5. MANAGEMENT REQUIREMENTS

5.1 COMMITMENT REQUIREMENTS			
1	Demonstrate your ongoing commitment.		Part 5.1 requirements must be met by your organization's top managers.
2	Support the development of your QMS.		
3	Ensure that a quality policy is established.		Part 5.3 discusses the requirements that your policy must comply with.
4	Ensure that quality objectives are established.		Part 5.4.1 discusses the need to establish quality objectives.
5	Support the implementation of your QMS.		
6	Communicate your commitment to quality.		
7	Explain why it's important to meet customer requirements.		
8	Explain why it's important to meet regulatory requirements.		
9	Provide suitable implementation resources.		Part 6 asks you to ensure that QMS resources are provided.
10	Support the maintenance of your QMS.		
11	Conduct management reviews.		
12	Provide maintenance resources.		
5.2 EXTERNAL REQUIREMENTS			
13	Ensure that external requirements are determined.		Part 5.2 requirements must be met by your organization's top managers.
14	Expect customer requirements to be determined.		
15	Expect regulatory requirements to be determined.		
16	Ensure that external requirements are being met.		
17	Expect customer requirements to be met.		
18	Expect regulatory requirements to be met.		
5.3 POLICY REQUIREMENTS			
19	Plan your quality policy.		Part 5.3 requirements must be met by your organization's top managers.
20	Make sure that it supports your organization's purpose.		
21	Make sure that it can be used to set quality objectives.		

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22	Make sure that it can be used to review objectives.		
23	Draft your quality policy.		A *quality policy* should express top management's commitment to the quality management system (QMS) and should allow managers to set quality objectives.
24	Make a commitment to comply with requirements.		
25	Make a commitment to maintain QMS effectiveness.		
26	Apply your quality policy.		
27	Communicate your quality policy.		
28	Ensure that it's understood within your organization.		
29	Review your quality policy.		
30	Make sure that your policy is still suitable.		
5.4 PLANNING REQUIREMENTS			
5.4.1 ESTABLISH QUALITY OBJECTIVES			
31	Plan the establishment of quality objectives.		Part 5.4 requirements must be met by your organization's top managers.
32	Make sure that your quality objectives are effective.		A *quality objective* is a quality result that you intend to achieve. *Quality objectives* are generally based on or derived from an organization's quality policy and must be consistent with it. They are usually formulated at all relevant levels within the organization and for all relevant functions.
33	Make sure that your quality objectives are measurable.		
34	Make sure that objectives are consistent with quality policy.		
35	Establish quality objectives for your organization.		
36	Set objectives needed to meet product requirements.		
37	Establish product oriented objectives in relevant functional areas.		
38	Establish product oriented objectives at relevant organizational levels.		
39	Set objectives needed to meet regulatory requirements.		
40	Establish regulatory objectives in relevant functional areas.		
41	Establish regulatory objectives at relevant organizational levels.		

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5. MANAGEMENT REQUIREMENTS

	5.4.2 CARRY OUT QUALITY PLANNING		
42	Plan how you're going to develop your QMS (per 4.1.1).		Part 5.4.2 expects top managers to ensure that QMS planning is carried out in order to meet the requirements listed in parts 4.1 and 5.4.1. We have, therefore, listed these requirements here so that you don't have to keep flipping back and forth between sections (section numbers are shown in parentheses for your convenience).
43	Plan how you're going to document your QMS (per 4.1.1).		
44	Plan how you're going to structure your QMS (per 4.1.2).		
45	Plan how processes will interact with one another (per 4.1.2).		
46	Plan how you're going to manage your QMS (per 4.1.1).		
47	Plan how you're going to apply a risk based approach (per 4.1.2).		According to ISO 13485 2016, when the term *risk* is used it refers to the need to think about what could potentially happen when a manufacturer fails to meet product safety or performance requirements or fails to comply with all applicable regulatory requirements. According to the ISO 14971 risk management standard for medical devices, the concept of *risk* combines two variables: the *probability of harm* and the *severity of harm*. For more information, see www.praxiom.com/14971.htm
48	Plan how you're going to comply with process requirements (per 4.1.4).		
49	Plan how you're going to manage changes to your processes (per 4.1.4).		
50	Plan how you're going to validate and revalidate software (per 4.1.6).		
51	Plan how you're going to monitor your QMS (per 4.1.1).		
52	Plan how you're going to monitor quality objectives (per 5.4.1).		
53	Plan how you're going to monitor outsourced processes (per 4.1.5).		
54	Plan how you're going to control your QMS (per 4.1.1).		
55	Plan how you're going to control the setting of quality objectives (per 5.4.1).		
56	Plan how you're going to develop actions to achieve objectives (per 5.4.1).		
57	Plan how you're going to modify actions to achieve objectives (per 5.4.1).		
58	Plan how you're going to control changes to your QMS (per 5.4.2).		
59	Plan how you're going to protect the integrity of your QMS (per 5.4.2).		
60	Plan how you're going to control outsourced processes (per 4.1.5).		
61	Plan how you're going to implement your QMS (per 4.1.1).		
62	Plan how you're going to maintain your QMS (per 4.1.1).		
63	Plan how you're going to support your processes (per 4.1.3).		
64	Plan how QMS integrity will be protected when changes are made (per 5.4.2).		

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5. MANAGEMENT REQUIREMENTS

5.5 MANAGERIAL REQUIREMENTS

5.5.1 CLARIFY RESPONSIBILITY AND AUTHORITY

65	Define QMS responsibilities and authorities.		Part 5.5 requirements must be met by your organization's top managers.
66	Document your organization's QMS responsibilities and authorities.		According to ISO 13485 2016 section 0.2, *"When a requirement is required to be 'documented', it is also required to be established, implemented and maintained".*
67	Communicate responsibilities and authorities within your organization.		
68	Maintain documents that define QMS responsibilities and authorities.		
69	Document how QMS personnel are interrelated.		
70	Consider people who manage work that affects quality.		
71	Consider how these managers relate to other personnel.		
72	Ensure that managers have the independence they need to do their work.		
73	Ensure that managers have the authority they need to do their work.		
74	Consider people who perform work that affects quality.		
75	Consider how these workers relate to other personnel.		
76	Ensure that these workers have the independence they need to do their work.		
77	Ensure that these workers have the authority they need to do their work.		
78	Consider people who verify work that affects quality.		
79	Consider how these people relate to other personnel.		
80	Ensure that these people have the independence they need to do their work.		
81	Ensure that these people have the authority they need to do their work.		

5.5.2 APPOINT MANAGEMENT REPRESENTATIVE

82	Appoint a member of management to oversee your organization's QMS.		
83	Give management representative the necessary authority and responsibility.		
84	Assign authority and responsibility for documenting your QMS.		
85	Assign authority and responsibility for documenting processes.		

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86	Assign authority and responsibility for maintaining process documents.		
87	Assign authority and responsibility for reporting to top management.		
88	Ask your representative to report on the effectiveness of the QMS.		
89	Ask your representative to report on the need for improvement.		
90	Assign authority and responsibility for promoting corporate awareness.		A note to this section says that you could also make your management representative responsible for liaising with regulatory authorities and other external parties.
91	Ask your representative to make people aware of applicable requirements.		
92	Make your personnel aware of all applicable regulatory requirements.		
93	Make your personnel aware of all applicable QMS requirements.		
5.5.3 ESTABLISH INTERNAL COMMUNICATIONS			
94	Establish appropriate internal communication processes.		
95	Encourage communication about the effectiveness of your QMS.		
5.6 REVIEW REQUIREMENTS			
5.6.1 PERFORM REGULAR MANAGEMENT REVIEWS			
96	Establish management review procedures.		Part 5.6 requirements must be met by your organization's top managers. The purpose of a *management review* is to evaluate the suitability, adequacy, and effectiveness of an organization's quality management system, and to look for improvement opportunities. *Management reviews* are also used to identify and assess opportunities to change an organization's quality policy and quality objectives, to address resource needs, and to look for opportunities to improve its products.
97	Document your management review procedures.		
98	Make sure that your QMS is still suitable.		
99	Make sure that your QMS is still adequate.		
100	Make sure that your QMS is still effective.		
101	Schedule your reviews at planned intervals.		
102	Document your management review schedule.		
103	Review your QMS at planned intervals.		
104	Review the need to change your QMS.		
105	Review the need to change your quality policy.		

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106	Review the need to change your quality objectives.		
107	Review the need to improve your QMS.		
108	Maintain a record of management reviews.		See section 4.2.5 for more on record keeping.
5.6.2 STUDY MANAGEMENT REVIEW INPUTS			
109	Study information about your QMS (inputs).		
110	Review previous management reviews.		
111	Review previous follow up actions.		
112	Review the results of previous audits.		
113	Review monitoring and measurement activities.		
114	Review process monitoring and measurement.		
115	Review product monitoring and measurement.		
116	Review complaint handling activities.		
117	Review previous remedial actions.		
118	Review previous corrective actions.		
119	Review previous preventive actions.		
120	Review new or revised regulatory requirements.		
121	Review reports to regulatory authorities.		
122	Review recommendations for improvement.		
123	Review changes that could affect the QMS.		
5.6.3 GENERATE MANAGEMENT REVIEW OUTPUTS			
124	Generate management review outputs.		
125	Generate decisions and actions to improve your QMS.		
126	Improve the suitability of your organization's QMS.		

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127	Improve the suitability of your QMS processes.		
128	Improve the adequacy of your organization's QMS.		
129	Improve the adequacy of your QMS processes.		
130	Improve the effectiveness of your organization's QMS.		
131	Improve the effectiveness of your QMS processes.		
132	Generate decisions and actions to deal with regulatory changes.		
133	Identify changes needed to respond to new requirements.		
134	Identify changes needed to respond to revised requirements.		
135	Generate decisions and actions to enhance your products.		
136	Enhance products' ability to meet customer requirements.		
137	Generate decisions and actions to address resource needs.		
138	Establish a record of management reviews.		See section 4.2.5 for more on record keeping.
139	Document your management review outputs.		
140	Keep a record of management review inputs.		

For those who wish to use our publication as a checklist, we have provided a column to the right of each task that you can use to record your response. You could record a *DONE*, *TO DO, or N/A* in this column, or you could simply place a **√** to indicate that the task has been or is being performed or you could record an *O/S* to indicate that an item is outstanding.

In the spaces below, enter the name and location of your organization, who completed this page, who reviewed it, and the dates.

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