Mockups for a Testing Lab's CCP-ASCA webform

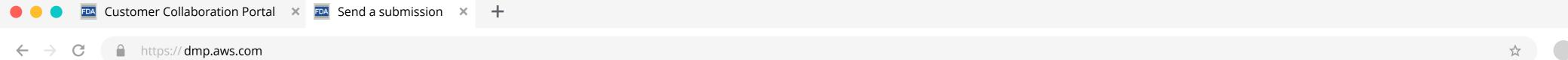
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Basic information	Scope of accreditation	Files and documents	Review & send to FDA
Basic info			
Laboratory info			
Testing laboratory name			
Acronym for testing labora	tory (optional)		
Address line 1			
Address line 2 (optional)			
City		State (US)	ZIP/Postal code
		~	
Country		Province/region	on (optional)
		~	
Business phone number			
Website URL (optional)			
Point(s) of contact			
Primary Point of Contac	rt .		
First Name			
Anthony			
Last name			
Fauci			
Title (optional)			
Phone number			
Email address			
anthony.fauci@abctestingl	ab.com		
Add more			





FDA

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Basic information Scope of accreditation Files and documents Review & send to FDA

Scope of accreditation

Accreditation body

ANSI National Accreditation Board (ANAB)

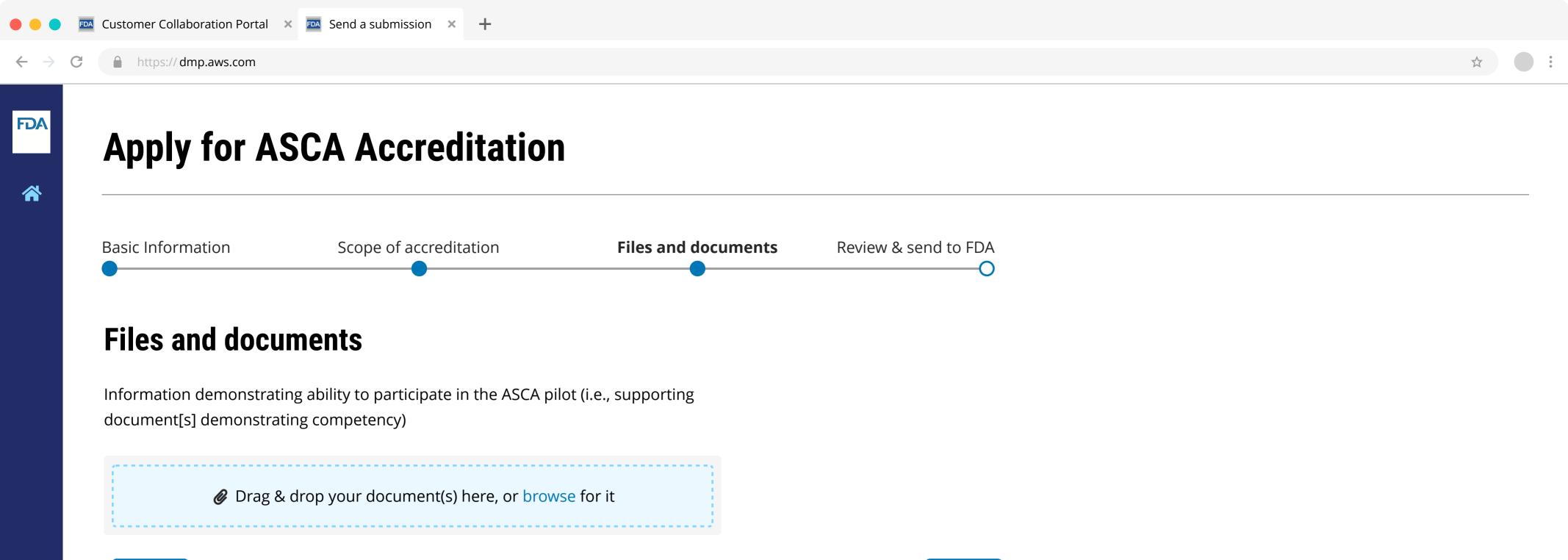
Consensus standards

Standard developing organization	Standard designation number	ASCA category	Title of standard	ŧ
ISO	10993-5 Third edition 2009-06-01	Biocompatibility	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	
IEC	60601-2-10 Edition 2.1 2016-04	Basic safety and essential performance	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators	
IEC	60601-2-18: Edition 3.0 2009-08	Basic safety and essential performance	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment	
ASTM	F756-17	Biocompatibility	Standard Practice for Assessment of Hemolytic Properties of Materials	
IEC	60601-2-10 Edition 2.1 2016-04	Basic safety and essential performance	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators	
IEC	60601-2-18: Edition 3.0 2009-08	Basic safety and essential performance	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment	
ASTM	F756-17	Biocompatibility	Standard Practice for Assessment of Hemolytic Properties of Materials	

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Basic Information

Laboratory details

ABC Testing Laboratory, Inc. Acronym: ABC

123 Main Street Fresno, California 12345 United States

+1-234-432-4224 https://www.abctestinglab.com

Point(s) of contact

Anthony Fauci

Test Manager +1-222-222-222 aaron.rodgers@abctestinglab.com

Eric Lucci

Tester

+1-222-222-2222

eric.lucci@abctestinglab.com

Scope of accreditation 🖍

AL2A

ISO	10993-5 Third edition 2009-06-01	Biocompatibility	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
IEC	60601-2-10 Edition 2.1 2016-04	Basic safety and essential performance	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
IEC	60601-2-18: Edition 3.0 2009-08	Basic safety and essential performance	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
ASTM	F756-17	Biocompatibility	Standard Practice for Assessment of Hemolytic Properties of Materials

Files and documents 🖍

Letter(s) from one or more accreditation bodies stating your prequalifications:

PrequalLetterfromAB.pdf

Additional supporting document(s) demonstrating competency:

Medtronics_nonIVD_Syringe.pdf

By submitting, you are agreeing with the terms of participation described in Section D of Appendix B of the ASCA Pilot program guidance document.

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Mockups for an Accreditation Body's CCP-ASCA webform

Accreditation body Accreditation body name Acronym for accreditation body (optional) Address line 1 Address line 2 (optional) City State (US) ZIP/Postal code Business phone number Website URL (optional) Point(s) of contact **Primary Point of Contact** First Name Marie Last name Curie Title (optional) Phone number **Email address**

marie.curie@newAB.com

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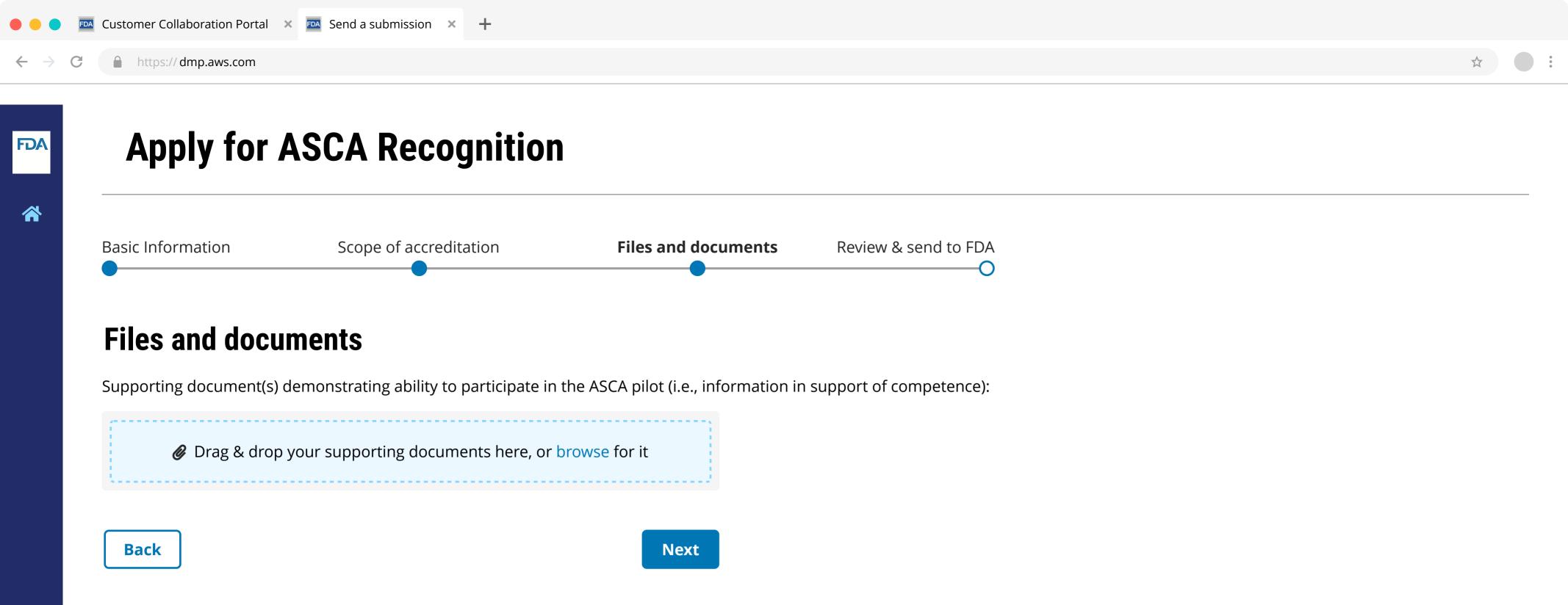
Scope of accreditation

Select all that apply

Standard developing organization	Standard designation number	ASCA category	Title of standard	:
ISO	10993-5 Third edition 2009-06-01	Biocompatibility	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	
IEC	60601-2-10 Edition 2.1 2016-04	Basic safety and essential performance	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators	
IEC	60601-2-18: Edition 3.0 2009-08	Basic safety and essential performance	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment	
ASTM	F756-17	Biocompatibility	Standard Practice for Assessment of Hemolytic Properties of Materials	
ISO	10993-5 Third edition 2009-06-01	Biocompatibility	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	
IEC	60601-2-10 Edition 2.1 2016-04	Basic safety and essential performance	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators	
IEC	60601-2-18: Edition 3.0 2009-08	Basic safety and essential performance	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment	
ASTM	F756-17	Biocompatibility	Standard Practice for Assessment of Hemolytic Properties of Materials	

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Basic Information

Accreditation body details

New Accreditation Body, Inc. Acronym: NAB

123 Main Street Fresno, California 12345 United States

+1-234-432-4224 https://www.NAB.com

Point(s) of contact

Marie Curie

Test Manager +1-222-222-222 marie.curie@NAB.com

Nels Anderson

Tester

+1-222-222-2222

nels.anderson@NAB.com

Scope of accreditation 🖍

ISO	10993-5 Third edition 2009-06-01	Biocompatibility	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
IEC	60601-2-10 Edition 2.1 2016-04	Basic safety and essential performance	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
IEC	60601-2-18: Edition 3.0 2009-08	Basic safety and essential performance	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
ASTM	F756-17	Biocompatibility	Standard Practice for Assessment of Hemolytic Properties of Materials

Files and documents 🖍

Supporting document(s) demonstrating competency:	
Competency.pdf	
☐ Additional_Data_here.xls	

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