NOVARTIS

Useful Tips

Before the audit

- Always be audit ready: do not perform any extra work in preparation for the audit
- Ensure documentation is always updated and available
- Always use document naming conventions consistently

During the audit

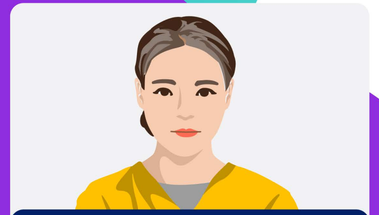
- Be on time
- Listen carefully to the questions
- Consider the question type and what type of answer is appropriate
- Share the exact information requested
- Stick to the facts
- Only answer questions from your area of responsibility

Afterwards

- Understand which observations require action on your behalf
- Define an action plan to complete the CAPAs on the target date
- Make sure your CAPAs are SMART
- Include the correct topics in you CAPA plan
- Engage with the right stakeholders

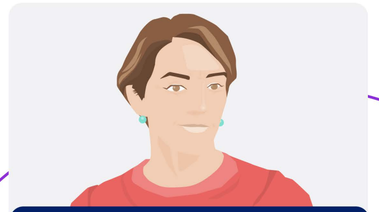
Checklist

- [ ] Lorem ipsum dolor sit amet
- [ ] Excepteur sint occaecat cupidatat non proident
- [ ] Donec lobortis risus a elit
- [ ] Ut enim ad minim veniam, quis nostrud exercitation
- [ ] Excepteur sint occaecat cupidatat non proident
- [ ] Curabitur pretium tincidunt lacu
- [ ] Nullam varius, turpis et commodo pharetra
- [ ] Pellentesque malesuada nulla a mi
- [ ] Curabitur pretium tincidunt lacu
- [ ] Nullam varius, turpis et commodo pharetra
- [ ] Pellentesque malesuada nulla a mi



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

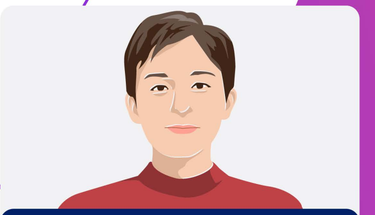
CAPA Coordinator
The person appointed by the auditees to liaise with the auditors.



CAPA Owner
This is the designated user responsible for the implementation of designated CAPAs.

CAPA Plan Approver
The designated user of the Business Owner/Stakeholder QA Team responsible for the audit and approval of the CAPA Plan (only non-GMP audits).

QA Approver
The designated user of the Business Owner/Stakeholder QA Team responsible for the final approval of implemented CAPAs for closure.



QPPV
The Qualified Person for Pharmacovigilance, Additional CAPA Plan Approver for PV Audits with a “Need Improvement”.