

Quality by Design Consultancy

Audit

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Conflict of interest

Nothing to disclose



Audit- Introductory Questions

Audit or self inspection? Who in the room has conducted an Audit?

🎈 Experience :-

🎈 0-1 years

🎈 1-5 years

🎈 5-10 years

🎈 10+ years



Scene setting

- 🎈 What is an audit?
- 🎈 Why do we audit?
- 🎈 What do we audit?
- 🎈 What are we trying to achieve?



Audit

- Standards!!!!
- Every country has different standards, are you familiar with yours?
- Do you know where to find them
- ISO? Does your facility have an ISO accreditation



Scene setting

ISO 19011-a systematic independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled



What is audit

An evaluation of a **person**, organisation, system, process, enterprise, project or product. Perform to ascertain the validity and reliability of information and to assess internal controls

But we do that for:-

- 🍎 Legal
- 🍎 Business
- 🍎 Risk assessment
- 🍎 Improvement



Scene setting

- 2008-2011, 150+ death due to contaminated heparin
- Escalating counterfeiting
- 2008- 300,000 victims of melamine in milk- 6 death
- 2004- 13 infant deaths- baby food



Scene setting

- Audits and the regulator
- Increasingly asking for more evidence and examples
 - Lord Carter Review, Local authorities, EU directives and regulations! Brexit implications



Why audit?

- Patient safety ⇨ focus
- Confirm the legal and contractual obligations fulfilled
- Assessment of QMS
- Objective
- Unbiased
- Build confidence!!!!



Why audit?

- Preparation for regulatory inspections
- A fresh pair of eyes
- Spread the *good news*
- Communicate the policy?
- Improve efficiency
- Benchmarking
- Feedback on company policy
- Share best practice
- Remove barriers



What do you audit

- 🎈 Person?!
- 🎈 Product?
- 🎈 Service?
- 🎈 Make sure you know what you are auditing!!!!!!



Auditing

- There are always challenges
- Time is always limited
- Process or system can be complex
- Managing the human element
- Fear
- Anxiety
- Apathy
- Aggression



Auditing

Remember you are auditing so don't
take it personally



Scene Setting

Rapport- oxford dictionary- a close and harmonious relationship in which people or groups concerned understand each other's feelings and ideas and communicate well

Wikipedia- a relationship of mutual trust and respect



Points for consideration

- The auditor is a guest
- The auditee is expert in his or her operation
- The auditor is a trained diplomat
- The auditor is representing his/her company(hospital)
- The auditor is **protecting his/her patients**



Points for considerations

- 🎈 Auditing is a human function- be human
- 🎈 Auditors are trained and practical communicators
- 🎈 A sense of humour may help



Auditing

- Potential to do a lot of goods- or harms
- Look for WIN:WIN
- People do not usually come to work to do a bad job



Auditing

Managing the audit

- Ask questions-gather evidence
- Taking notes
- Preparation
- Set agenda
- Handle difficult auditees
- Expect resistance, apathy, fear, even aggression
- Build Rapport



Remember

 Be Professional

 Be Human



Introduction

- Two systems that involve the requirement to perform formal AUDITS are:
 - Internal audit system
 - Supplier management system



Internal audit or self-inspection

Why do we perform self-inspection?



Internal audits or self inspection

- Be Professional
- Why do we perform Self-inspection?
- Critical elements of any QMS
- To detect non-compliance before others do
- Part of commitment to continuous improvement
- An expectation in any QMS(what ever facility you have and Standards)



Internal audits or self inspection

- 🍎 Important for regulators
- 🍎 To see that internal inspections take place
- 🍎 Actions recorded and assigned
- 🍎 Actions closed out
- 🍎 **Continuous improvement is practiced**



Internal vs external

Terms often used synonymously to indicate self review at site, department, A hugely important role, often under-recognised in importance, that sets the foundations for quality expectations for the entire organisation.

This is the time driver of conformity of standards, consistency, and best practice. If this is done well, the rest easily falls in to place.



Benefits

- Simply stated, the main focus of auditing is patient safety. That said the true value of audits extends far beyond just patient safety audit and self inspection can help
- Establish whether legal and contractual obligations are being fulfilled
- Gain an objective and unbiased assessment of the QA system working within the organisation
- To build confidence in the quality system
- To provide a basis for mutual trust
- Expose all elements of the organisation to outside scrutiny
- Spread the Good News 😊



The Supplier Management System

The selection, evaluation and on going monitoring of suppliers, contractors and service providers must be a well described process or system that **is a part of the overall Quality Management System**

Your business is in their hands!!!!



Definition of Supplier

- Who is a supplier?
- Anyone who is involved in the supply chain
- It is not only the pharma company!
- Suppliers of material, components, products and services



Supplier Life cycle Management

Integrated quality risk management

- Priorities driven by **RISK**
- **To the patient**
- **To the business**
- Responsibilities clearly defined and communicated
- Transparency of sequence- ie, audit trails
Plan > Do > Check > Act and in cycle
- **Continual improvement** →



Quality/Technical/service agreements

- Standards!
- Describe services/ and what is provided
 - Determine the scope of audit
 - It also includes the right of contract giver and acceptor
 - Make sure you review the agreement as an audit preparation



External suppliers audit

- 🎈 Consider the PDCA cycle
 - 🎈 Plan > Do > Check > Act

- 🎈 Following this through the process list the components of your program



The external Audit Program

- Don't forget.....continual review, monitoring and improvement of the system
- Key quality metrics
- To confirm that the system is working
- To ensure serious issues are escalated and dealt with
- To review trends
- To review their consistency of auditors
- To identify opportunity for improvement



Summary

- Auditing is an essential element of any quality management system
- Both internal and external
- If it's valuable to know or remember then a **documented** auditing system is essential!



Summary

- Internal and external audit programmes are key components of the quality management system
- Continual improvement is the aim so analyse and trend the audit data both
 - From the products and processes and
 - From the auditing system



Remember.....

All based on RISK

 To the patient

 To the Business



Problems !

- Un-cooperative department?
- Difficulty in getting time?
- Difficulty in travelling?
- Quality history
- Product or service inspected
- Other information inside/outside the organisation
- Audit by questionnaire
- Alternatives



Escalation

 Management

 Head of Quality



Purpose

- 🍷 Confirm minimum standard
- 🍷 Enforce corporate standards
- 🍷 Pre-audit information required to give context?
- 🍷 **Self inspection**



Thank you for listening

Questions ?

