



최낙의/Nick Choi

대표이사/CEO

(주)팀누비즈/TEAMNUBIZ Co., Ltd.

겸임교수(건양대학교 의공학부)/Adjunct professor, department of biomedical engineering, KONYANG University, Korea

FDA QMSR 도입에 따른 효율적인 품질경영시스템 적합성(compliance) 확보방안

How to ensure effective quality system compliance with the FDA Quality Management System Regulation (QMSR)

Abstract

On 2 February 2024, the FDA published the new Quality Management System Regulation (QMSR), which is scheduled to be fully implemented by 2 February 2026, marking a new cornerstone of the medical device regulatory landscape. The regulation marks a significant shift from the guidance previously set forth in 21 CFR 820.5, paving the way for a unified approach that is aligned with global standards. Under the QMSR, clause 4.1.1 of ISO 13485 now requires organisations to document their quality management system (QMS) and maintain its effectiveness in accordance with the requirements of the standard and international regulations.

Note) ISO 13485, Clause 4.1.1 - The organisation shall document its quality management system in accordance with the requirements of this International Standard and applicable regulatory requirements and shall maintain the effectiveness of the quality management system.

Brief Bio sketch

Nick Choi is Chief Executive Officer at Teamnubiz and adjunct professor, department of biomedical engineering, Konyang University, Korea. He is an expert in product development, project management, engineering and quality management system within the medical device and biotech industries. He was at the position of executive vice president with Samsung Electronics and has established Teamnubiz together with expert engineers from Samsung Electronics with the purpose of technical supporting to innovative deep-tech startups. He serves as an advisor for Hongneung Digital Healthcare Special Zone (Hongneung Innopolis) and Korea University Medical Center (KUMC). He is a member of the RA Section of the Korean Society of Medical and Biomedical Engineers. Nick holds a BS in electrical engineering from Korea University.

He can be reached at

nick.choi@teamnubiz.co.kr

and the company Teamnubiz can be referred at

<https://blog.naver.com/teamnubiz>

www.teamnubiz.com