CASE FOR QUALITY

Library of Successful Quality Practices for Medical Devices

The medical device and diagnostics industry plays a crucial role in the prevention, monitoring, and treatment of diseases, and in the improvement of the quality of life for people with various ailments and disabilities. As the world’s largest medical technology association, AdvaMed is dedicated to ensuring timely patient access to safe and effective medical products, and to providing physicians, medical technology professionals, and others with the advocacy and tools they need to help create life-changing innovation.

Along with FDA, AdvaMed believes that product quality goes beyond compliance with the current Quality System Regulation (21 C.F.R. Part 820). The Library of Successful Quality Practices stems from this belief, and was created by AdvaMed and its members to help medical technology quality professionals.
This “Library of Successful Quality Practices” is not technology-specific, nor is it intended to be exhaustive or all-inclusive. However, our aim is to provide several key benefits:

- This Library is a compilation of successful quality practices employed by contributing AdvaMed member companies.
- The Library provides a selection of current industry practices with explanations of their value.
- It is intended for quality professionals to use as a resource, not as a prescriptive guidance/textbook/checklist.
- It can serve as a road map or toolkit for companies seeking to improve their quality systems and/or product quality by leveraging proven industry methods.
- Large and small companies also may benefit from using the Library’s catalog of wider ranges of industry practices to enhance their own.

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