➲ Chapter 1 : Process Management

Task	Item	ISO13485:2016 Clause	Jurisdiction Requirements
1	Quality Manage System Planning	4.1.1, 4.1.2, 4.1.3, 4.2.2, 4.1.4, 5.4.2	
2	Management representative	5.5.2	
3	Quality Policy and Quality Objective	5.3, 5.4.1	
4	Organization structure, Responsibility, Authority, resource	5.1, 5.5.1, 5.5.2, 6.1, 6.2	
5	Extent of outsourcing	4.1.5, 4.2.1	**TGA :** if outsource to Australian Sponsor confirm qualification /control **Canada :** document / qualify control of supplier for regulatory , importer , sponsor , provider of service.
6	Personnel competency and Training	4.2.1, 6.2	**Brazil (ANVISA) :** Consultant of medical devices QMS process has : - Proper qualification - Contracted as a formal service supplier
7	Risk management planning and review	4.1.2 (b), 7.1	
8	Document Control	4.1.4, 4.2.1, 4.2.4, 4.2.5	**Australia (TGA) :** Document retention at least 5 years.

Task	Item	ISO13485:2016 Clause	Jurisdiction Requirements
			Brazil (ANVISA) : - Change records, the approval signature, date , and when the change effective - Electronic record and documents have backups - retained periods (5 years for training records and documentation) **Japan** - 15 years for 'specially designated' - 5 years for other the products **United States (FDA)** Verify that electronic records and documents have backups
9	Management review	5.6	
10	Distribution of device with appropriate Marketing Authorization	4.1.1, 4.2.1, 5.2, 7.2.1, 7.2.3	
11	Top management commit to quality	4.1.1, 4.1.4, 5.1, 5.5.3	

➲ Chapter 2 : Process : Device Marketing Authorization and Facility Registration

Task	Item	ISO13485:2016 Clause	Jurisdiction Requirements
1	Submission for Device MA & FR	4.1.1, 4.2.1, 5.2, 7.2.1, 7.2.3	Please read in Companion document
2	Evidence of Marketing clearance and Approval	4.1.1, 4.2.1, 5.2, 7.2.1, 7.2.3	Please read in Companion document
3	Notification of change to Marketed device or to the QMS	4.1.1, 4.2.1, 5.2, 7.2.1, 7.2.3, 7.3.9	Please read in Companion document

➲ Chapter 3 : Process : Measurement , Analysis and Improvement (MAI)

Task	Item	ISO13485:2016 Clause	Jurisdiction Requirements
1	Procedure for MAI of QMS effective and product conformity	4.2.1, 8.1, 8.2.1, 8.2.6, 8.5	**Brazil (ANVISA) :** Information about NC product communicate to direct concern person **US FDA :** same with Brazil + need procedure and CAPA need to submit to management review
2	Sources of Quality Data	7.5.4, 8.1, 8.2.1, 8.2.6, 8.4	
3	Investigation of NC	8.5.2	
4	Investigation of Potential NC	8.5.3	

Correspondence Between

ISO 13485:2016 and MDSAP (Country requirements)

Task	Item	ISO13485:2016 Clause	Jurisdiction Requirements
5	Correction , CA and PA	8.2.1, 8.2.5, 8.3.1, 8.5.2, 8.5.3	
6	Assessment of Design change resulting from CAPA	7.1, 7.3.9	
7	Assessment of Process change resulting from CAPA	4.1.2, 4.1.1, 4.1.6, 4.2.1, 7.1, 7.5.2, 7.5.6, 7.5.7	**Australia (TGA):** Before implement of change of critical process, mfg will notify to AO **Canada (HC) :** Class III or IV device need procedure for significant change verify that need to submit the medical device license amendment application **Japan :** Registered mfg site need to inform to MAH for significant change
8	Identification and control of NC product	8.3.1, 8.3.2	
9	Action Regarding NC product detected after delivery	8.3.3, 8.5.2	
10	Internal Audit	6.2, 8.2.4	
11	Information Supplied for Management review	5.6.2	
12	Evaluation of Information from Post production including complaint	4.2.1, 7.2.3, 7.5.4 (a) , 8.2.1, 8.2.2	**TAG :** Post production experience procedure. **Brazil :** Complaint procedure

Task	Item	ISO13485:2016 Clause	Jurisdiction Requirements
			Canada : maintain of record of complaint and procedure for complaint / recall **Japan :** confirm communication system to JMAH. **US FDA :** Complaint procedure [Processed, oral complaint, reportable] necessary for investigate , record included
13	Communication with External parties involved on complaint	4.1.5, 7.4.1, 8.3.1	
14	Notification of Adverse Event	4.2.1, 7.2.3, 8.2.3	
15	Notification of Advisory Notices	4.2.1, 7.2.3, 8.3.3	
16	Top Management commitment to MAI process	4.1.3, 5.2, 8.1, 8.5.1	

➲ Chapter 4 : Process : Medical Device Adverse Events and Advisory Notices Reporting

Task	Item	ISO13485:2016 Clause	Jurisdiction Requirements
1	Notification of Adverse Event	4.2.1, 7.2.3, 8.2.2, 8.2.3	Detail in Companion Document
2	Notification of Advisory Notices	4.2.1, 7.2.3, 8.2.2, 8.2.3	Detail in Companion Document

➲ Chapter 5 : Process : Design and Development

Task	Item	ISO13485:2016 Clause	Jurisdiction Requirements
1	Identification of Device Subjected to D&D procedure , Technical Document	4.1.1, 4.2.1, 7.1, 7.3.10	**TGA :** TGR Reg Division 3.2 with Full QA [TG (MR)R Sch.3 Part 1] , need procedure. **Brazil :** No exception to design Control If outsource – Review DMR and Design transfer record **Canada :** Class II – not subject to design, verify meet of safety and effectiveness **Japan :** Class 1 not require
2	Selection of a Completed Design and Development project		
3	Design and Development Planning	4.2.1, 7.1, 7.3.2	**TGA :** documented , typically as part of Quality plan **Canada :** Class IV maintain Quality Plan (Quality Practices, Resources, sequence

Task	Item	ISO13485:2016 Clause	Jurisdiction Requirements
			of activity)
4	Implementation of the D&D process – Procedure	4.2.1, 7.3.1, 7.3.10	**US FDA :** design input procedures contain a mechanism for addressing incomplete ,ambiguous , or conflicting requirements
5	Design and Development Input	4.2.1,5.2, 7.2.1, 7.3.3	**TGA :** identified the relevant Essential Principles **US FDA :** appropriate marketing clearance [510(K)] or pre – market approval (PMA)
6	Completeness , coherence and unambiguity of D&D input	7.3.3	
7	D&D output and Design Verification	4.2.1, 4.2.3, 7.3.4	**TGA :** state of the art std applied. / Device incorporating with medicinal , data relation to substance / interaction
8	Risk Management Activities Applied throughout the D&D project	4.2.1, 7.1, 7.3.3, 7.3.4	**Brazil :** establish / maintain of RM entire life cycle of product / Hazard identified in normal and fault condition **US FDA :** Hazard identified, risk estimate in normal and fault condition, / reduce risk in appropriate mean, change not introduce new hazard.

Task	Item	ISO13485:2016 Clause	Jurisdiction Requirements
9	Design Verification or Design Validation to confirm effectiveness of risk control measure	7.1, 7.3.6, 7.3.7	
10	Design Validation	4.2.1, 7.3.7	
11	Clinical Evaluation and / or Evaluation of Medical device Safety and Performance	4.2.1, 7.3.7	**TGA :** Verify that record of the validation include clinical evidence as required by the clinical evidence procedures
12	Software Specifics	7.3.2, 7.3.10	
13	Design and Development Change	4.2.1, 4.2.3, 7.1, 7.3.9, 7.3.10	**TGA :** procedure to notify change to AO , identifying a proposed substantial change of class AIMD , Class III device and notify prior change **Brazil :** design change was correctly and promptly submitted to ANVISA for approval **Canada:** procedure for identifying a “significant change” to a Class III or IV medical device. Significant changes” is submitted in a medical device license amendment application [CMDR 1, 34]. **Japan :** MAH has submitted a new, a change application, or a change notification to PMDA, mfg site has a

Task	Item	ISO13485:2016 Clause	Jurisdiction Requirements
			mechanism to communicate with the MAH about device modifications **US FDA :** Verify that the organization obtained a new 510(K) or supplement to the per-market approval
14	Design Review	4.2.1, 7.3.2, 7.3.5	**US FDA :** ensure that participants include representatives of all function concerned and an individual(s) who does not have direct responsibility for the design stage, as well as any specialists needed
15	Impact Review of D&D change on Previously Made and Distributed Device	7.3.9	
16	Design transfer	4.2.1, 7.2.3, 7.3.8	**Brazil :** design is not released for production until its approval by the persons assigned by the manufacture and that the persons assigned review all records required to the design history file, Confirm that this release , including date and manual or electronic signature of the responsible is documented
17	Top Management commitment to D&D process	4.1.3, 5.1, 5.5.1	

➲ Chapter 6 : Production and Service Controls

Task	Item	ISO13485:2016 Clause	Jurisdiction Requirements
1	Planning of PS process	7.1, 7.2.1, 7.5.1	**US FDA :** UDI
2	Selection of PS process		
3	Control for the Implementation of selected PS process	7.5.1, 8.2.5, 8.2.6	
4	Control of product cleanliness – remove or process agents	4.2.1, 8.4.2, 7.5.2	**Brazil :** pest control program, housekeeping procedures
5	Infrastructure	4.2.1, 6.3, 7.5.1	**Brazil :** provide adequate means for people flow
6	Work Environmental	4.2.1, 6.4	
7	Identification of processes subjected to validation	4.2.1, 4.1.6, 7.5.6	**Brazil :** analytical methods, supporting auxiliary systems for production and environmental control that can adversely affect product quality or the quality system are validated. **US FDA :** Process validation is required for sterilization, aseptic processing, injection molding, and welding

Correspondence Between

ISO 13485:2016 and MDSAP (Country requirements)

Task	Item	ISO13485:2016 Clause	Jurisdiction Requirements
8	Process Validation	4.2.1, 7.5.6	**TGA :** validation have regard to the generally acknowledged stage of the art
9	Validation of sterilization process – Annex 2	4.2.1, 7.5.5, 7.5.6, 7.5.7	**TDA :** Verify that methods of sterilization validation have regard to the generally acknowledged stage of the art
10	Monitoring and measurement of product conformity	7.1, 7.5.1, 8.1, 8.2.6	
11	Control , operation and monitoring of the PS process , risk control	7.1, 7.5.1, 8.1, 8.2.5	
12	Competence of Personnel	6.2	
13	Control of Monitoring and Measurement Device	7.5.1, 7.6	
14	Impact analysis of monitoring and measuring device found out of specification	7.6	
15	Validation of software use for the control of PS process	4.1.6, 7.5.6, 7.6	
16	Device Master File – Traceability base on risk	4.2.1, 4.2.3, 7.1, 7.5.8, 7.5.9.1	**Brazil :** procedure to ensure integrity and to prevent accidental mixing of

Task	Item	ISO13485:2016 Clause	Jurisdiction Requirements
			labels, instructions, and packaging materials / labels are designed, printed , applied / remain legible and attached to the product during processing , storage , handing and use **Canada :** evident that device meet safety / requirement of DMDR , Label requirement detail, distribution record. **US FDA :** control number is accompany the device throughout distribution
17	Production Record , Evidence of compliance of release devices	4.2.1, 7.5.1, 7.5.8, 7.5.9.1, 8.2.6	**Brazil :** DHR detail / Label examine prior use , approval detail **US FDA :** label examine prior use / UDI , prevent mix up of label / use of label for identification.
18	Traceability Applied to implantable , life-sustaining medical device	4.2.1, 7.5.9.2, 8.2.6	**Canada :** Schedule 2 implants and provides implant registration cards **US FDA :** tracking system for devices for which the manufacturer has received a tracking order from FDA, periodic audit.
19	Identification of Product	7.5.8	

Task	Item	ISO13485:2016 Clause	Jurisdiction Requirements
	status		
20	Customer properties	7.5.10	
21	Acceptance Activities documented – commensurate with the risk posed by the device.	4.2.1, 7.4.3, 7.5.8, 8.2.6	**Brazil :** sampling plans are defined and based on valid statistical rationale **US FDA :** procedure to ensure that sampling methods are adequate for their intended use
22	Identification , control and disposition of NC products	7.5.8, 8.3	
23	Rework of NC product	8.3.4	
24	Preservation of the product	7.5.8, 7.5.11	
25	Review of customer requirement , distribution record	4.2.1, 5.2, 7.2.2, 7.5.9	**Brazil :** Distribution record detail Canada : Distribution record detail / retention time of distribution record [useful life / 2 yr after distributed] **US FDA :** Distribution record detail
26	Installation activities	7.5.3	
27	Servicing activities	4.2.1, 7.5.4, 8.4	**Brazil :** Servicing record detail / periodically review for CAPA **US FDA :** Reportable / servicing report detail
28	Risk control , applied to Transport, installation,	7.1, 7.5.1, 7.5.3, 7.5.4, 7.5.11	

Task	Item	ISO13485:2016 Clause	Jurisdiction Requirements
	servicing		
29	Top management commitment to PS process	5.1, 5.2	

➲Chapter 7 : Purchasing

Task	Item	ISO13485:2016 Clause	Jurisdiction Requirements
1	Planning Activity – Purchased product / outsource process	4.1.2, 4.1.3, 4.1.5, 7.1, 7.4.1, 7.4.2, 7.4.3	
2	Selection of Supplier file to audit		
3	Procedure – Purchased product / outsource process	7.4.1	
4	Extent of control – Supplier / Purchased product , Criteria for supplier [Selection , evaluation and re-evaluate]	7.4.1	
5	Selection of supplier – base on ability to satisfy purchase specification / Record of Supplier evaluation	4.2.1, 7.1, 7.4.1	**TGA :** outsource to Australian Sponsor – need control **Canada :** regulatory correspondent used by manufacture is treated as s

Task	Item	ISO13485:2016 Clause	Jurisdiction Requirements
			supplier and is adequately qualified. Japan : MAH outsource process to RMS – Verify / RMS outsource to RMS – Verify QMS
6	Effective control over suppler and product	7.4.1	
7	Supplier – Re-evaluation	7.4.1	
8	Verification of Purchasing information [Purchase requirement , Written agreement] – Risk Control measure	4.2.1, 7.4.9	**Brazil :** PO approved by designated person / date , signature – documented
9	Documented Purchasing information / purchase requirement	7.4.9, 7.5.9	
10	Verification of purchased product – commensurate with risk / maintain record	4.2.1, 7.1, 7.4.3	**Brazil :** procedure for retention of component , Raw material , in process product, returned product
11	Purchasing control data – MAT source of quality data	8.4	
12	Top Management	4.13, 4.15, 5.2	