Contamination Control Strategy Considerations

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Introduction

The forthcoming implementation of the new GMP Annex 1 in August 2023 has prompted companies adhering to GMP standards to diligently work towards meeting the new regulations and demonstrating compliance or progress towards compliance. A critical document that will aid in achieving compliance with the new GMP Annex 1 is the contamination control strategy (CCS). This document serves as an overview of all contamination control measures in place, referencing relevant documentation that allows for a comprehensive understanding of the strategies employed.

Considerations for CCS

STRUCTURE OF THE CCS

When structuring the CCS document, it is advisable to refer to the guidance provided by GMP Annex 1, the ECA, and ICH Q9. The ECA resource suggests a 3-stage approach to creating the CCS: development, compilation, and evaluation.

During the development stage, the CCS should undergo thorough review and refinement, with a focus on understanding processes, implementing a quality risk management system, identifying potential contamination points, and establishing effective control measures.

In the compilation stage, the necessary CCS documentation, such as risk assessments, maintenance programs, SOPs, policies, and environmental monitoring programs, should be gathered and referenced using appendices rather than listing them exhaustively within the document.

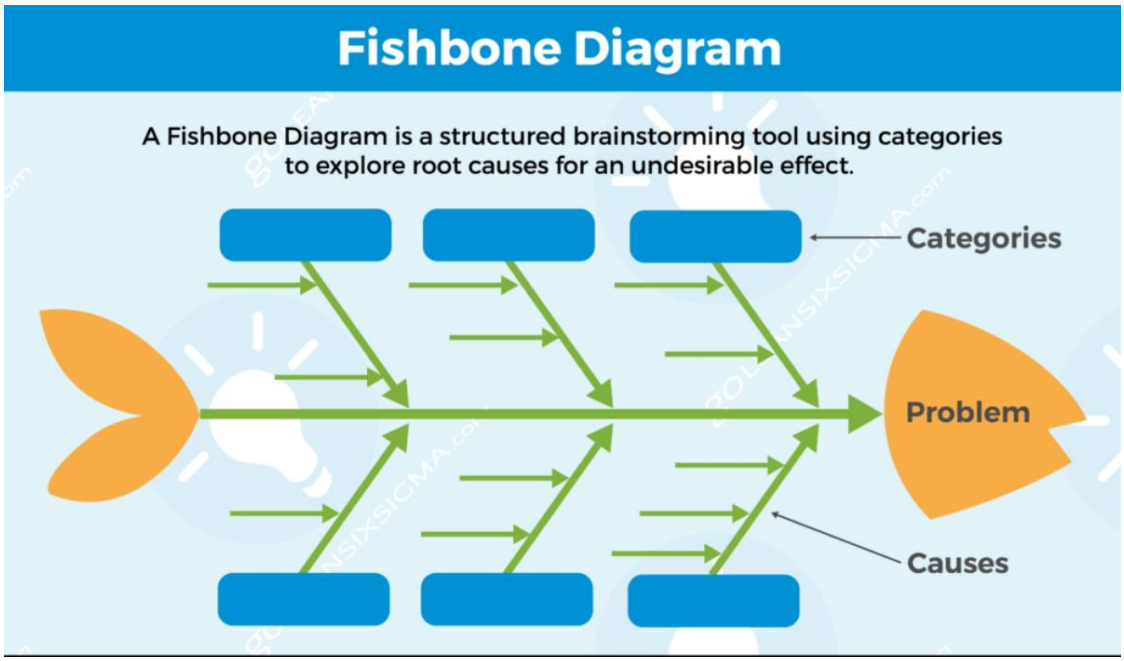
Finally, the evaluation stage involves scheduling regular assessments to improve the CCS, either annually or more frequently, and initiating evaluations in response to major deviations and implemented change controls.

UNDERSTANDING PROCESSES

To enhance the effectiveness of the CCS, it is crucial to conduct facility walkthroughs and observe processes in action. This practice can aid in identifying overlooked areas with a high risk of contamination, which can then be incorporated into the contamination control strategy. For example, during a cleaning regime, the transfer of mop heads from one location to another without changing the heads may pose problems that need to be captured in the CCS, leading to corrective actions.

WORKFLOW OF THE CCS DOCUMENT

Utilizing visual aids such as diagrams and tables can significantly facilitate the presentation of information and the execution of risk assessments for key areas such as maintenance and equipment. These tools help in identifying potential sources of contamination systematically. Fishbone diagrams, where each category (Methods, Equipment, Raw Material) is placed at the top of the diagram, enable a methodical exploration of potential contamination sources within each category. Additionally, flow diagrams can guide the identification of critical points requiring improvement, such as cleaning processes.



Flow diagrams can also help guide through certain processes to find pinch points that need improvement such as cleaning processes.

PREVENTION OF RISK

The primary objective of the CCS is to ensure the implementation of appropriate contamination control measures to prevent the risk of product contamination. Besides identifying areas of potential risk, the CCS also questions the efficacy of existing strategies in controlling contamination. For instance, assessing whether replacing a biological cabinet with an isolator during the filling process could provide enhanced prevention of contamination.

Assessing the problem

When faced with a challenge where the source of contamination is not easily identifiable, implementing a 5 whys process within the CCS document can prove beneficial. The 5 whys process (pioneered by Sakichi Toyoda) involves repeatedly asking "why" to drill down to the root cause of a problem. By applying this method, the underlying causes of contamination can be unearthed and addressed effectively.

Example:

1. Why was there Out of Specification contamination in Area B?
    a. Finger dab plate from that area grew bacteria.
2. Why did the agar plate grow bacteria?
    a. The gloves were contaminated.
3. Why were the operator's hands contaminated?
    a. The operator used the alcohol spray as required by the SOP.
4. Why was the alcohol spray not effective?
    a. Records show concentration was created at 70% IPA.
5. If the concentration of IPA was appropriate, why was it still ineffective?
    a. The made-up solution had expired by the time the operator came to use the spray and was no longer an effective cleaning agent.

PRIORITISING ACTIONS

The CCS generates a series of actions required to enhance compliance with GMP Annex 1 and ISO/EN regulations. It is important to prioritise these actions based on their urgency, considering whether they are short-term or long-term solutions. Furthermore, the focus should be on actions that have the most significant impact rather than those that can be quickly completed.

IS THE CCS COMPLETE ONCE ALL ACTIONS ARE COMPLETE?

This document should be a living document, that can be reviewed and developed as processes change, production increases, or as the facility expands. Scheduling time to review the document will ensure continued compliance with GMP Annex 1 and ISO/EN. There should be other triggers such as deviations, completed out of specification investigations on contamination, and implemented change controls, can prompt a document review.

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