

Technical Information Report



AAMI TIR100: 2021

End-to-end microbiological
quality and sterility
assurance

End-to-end microbiological quality and sterility assurance

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AAMI

Abstract: This technical information report (TIR) provides guidance for a comprehensive framework that integrates and connects Microbiological Quality & Sterility Assurance (MQ&SA) into an organization's end-to-end process for the development, validation, and routine control of sterile health care products.

Keywords: aseptic processing, end-to-end, microbiologically controlled processing, sterility assurance, terminal sterilization, process

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

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Committee representation

Association for the Advancement of Medical Instrumentation

AAMI Assurance of Sterility Working Group

This technical information report was developed by the AAMI Assurance of Sterility Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the technical information report does not necessarily mean that all working group members voted for its approval.

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Foreword

The following verbal forms are used within AAMI documents to distinguish requirements from other types of provisions in the document:

- “shall” and “shall not” are used to express requirements;
- “should” and “should not” are used to express recommendations;
- “may” and “may not” are used to express permission;
- “can” and “cannot” are used as statements of possibility or capability;
- “might” and “might not” are used to express possibility;
- “must” is used for external constraints or obligations defined outside the document; “must” is not an alternative for “shall.”

Suggestions for improving this document are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203 or standards@aami.org.

NOTE This foreword does not contain provisions of the AAMI TIR100, *End-to-end microbiological quality and sterility assurance*, but it does provide important information about the development and intended use of the document.

Introduction

This AAMI Technical Information Report (TIR) was developed to describe a comprehensive framework that integrates and connects Microbiological Quality & Sterility Assurance (MQ&SA) into an organization's end-to-end process for the development, validation, and routine control of sterile health care products.

The Supply Chain for a health care product is an end-to-end process that begins and ends with the customer. The health care product requirements are established based on the specific customer needs, and, in the end, the customer is the ultimate user of the health care product. The end-to-end process is defined as the following: Research and Development (R&D), Plan, Source, Make, Deliver, & Customer (See Figure 1). Addressing MQ&SA throughout the end-to-end process is critical to ensure that the finished health care product meets its defined requirements.



Figure 1—End-to-end process

The interactions and information flow within the end-to-end process are interwoven and not necessarily linear as shown in Figure 1. For smaller companies, the same personnel could perform numerous activities whilst in a large company, there might be specific groups of individuals that perform each activity within the end-to-end process. Additionally, smaller companies might not have as definitive distinctions between the activities shown. Understanding the roles and responsibilities within the organization is important to facilitate collaboration. An example of the interactions and information flow between the individuals that provide these functions is shown in Figure 2.

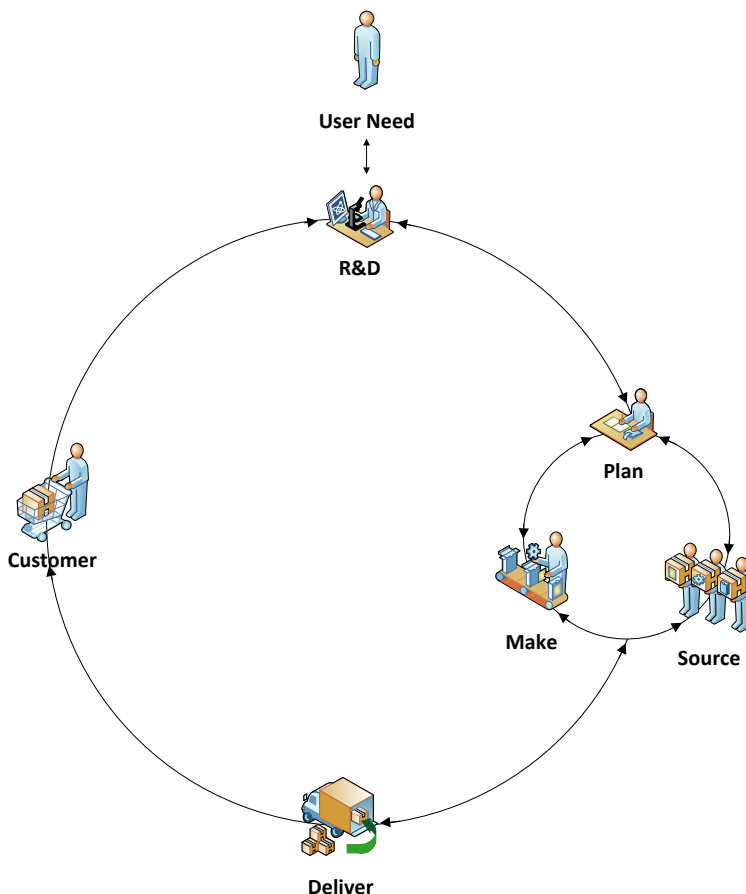


Figure 2—Interactions and information flow within the end-to-end process

Interactions and information flow between personnel that support the different aspects of the end-to-end process will ensure that the product is designed to meet customer expectations. R&D works with the customer to understand their expectations and translate their needs into product requirements. R&D in collaboration with the rest of the Supply Chain (e.g., Plan, Source, Make, and Deliver) will develop the product plan for manufacturing (a.k.a. production) and delivery to the customer. Throughout the end-to-end process, a feedback loop is important between R&D, Plan, Source, Make and Deliver to ensure the product continues to meet the needs of the customer. This collaboration and information flow can be used for internally and externally manufactured products, or during the assessment and integration of products acquired through mergers or acquisitions.

MQ&SA requirements should be integrated throughout the end-to-end process rather than just at the beginning and end of the process. For example, if during the product design phase, MQ&SA is only considered once the design has been finalized, this can have significant impact on cost or product launch timelines (e.g., launch delays) due to need to modify product design to address MQ&SA requirements identified during the final design review. In addition, if the Plan for manufacturing has already been developed, it might not include considerations for critical facility design criteria, as well as microbiological controls (e.g., air, water, personnel).

This technical information report (TIR) provides guidance on a framework that integrates and connects MQ&SA during the entire end-to-end process for terminally-sterilized and aseptically-processed products. As new product innovations challenge current terminal sterilization and aseptic processing, the need for continued focus on the end-to-end process to meet the MQ&SA needs for future products becomes more critical.

End-to-end microbiological quality and sterility assurance

1 Scope

This document provides guidance on integration of Microbiological Quality & Sterility Assurance (MQ&SA) into the end-to-end process. This framework is intended to connect the MQ&SA activities that should be addressed throughout the end-to-end process: from defining MQ&SA requirements during R&D through customer receipt and use of the product.

NOTE 1 These principles can be applied to other microbiologically controlled products. For example, certain hand care products, wound dressings, drainage bags, etc.

NOTE 2 While reusable devices are not included in the scope of this document, the general principles of design inputs, design process, design outputs, design verification and design validation can be applied.

2 Normative references

There are no normative references for this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

aseptic processing

handling of sterile product, containers, and/or the product in a controlled environment in which the air supply, materials, equipment, and personnel are regulated to maintain sterility.

[SOURCE: ISO 11139:2018, 3.14]

3.2

clean

visually free of soil and below specified levels of analytes

[SOURCE: ISO 11139:2018, 3.45]

3.3

customer

person (e.g., patient, clinician, health care provider) or organization that receives a product

3.4

deliver

provide ordered services or products to the customer

3.5

disinfection

process to inactivate viable microorganisms to a level previously specified as being appropriate for a defined purpose

[SOURCE: ISO 11139:2018, 3.84]