Correspondence between ISO13485:2016 and MHLW MO 169 Chapter 2, as revised in 2021

MHLW MO 169 Chapter 2 Basic Requirements Regarding Manufacturing Control and Quality Control of Medical Devices	ISO 13485:2016 Medical devices -- Quality management systems -- Requirements for regulatory purposes	Note for understanding the requirements of MHLW MO 169 Chapter 2, as amended in 2021
Section 1 General Rules	1 Scope	
4	1, paragraph 4 and 5	Scope of the requirements of this chapter is explained in this Article. Article 4.1 specifies that Class 1 medical devices are exempted from the requirements of design and development, Article 30 to Article 36-2. Article 4.2 and 4.3 specifies the rule of exclusion and non-application of the requirements. These articles are identical to the description of ISO13485:2016 clause 1, paragraph 4 and 5.
Section 2 Quality Management System	4. Quality management system	
5-1	4.1.1	Roles undertaken by the organization are Marketing Authorization Holder provided by Article 23-2.1 of PMD Act, Registered Manufacturing Site provided by Article 23-2-3.1 and 23-2-4.1 of PMD Act, Seller of pharmaceutical products provided by Article 24.1 of PMD Act, Seller and Leaser of specially-controlled medical devices provided by Article 39.1 of PMD Act, Repairer of medical devices provided by Article 40-2.1 of PMD Act, or Seller and Leaser of controlled medical devices provided by Article 39-3.1 of PMD Act.
5-2	4.1.2	
5-3	4.1.3	
5-4	4.1.4	
5-5	4.1.5	
5-6	4.1.6	
6	4.2.1	
7-1	4.2.2	
7-2	4.2.3	
8	4.2.4	The retention period of obsolete documents required by the ordinance is specified by Article 67.
9	4.2.5	The record retention period required by the ordinance is specified by Article 68.
Section 3 Management responsibility	5. Management responsibility	
10	5.1	
11	5.2	
12	5.3	
13	5.4.1	
14	5.4.2	

15	5.5.1	
16	5.5.2	
17	5.5.3	
18	5.6.1	
19	5.6.2	The organization is not required to input “reporting to regulatory authorities”, the item specified in ISO13485:2016 5.6.2 c), to management review, when the organization is the person operating the registered manufacturing site.
20	5.6.3	
Section 4 Resource Management	6. Resource Management	
21	6.1	
22	6.2, paragraph 1 and 2	
23	6.2, paragraph 3	
24	6.3	
25-1	6.4.1	
25-2	6.4.2	
Section 5 Product realization	7. Product realization	
26	7.1	
27	7.2.1	
28	7.2.2	
29	7.2.3	
30	7.3.1, 7.3.2	
31	7.3.3	
32	7.3.4	
33	7.3.5	
34	7.3.6	
35-1	7.3.7	Clinical evaluations and/or evaluation of performance of the medical devices are required to be implemented as part of design and development validation, in the case that the medical device is designated by 23-2-5.3 or 23-2-9.4 of PMD Act.
35-2	7.3.8	
36-1	7.3.9	
36-2	7.3.10	
37	7.4.1	
38	7.4.2	
39	7.4.3	
40	7.5.1	
41	7.5.2	

42	7.5.3	
43	7.5.4	
44	7.5.5	
45	7.5.6	
46	7.5.7	
47	7.5.8	
48	7.5.9.1	
49	7.5.9.2	The requirements of Article 49.2 and Article 49.3, which are identical to the requirements of ISO13485:2016 7.5.9.2 paragraph 2 and 3, are not applied, when the organization is the person operating the registered manufacturing site.
51	7.5.10	
52	7.5.11	
53	7.6	
Section 6 Measurement, analysis and improvement	8 Measurement, analysis and improvement	
54	8.1	
55-1	8.2.1	
55-2	8.2.2	This article is identical to the requirement of ISO13485:2016 8.2.2. However, it should be noted that the organization is required to determine the need to report the information to the Marketing Authorization Holder instead of the regulatory authorities, when the organization is the person operating the registered manufacturing site.
55-3	8.2.3	This article is identical to the requirement of ISO13485:2016 8.2.3. However, it should be noted that the organization is required to notify the information to the Marketing Authorization Holder instead of the regulatory authorities, when the organization is the person operating the registered manufacturing site. Record of the notification shall also be maintained.
56	8.2.4	
57	8.2.5	
58	8.2.6, paragraph 1-3	
59	8.2.6, paragraph 4	
60-1	8.3.1	
60-2	8.3.2	
60-3	8.3.3	
60-4	8.3.4	
61	8.4	
62	8.5.1	
63	8.5.2	

64	8.5.3	