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Top Ten FDA Form 483 Observations for Medical Devices

What's a Form 483?

Medical Device manufacturers regulated by the FDA are subject to cGMP (Current Good Manufacturing Practice) regulations and may be inspected by the FDA to ensure compliance. If the FDA inspector(s) observes conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts, they will issue a Form 483 to the firm management at the conclusion of the inspection.

Top 10 483 Observations (FY 2010 – 2012)

The FDA has issued over a thousand 483s every year for medical devices over the past three years. The top ten citations are listed below:

Top 10 Citations FY 2010 - 2012				% of Top 10		
Rank	Short Description	Long Description	Ref No	FY 2012	FY 2011	FY 2010
1	Lack of or inadequate procedures	Procedures for corrective and preventive action have not been [adequately] established. Specifically, ***	21 CFR 820.100(a)	21.7%	22.2%	15.3%
2	Lack of or inadequate complaint procedures	Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been [adequately] established. Specifically,***	21 CFR 820.198(a)	15.1%	16.5%	18.3%
3	Documentation	Corrective and preventive action activities and/or results have not been [adequately] documented. Specifically, ***	21 CFR 820.100(b)	6.7%	8.7%	12.9%
		Process validation [activities] [results] have not been [documented] [approved] [adequately documented] [adequately approved]. Specifically, ***	21 CFR 820.75(a)	3.3%	3.0%	
		In-process inspections, tests, or other verification activities and approvals were not documented. Specifically, ***	21 CFR 820.80(c)	0.8%	0.5%	
		Acceptance activities were not [documented] [maintained as part of the device history record] [adequately documented]	21 CFR 820.80(e)	2.3%	2.7%	

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		[adequately maintained as part of the device history record]. Specifically, ***				
4	Lack of Written MDR Procedures	Written MDR procedures have not been [developed] [maintained] [implemented]. Specifically, ***	21 CFR 803.17	8.2%	9.1%	14.1%
5	Purchasing controls, Lack of or inadequate procedures	Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been [adequately] established. Specifically, ***	21 CFR 820.50	7.4%	6.4%	
6	Nonconforming product control procedures	Procedures have not been [adequately] established to control product that does not conform to specified requirements. Specifically, ***	21 CFR 820.90(a)	6.4%	6.0%	8.3%
7	Lack of or inadequate process validation	A process whose results cannot be fully verified by subsequent inspection and test has not been [adequately] validated according to established procedures. Specifically, ***	21 CFR 820.75(a)	6.0%	7.6%	9.6%
8	Design changes - Lack of or Inadequate Procedures	Procedures for design change have not been [adequately] established. Specifically,***	21 CFR 820.30(i)	5.9%	5.3%	
9	Investigation of device failures	Complaints involving the possible failure of [a device] [labeling] [packaging] to meet any of its specifications were not [reviewed] [evaluated] [investigated] where necessary. Specifically, ***	21 CFR 820.198(c)	5.6%		7.0%
10	Quality audits - Lack of or inadequate procedures	Procedures for quality audits have not been [adequately] established. Specifically, ***	21 CFR 820.22	5.3%	5.2%	14.6%
10	DMR - not or inadequately maintained	A device master record has not been [adequately] maintained. Specifically, ***	21 CFR 820.181	5.3%	6.8%	
				100%	100%	100%

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Avoiding 483s with a Product Lifecycle Management Solution

Product Lifecycle Management (PLM) solutions integrate Product Development with Quality Management. A PLM can thus impact many of these areas outlined in the Quality System Regulation helping avoid 483 observations.

21-CFR-820	Sections	PLM Impact
Quality System Requirements	§ 820.20 - Management responsibility.	**Direct**
	§ 820.22 - Quality audit.	
	§ 820.25 - Personnel.	
Design Controls	§ 820.30 - Design controls.	**Direct**
Document Controls	§ 820.40 - Document controls.	**Direct**
Purchasing Controls	§ 820.50 - Purchasing controls.	**Partial**
Production and Process Controls	§ 820.70 - Production and process controls.	**Partial**
	§ 820.72 - Inspection, measuring, and test equipment.	
Acceptance Activities	§ 820.80 - Receiving, in-process, and finished device acceptance.	**Partial**
	§ 820.86 - Acceptance status.	
Nonconforming Product	§ 820.90 - Nonconforming product.	**Direct**
Corrective and Preventive Action	§ 820.100 - Corrective and preventive action.	**Direct**
Records	§ 820.180 - General requirements.	**Direct**
	§ 820.181 - Device master record.	
	§ 820.184 - Device history record.	
	§ 820.186 - Quality system record.	
	§ 820.198 - Complaint files.	

We hope this has been a helpful overview on 483 observations.

Please call SPK and Associates today for guidance on PLM solutions and software engineering best practices with a focus on avoiding 483 observations.

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