Documents to be submitted list for QMS compliance inspection application.

- You have to submit documents shown in the following table 1 when you will apply for QMS compliance inspection.
- It is possible to submit documents shown in the following table 2 after the decision of desktop or on-site QMS compliance inspection.

※Documents highlighted in orange is related to RMS.

※MAH：Marketing Authorization Holder.　RMS：Registered Manufacturing Site.

Table 1. Submitted documents for QMS compliance inspection application（Decision of desktop or on-site QMS compliance inspection）

Doc. No.	Submitted documents list	Form/ Sample	Pre-approval/ Pre-partial change QMS inspection	Periodic post-approval QMS inspection
1-1-1	The copy of Pre-approval or Pre-partial change application. (The copy of notifications for exporting MD/IVDs as applicable.)	—	□	—
1-1-2	The copy of Pre-partial change applications and Minor change notifications over the previous QMS compliance inspection performed by PMDA.	—	□ ※Only Pre-partial change	□
1-1-3	One of the following items. ・ISO13485 certification and audit report over the past 3 years. ・On-site QMS compliance inspection report over the past 3 years issued by registered certification bodies in Japan ・QMS inspection report issued by the foreign governments under MOU, etc.	—	□	□
1-1-4	Manufacturing process flow.（Only application product）	Sample1	□	□
1-1-5	Outline of contents of MAH/RMS activities and documents which can identify mutual relations of QMS between MAH and RMS.	Sample2	□	□
1-1-6	Outline of Recall which MAH had over the previous QMS inspection performed by PMDA.	—	—	□
1-1-7	Self-Declaration of QMS compliance inspection application.	Form1	—	□
1-2-1	Outline of MAH/RMS.	Form2	□	□
1-2-2	Product list for QMS compliance inspection and QMS compliance Certification.	Form3	□	□
1-2-3	The production and marketing number of application product over the past 3 years in Japan.	—	—	□
—	Others if any request from PMDA.	—	□	□

Table 2. Submitted documents for desktop QMS compliance Inspection

Doc. No.	Submitted documents list	Form/ Sample	Pre-approval/ Pre-partial change QMS inspection	Periodic post-approval QMS inspection
2-1-1	Layout of RMS building (location map). ※Without Design facility and MAH.	Sample3	□	□
2-1-2	Floor plan, representative list of manufacturing and inspection equipment. ※Without Design facility and MAH.	Sample4	□	□
2-2-1	Organization chart.	Sample5	□	□
2-2-2	Quality management system.	—	□	□
2-2-3	List of documents identified with QMS.	Sample6	□	□
2-3-1	Seihin Hyojun Sho of application product. Ex.: Outline of DMR.	Sample7	□	□
2-3-2	Outline of application product. Ex.: Information for use in Japanese.		□	□
2-3-3	Implementation status of the validation of manufacturing and sterilization process.	Sample8	□	□
2-3-4	Documents of self-inspection performed about quality and safety of MD/IVDs used bio-based raw materials.	—	—	□
2-4-1	The procedure of reporting adverse events from RMS to MAH.	—	□	□
2-4-2	Self-Declaration of ability of the domestic quality assurance manager.	Form4	□	□
2-4-3	The operating procedures of the domestic quality assurance manager.	—	□	□
2-4-4	Quality Agreement between MAH and RMS.	—	□	□
2-4-5	The procedure of the following items, (1)Response to notices from repairers of medical devices. (2)Ensuring quality in retailers or leasers of medical devices. (3)Response to notices from retailers or leasers of used medical devices	—	□	□