ISO 13485:2003 and FDA QSR (21 CFR 820) Internal Audit and Gap Analysis Checklist

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In addition to compliance-related questions this checklist also includes an additional column called: - What to look for and how - ; a tutorial with tips and auditing techniques pertaining to the question. This is especially helpful for less experienced auditors and for auditor training.

The checklist is also an excellent gap analysis tool. It can be used in early stages of ISO 13485 and/or FDA QSR (21 CFR 820) implementation project to identify areas where a company s quality system is not fulfilling the requirements of ISO 13485 and/or FDA QSR (21 CFR 820).

The ISOXpress checklist is ideal for auditors, internal auditors, auditor training and for consultants or internal teams implementing and/or managing ISO 13485 and/or FDA QSR (21 CFR 820) quality systems.

The ISOXpress ISO 13485:2003 and FDA QSR (21 CFR 820) Internal Audit and Gap Analysis Checklist comes on a CD-Rom with a 30 page Microsoft Word file and a license to implement in one company. It can be integrated into the ISOXpress Document Control and ISO Management software, and can be used together with ISO 13485 template manual and procedures, training materials and Medical Device Risk Analysis Manual (ISO 14971 Hazard Analysis Process). **These products can be purchased together in our ISOXpress Complete Package.**

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