



# Design Option 2

## E2E Audit Process Training

Welcome to your E2E Audit Process course, which will take you about 30 minutes to complete.

The course contains some audio. If you wish to hear the audio, check your system volume levels and use headphones if appropriate. Transcripts are available to replace voiceover.

Select **Start** when you are ready to begin.

**Start**

 30 min



# Introduction

Welcome!

The Pharma Company has had problems with audits in the recent past. That's why you, with your years of audit experience, have been recruited. It will be your job to help understand why the Pharma Company has had issues and implement the corrective actions needed to ensure future success.

With another audit due, the pressure is on!  
Good luck!

Select ► to continue.



Transcript

Before you start your assignment, let's consider the reasons why audits are so important in the pharmaceutical industry.

Select **Play** to find out more or select **Transcript** to read what is being said. Once completed select ➤ to continue.



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important in the pharm

Select **Play** to find out r  
select **Transcript** to rea  
Once completed select

Transcript

Audits ensure regulatory compliance...

...operational efficiency...

...and ethical conduct...

...while fostering investor confidence...

...and public trust.

Let's take a closer look. Pharmaceutical companies operate under strict regulations.

They must follow financial reporting guidelines...

...and comply with healthcare laws. A proper audit helps improve transparency...

...which is crucial in an industry that faces lots of public scrutiny. An audit can reveal where resources are being wasted...

...or where processes could be streamlined. Audits can uncover practices that may be deemed unethical...

Investor  
confidence



# Roles and Responsibilities of the Team

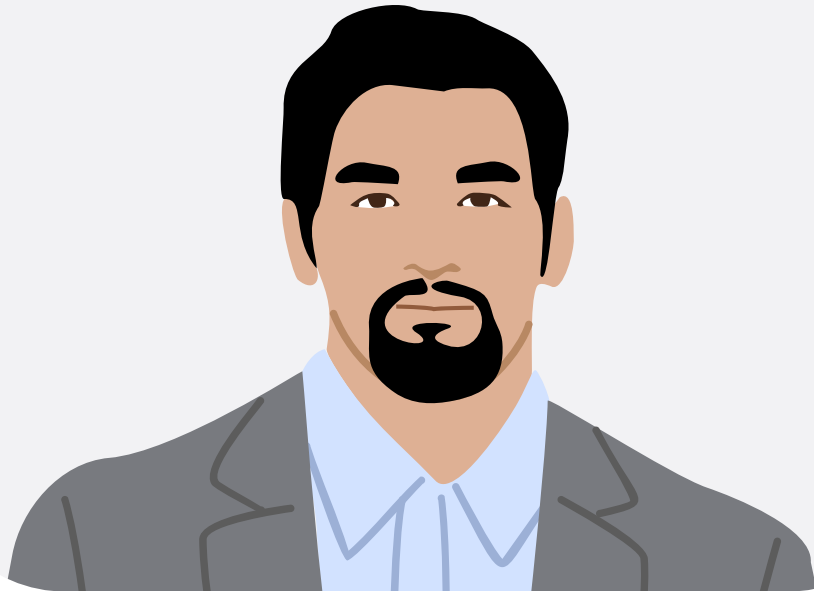
Although you’ve seen many audits in the past, you know that every organization has different needs. That’s why your first task after arriving at the company is to familiarise yourself with the roles and responsibilities of everyone involved in the audit process.

Select each individual to learn more about what they do. Select > to continue.

Auditor



CAPA Coordinator



CAPA Owner



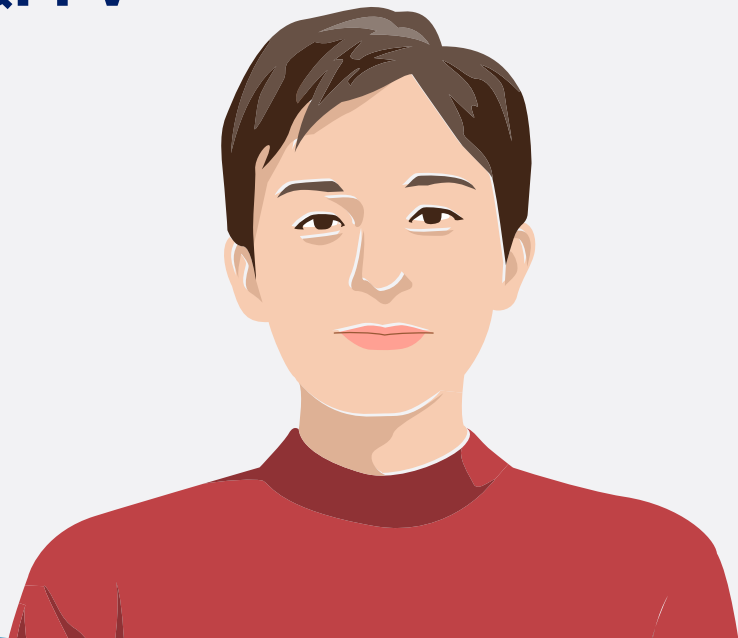
CAPA Plan Approver



QA Approver



QPPV



# Roles and Responsibilities of the Team

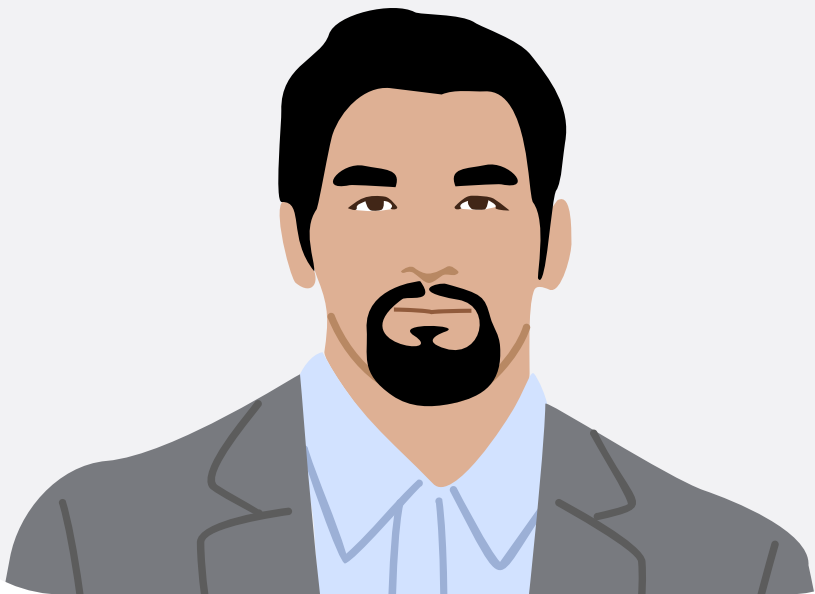
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## Auditor

The person assigned to conduct the audit. They might be an internal certified Novartis auditor or a contracted external auditor.

## CAPA Coordinator



## CAPA Owner



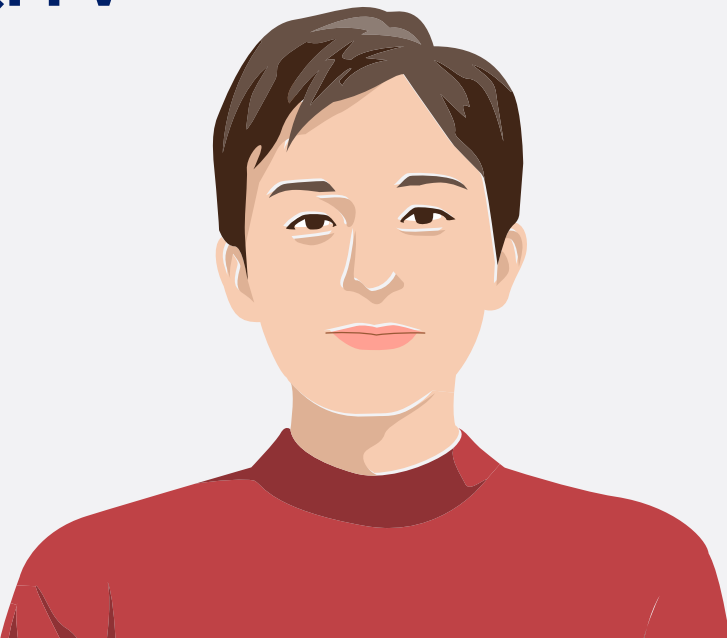
## CAPA Plan Approver



## QA Approver



## QPPV





# The CAPA Coordinator

You sit down with Marco, the CAPA Coordinator, to find out what went wrong in the previous audit. He highlights two key problem areas.

Select **Marco** to find out more. Select ► to continue.





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We failed because our procedures didn't fully meet the regulatory requirements and weren't documented correctly.



# The Best Advice

These are fundamental reasons for failing an audit. You meet with some Pharma Company auditees who believe they have the solution. Whose advice is sound?

Select your answers then **Submit**.

Auditee 1

We need to make sure our Standard Operating Procedures are accurate.

☐

Auditee 2

We need to make sure our data is accessible and up to date.

☐

Auditee 3

We should withhold some of the information they ask for.

☐

Auditee 4

We should delay the audit until we're ready to go.

☐





# The Best Advice

These are fundamental reasons for failing an audit. You meet with some Pharma Company auditees who believe they have the solution. Whose advice is sound?

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**Auditee 1**

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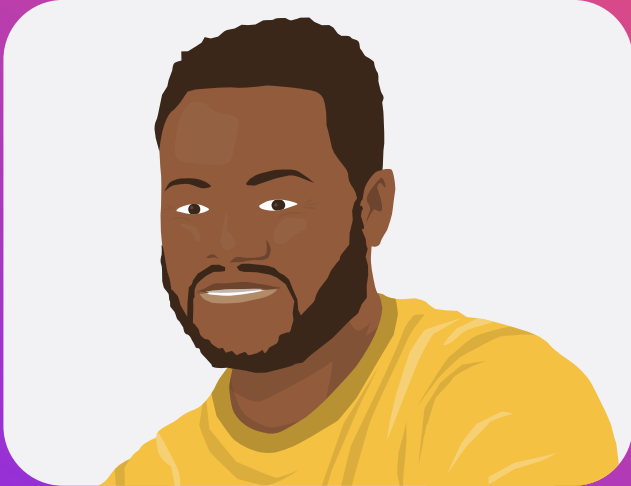
**Auditee 2**

We need to make sure our data is accessible and up to date.





**Auditee 3**

We should withhold some of the information they ask for.



**Auditee 4**

We should delay the audit until we're ready to go.



**That's correct.**

Standard operating Procedures must be accurate, and all data must be accessible and up to date. No documentation should be withheld. Delays go against the two-way spirit of the audit and suggest that there is something to hide.

Select > to continue.



## Be Audit Ready

Always be audit ready – it's one of the best pieces of advice you like to share.

- Request all information ahead of the audit
- Follow the agenda, which provides the cope of the audit
- Know your process
- Familiarise yourself with the relevant Standard Operating Procedures
- Read all documentation before the audit begins

Select ► to continue.

