



# Guidelines for Failure Modes and Effects Analysis for Medical Devices

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## **Guidelines for Failure Modes and Effects Analysis for Medical Devices** Dyadem Press

Challenged by stringent regulations, vigorous competition, and liability lawsuits, medical device manufacturers must develop safe, reliable, and cost-effective products, and managing and reducing risk is a vital element of reaching that goal. A practical guide to achieving corporate consistency while dramatically cutting the time required for studies, *Guidelines for Failure Modes and Effects Analysis for Medical Devices* focuses on Failure Modes and Effects Analysis (FMEA) and its application throughout the life cycle of a medical device. It outlines the major U.S. and E.U. standards and regulations and provides a detailed yet easy-to-read overview of risk management and risk analysis methodologies, common FMEA pitfalls, and FMECA-Failure Mode, Effects, and Criticality Analysis.

Discover how the FMEA methodology can help your company achieve a more cost-effective manufacturing process by improving the quality and reliability of your products. This new FMEA manual from the experts at Dyadem is the ultimate resource for you and your colleagues to learn more about Failure Modes and Effects Analysis and then teach others at your facility. This comprehensive manual is sure to become a standard reference for engineering professionals.

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