

FDA warning letters: Key trends medical device manufacturers should know

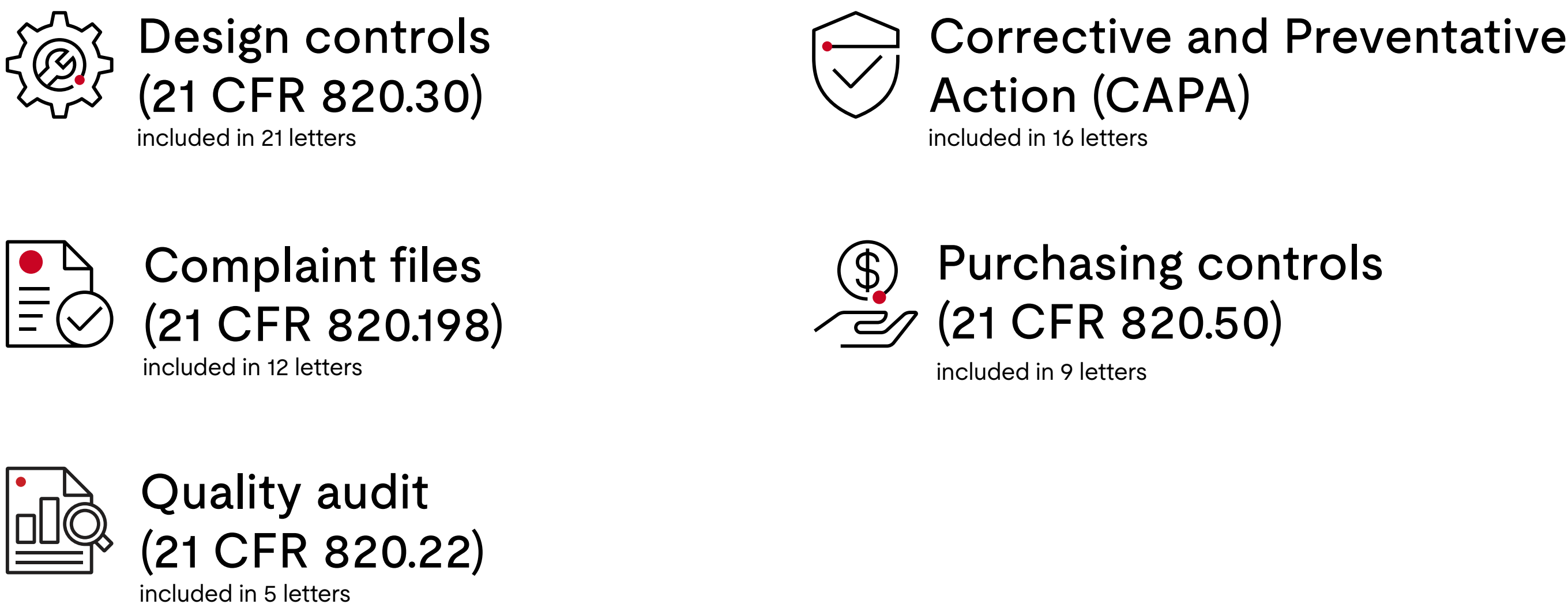


Workforce training is key to building a culture of quality and reducing regulatory risk. In the 2024 fiscal year (Oct. 1, 2023 – Sept. 30, 2024), the U.S. Food and Drug Administration (FDA) issued dozens of warning letters linked to lapses in training, documentation, oversight and Quality System Regulation (QSR) compliance.

The number of Warning Letters issued by the FDA is notably increasing:



Top 5 deficiencies in the warning letters were related to



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It's important to understand that FDA expects medical device manufacturers, led by individuals with executive responsibility or top management, to embrace culture and quality as a key component in ensuring safe and effective medical devices.

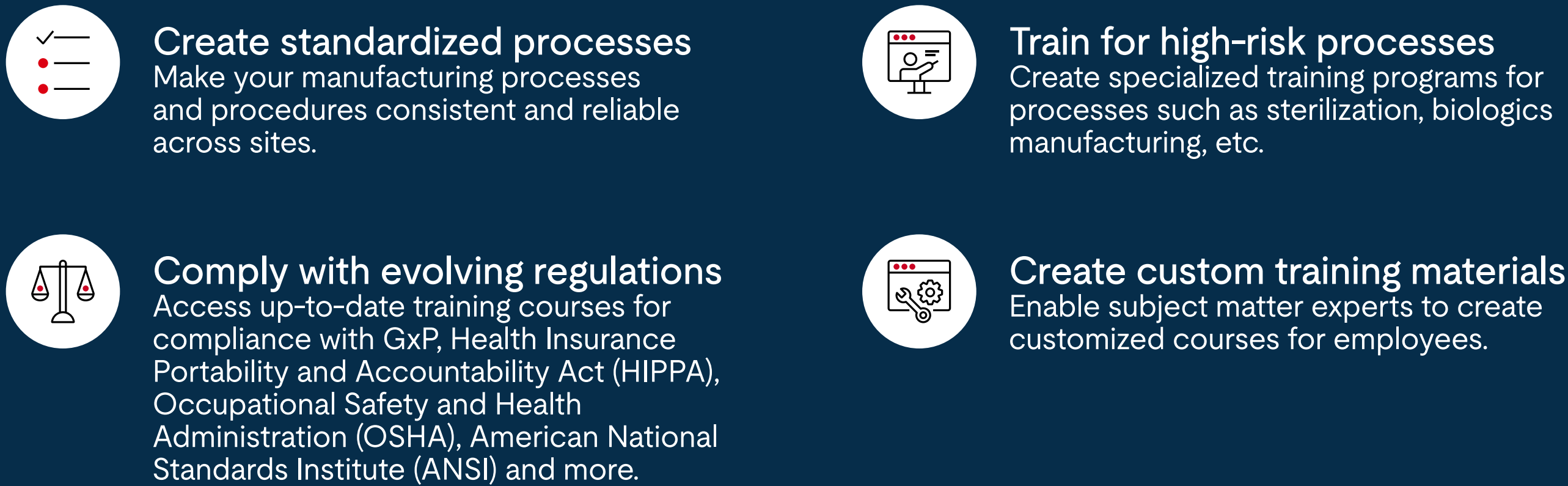
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¹Data attributed to: ECA Academy, 2025. “FDA Warning Letter Statistics on Medical devices in the past Fiscal Year.”
t: Regulatory Focus, 2025. “MedCom: FDA officials review QMSR as deadline approaches.”