IVA5	428	It will need to be clarified that these recorded results of the management review are considered internal audit documentation	For a quality planning system to be effective, parts will be outside of inspectional jurisdiction.
IVB1	447	Suggest deletion of the word "sufficient"	It is unclear how "sufficient allocation" of resources will be measured.
IV B 1	449	Please include a role for all employees instead of a defined role only specified for senior management.	Under a quality system employees should also be expected to play an active role in monitoring and controlling the systems/processes they work with.
IV B	455	Warehousing should be included as an additional bullet point.	The guidance only discusses the acquisition and receipt of materials. The proper shipping, storage, and warehousing of materials and products should be included in the scope of this guidance.
IV B	456	There should be a bullet added for resources to operate the quality system.	This is consistent with the concept of resource allocation.
IV B. 2	462	Change “cross-cutting” for “cross-functional”	More conventional and clearer terminology
IV B 2	474	Please separate the training element of a quality system as its own section.	Training is an integral part of every quality and manufacturing system.
	487	Please add in the phrase in italics: Evaluation of effectiveness of training "to assure learning or knowledge transfer has occurred"	This addition helps to define the purpose of the evaluation
IV B 3	499	Please revise the mention of FDA reviewing facilities. Instead, it would be better to have more discussion of design for purpose, validation/qualification, calibration, operation, maintenance, control of facilities, and the role that product and engineering play in this area.	
	515	A quality agreement is more applicable to a contract manufacturing arrangement. A contractor should be covered under a service agreement. Consultants should be managed as described in CFR 211.34	Currently quality agreements are necessary for contract manufacturing relationships. Records of consultants including the nature of the work performed and the consultant's competencies to perform their activities are kept.
IVB4	523	It is unclear whether the agency will allow a contractor to be authorized to release final product	If contractor has good quality systems as determined by audit, history, etc., the contract giver should be able to delegate the authority to release product.
IV C 1	545	Suggest adding in technology transfer from R&D to production as a quality system.	
IV C	558	Expand from "validation activities" to "process control activities"	Validation is too limiting a concept.
	559	Change from "effects" to "interaction of"	Interaction is a broader concept