Section	Guidance Line	Comment	Rationale
I	24	Suggest adding to the phrase to the sentence ending with parts 210 and 211 "and to continuously improve the quality and compliance of the product in a methodical manner".	Implementation of quality systems goes beyond fulfilling GMP requirements.
II.A.	47	The agency states that it saw a need to address the harmonization across other regulatory systems (both within and external to the CDER). Pfizer agrees this is a valuable goal and supports an initiative to harmonize across other regulatory systems within FDA and across other agencies.	
II.B.	71	From the guidance: "This guidance describes a comprehensive quality systems model, which, if implemented, will allow manufactures to operate robust, modern quality systems that are fully compliant with cGMP regulations". In order to achieve this there needs to be more focus, if not the main focus on how to design, implement, operate, or improve systems. This needs to be discussed in a future guidance.	FDA is defining what quality systems are needed but not what good quality systems are and how to implement quality systems.
II.B	92	There should be further harmonization across the QSR (CFR 820) and other non-US requirements in the form of guidances. The ICH process provides an excellent vehicle for harmonization.	Harmonization of GMPs, ISO9000, non-US Pharma requirements, and medical devices are admirable goals. While this guideline is an admirable step forward in the goal of harmonization, it is only a beginning not an endpoint
	103	Please add in the phrase in italics: In addition, an effective quality system, by lowering the risk of manufacturing problems, may result in shorter and fewer FDA inspections "and the ability to enact changes with greater regulatory flexibility"	Please refer to Item C in the cover letter
II C	113	"...applies to manufacturers of drug products (finished pharmaceuticals) including products regulated…." Please revise to allow the application to Active Pharmaceutical Ingredients	Please refer to Item D in the cover letter
II	118	There will need to be significant training of inspectors who will be able to correctly assess quality systems and to separate comments on quality systems from observations related to GMP deficiencies.	Please refer to Item E in the cover letter
III	146	There is no definition as to what constitutes a system. For example a system has system design, quality planning, inputs, outputs and a system owner.	In order to fully understand how to develop and implement quality systems, there need to be a basic understanding of a system
III A	156	Please broaden definition of achieving quality to include concepts discussed in this document such as risk management.	Please refer to Item A in the cover letter