


Base Standard Program		
ISO 13485 Medical Device CB Application for Accreditation		
FA 5006	Authority: Accreditation Manager	

Section 1: CB Name, Contact Information, and Processing Fees

CB name:

Street address:

City:

State/province:

Postal code:

Country:

Name of person completing application:

Email:

Application fee: \$5,000

Fees are payable when purchasing application

Application and all supporting documents shall be submitted in English.

Instructions on application process are at <http://anab.org/programs/isoiec-17021/certification-bodies/become-a-cb/>.

Application shall be obtained through ANAB's Enterprise Quality Manager (EQM) database at <http://anab.jadian.com> and completed electronically (including submission of all supporting evidence) and submitted to ANAB via EQM. Instructions on how to obtain and upload the application in EQM can be found at <http://anab.org/programs/isoiec-17021/certification-bodies/become-a-cb/>.

If the completed application is not accepted by ANAB after three reviews, the application will be declined. The CB may re-apply (including payment of application fees) after 60 days.

For details on this ANAB accreditation program, refer to [Accreditation Rule 35](#) (at <http://anab.org>, under Documents select ISO/IEC 17021 Docs and scroll down for the link to Accreditation Rules).

Section 2: ISO/IEC 17021-1 Requirements for CBs Not Already Accredited by ANAB

Provide evidence that the CB's certification system includes the requirements of ISO/IEC 17021-1.

___ Not applicable – mark X at left if CB is already an applicant or accredited by ANAB for another program and proceed to Section 3.

Requirement	To Be Completed by CB		To Be Completed by ANAB
	Refer to Supporting Documents Including Specific Section References	Comment/Response	Comment/Response
1. Execute (signed) ANAB CB Applicant Agreement , which can be found in EQM under Reference Documents. An electronic signature is acceptable but a typed name is not. If the signature is handwritten, scan the signed document and attach to application electronically.	Initial Response		Approved?
	Second Response		Approved?
	Final Response		Approved?
2. If CB is accredited by another IAF MLA accreditation body signatory, execute and attach AG 5001, CB Agreement for Cooperative Accreditation , which can be found in EQM under Reference Documents. Requirement: Accreditation Rule 6	Initial Response		Approved?
	Second Response		Approved?
	Final Response		Approved?
3. Is CB's head office located in Europe? <input type="checkbox"/> Yes <input type="checkbox"/> No Does the local national accreditation body offer accreditation to ISO 13485? <input type="checkbox"/> Yes <input type="checkbox"/> No If you answered Yes to <i>both</i> questions, provide evidence of CB's accreditation by local /national accreditation body (e.g., copy of accreditation certificate). Requirement: EU Regulation (EC) No 765/2008	Initial Response		Approved?
	Second Response		Approved?
	Final Response		Approved?
4. Complete ANAB form FM 5302, CB Key Processes Form , which can be found in EQM under Reference Documents. Requirement: MA 5000, ANAB Management Systems Accreditation Manual, Article 2	Initial Response		Approved?
	Second Response		Approved?
	Final Response		Approved?
5. Complete ANAB form FM 5303, CB Profile Form , which can be found in EQM under Reference Documents. Requirement: MA 5000, Article 2	Initial Response		Approved?
	Second Response		Approved?
	Final Response		Approved?

<p>6. Update as necessary ANAB form FM 5304, CB Structure, which can be found in EQM under Reference Documents. Any location identified as critical shall be assessed prior to initial accreditation (assessment may be conducted by another AB.)</p> <p>Note: CB was required to complete FM 5304 for step 1 of the application process. If no revisions are required, enter “not applicable” for this item.</p> <p>Requirement: MA 5000, Section 3</p>	Initial Response	
		Approved?
	Second Response	
		Approved?
<p>7. Complete CL 5313, ISO/IEC 17021-1 Requirement Matrix, which can be found in EQM under Reference Documents. Be sure to include copies of all documentation referred to on CL 5313. Column 2 of CL 5313 shall contain sufficient detail to readily locate information within the documentation submitted.</p>	Initial Response	
		Approved? ANAB-specific comments will be included on completed ISO/IEC 17021-1 Requirement Matrix
	Second Response	
		Approved?
<p>8. Complete impartiality analysis of risks related to conflicts of interest arising from provision of certification, including any conflict arising from CB’s relationships and identification of residual risk.</p> <p>Requirement: ISO/IEC 17021-1, 5.2.3, and ANAB Accreditation Rule 10</p>	Initial Response	
		Approved?
	Second Response	
		Approved?
<p>9. Provide process CB will use to identify and consult with interested parties to advise on matters affecting impartiality. Include identified interested parties and evidence interested parties were consulted</p> <p>Requirement: ISO/IEC 17021-1, 5.2.3</p>	Initial Response	
		Approved?
	Second Response	
		Approved?
<p>10. Current list of organizations to which CB outsources work associated with management systems certification and associated outsourced activities.</p> <p>Requirement: ISO/IEC 17021-1, 7.5</p>	Initial Response	
		Approved?
	Second Response	
		Approved?
<p>11. Copy of enforceable arrangements with each outsourced organization.</p> <p>Requirement: ISO/IEC 17021-1, 7.5.1</p>	Initial Response	
		Approved?
	Second Response	
		Approved?
	Final Response	

		Approved?
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Section 3: CB Requirements Specific to ISO 13485

Provide evidence that the CB's certification system includes the requirements for ISO 13485.

Requirement	To Be Completed by CB		To Be Completed by ANAB
	Refer to Supporting Documents Including Specific Section References	Comment/Response	Comment/Response
1. Complete CL 5313, ISO/IEC 17021-1 Requirement Matrix , which can be found in EQM under Reference Documents, with documentation references revised to address this program highlighted. Column 2 of CL 5313 shall contain sufficient detail to readily locate information within the documentation. Also include all documentation referenced that was revised for this program. Note: Disregard if provided in Section 2 above.	Initial Response		Approved?
			Approved?
	Second Response		Approved?
			Approved?
2. List technical areas being sought with initial accreditation for ISO 13485. Evidence of competence for requested technical areas is reviewed during initial accreditation office assessment activities. Based on the outcome of the assessment, ANAB's assessment team recommends technical areas to be included in scope of accreditation. Note: The number of technical areas sought affects the amount of time scheduled for the on-site office assessment. Requirement: ANAB Accreditation Rule 35 and IAF MD 9, Annex A	Initial Response		Approved?
			Approved?
	Second Response		Approved?
			Approved?
3. If CB is currently accredited to ISO 13485 by another IAF MLA accreditation body signatory, provide copy of accreditation certificate listing technical areas for which CB is currently accredited. Provide a copy of a recent audit report for each technical area for which the CB is currently accredited by another AB.	Initial Response		Approved?
	Approved?		
	Second Response		Approved?
	Approved?		
4. Provide CB's process and competence for CB personnel managing program for ISO 13485 certification.	Initial Response		Approved?
			Approved?
	Second Response		Approved?

Requirement: ISO/IEC 17021-1, 7.1.2. and 7.2.1 , and IAF MD 9:2015, 7.1 and Annex B	Final Response		Approved?
5. Provide CB's process and competence for ISO 13485 auditors and technical experts for each technical area for which CB is seeking accreditation (minimum 2 auditors per technical area).	Initial Response		Approved?
Requirement: ISO/IEC 17021-1, 7.1.2., 7.2.2 and 7.2.4-7.2.7 , and ISO 13485:2015, 7.2.1, 7.2.4, and Annexes A, B, and C	Second Response		Approved?
6. Provide CB's process and competence for group or person who will make decisions relevant to certification for ISO 13485 (including but not limited to initial certification, scope expansions, recertification, and suspension decisions).	Final Response		Approved?
Requirement: ISO/IEC 17021-1, 7.2.8, and IAF MD 9, 7.1.1, 7.2.9, and Annex B	Initial Response		Approved?
7. Provide CB's process and competence for group or person responsible for (a) application review, including determination of competencies needed for audit team and certification decisions; (b) appointment of audit team members; and (c) appointment of individuals to make ISO 13485 certification decisions.	Second Response		Approved?
Requirement: ISO/IEC 17021-1, 9.1.2 and 9.2.2.1.1, and IAF MD 9, 7.1.1 and Annex B	Final Response		Approved?
8. Provide CB's process and competence for group or person responsible for determining audit time for ISO 13485 certification audits.	Initial Response		Approved?
Requirement: ISO/IEC 17021-1, 9.1.4, and MD 9, Annexes B and D	Second Response		Approved?
9. Provide information CB provides to clients regarding requirements for ISO 13485 certification.	Final Response		Approved?
Requirement: ISO/IEC 17021-1, 8.5.1	Initial Response		Approved?
10. Provide copy of CB's application and legally enforceable client agreement for ISO 13485.	Second Response		Approved?
Requirement: ISO/IEC 17021-1, 5.1.2 and 9.1.1	Final Response		Approved?
	Initial Response		Approved?
	Second Response		Approved?

	Final Response		Approved?
11. Provide information about CB's process for determining sampling plan when multi-site sampling is used for multiple sites for ISO 13485 certification audits. Requirement: ISO/IEC 17021-1, 9.1.5 , and IAF MD 1	Initial Response		Approved?
	Second Response		Approved?
	Final Response		Approved?
			Approved?
12. Provide sample of certification documents for ISO 13485 (e.g., certificate). Include process for establishing dates on certification documents. Requirement: ISO/IEC 17021-1, 8.2 , and MD 9, 8.2.1	Initial Response		Approved?
	Second Response		Approved?
	Final Response		Approved?
			Approved?
13. If CB has issued ISO 13485 certificates (unaccredited or accredited by another AB) prior to accreditation by ANAB, provide plan to transition them to ANAB-accredited certificates after CB is accredited by ANAB. Requirement: MA 5000, Article 6	Initial Response		Approved?
	Second Response		Approved?
	Final Response		Approved?
			Approved?

Section 4: ISO 13485 initial Audits

ANAB requires initial full-system stage 1 and stage 2 witnessed audits for accreditation for ISO 13485 certification.

Section 5: CB Management Endorsement

Submission steps:

1. Verify responses to all questions are complete and all required information (attachments) is included.
2. Upload application to EQM (<http://anab.jadian.com>). Instructions on how to upload the application and supporting evidence to EQM can be found at <http://anab.org/programs/isoiec-17021/certification-bodies/become-a-cb/>.
3. The initial (off site) document review takes approximately two weeks after the reviewer is assigned.
4. The CB will be notified when the review is complete.

CB personnel who completed the application:

Name:

Title:

Date:

CB management who reviewed the information and determined that it meets all applicable requirements and application requests prior to submission to ANAB:

Name:

Title:

Date: