2012 21 CFR 820.30 Citations			
21 CFR 820.30(g)	33	25.6%	Failure to establish and maintain procedures for validating the device design to include risk analysis
21 CFR 820.30(i)	22	17.1%	Failure establish and maintain adequate procedures for the identification, documentation, validation or where appropriate verification, review and approval of design changes before their implementation
21 CFR 820.30(a)	20	15.5%	Failure to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met
21 CFR 820.30(f)	13	10.1%	Failure to adequately establish procedures for design verification
21 CFR 820.30(c)	9	7.0%	Failure to establish and maintain adequate procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient
21 CFR 820.30(h)	9	7.0%	Failure to establish and maintain adequate procedures to ensure that the device design is correctly translated into production specifications
21 CFR 820.30(e)	7	5.4%	Failure to establish and maintain adequate procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device design development
21 CFR 820.30(b)	6	4.7%	Failure to establish and maintain adequate plans that describe or reference the design and development activities and define responsibility for implementation
21 CFR 820.30(d)	5	3.9%	Failure to adequately document design outputs
21 CFR 820.30(j)	5	3.9%	Failure to establish and maintain a design history file
Total Citations	**129**		
3 21 CFR 820.30 Citations			
21 CFR 820.30(g)	21	28.8%	Failure to establish and maintain adequate procedures for validating the device design, including software validation and risk analysis, where appropriate
21 CFR 820.30(i)	15	20.5%	Failure to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation
21 CFR 820.30(f)	11	15.1%	Failure to establish and maintain adequate procedures for verifying device design to confirm that the design output meets the design input requirements
21 CFR 820.30(a)	10	13.7%	Failure to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met
21 CFR 820.30(e)	6	8.2%	Failed to adequately establish procedures for design review
21 CFR 820.30(j)	4	5.5%	Failure to establish and maintain a DHF for each type of device to demonstrate that the design was developed in accordance with the approved design plan
21 CFR 820.30(h)	3	4.1%	Failure to establish and maintain procedures to ensure that the device design is correctly translated into production specifications
21 CFR 820.30(c)	2	2.7%	Failure to establish and maintain adequate procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient
21 CFR 820.30(b)	1	1.4%	Failure to establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation
Total Citations	**73**		
2 21 CFR 820.198 Citations			
21 CFR 820.198(a)	82	65.6%	Failure to adequately establish procedures for receiving, reviewing, and evaluating complaints by a formally designated unit
21 CFR 820.198(c)	17	13.6%	Failure to review, evaluate, and investigated complaints involving the possible failure of a device, labeling, and packaging to meet any of its specifications
21 CFR 820.198(b)	16	12.8%	Failure to review all complaints to determine if an investigation is necessary
21 CFR 820.198(e)	7	5.6%	Failure to adequately maintain a record of investigation, when an investigation is made
21 CFR 820.198(d)	3	2.4%	Failure to include required information in investigations of reportable complaints
Total Citations	**125**		
3 21 CFR 820.198 Citations			
21 CFR 820.198(a)	38	64.4%	Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit
21 CFR 820.198(c)	9	15.3%	Failure to investigate where necessary complaints involving the possible failure of a device to meet any of its specifications
21 CFR 820.198(e)	8	13.6%	Failure to include required information in records of complaint investigations
21 CFR 820.198(b)	3	5.1%	Failure to review and evaluate all complaints to determine whether an investigation is necessary
21 CFR 820.198(d)	1	1.7%	Failure to promptly review, evaluate, and investigate by a designated individual(s) any complaint that represents an event which must be reported to FDA under 21 CFR Part 803 and failure to maintain these complaints in a separate portion of the complaint files or otherwise clearly identified
Total Citations	**59**		
2 21 CFR 820.100 Citations			
21 CFR 820.100(a)	82	91.1%	Failure to establish and maintain procedures for implementing corrective and preventive action
21 CFR 820.100(b)	8	8.9%	Failure to adequately document corrective and preventative action activities and their results
Total Citations	**90**		
3 21 CFR 820.100 Citations			
21 CFR 820.100(a)	50	87.7%	Failure to establish and maintain corrective and preventive action procedures that include requirements for ensuring the corrective and preventive action is effective
21 CFR 820.100(b)	7	12.3%	Failure to adequately document corrective and preventive action activities and/or results
Total Citations	**57**		