This template is best implemented in an excel / sheets file. Note that an audit program most commonly covers all ISO 13485 requirements in the course of three years at minimum.

Audit Program <Company Name> 2023 - 2026

1. General Information

Auditing Interval	01/2023 - 01/2026
Auditing objective:	<e.g. "13485 compliance" or "preparation for MDR conformity assessment" or "supplier surveillance">
Chances and risks:	<for example: chances - "small company, planning to be audited by an external party to avoid blind spots">

2. Audit Program Plan

Audit ID	#1	#2	#3	(. . .)
Date	<dd.mm.2023>	<dd.mm.2024>	<dd.mm.2025>	<dd.mm.2026>
Lead auditor	(. . .)	(. . .)	(. . .)	(. . .)
ISO 13485:2016, para. 4.1, 4.21:General QMS requirements	x			x
ISO 13485:2016, para. 4.2.2, 5.3, 5.4:Quality manual and QMS planning	x			x
ISO 13485: 2016, para. 4.2.3:Medical device file		x	x	
ISO 13485:2016, para. 4.2.4, 4.2.5:Control of documents and records	x			x
ISO 13485:2016, para. 5.1, 5.2, 5.3., 5.4, 5.5:Management responsibility	x			x
ISO 13485:2016, para. 5.6:Management review	x			x
ISO 13485:2016, para. 6.1, 6.3:Resource management	x			x
ISO 13485:2016, para. 6.2:Human resources management	x			x
ISO 13485:2016, para. 6.4:Work environment and contamination control	n/a	n/a	n/a	n/a
ISO 13485:2016, para. 7.1:Planning product realization		x		

Audit ID	#1	#2	#3	(...)
ISO 13485:2016, para. 7.2:Customer-related processes			x	
ISO 13485:2016, para. 7.3:Design and development		x		
ISO 13485:2016, para. 7.4:Purchasing		x		
ISO 13485:2016, para. 7.5:Production and service provision		x		
ISO 13485:2016, para. 7.6:Measuring equipment		x		
ISO 13485:2016, para. 8.1, 8.2.1, 8.2.2:Feedback and complaints handling			x	
ISO 13485:2016, para. 8.1, 8.2.3:Reporting to authorities			x	
ISO 13485:2016, para. 8.1, 8.2.4:Internal auditing			x	
ISO 13485:2016, para. 8.1, 8.2.5, 8.2.6:Measurement of products and processes			x	
ISO 13485:2016, para. 8.3:Nonconforming products			x	
ISO 13485:2016, para. 8.4:Analysis of data			x	
ISO 13485:2016, para. 8.5:Improvement			x	
Reg. (EU) 2017/745, Chapter VII, Art. 83-86:Post-Market Surveillance			x	
Reg. (EU) 2017/745, Chapter VII, Art. 87-90:Vigilance			x	