

Refs	Requirements	What to look for and how	Compl	Auditor notes and evidence
		<i>considered?</i>		
4.2.3 820.40(b)	<p>Are document changes reviewed and approved by the same function that performed the original review and approval (unless specifically designated otherwise)?</p> <p>Are change records maintained, including description of the change, identification of the affected documents, approval signatures and date, and when the change becomes effective?</p>	<p>Is there a clearly stated requirement that changes to documents must be reviewed and approved by the same function that issued the original document, or by another, explicitly designated function? Is it implemented?</p> <p>Are changes in documents (mostly product and process specifications) backed by design change and/or process change records, such as engineering change notices? How is it defined/documented when document changes become effective?</p>		
4.2.4 Control of Records				
4.2.4	Is there a documented procedure for the identification, storage, protection, retrieval, retention, and disposition of records?	Are there documented instructions how to identify, organize, store, protect, and retrieve records? Are storage locations for records defined?		
4.2.4 820.180(b)	<p>Are retention periods for records defined?</p> <p>Are records retained for at least the period of time equivalent to the expected life of the device, and no less than 2 years?</p>	<p>Is a retention period defined for each type of record? How is this period determined? Is the retention period at least two years or equivalent to the lifetime of the device, whichever is greater? Are regulatory requirements considered?</p>		
4.2.4 820.180	<p>Are records organized and maintained to ensure that they remain legible, readily identifiable and retrievable, and to prevent deterioration and loss?</p> <p>Are records accessible to the regulatory inspections?</p> <p>Are electronic records backed up?</p>	<p>Are records stored in dry, clean locations to minimize deterioration? Is there a system for organizing the records? Are boxes, drawers, binders holding records properly identified? Are records easily retrievable (not by asking for retrieval of specific records)?</p> <p>Are records kept in a location that is accessible to regulatory inspections?</p> <p>Are electronic records backed up? Are there specific schedules, instructions, etc. for backing up data? Where are the back-up media (tapes, disks, etc.) kept?</p>		
4.2.4 820.181	For each type of device, is there a Device Master Record (DMR) including, or referring to appropriate device specifications, production process specifications, quality assurance procedures, packaging and labeling specifications, and installation, maintenance and servicing procedures and methods?	How is the DMR organized? Is it a file containing the actual specifications documents, or is it a list referring to these documents and their locations? Is the DMR complete, e.g., includes all required categories of documents? Who decides, and how, which documents are included in the DMR? Are all documents included in the DMR correctly identified, reviewed, approved and otherwise controlled? Are the DMR documents the same		

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Jean-Pierre Boutrand

A red circular graphic with a gradient, appearing as a stylized arrow or a partial circle, located to the right of the author's name.

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Iso 13485 Audit Checklist: Bestsellers in 2023 The year 2023 has witnessed a noteworthy surge in literary brilliance, with numerous compelling novels captivating the hearts of readers worldwide. Lets delve into the realm of bestselling books, exploring the engaging narratives that have enthralled audiences this year. Iso 13485 Audit Checklist : Colleen Hoover's "It Ends with Us" This poignant tale of love, loss, and resilience has captivated readers with its raw and emotional exploration of domestic abuse. Hoover skillfully weaves a story of hope and healing, reminding us that even in the darkest of times, the human spirit can triumph. Uncover the Best : Taylor Jenkins Reid's "The Seven Husbands of Evelyn Hugo" This spellbinding historical fiction novel unravels the life of Evelyn Hugo, a Hollywood icon who defies expectations and societal norms to pursue her dreams. Reid's compelling storytelling and compelling characters transport readers to a bygone era, immersing them in a world of glamour, ambition, and self-discovery. Iso 13485 Audit Checklist : Delia Owens' "Where the Crawdads Sing" This evocative coming-of-age story follows Kya Clark, a young woman who grows up alone in the marshes of North Carolina. Owens weaves a tale of resilience, survival, and the transformative power of nature, captivating readers with its evocative prose and mesmerizing setting. These bestselling novels represent just a fraction of the literary treasures that have emerged in 2023. Whether you seek tales of romance, adventure, or personal growth, the world of literature offers an abundance of captivating stories waiting to be discovered. The novel begins with Richard Papen, a bright but troubled young man, arriving at Hampden College. Richard is immediately drawn to the group of students who call themselves the Classics Club. The club is led by Henry Winter, a brilliant and charismatic young man. Henry is obsessed with Greek mythology and philosophy, and he quickly draws Richard into his world. The other members of the Classics Club are equally as fascinating. Bunny Corcoran is a wealthy and spoiled young man who is always looking for a good time. Charles Tavis is a quiet and reserved young man who is deeply in love with Henry. Camilla Macaulay is a beautiful and intelligent young woman who is drawn to the power and danger of the Classics Club. The students are all deeply in love with Morrow, and they are willing to do anything to please him. Morrow is a complex and mysterious figure, and he seems to be manipulating the students for his own purposes. As the students become more involved with Morrow, they begin to commit increasingly dangerous acts. The Secret History is a masterful and gripping novel that will keep you guessing until the very end. The novel is a warning tale about the dangers of obsession and the power of evil.

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