CFR Part 111 Current Good Manufacturing Practice (CGMP) Dietary Supplements Compliance Checklist

Item Num	CFR Part 111 Description	Yes	No	NA	Comments
182	(d) Establish and use appropriate controls for automated, mechanical, and electronic equipment (including software for a computer controlled process) to ensure that any changes to the manufacturing, packaging, labeling, holding, or other operations are approved by quality control personnel and instituted only by authorized personnel; and				
183	(e) Establish and use appropriate controls to ensure that the equipment functions in accordance with its intended use. These controls must be approved by quality control personnel.				
	Sec. 111.35 Under this subpart D, what records must you make and keep?				
184	(a) You must make and keep records required under this subpart D in accordance with subpart P of this part.				
185	(b) You must make and keep the following records:				
186	(1) Written procedures for fulfilling the requirements of this subpart, including written procedures for:				
187	(i) Calibrating instruments and controls that you use in manufacturing or testing a component or dietary supplement;				
188	(ii) Calibrating, inspecting, and checking automated, mechanical, and electronic equipment; and				
189	(iii) Maintaining, cleaning, and sanitizing, as necessary, all equipment, utensils, and any other contact surfaces that are used to manufacture, package, label, or hold components or dietary supplements;				
190	(2) Documentation, in individual equipment logs, of the date of the use, maintenance, cleaning, and sanitizing of equipment, unless such documentation is kept with the batch record;				