IIIF	222	Validation and Quality Planning should be added to this statement.	These are important aspects of a quality system.
	229	Add “raw material” or “component’s following the word “rejecting"	Release of raw materials and components is an important aspect of the QC function. Addition of these items completes the listing of items tested throughout the process
III F	230	Add the word “other” prior to the word “manufacturing”	To clarify that the quality unit although separate is part of the overall manufacturing operation
	232	Change "reviewing production records and investigating any unexplained discrepancies" to "actively participating in the investigation of an unexplained discrepancy"	The primary responsibility for investigating unexplained discrepancies should be in the area where the discrepancy occurred. QA should participate and facilitate the investigation but not be solely responsible for the investigation. Quality unit is responsible for assuring investigation not necessarily conducting the investigation
IVA2	235	Please add in that the Quality Unit Manager should have the authority to detect problems and affect solutions.	
III G	272	It is recommended that there be a listing of the six quality systems rather than referring solely to the diagram. Also, suggest a link from the Six System Inspection Approach to the Quality System Model	While the document provides a good linkage from the regulations to the quality system model, there is no linkage between the model and the 6 systems. For example, the Quality System is linked to Management, Resource, and Evaluation Activities; Laboratory Controls Systems is linked to Management, Resources, and Evaluation Activities
IV	282	Please add in phrase in italics: This section describes a robust quality systems that if "designed", implemented and "operated properly" could provide.....	It is not enough to implement.
IV A	306	Please add in phrase in italics: in the design, implementation, "monitoring and continuous improvement" of the quality system.	Continuous improvement is an important aspect of quality systems.
IV A	311	Please add in phrase in italics: in the design, implementation, "monitoring and continuous improvement" of the quality system.	Continuous improvement is an important aspect of quality systems.
IV A 1	317	“Aligning quality plans with the manufacturers…” please delete the word "system"	Quality Planning is a process that is part of a quality system. A section on quality planning would be beneficial.
IV A 1	328	It should be noted a quality system need not be global to be effective. A single site can be successful	
	331	It is suggest that there be an inclusion of a formal mechanism between management and senior management in the form of a documented quality plan and quality systems review.	consistent with QSR requirements for Management responsibility (§ 820.20)