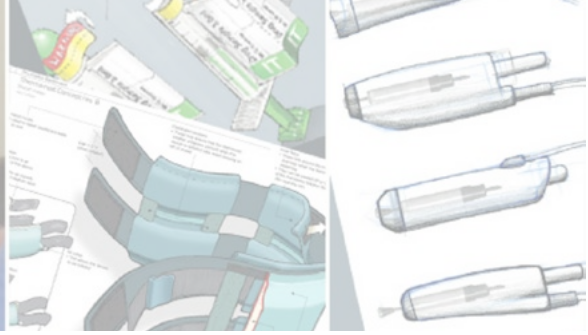


StarFish MEDICAL

FDA, European Union and Health Canada Regulatory/QMS Checklist

The intent of this checklist is to aid self-assessment of your medical device commercialization readiness relating to regulatory requirements. Compare the answers you provide with stages from the StarFish Product Development Process at the end of the checklist to identify how ready you are for applicable regulatory requirements.

Intended Use

Things to consider when specifying the intended use:

- Nature of device: diagnostic, therapeutic, prophylactic, tool
- Target patient population: elderly, adults, children, neonates
- Disease: single or related groups
- Diagnostic nature: does the device actually diagnose or a tool to aid in diagnosis along with traditional methods such as signs and symptoms
- Nature of treatment: temporary, permanent
- Contraindications: not to be used on broken skin, around the eyes, etc.
- Predicate Requirements: specific indications required to more closely match a possible predicate (more below)

Intended Use: (one only)

- ☐ Not yet Defined/Don't know
- ☐ Working Draft
- ☐ Fully defined (e.g. mandated by predicate)

Target Market

Have you defined the target market?

Note: Different regulatory standards apply in different markets – for example, ISO14971:2007 is recognized in the US, but EN ISO14971:2012 is required in Europe.

Target Markets (Tick all that apply):

- ☐ USA – FDA regulatory required
- ☐ Canada – Health Canada Regulatory Required
- ☐ Medical Device Directive Required
- ☐ Directive Required
- ☐ Other:

Device Risk Class & Product Code

The device risk class usually prescribes the regulatory pathway, with Class 1 being lowest. Both FDA and Health Canada have prescribed Risk Classifications for a large number of pre-existing devices, based on a product code. The European Union uses a rule based approach to device classification, which is discussed in MedDev 2.4/1 guidance. In the EU, Class I devices which are sterile or have a measuring function (with recognized units) are special.

FDA (one only):

- ☐ Unclassified
- ☐ Class I
- ☐ Class II
- ☐ Class III

Product Code: _____

- ☐ Not a target market

European Union (one only):

- ☐ Class I
- ☐ Class I (Sterile/Measuring)
- ☐ Class IIa
- ☐ Class IIb
- ☐ Class III
- ☐ Not a target market

Health Canada (one only):

- ☐ Class 1
- ☐ Class 2
- ☐ Class 3
- ☐ Class 4
- ☐ Not a target market

Regulatory Pathway

Is the regulatory pathway investigated and defined? If going for a 510(k), have you selected an appropriate predicate, with justification?

FDA (one only):

- ☐ Exempt
  - ☐ Class I Exempt
  - ☐ Class II exempt
- ☐ 510(k)
  - ☐ Unclassified Device
  - ☐ Class I (Special)
  - ☐ Class II
  - ☐ Class III

  Predicate: K _____
- ☐ PMA
  - ☐ Class II
  - ☐ Class III
- ☐ DeNovo

- ☐ Don't Know
- ☐ Not a target market

European Union CE mark (one only):

- ☐ Self Declare & Registration (non sterile, non measuring)
- ☐ 3rd Party Design review
  - ☐ Manufacturing ISO13485 & Technical File (typical for Class I Sterile/ measuring function)
  - ☐ Full ISO13485 & Technical file (Typical for Class IIa/IIb)
  - ☐ Full ISO13485 & Design Dossier (typical for Class III)

- ☐ Don't Know
- ☐ Not a target market

Health Canada (one only):

- ☐ Medical Device Establishment License (typical for Class 1)
- ☐ Medical Device License
  - ☐ ISO13485 Manufacturing & Attestation (typical for Class 2)
  - ☐ Full ISO13485 and Premarket Review (typical for Class 3 & 4)

- ☐ Don't know
- ☐ Not a target market

Quality Management System

Is a Quality Management system required for your target markets? In Canada, class II devices must be manufactured under an ISO13485 QMS but Product Realization (similar to FDA Design Controls) may be excluded, and similarly in Europe some Class I (typically supplied sterile or with a measuring function) require ISO13485 QMS for their particular functionality. For ISO13485, scope must also be described, and Health Canada has some good advice. Knowing whether you need GMP, full QSR, ISO 13485 for manufacturing or full ISO13485 is essential, as this affects the design process (due to generation of appropriate documentation) and the manufacturing resources required. Note that for the European Union, you must have a quality system that complies with the MDD for Class II device

and above, but you must also demonstrate you are in compliance with the MDD. Simply having an ISO 13485 quality system is not sufficient. Also note the FDA have their own requirements for PMA Quality Systems.

Tick all that apply:

- ☐ None
- ☐ GMP
- ☐ ISO13485 – Manufacturing only Scope
- ☐ ISO13485 – Product Realization Scope
- ☐ FDA CFR §820.30 Design Control
- ☐ FDA PMA Quality System (CFR §820 & §814)
- ☐ Demonstrate meet MDD Essential Requirements

- ☐ Don't know

Consensus standards

Do you know which consensus standards apply to your medical device? Are there any FDA guidance documents which are applicable? Of note, IEC60601-1 is a standard for electro-medical devices with a patient applied part which covers both performance and processes, and the 3rd edition also requires that usability is addressed. Other 60601, and more recently 80601, collateral standards prescribe specific performance requirements or testing conditions for a particular device type, such as ISO80601-2-61 for Pulse Oximeters, IEC60601-2-37 for Ultrasound Diagnostic and monitoring equipment. The FDA Guidance Documents for these are ucm341718 and ucm070911, respectively. There are also product specific standards, such as IEC60825 for laser safety & ISO5840 for implantable heart valve substitutes. Health Canada has a list of recognized standards, the FDA also has a list of recognized standards and EU publish harmonized standards in the Official Journal of the European Union (OJEU).

Consensus Standards and FDA Guidance (tick all that apply):

- ☐ IEC60601-1 Basic safety and essential performance for electrical medical devices
- ☐ IEC60601-1-2 EMC
- ☐ Other 60601 or 80601 performance and safety related collateral standard

_____

_____

_____

- ☐ IEC10993 Biocompatibility standard or sub-part
- ☐ Applicable FDA guidance documents

_____

_____

_____

- ☐ Product specific standards

_____

_____

_____

Essential Performance

Is your essential performance statement defined? This is particularly relevant to 60601-1 testing and CE marking.

Essential performance (tick one):

- ☐ Not Required
- ☐ Don't know
- ☐ Yes – Proprietary
- ☐ Yes – defined in an IEC60601-1 collateral standard

- ☐ Not a target market

Interpreting your results

Compare the answers you provided with stages from the StarFish Product Development Process at the end of the checklist to identify how ready you are for applicable regulatory requirements.

Technology Development

No particular regulatory requirements (apart from safety) are required provided experiments are not performed on humans or animals. However, consideration of Intended Use and Device Risk Class is advisable.

Proof of Concept

Target Markets, Intended Use, Device Risk Class and Regulatory Pathway should be well understood before the end of this phase of work. These items fill out the Business Plan, and it is at the end of this stage that some clients seek Series A funding.

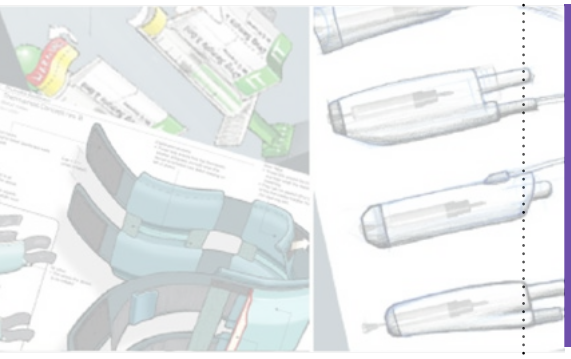
Alpha & Beta Device Development

The implementation of a Quality Management System that covers Design Controls is required at the start of the product realization phase. This demonstrates a design process has been followed, with the output being an appropriate DHF at the end of Beta development. Furthermore, review of consensus standards and essential performance will also be required in addition to the items above. It is at the end of this stage that some clients apply for a 510(k).

Transfer, Pre-Production Units, Pilot Manufacturing

A full QMS will be required, which includes GMP/manufacturing controls. Anecdotal evidence demonstrates it can be difficult to CE mark before this stage, since, although you may have an ISO13485 QMS in place, there are insufficient manufacturing records in place to demonstrate compliance with the MDD.

The above interpretation results are only a guide: for example, if you are developing class III devices, you may want to review consensus standards at the technology development stage.



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REGULATORY CONSULTATION

StarFish Medical is a Medical Device Design company with a full complement of design, development, and manufacturing services. We use the PathFinder™ process to reduce wasted effort and increase success for medical device product definition, technical engineering, and product development. Prototype and volume production are delivered in an ISO 13485 certified Quality Management System and FDA registered manufacturing and clean room facility.