PRINCIPLES OF AUDITING

Which competencies are necessary for an auditor?

- Personal attributes and behaviour
- Generic and specific knowledge and skills

These competencies are acquired through education, training and experience

• Personal attributes •

Personal attributes

- Ethical
- Diplomatic
- Open-minded
- Perceptive
- Observant
- Objective
- Versatile
- Tenacious
- Determined
- Self-reliant

Exercise

The Monkey Business Illusion

(Daniel J. Simons, 2010)

- https://www.youtube.com/watch?v=o62HdDy-9do

Personal behavior

The auditor **should**:

- Communicate clearly
- Use active listening skills
- Have a relaxed attitude
- Adopt an investigator and curious attitude
- Back off when there are signs of nervousness
- Thank the collaboration of the audited person

Active Listening

- Concentrate in what others are saying
- Send verbal and non-verbal messages that you are listening
- Avoid early evaluations
- Avoid getting defensive
- Practice paraphrasing
- Listen and observe for feelings
- Ask questions

Exercise

Duplik game

Personal behavior

The auditor **should not**:

- Argue with the audited person
- Create problems
- Start a discussion if the audited person does not cooperate
- Conduct the audit as if it a police interrogatory

• Generic knowledge and skills •

- Knowledge and relevant experience in clinical units, collection units and/or processing units

- Teamwork skills

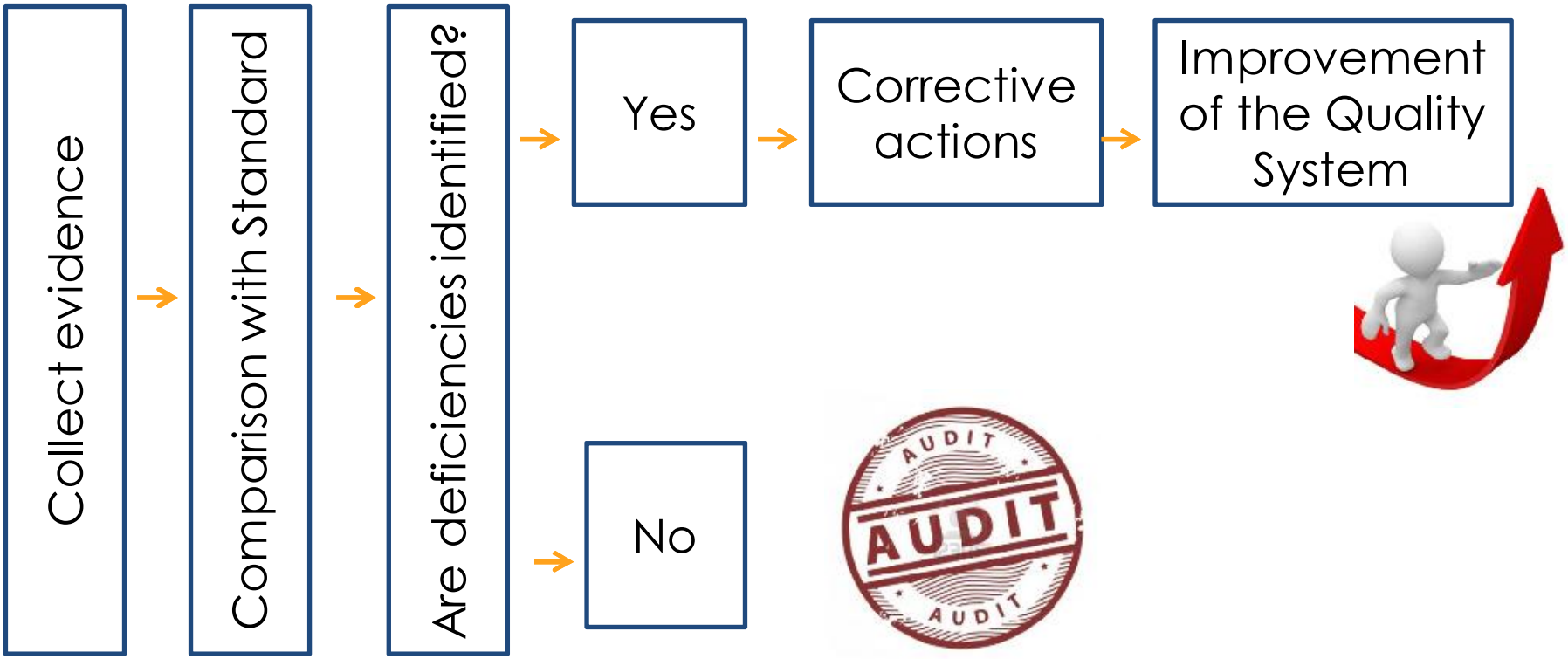
• Specific knowledge and skills •

INTERNATIONAL STANDARDS FOR CELLULAR THERAPY PRODUCT COLLECTION, PROCESSING, AND ADMINISTRATION

JACIE standards

Auditing principles

What's the purpose of an audit?



Auditing principles

- Integrity
- Fair presentation
- Due professional care
- Independence
- Evidence based approach be alert not to be influenced
- Confidentiality

Auditing principles

- **Integrity** – is essential to auditing

- **Fair presentation** - is the obligation to report audit findings and conclusions truthfully and accurate

- **Due professional care** – requires the application of diligence and judgment in auditing

Auditing principles

- **Independence** – is the basis for the impartiality of auditing and the objectivity of the audit conclusions
- **Evidence-based approach** – is the method for arriving at reliable and reproducible audit conclusions in a systematic audit process
- **Confidentiality** – it relates to the security of the information acquired during auditing activities

Auditing principles

The audit is:

- NOT intended for tracing faults
- NOT intended to evaluate persons or their work
- NOT an exam

International Society for Cellular Therapy
ISCT

Auditing principles

- Familiarity with the process that will be audited
- Social Skills
- Both important!

What are and are not the auditor responsibilities?

The auditor's responsibility

- Verify that the information provided by the centre is accurate
- Verify that all procedures in place are in compliance with the FACT-JACIE Standards
- Prepare a detailed report about the centre, enabling JACIE to accredit it

The auditor's responsibility

- Inspectors cannot examine all areas and documentation during an inspection. They are not responsible if, due to limited time, scope or inability to conduct certain processes, **they do not observe a particular non-compliance**

- However, the inspector has the responsibility **to indicate in the report which areas/documentations were not audited and why** (ex. time constrains, lack of access)

The auditee's responsibility

- Make feel welcome to the auditor, the centre has asked for your services

- Have in mind that the auditor is also a person, so he/she doesn't have all the answers nor never makes mistakes

It's a learning experience for both parties and they benefit from collaborating

What is important to remember?

Things to Remember

- Obligation to prove, but also the right to prove
- Incident versus systematic deviation
- Inspection is sample taken at random
- Check the relationship between the different departments

Things to Remember

See if it really works

- Observe people on the job
- Take enough time to visit working places

Be careful not to compare to your own setting

- References are the JACIE Standards, **<u>not</u>** what you do in your facility

JACIE is available to support auditors and centers during the entire process

…Thank you for listening!

Examples of audit interactions

- https://www.youtube.com/watch?v=XuBpOkoroKc
- https://www.youtube.com/watch?v=tZsd5Jf0SPI
- https://www.youtube.com/watch?v=an1NGJIEgHg