ISO 13485:2016 - 9001:2015 CLIENT TRANSITION CHECKLIST

Audit Conclusions:

	All requirements have been addressed. The organization is recommended for ISO 13485:2016 ISO 9001:2015 certification.
	Recommendation for registration is dependent upon the organization submitting a corrective action plan to address the findings that have been raised.
	Recommendation for registration cannot be made at this time. An on-site special visit will be required to review the corrective actions taken to address the findings raised.

Standard Concepts: Please complete the tables below to demonstrate that the organization has addressed each of these new concepts and themes throughout their integrated QMS. These concepts and themes will bridge multiple processes, clauses and functional areas. Ensure that these have been deployed in a manner that supports the methodology of the process approach and risk based thinking.

This checklist should be used to validate organizations integrated quality management system and record objective evidence of a full integrated system, if organizations has failed to integrate their management system then full AMDAC days will be applied for both to ISO 9001:2015 and ISO 13485:2016 assessments.

Organization shall consider “where applicable” to apply unless a fully documented and where possible with customer approval.

Clause in ISO 13485:2016	Clause in ISO 9001:2015	Evidence/Reference/ Documented Exclusion	Finding/Concern Reference
1 Scope **4.1.1** (no title)	**1** Scope **4.3** Determining the scope of the quality management system		
4 Quality management system	**4** Context of the organization **4.1** Understanding the organization and its context **4.2** Understanding the needs and expectations of interested parties **4.4** Quality management system and its processes		
4.1 General requirements	**4.4** Quality management system and its processes **8.4** Control of externally provided processes, products and services		
4.2 Documentation requirements	**7.5** Documented information		

Clause in ISO 13485:2016	Clause in ISO 9001:2015	Evidence/Reference/ Documented Exclusion	Finding/Concern Reference
4.2.1 General	**7.5.1** General		
4.2.2 Quality manual	**4.3** Determining the scope of the quality management system **4.4** Quality management system and its processes **7.5.1** General		
4.2.3 Medical device file	No equivalent clause, must be in place without exception		
4.2.4 Control of documents	**7.5.2** Creating and updating **7.5.3** Control of documented information		
4.2.5 Control of records	**7.5.2** Creating and updating **7.5.3** Control of documented information		
5 Management responsibility	**5** Leadership		
5.1 Management commitment	**5.1** Leadership and commitment **5.1.1** General		
5.3 Quality policy	**5.2** Policy **5.2.1** Establishing the quality policy **5.2.2** Communicating the quality policy		

Clause in ISO 13485:2016	Clause in ISO 9001:2015	Evidence/Reference/ Documented Exclusion	Finding/Concern Reference
5.4 Planning	**6** Planning		
5.4.1 Quality objectives	**6.2** Quality objectives and planning to achieve them		
5.4.2 Quality management system planning	**6** Planning **6.1** Actions to address risks and opportunities **6.3** Planning of changes		
5.5 Responsibility, authority and communication	**5** Leadership		
5.5.1 Responsibility and authority	**5.3** Organizational roles, responsibilities and authorities		
5.5.2 Management representative	**5.3** Organizational roles, responsibilities and authorities		
5.5.3 Internal communication	**7.4** Communication		
5.6 Management review	**9.3** Management review		
5.6.2 Review input	**9.3.2** Management review inputs		
5.6.3 Review output	**9.3.3** Management review outputs		
6 Resource management	**7.1** Resources		

Clause in ISO 13485:2016	Clause in ISO 9001:2015	Evidence/Reference/ Documented Exclusion	Finding/Concern Reference
6.1 Provision of resources	**7.1.1** General **7.1.2** People		
6.2 Human resources	**7.2** Competence **7.3** Awareness		
6.3 Infrastructure	**7.1.3** Infrastructure		
6.4 Work environment and contamination control	**7.1.4** Environment for the operation of processes		
7 Product realization	**8** Operation		
7.1 Planning of product realization	**8.1** Operational planning and control		
7.2 Customer-related processes	**8.2** Requirements for products and services		
7.2.1 Determination of requirements related to product	**8.2.2** Determining the requirements for products and services		
7.2.2 Review of requirements related to product	**8.2.3** Review of the requirements for products and services **8.2.4** Changes to requirements for products and services		
7.2.3 Communication	**8.2.1** Customer communication		

Clause in ISO 13485:2016	Clause in ISO 9001:2015	Evidence/Reference/ Documented Exclusion	Finding/Concern Reference
7.3 Design and development	**8.3** Design and development of products and services		
7.3.1 General	**8.3.1** General		
7.3.2 Design and development planning	**8.3.2** Design and development planning		
7.3.3 Design and development inputs	**8.3.3** Design and development inputs		
7.3.4 Design and development outputs	**8.3.5** Design and development outputs		
7.3.5 Design and development review	**8.3.4** Design and development controls		
7.3.6 Design and development verification	**8.3.4** Design and development controls		
7.3.7 Design and development validation	**8.3.4** Design and development controls		
7.3.8 Design and development transfer	**8.3.4** Design and development controls		
7.3.9 Control of design and development changes	**8.3.6** Design and development changes **8.5.6** Control of changes		

Clause in ISO 13485:2016	Clause in ISO 9001:2015	Evidence/Reference/ Documented Exclusion	Finding/Concern Reference
7.3.10 Design and development files	**7.5.3** Control of documented information		
7.4 Purchasing	**8.4** Control of externally provided processes, products and services		
7.4.1 Purchasing process	**8.4** Control of externally provided processes, products and services **8.4.1** General **8.4.2** Type and extent of control		
7.4.2 Purchasing information	**8.4.3** Information for external providers		
7.4.3 Verification of purchased product	**8.4.2** Type and extent of control **8.4.3** Information for external providers **8.6** Release of products and services		
7.5 Production and service provision	**8.5** Production and service provision		
7.5.1 Control of production and service provision **8.5.1** Control of production and service provision	**8.5.1** Control of production and service provision		
7.5.2 Cleanliness of product	No equivalent clause		
7.5.3 Installation activities	No equivalent clause		
7.5.4 Servicing activities	No equivalent clause		

Clause in ISO 13485:2016	Clause in ISO 9001:2015	Evidence/Reference/ Documented Exclusion	Finding/Concern Reference
7.5.5 Particular requirements for sterile medical devices	No equivalent clause		
7.5.6 Validation of processes for production and service provision	**8.5.1** Control of production and service provision		
7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier system	No equivalent clause		
7.5.8 Identification	**8.5.2** Identification and traceability		
7.5.9 Traceability	**8.5.2** Identification and traceability		
7.5.10 Customer property	**8.5.3** Property belonging to customers or external providers		
7.5.11 Preservation of product	**8.5.4** Preservation		
8 Measurement, analysis and improvement	**9** Performance evaluation **9.1** Monitoring, measurement, analysis and evaluation		
8.1 General	**9.1.1** General		
8.2 Monitoring and measurement	**9.1** Monitoring, measurement, analysis and evaluation		

Clause in ISO 13485:2016	Clause in ISO 9001:2015	Evidence/Reference/ Documented Exclusion	Finding/Concern Reference
8.2.1 Feedback	**8.5.5** Post-delivery activities **9.1.2** Customer satisfaction		
8.2.2 Complaint handling	**9.1.2** Customer satisfaction		
8.2.3 Reporting to regulatory authorities	**8.5.5** Post-delivery activities		
8.2.4 Internal audit	**9.2** Internal audit		
8.2.5 Monitoring and measurement of processes	**9.1.1** General		
8.2.6 Monitoring and measurement of product	**8.6** Release of products and services		
8.3 Control of nonconforming product	**8.7** Control of nonconforming outputs		
8.3.1 General	**10.2** Nonconformity and corrective action		
8.3.2 Actions in response to nonconforming product detected before delivery	**8.7** Control of nonconforming outputs		
8.3.3 Actions in response to nonconforming product detected after delivery	**8.7** Control of nonconforming outputs		

Clause in ISO 13485:2016	Clause in ISO 9001:2015	Evidence/Reference/ Documented Exclusion	Finding/Concern Reference
8.4 Analysis of data	**9.1.3** Analysis and evaluation		
8.5 Improvement	**10** Improvement		
8.5.1 General	**10.1** General **10.3** Continual improvement		
8.5.2 Corrective action	**10.2** Nonconformity and corrective action		
8.5.3 Preventive action	**0.3.3** Risk-based thinking **6.1** Actions to address risks and opportunities **10.1** General **10.3** Continual improvement