

ISO 13485:2016 vs MDRAP Checklist			Prepared by: Greenlight Guru and Regulatory Data		greenlight guru		REGULATORY GLOBE			
ISO 13485:2016			MDRAP			Assessment		Implementation Tracker		
Clause	Sub-Clause	Description	MDRAP	Req	MDRAP/Req	MDRAP/Req	Compliance	Implementation Date	Start	End
4.1	4.1.1	Context of the organization	4.1	+						
4.1	4.1.2	Understanding the needs and expectations of customers and other interested parties	4.1	+						
4.1	4.1.3	Understanding the requirements that are applicable to the organization	4.1	+						
4.1	4.1.4	Understanding the organization and its context	4.1	+						
4.2	4.2.1	Leadership and commitment to quality	4.2	+						
4.2	4.2.2	Customer focus	4.2	+						
4.2	4.2.3	Personnel	4.2	+						
4.2	4.2.4	Infrastructure	4.2	+						
4.2	4.2.5	Process management	4.2	+						
4.2	4.2.6	Measurement, monitoring, and analysis	4.2	+						
4.2	4.2.7	Improvement	4.2	+						
4.2	4.2.8	Management of change	4.2	+						
4.2	4.2.9	Retention of information	4.2	+						
4.2	4.2.10	Control of nonconforming products and services	4.2	+						
4.2	4.2.11	Control of records and data	4.2	+						
4.2	4.2.12	Control of outsourced processes	4.2	+						
4.2	4.2.13	Control of subcontracted processes	4.2	+						
4.2	4.2.14	Control of purchased products and services	4.2	+						
4.2	4.2.15	Control of production and service provision	4.2	+						
4.2	4.2.16	Control of monitoring and measuring equipment	4.2	+						
4.2	4.2.17	Control of calibration and measurement traceability	4.2	+						
4.2	4.2.18	Control of customer property	4.2	+						
4.2	4.2.19	Control of returned products and services	4.2	+						
4.2	4.2.20	Control of nonconforming products and services	4.2	+						
4.2	4.2.21	Control of production and service provision	4.2	+						
4.2	4.2.22	Control of production and service provision	4.2	+						
4.2	4.2.23	Control of production and service provision	4.2	+						
4.2	4.2.24	Control of production and service provision	4.2	+						
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# Iso 13485 2016 Gap Analysis And Tracking Tool

**RJ Shavelson**



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