

PROJECT DESCRIPTION

The objective of this project is for the student to create a case study demonstrating an understanding of the audit process and the relationship with the ISO 9001:2015 requirements.

Each student team will be responsible for creating the narrative and describing how their audit would be performed. The team shall select a product, audit type and rationale for the audit.

Deliverables

A narrative describing/defining Auditee and Auditor and the overall scope of the audit. This should include a flow of the product/process, which includes references to the applicable clauses. The audit should encompass a minimum of 3 Clauses (4, 5, 6, 7, 8, 9 or 10) and a minimum of 6 sub-clause references (i.e. 5.1, 7.1, 7.2, 8.2, 8.3, etc.)

A general description of how the Auditor will approach the Auditee (opening meeting) and how the audit would be conducted including who needs to be present/participate.

Audit checklists that include questions to be asked and what the anticipated evidence would be. The checklists should contain a minimum of three questions per ISO 9001:2015 clause. Consideration should also be given to the applicable FDA regulations (21CFR 210/211 or 21CFR 820), whichever apply.

Example:

Team ABC will be conducting an “internal audit” of the “material receipt and acceptance processes” for the cold medicine (syrup) filling operation. This aspect of the business is of concern due to recent manufacturing problems regarding breakage of bottles on-line and incorrectly printed labels.

Clause references: 6 – Planning, Subclause 6.3 Changes

7 – Support - Subclause 7.1.5 Monitoring & Measuring Resources
Subclause 7.2 Competence

Subclause 7.5.3 Control of documented information

8 – Operation – Subclause 8.4 Control of externally provided
Subclause 8.7 Control of nonconforming outputs

Presentation:

The team will provide an overview of the process under audit, followed by the audit plan including which clauses of the standard will be reviewed, the procedures/documents/records expected, and examples of the questions/checklist.

Grading - 75 points total

20 points Clarity and cohesiveness of narrative

40 points Audit Type selected, checklist created, relationship/understanding of ISO 9001:2015 requirements.

15 points Presentation

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Product Options

<https://www.youtube.com/watch?v=E6lz8MB3Ids> (surgical sutures)

<https://www.youtube.com/watch?v=ZjIzHPdE6gY> (syringe needles)

<https://www.youtube.com/watch?v=qfGZ9Rk72zI> (band aids)

<https://www.youtube.com/watch?v=TrAHTmq-DLE> (pill manufacture)

<https://www.youtube.com/watch?v=xUioSOvLTPU> (lipstick manufacture)

Audit Type Options

Select either a Process or Product audit.

Preparing for a system audit is not recommended as the scope can be too broad.

Process audit could include - direct manufacture of the product or control of quality, etc.

Product audit could include – specific size (i.e. needle or suture gauge), specific drug or color

Audit Rationale Options

Internal Audit – The Company represented by the team has established an internal schedule and your team has been selected to review a portion of the overall operation

- A) Previous internal audits have indicated there are concerns with the individual process
- B) There has been an increase in customer complaints related to the product

External Audit - The Company represented by the team has contracted the manufacturing of the product to an outside vendor. The team will be conducting an audit at their Vendor to review their operations

- A) To evaluate suitability to manufacture the product
- B) To further examine their processes due to an increased amount of complaints