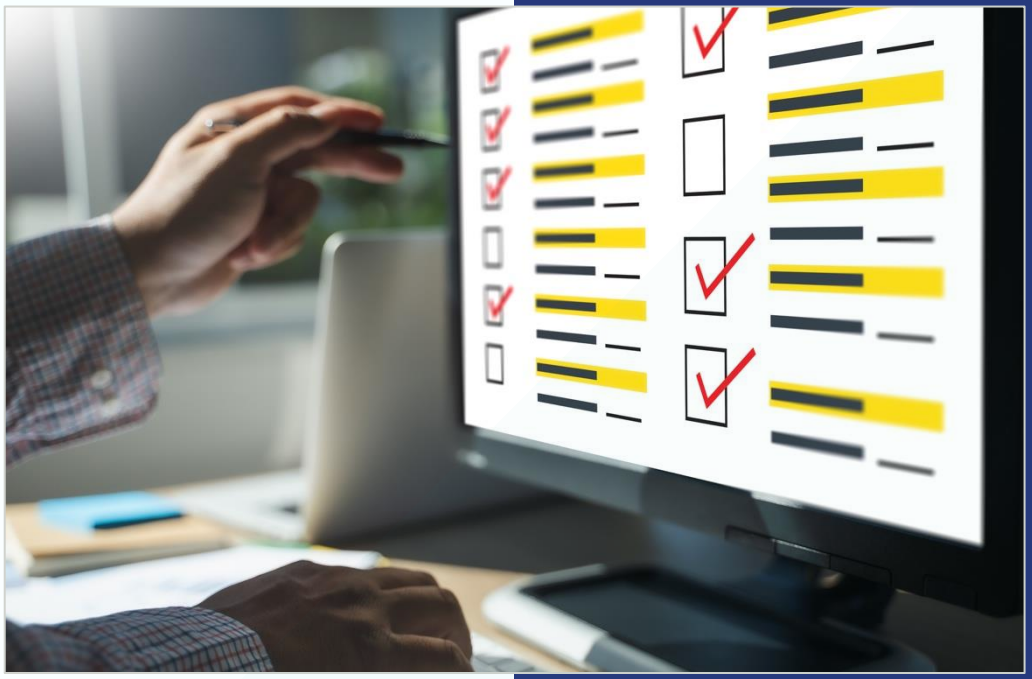
There is no limit of time when answering the questions, but you must reach at least 80% of correct answers to be certified for the training.

You are working on a new cancer treatment and you receive a shipment of IMPs. You notice the expiry date is printed on a separate document, not directly on the packaging.

1. According to the new IMP regulations, this shipment is compliant.

◯ A. True

◯ B. False (Correct)



SUBMIT

Notes:

- Add layers to show the feedback. The one in the bracket is the feedback that would appear in a separate layer.
- Feedback for incorrect answer: The new regulations require the expiry date to be clearly displayed on the primary packaging component of the IMP itself.

ASSESSMENT

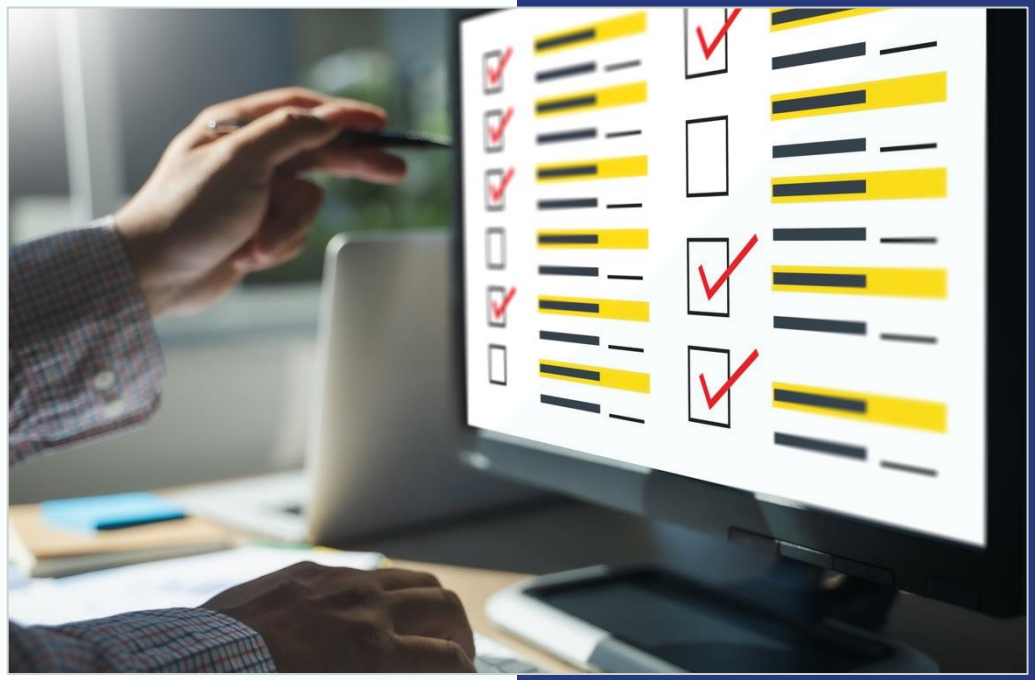
There is no limit of time when answering the questions, but you must reach at least 80% of correct answers to be certified for the training.

A clinical trial coordinator, Ms. Lee, is finalizing the paperwork for a new IMP shipment. She remembers the new regulations require some updates to the Product Specification File (PSF).

2. Which of the following is not required to be included in the PSF according to the updated regulations?

- ◯ A. Manufacturing Procedures
- ◯ B. Applicable sections of the PSF
- ◯ C. Stability Data for the IMP
- ◯ D. Investigator Contact Information (Correct)

SUBMIT



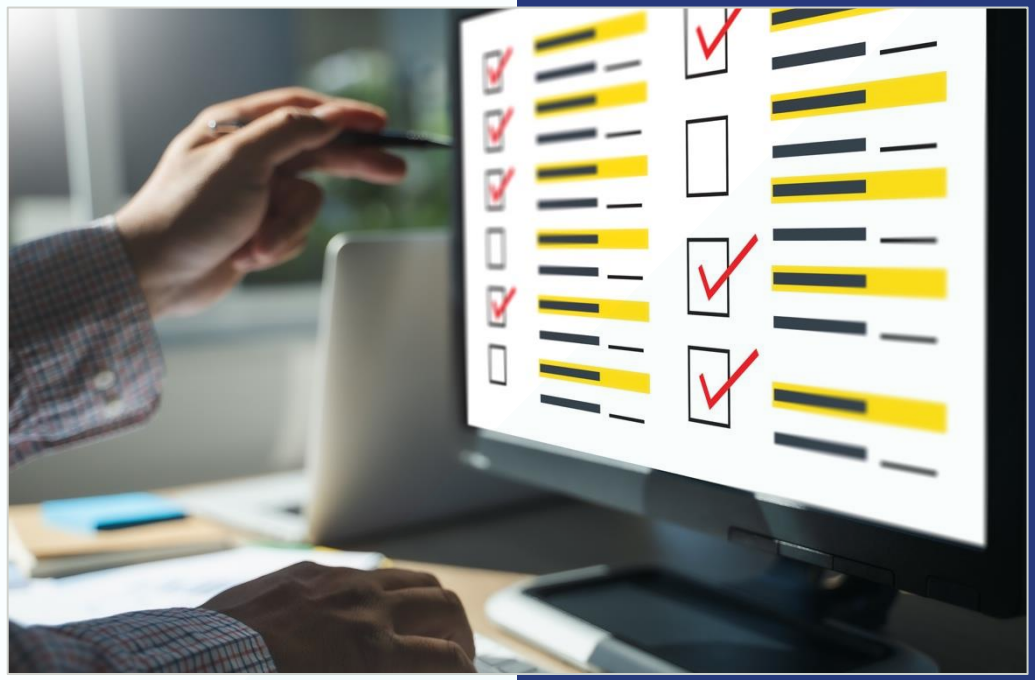
Notes:

- Add layers to show the feedback for incorrect answers. The one in the bracket is the feedback that would appear in a separate layer.
- Feedback for incorrect answer: Investigator contact information, is not a requirement for the PSF itself.

ASSESSMENT

There is no limit of time when answering the questions, but you must reach at least 80% of correct answers to be certified for the training.

You are a quality control officer, reviewing training records for personnel involved in IMP handling.



3. Only personnel directly involved in IMP manufacturing require specific training under the new regulations.

- ◯ A. True
- ◯ B. False (Correct)

SUBMIT

Notes:

- Add layers to show the feedback. The one in the bracket is the feedback that would appear in a separate layer.
- Feedback for incorrect answer: The new regulations require all personnel involved in the IMP lifecycle to receive training specific to these products.

ASSESSMENT

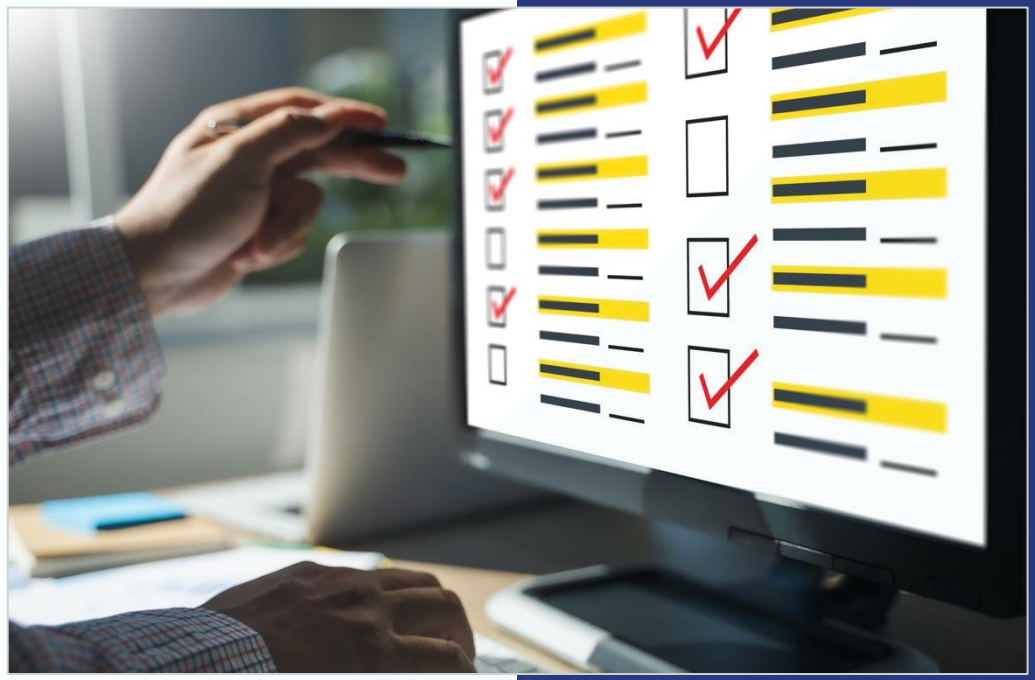
There is no limit of time when answering the questions, but you must reach at least 80% of correct answers to be certified for the training.

The laboratory is planning to modify a step in the manufacturing process for an existing IMP.

4. What is the most important step to take according to the new regulations regarding this change?

- ◯ A. Inform the sponsor of the planned change.
- ◯ B. Document the change and assess its potential impact. (Correct)
- ◯ C. Update the manufacturing logbook.
- ◯ D. Continue with the existing manufacturing process.

SUBMIT



Notes:

- Add layers to show the feedback for incorrect answers.
- Feedback for incorrect answer: While all the options may be involved, documenting the change and assessing its potential impact is the most crucial first step according to the new regulations on change management.

CONGRATULATIONS!

Click the download icon to download your certificate of completion.

Notes:
- Clicking the download button will allow learners download the course completion certificate.
- Clicking the replay button will allow learners to revisit the course.

Click here to revisit the course.