Device Validation Forum: Validation of Software “In-Product” or “As-Product”

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Methodology and documentation required by the US Food and Drug Administration to effectively verify, test, and validate software or firmware that is in a medical device Software validation is required for software used in-product, as-product, in processes, facilities, or in quality systems FDA has specified 11 elements of documentation recommended for software validation Software terminology definitions are provided All FDA-regulated companies should have a master validation plan that addresses all processes, equipment, and product requiring validation, frequency of revalidation, and methodologies Contents...