

Devine Guidance for Complying with the FDA'S Quality System Regulation: 21 CFR, Part 820

By Dr. Christopher Joseph Devine PhD



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The purpose of Dr. D's first book is to breakdown and analyze the requirements depicted in the 21 CFR, Part 820, also known as the FDA's Quality System Regulation (QSR). The doctor tackles each of the sections of the QSR sequentially and hopes the readers are able to glean some useful information while enjoying the common-sense, objective, and no-nonsense approach to complying with each of the requirements.



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Editorial Review

About the Author

Dr. Christopher Joseph Devine is the President of Devine Guidance International, Inc., a consulting firm specializing in providing solutions for regulatory compliance, quality, supplier management, and supply-chain issues facing the medical device industry. Additionally, Dr. Devine is the author of Devine Guidance, a weekly blog focusing on the understanding of regulations mandated by the FDA and other regulatory bodies; and published by the Medical Device Summit, an e-magazine. Furthermore, Dr. Devine is a member of the editorial board of the Medical Device Summit. Dr. Devine has 32-years of experience in quality assurance, regulatory affairs, and program management. He is a senior member of the American Society of Quality (ASQ), a member of Regulatory Affairs Professionals Society (RAPS), a member of the Project Management Institute (PMI) and resides on several technical advisory boards. Dr. Devine received his doctorate from Northcentral University, with his doctoral dissertation entitled, "Exploring the Effectiveness of Defensive-Receiving Inspection for Medical Device Manufacturers: A Mixed-Method Study." Dr. Devine also holds a graduate degree in organizational management (MAOM) and an undergraduate degree business management (BSBM). Prior to launching his professional career, Dr. Devine served honorably as a United States Marine.

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