7. REALIZATION GAP ANALYSIS QUESTIONNAIRE

7.1 PLANNING REQUIREMENTS

1	Do you plan the processes that are needed to realize products?		According to ISO 13485 2016 section 0.2, organizations may ignore or exclude any requirement in sections 6, 7, or 8 if they can justify doing so because of the nature of their activities or products and if doing so does not undermine regulatory compliance.
2	Do you develop the processes that you need to realize products?		
3	Did you develop a risk management process for product realization?		
4	Did you document your product realization risk management process?		
5	Do you maintain records of your risk management activities?		
6	Do you plan how you're going to realize each product?		
7	Do you formulate quality objectives for each product?		
8	Do you establish quality requirements for each product?		
9	Do you clarify specific product realization requirements?		
10	Do you identify your process development requirements?		
11	Do you identify your documentation requirements?		
12	Do you identify your measurement requirements?		
13	Do you identify your monitoring requirements?		
14	Do you identify your inspection requirements?		
15	Do you identify your testing requirements?		
16	Do you identify your storage requirements?		
17	Do you identify your handling requirements?		
18	Do you identify your validation requirements?		
19	Do you identify your verification requirements?		
20	Do you identify your acceptance requirements?		
21	Do you clarify product acceptance criteria?		

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22	Do you identify your traceability requirements?		
23	Do you identify your resource requirements?		
24	Do you identify infrastructure requirements?		
25	Do you identify work environment requirements?		
26	Do you generate product realization planning outputs?		
27	Do you document product realization planning outputs?		
28	Do you ensure that outputs are suitable for your operations?		
29	Do you establish records of your product realization activities?		
30	Do you use records to show that realized product meets requirements?		
31	Do you use records to show that realization processes meet requirements?		
7.2 CUSTOMER REQUIREMENTS			
7.2.1 DETERMINE PRODUCT REQUIREMENTS			
32	Do you clarify your product requirements?		
33	Do you identify requirements specified by your customers?		
34	Do you identify your customers' product requirements?		
35	Do you identify your customers' delivery requirements?		
36	Do you identify your customers' post-delivery requirements?		
37	Do you consider customers' warranty requirements?		
38	Do you consider customers' contractual requirements?		
39	Do you consider customers' maintenance requirements?		
40	Do you consider customers' supplementary requirements?		
41	Do you consider customers' recycling requirements?		

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42	Do you consider customers' disposal requirements?		
43	Do you identify requirements dictated by your product's intended use?		
44	Do you identify requirements imposed by your regulatory bodies?		
45	Do you identify requirements defined by your organization?		
46	Do you identify user training needs and requirements?		
47	Do you ensure that your medical device will perform as promised?		
48	Do you ensure that people will make safe use of your medical device?		
7.2.2 REVIEW YOUR PRODUCT REQUIREMENTS			
49	Do you evaluate product requirements before you accept orders?		
50	Do you review product requirements before you supply products?		
51	Do you review product requirements before you accept an order?		
52	Do you review product requirements before you submit a tender?		
53	Do you review product requirements before you accept a contract?		
54	Do you review product requirements before you accept changes?		
55	Do you verify product requirements before you agree to accept orders?		
56	Do you verify that product requirements are defined before you agree?		
57	Do you resolve differences between initial proposals and final contracts?		
58	Do you verify that product requirements are documented before you agree?		
59	Do you confirm the accuracy of unwritten orders before you accept them?		
60	Do you amend documents whenever product requirements are changed?		
61	Do you make relevant personnel aware of any changes that are made?		
62	Do you verify that regulatory requirements are being met before you agree?		

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63	Do you verify that user training requirements are specified before you agree?		
64	Do you verify that user training plans exist before you accept orders?		
65	Do you verify that user training will be available when users need it?		
66	Do you confirm that product requirements can be met before you proceed?		
67	Do you confirm that your organization is capable of meeting requirements?		
68	Do you maintain a record of your organization's product requirement reviews?		
69	Do you record the results of your reviews and any actions that are taken?		
7.2.3 COMMUNICATE PRODUCT REQUIREMENTS			
70	Do you plan arrangements to communicate with customers?		
71	Do you document your customer communication arrangements?		
72	Do you clarify how product information should be handled?		
73	Do you clarify how customer interactions should be handled?		
74	Do you clarify how customer enquiries should be handled?		
75	Do you clarify how customer orders should be handled?		
76	Do you clarify how amendments to orders should be handled?		
77	Do you clarify how customer contracts should be handled?		
78	Do you clarify how contractual changes should be handled?		
79	Do you clarify how customer feedback should be handled?		
80	Do you clarify how customer complaints should be handled?		
81	Do you clarify how advisory notices should be handled?		
82	Do you implement your customer communication arrangements?		
83	Do you maintain your customer communication arrangements?		

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84	Do you make sure that your customer communications are effective?		
85	Do you establish arrangements to communicate with regulatory authorities?		
86	Do you use your arrangements to communicate with regulatory authorities?		
87	Do you ensure that communications comply with regulatory requirements?		
7.3 DEVELOPMENT REQUIREMENTS			
7.3.1 PREPARE DESIGN AND DEVELOPMENT PROCEDURES			
88	Do you establish procedures for design and development?		
89	Do you document procedures for design and development?		
90	Do you use your procedures to carry out design and development?		
91	Do you maintain your organization's design and development procedures?		
7.3.2 ORGANIZE DESIGN AND DEVELOPMENT ACTIVITIES			
92	Do you plan the design and development of your products?		
93	Do you document your product design and development plans?		
94	Do you document your assignment of authority and responsibility?		
95	Do you document your product design and development stages?		
96	Do you document your review activities for each stage?		
97	Do you document your validation activities for each stage?		
98	Do you document your verification activities for each stage?		
99	Do you document your design transfer activities for each stage?		
100	Do you document your design and development traceability methods?		
101	Do you document how your outputs will be traced back to your inputs?		

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102	Do you document your design and development resource requirements?		
103	Do you document design and development competence requirements?		
104	Do you maintain your design and development planning documents?		
105	Do you update your planning documents as your work progresses?		
106	Do you control the design and development of your products?		
107	Do you control the assignment of authority and responsibility?		
108	Do you control your product design and development stages?		
109	Do you control your review activities for each stage?		
110	Do you control decision making for each stage?		
111	Do you control your validation activities for each stage?		
112	Do you control your verification activities for each stage?		
113	Do you control your design transfer activities for each stage?		
114	Do you control your design and development traceability methods?		
115	Do you control how your outputs will be traced back to your inputs?		
116	Do you control the allocation of design and development resources?		
117	Do you control the assignment of design and development personnel?		
7.3.3 DETERMINE DESIGN AND DEVELOPMENT INPUTS			
118	Do you determine product design and development inputs?		
119	Do you consider design and development input requirements?		
120	Do you clarify your product's performance requirements?		
121	Do you clarify your product's functional requirements?		
122	Do you clarify your product's process requirements?		

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123	Do you clarify your product's regulatory requirements?		
124	Do you identify applicable regulatory standards?		
125	Do you clarify your product's usability requirements?		
126	Do you clarify your product's safety requirements?		
127	Do you consider applicable risk management outputs?		
128	Do you consider information about other similar designs?		
129	Do you review your product design and development inputs?		
130	Do you ensure design and development inputs are adequate?		
131	Do you make sure that all input requirements are adequate?		
132	Do you make sure that all input definitions are complete?		
133	Do you make sure that all input ambiguities are eliminated?		
134	Do you make sure that all input contradictions are resolved?		
135	Do you make sure that all input requirements are verifiable?		
136	Do you make sure that input requirements can be validated?		
137	Do you approve your product design and development inputs?		
138	Do you ensure that all essential requirements have been identified?		
139	Do you ensure that essential product requirements have been identified?		
140	Do you ensure that essential process requirements have been identified?		
141	Do you maintain a record of design and development inputs?		
7.3.4 GENERATE DESIGN AND DEVELOPMENT OUTPUTS			
142	Do you generate suitable design and development outputs?		
143	Do you create outputs that can be verified against inputs?		

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144	Do you specify product characteristics that are essential?		
145	Do you specify product characteristics that are essential to its safe use?		
146	Do you specify product characteristics that are essential to its proper use?		
147	Do you provide information that your processes need?		
148	Do you provide information that your purchasing process needs?		
149	Do you provide information that your production process needs?		
150	Do you consider explaining how products are preserved during production?		
151	Do you provide information that your service provision process needs?		
152	Do you consider explaining how products are preserved during service provision?		
153	Do you reference or specify product acceptance criteria?		
154	Do you verify your product design and development outputs?		
155	Do you approve your product design and development outputs?		
156	Do you approve outputs before they are officially released?		
157	Do you maintain records of design and development outputs?		
7.3.5 CARRY OUT DESIGN AND DEVELOPMENT REVIEWS			
158	Do you plan your organization's design and development reviews?		
159	Do you make arrangements to carry out reviews at suitable stages?		
160	Do you document your design and development review arrangements?		
161	Do you implement your design and development review arrangements?		
162	Do you ask people from concerned functions to participate at each stage?		
163	Do you consider regulatory design and development review requirements?		
164	Do you ask independent persons to participate at each stage (if required)?		

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165	Do you maintain your design and development review arrangements?		
166	Do you perform reviews in accordance with your planned arrangements?		
167	Do you assess how well design and development results meet requirements?		
168	Do you identify and propose actions to address any shortcomings?		
169	Do you maintain records of your design and development reviews?		
170	Do you record the unique identity of the design under review?		
171	Do you record the names of design and development participants?		
172	Do you record the dates of your design and development reviews?		
173	Do you record the results of your design and development reviews?		
174	Do you record any actions that must be taken in response to reviews?		
7.3.6 PERFORM DESIGN AND DEVELOPMENT VERIFICATIONS			
175	Do you plan your organization's design and development verification activities?		
176	Do you make arrangements to perform design and development verifications?		
177	Do you document your design and development verification arrangements?		
178	Do you plan how you intend to verify that design outputs meet inputs?		
179	Do you consider regulatory requirements when planning verifications?		
180	Do you plan verifications for devices that connect to other devices?		
181	Do you plan to verify that inputs meet outputs when connected?		
182	Do you implement your design and development verification arrangements?		
183	Do you maintain your design and development verification arrangements?		
184	Do you document your organization's design and development verification plans?		
185	Do you document your design and development verification methods?		

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186	Do you document your design and development acceptance criteria?		
187	Do you document your statistical techniques (when appropriate)?		
188	Do you document how sample size is chosen and explain your rationale?		
189	Do you implement your design and development verification methods?		
190	Do you maintain your design and development verification methods?		
191	Do you perform verifications in accordance with your planned arrangements?		
192	Do you verify that design and development outputs meet input requirements?		
193	Do you perform verifications for devices that connect to other devices?		
194	Do you verify that outputs meet inputs when devices are connected?		
195	Do you maintain records of your design and development verification activities?		
196	Do you record design and development verification results and conclusions?		
197	Do you record actions taken in response to results and conclusions?		
7.3.7 CONDUCT DESIGN AND DEVELOPMENT VALIDATIONS			
198	Do you plan your organization's design and development validation activities?		
199	Do you make arrangements to perform design and development validations?		
200	Do you document your design and development validation arrangements?		
201	Etcetera...		

Now that you've seen a sample of our approach, please consider purchasing our complete ISO 13485 2016 Gap Analysis Tool (Title 46). If you purchase our Gap Analysis Tool, you'll find that it's integrated, detailed, exhaustive, and easy to understand. We guarantee it.

Title 46 is 99 pages long and comes in both pdf and MS Word file formats.

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