Technical Information Report

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Quality Management System (QMS) Recommendations on the Application of the U.S. FDA's CGMP Final Rule on Combination Products

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Abstract:

This Technical Information Report (TIR) provides information on how to effectively implement FDA's regulation on Current Good Manufacturing Practices (CGMP) for combination products. Combination products are therapeutic or diagnostic medical products that combine drugs, devices, and/or biological products with one another, and the FDA regulation became effective July 22, 2013 (21 CFR Part 4).The TIR, where appropriate, also considers best practices, guidelines, and standards used both in the United States and other regions. The overall goal of the TIR is to aid informed, risk-based decisions in establishing CGMP operating systems that support development, manufacture, premarket regulatory evaluation, and ultimately commercialization of combination products. It should be noted that, while the information contained in the TIR has been carefully considered, it is up to the individual manufacturer to ensure compliance with all regulatory requirements that apply to its products.

Keywords:

CGMP for combination products, Combination product, Constituent part, Quality Systems,21 CFR Part 4,21 CFR Part 211,21 CFR Part 820,21 CFR Parts 600-680,21 CFR Part 1271,CGMP, Design Controls, Risk management, Streamlined Approach, Single entity combination product, Co-packaged combination product, Cross-labeled combination product, FDA, Office of Combination Products (OCP),Management responsibility, Purchasing Controls, Corrective and preventive action (CAPA),Installation, Servicing, Component testing, Container testing, Closure testing, Calculation of yield, Tamper-evident packaging, Expiration dating, Release and distribution testing, Stability testing, Special testing, Reserve samples.

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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.