

Table: People

[illegible]

Table: Biologics

Center Name	Cite Id	Reference Number	Short Description
Biologics	76	21 CFR 606.100(b)	Establish, maintain and follow manufacturing SOPs
Biologics	154	21 CFR 606.160(a)(1)	Concurrent documentation
Biologics	98	21 CFR 606.100(c)	Thorough investigations
Biologics	160	21 CFR 606.160(a)(1)	Person performing, test results, interpretation
Biologics	9225	21 CFR 606.171	Biological product deviation report
Biologics	57	21 CFR 606.60(a)	Maintain and clean equipment
Biologics	155	21 CFR 606.160(b)	Required records
Biologics	4425	21 CFR 606.60(a)	Equipment observed, standardized, calibrated
Biologics	41	21 CFR 606.40(a)(1)	Provide space for examination
Biologics	67	21 CFR 606.65(e)	Following manufacturer's instructions

Table: Procedures

Center Name	Cite Id	Reference Number	Short Description	Long Description	Frequency
Devices	3130	21 CFR 820.100(a)	Lack of or inadequate procedures	Procedures for corrective and preventive action have not been finished	344
Devices	14713	21 CFR 820.198(a)	Lack of or inadequate complaint procedures	Procedures for receiving, reviewing, and evaluating complaints by a formally designed.	264
Devices	630	21 CFR 803.17	Lack of Written MDR Procedures	Written MDR procedures have not been [developed] [maintained] [implemented].	146
Devices	3282	21 CFR 820.90(a)	Nonconforming product, Lack of or inadequate procedures	Procedures have not been [adequately] established to control product that does not conform to.	135
Devices	479	21 CFR 820.50	Purchasing controls, Lack of or inadequate procedures	Procedures have not been [adequately] established to control product that does not conform to.	122
Devices	546	21 CFR 820.75(a)	Lack of or inadequate process validation	Procedures have not been [adequately] established to control product that does not conform to.	119
Devices	3696	21 CFR 820.100(b)	Documentation	Procedures have not been [adequately] established to control product that does not conform to.	99
Devices	3103	21 CFR 820.30(i)	Design changes - Lack of or Inadequate Procedures	Procedures have not been [adequately] established to control product that does not conform to.	78
Devices	2327	21 CFR 820.22	Quality audits - Lack of or inadequate procedures	Procedures have not been [adequately] established to control product that does not conform to.	76
Devices	3331	21 CFR 820.181	DMR - not or inadequately maintained	Procedures have not been [adequately] established to control product that does not conform to.	65
Devices	3233	21 CFR 820.72(a)	Calibration, Inspection, etc. Procedures Lack of or Inadequ	Procedures have not been [adequately] established to control product that does not conform to.	61
Devices	14712	21 CFR 820.184	DHR - not or inadequately maintained	Procedures have not been [adequately] established to control product that does not conform to.	56
Devices	3172	21 CFR 820.198(c)	Investigation of device failures	Procedures have not been [adequately] established to control product that does not conform to.	53