

Technical Information Report

AAMI TIR100: 2021

End-to-end microbiological
quality and sterility
assurance

End-to-end microbiological quality and sterility assurance

Approved 1 October 2021 by
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.

Published by

AAMI
901 N. Glebe Road, Suite 300
Arlington, VA 22203
www.aami.org

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Printed in the United States of America

ISBN 978-1-57020-837-9

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