SUCCESSFUL CONDUCT OF THE AUDIT

Successful Audits

- **Conduct of Audit**
  - **Opening meeting**
  - **Introductions**
  - **Prepared paperwork**
    - List of current SOPs
    - Organisation chart
    - Floor plan

SUCCESSFUL CONDUCT OF THE AUDIT

Tour

- **Auditee**
  - Plan route
  - Access considerations
  - Safety considerations
  - PPE
  - Policy on photographs
- **Auditor**
  - Respect working practices
  - Make clear notes

Questions - Auditor

- **Flow cytometer**
  - What is the maintenance schedule?
  - How is maintenance documented?
  - Do users perform maintenance? How is this documented?
  - How do users know if the instrument is within its calibration?
  - Are the above in an SOP?

What is the maintenance schedule?

How do the users know the calibration is in date?

How old is the equipment?

How is user maintenance documented?

Question

Validation procedure. IQ/OQ/PQ documentation

Equipment log book

Verify

Training records

Maintenance records/Q-Pulse

SOP (s)

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SUCCESSFUL CONDUCT OF THE AUDIT

Auditor

- **Attributes**
  - Non-confrontational
  - Asks open questions
  - Good listener
  - Attention to detail
  - Able to see the big picture
  - Reads body language
  - Respectful
  - Good communicator
  - Decisive
  - Open minded
  - Mindful of time

SUCCESSFUL CONDUCT OF THE AUDIT

Auditee

- **Attributes**
  - Open
  - Honest
  - Knows when to shut up
  - Isn’t afraid of silences
  - Knows the systems and SOPs for their organisation
  - Remembers which side of the fence they are on
  - Knows what they don’t know
  - Knows who is best able to answer a question
  - Mindful of time

SUCCESSFUL CONDUCT OF THE AUDIT

Closeout Meeting

- **Auditor**
  - Thank everyone for co-operation
  - Summary of the audit
  - Initial classification of findings
  - State the reporting process, expectations and timelines
- **Auditee**
  - Opportunity to clarify findings
  - Correct mis-understandings

Recording and Reporting Findings- Auditor

- **Findings need to be:**
  - **Sufficiently detailed to enable reconstruction**
    - Identify what was found, where it was found and the reason why it isn't compliant
  - **Clear**
  - **Jargon free**
- **Multiple findings on the same subject:**
  - **Consider making a general finding with just 1 or 2 examples**
- **Report**
  - **Make timelines clear & re-state expectations**

Definitions of Findings -1

- **Critical:**
  - **a) Where evidence exists that significant and unjustified departure(s) from applicable legislative requirements has occurred with evidence that**
    - i) the safety or well-being of trial subjects either have been or have significant potential
    - to be jeopardised, and/or ii) the clinical trial data are unreliable and/or iii) there are a number of Major non-compliances (defined in (c) and (d)) across areas of
    - responsibility, indicating a systematic quality assurance failure, and/or
  - **b) Where inappropriate, insufficient or untimely corrective action has taken place regarding previously reported Major non-compliances (defined in (c) and (d))**

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Definitions of Findings -2

- **Major:**
  - **c) A non-critical finding where evidence exists that a significant and unjustified departure from applicable legislative requirements has occurred that may not have developed into a critical issue, but may have the potential to do so unless addressed, and/or**
  - **d) Where evidence exists that a number of departures from applicable legislative requirements and/or established GCP guidelines have occurred within a single area of responsibility, indicating a systematic quality assurance failure.**

Definitions of Findings -3

- **Other:**
  - **e) Where evidence exists that a departure from applicable legislative requirements and/or established GCP guidelines and/or procedural requirement and/or good clinical practice has occurred, but it is neither Critical nor Major.**