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**Yvelyne Germain- Mc Carthy**



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dec 17 2021 a device master record dmr is a collection of all the records that must be used to produce a medical device



product let s imagine that your medical devices company is planning on manufacturing a new and improved coronary stent which is a

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sep 30 2011 section 820.3(j) of the federal code defines device master record dmr is a set of documents containing procedures and specifications for a finished medical device simply put device master record dmr is a collection of all the documents required to manufacture and test a medical device

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a device master record dmr is a compilation of all the instructions drawings and other records that must be used to produce a product the term is used in quality management systems that cover product design and production contents

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aug 17 2021 overview what is a device master record when it boils down to it investing in a quality management system qms is the single most important thing you can do to ensure the safekeeping of your device master record as well as your design history files and device history records for that matter

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apr 14 2016 for a device master record dmr i recommend creating a dmr index using a template that is organized in accordance with an international standard to meet the needs of a dmr and a technical file

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definitions 21 cfr 820.3 device master record dmr compilation of records containing procedures and specifications for a finished device 21 cfr 820.3(j) device history record