Sneak Peek

Advanced Strategies and Future Trends in GMP Auditing

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ONLINE
TRAINING

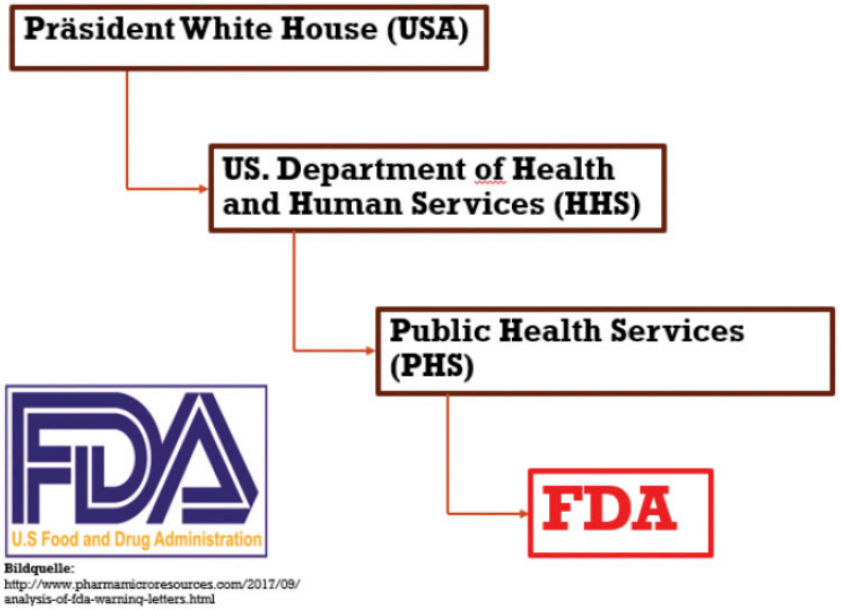
GMP AUDITS

01

WHAT SHOULD BE CONSIDERED REFERRING TO AUTHORITY INSPECTION?

Food And Drug Administration

- Health authority of the USA
  - Strong dependence on political decisions
  - About 3.000 employees / 1.500 auditors
  - Responsible for the approval and the surveillance
- Strict authority
  - Do not let them wait too long onto documents
  - No confusion
  - Fast suspected fraud
  - Well organised and fast creating clusters referring to topics
  - Very interested and open to new technologies



Bildquelle:
http://www.pharmamicroresources.com/2017/09/analysis-of-fda-warning-letters.html

QUESTION 3

What is in the focus of an external audit?

A) CMOs

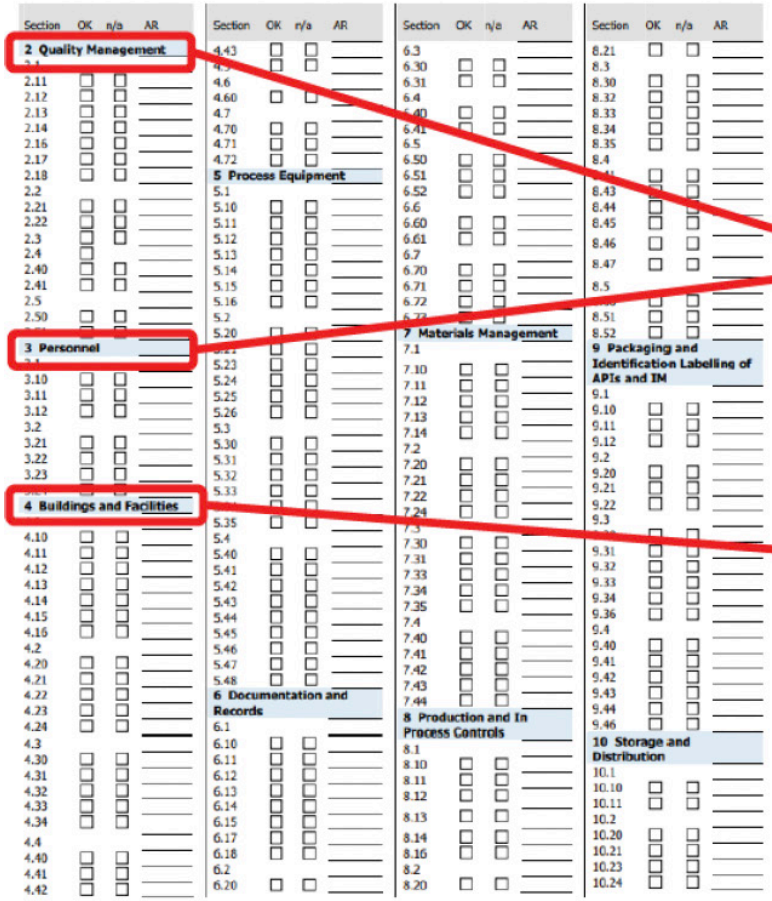
B) CLaOs

C) Both CMO and CLO

EXAMPLE 2: GMP-AUDIT REPORT

STANDARDISATION OF THE MAIN PART

Audit Report



Audit Report

4. General information

Give an overview of the company and site such as whether it is part of another group, how the company was formed, previous site names, what is the nature of the sites business and how many APIs or intermediates are manufactured, site size

Give an overview of their inspection record and which health authorities have inspected the auditee

5. Organisation and Personnel

Give an overview of the staffing levels for the site and departments plus working patterns.

Give an overview of the training system and the level and frequency of GMP training. Indicate if contract staff are used and if so for what operations and how they are trained.

6. Quality Systems

Give an overview of the quality management system and practices of the site. Give an overview of the quality systems reviewed, including but not limited to change controls, deviation investigations and reporting, CAPA management, risk management applications, validation, recall systems, complaint management, internal audit programme

Give an overview Annual Product Review(s) reviewed and their compliance to ICH Q7 and conclusions.

7. Facilities

Give an overview of the facilities visited and assessed. Indicate what utilities are used on the site and are under the responsibility of the site/or third party.

If necessary indicate the buildings and infrastructure ages and include main areas such as production buildings, solvent storage, warehousing and laboratory. If more than one API or facility is used for manufacture, indicate which ones are relevant to the product(s) being assessed.

Indicate if facilities are of suitable design and permit access to equipment for ease of cleaning and maintenance.

Indicate if the warehouse(s) are adequately monitored and controlled for temperature and relative humidity. Ensure facilities and utilities that need to be monitored are suitably

DATA INTEGRITY

04

AUDIT EXPERIENCES

- Access rights to GMP systems not available or not acceptable
- User-level are not defined (admin vs user)
- General accounts
- Storage of orginals with effect onto document integrity
- Restest without reason
- Falsification of results
- No back-up system

DATA INTEGRITY

05

EXAMPLES: REQUIREMENTS FROM THE FDA GUIDANCE

Registration

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