

Design control for medical devices

How growing complexity and regulatory oversight challenges medical device development

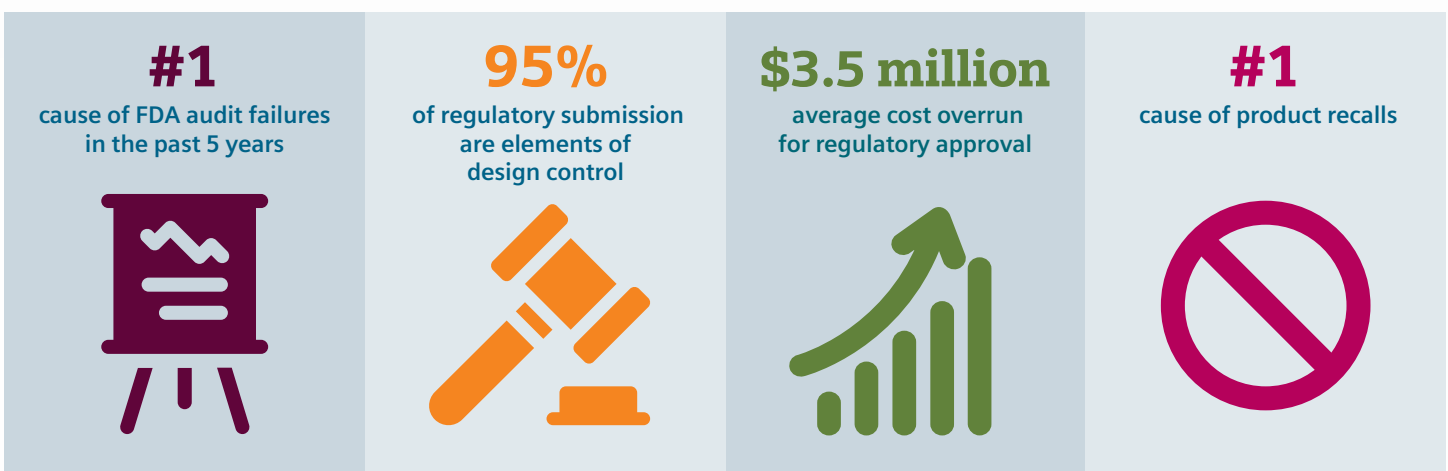


510(k) premarket submissions; (source: MDMA)



(Source: Software-Related Recalls: An Analysis of Records, FDA)

Design controls are critical



A comprehensive solution for device design control

Siemens offers a complete logical system to build and maintain design controls 	Requirements and risk management	Design output management	Document control
	Verification and validation management	Simulation and test management	Device master record (DMR)/technical file (TF)
	Design history file	BOM and configuration management	Change control

Design control delivers competitive advantage



To learn more about design control, visit www.plm.automation.siemens.com/global/en/industries/medical-devices-pharmaceuticals/intelligent-design-control.html