ISO 13485:2003 Activity	ISO 13485:2016 Activity	Notes
4 Quality Management System		
4.1 General Requirements	**4.1 General Requirements**	
Establish, document, implement, and maintain a QMS in accordance with ISO 13485:2003. [4.1]	Establish, ~~document~~, implement, and maintain a QMS in accordance with *ISO 13485:2016 and applicable regulatory requirements*. [4.1.1]	
***	*Establish, implement, and maintain activities required to be documented by ISO 13485:2016 or applicable regulatory requirements. [*4.1.1]	
***	*Document any roles of the organization under applicable regulatory requirements. [*4.1.1]	Roles can include manufacturer, authorized representative, importer, distributor, *etc*.
Maintain the QMS effectiveness. [4.1]	Maintain the QMS effectiveness. [4.1.1]	
Identify the QMS process and how they apply throughout the organization. [4.1]	Identify the QMS process and how they apply throughout the organization *taking into account the organization's documented roles.* [4.1.2[	
Determine process sequences and how they interact. [4.1]	Determine process sequences and how they interact. [4.1.2]	