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Regulatory Strategy from day one

EPIC MEETING-ICFO
4th December 2024

Do you know what your Project needs to reach the market?

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80% of projects fail because they don't know how to move forward after the idea

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Let me tell you a personal story:

I worked as a researcher in the University.

And we had an idea about a new medical device.

Synthetic bone graft for bone regeneration. GREAT PRODUCT.

Why don´t create a company to manufacture and commercialize it?

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The founders came from the academic

And we thought we knew everything to put this product on the market.

We knew that our products needs CE mark.

But we thought that it would be not very difficult to obtain it.

10 months later, we contacted with Notified çbody to have CE mark for our device (Class III)

NB detected some Non-Conformities as a result of our ignorance in regulatory matters (Risk Analysis, packaging, sterilization,..)

To correct these issues, we need one year and an extra investment of more than 350.000 euro.

We lost a great opportunity to access faster to the market by not having designed a regulatory strategy.

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Delays. Frustration.

Loss of funding.

PROJECTS IN LIMBO

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Between the lab and the patient, there's a gap that many don't see.

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Simple question:

WHERE DO I START?

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The key:
Regulatory strategy from day one

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First, try to answer these questions:

1. Will my device fill a clinical unmet need?
2. Who would buy my device?
3. What are the competitive products currently available?

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The key steps of the regulatory strategy: **9 steps**

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Regulatory strategy:
9 steps

Step 1: Description of my device

Step 2: Clinical Need

Step 3: Intended Use of my device

Step 4: Indications of my device

Step 5: Is my product a medical device?

Step 6: How is my device classified?

Step 7: Legal requirements and Standards

Step 8: Conformity Assessment Route

Step 9: What documents do I need to do?

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Step 1.- **Description of my device**

You should write a complete description of your device and try to answer the next questions:

- Will my device fill an unmet clinical need?
- Who are the potential buyers of the device?
- What other products serve a similar function to the device I´m planning to develop?
- How is my device going to be superior to these competing products?

Step 2.- **Clinical Need**

You need to describe, in the clearest and most precise way, the **unmet clinical need** with the products currently on the market and how your new product could address these gaps.

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Step 3.- **Intended Use**

- **Defining the Intended Use is crucial when planning Regulatory Strategy of your device.**

- It should be an statement that indicates the use for which a device is intended according to the developer´s information.

- Intended Use must be consistent and present across all product documentation.

Step 3.- **Intended Use. An example**

Medical Device that consists of an algorithm to help clinical decision-making for people with atrial fibrillation with the aim of preventing ischemic stroke in high-risk patients with atrial fibrillation.

The functions of the XXXX algorithm are:

- Improve the detection of atrial fibrillation in patients
- Classify detected atrial fibrillation
- Assess the contraindications of anticoagulant treatment in patients with AF.
- Apply the criteria for starting anticoagulation treatment in patients with AF.
- Choice of anticoagulant drug
- Determine the dose of anticoagulant treatment.
- Detect patients poorly controlled with anticoagulant treatment.
- Exchange of anticoagulants for the patient.

Step 4.- **Indications**

You must describe, as thoroughly as possible, all the **indications for which the product has been designed**.

Special attention should be given to including the patient population and their medical condition.

Step 5.- **Is my product a Medical Device?- QUALIFICATION**

- We shoud clarify whether our device meets the definition of a medical device at all.

- Product´s qualification consist of evaluating if our device falls under EU MDR 2017/745.

- Qualification is a comparison of the intended use of our device and the definition of the Medical Device (Art.2 of MDR). **If it matches, then our product is a medical device.**

Step 6.- **How your device is classified?**

- In accordance with MDR 2017/745, medical devices shall be classified into classes I, IIa, IIb and III, taking into account the intended use and their inherent risks.

- Classification shall be carried out in accordance with Annex VIII of MDR (22 Rules).

- Classification has to be done accurately, since an incorrect classification has huge consecuences.

  Too low: Force products to be removed from the market.

  Too high: Additional work, additional clinical investigations and higher costs.

Step 7.- **Legal requirements and Standards**

Manufacturers of Medical Devices have some guidelines and standards to support them comply the GSPRs set out in Annex I of the MDR.

It is critical to identify these standards early in the development of the product as some may contain specifications which can impact the design of the device.

Step 7.- **Legal requirements and Standards**

IMPORTANT TIPS:

- Start considering whether the Medical Device Coordination Group (MDCG) or the International Medical Device Regulator Forum (IMDRF) have issued any guidance document that may impact in your device.

- Identify the General Safety and Performance Requirements (IVDR) that apply to your device

- Identify the key harmonized standards (ISO,ASTM,…) that apply to your device

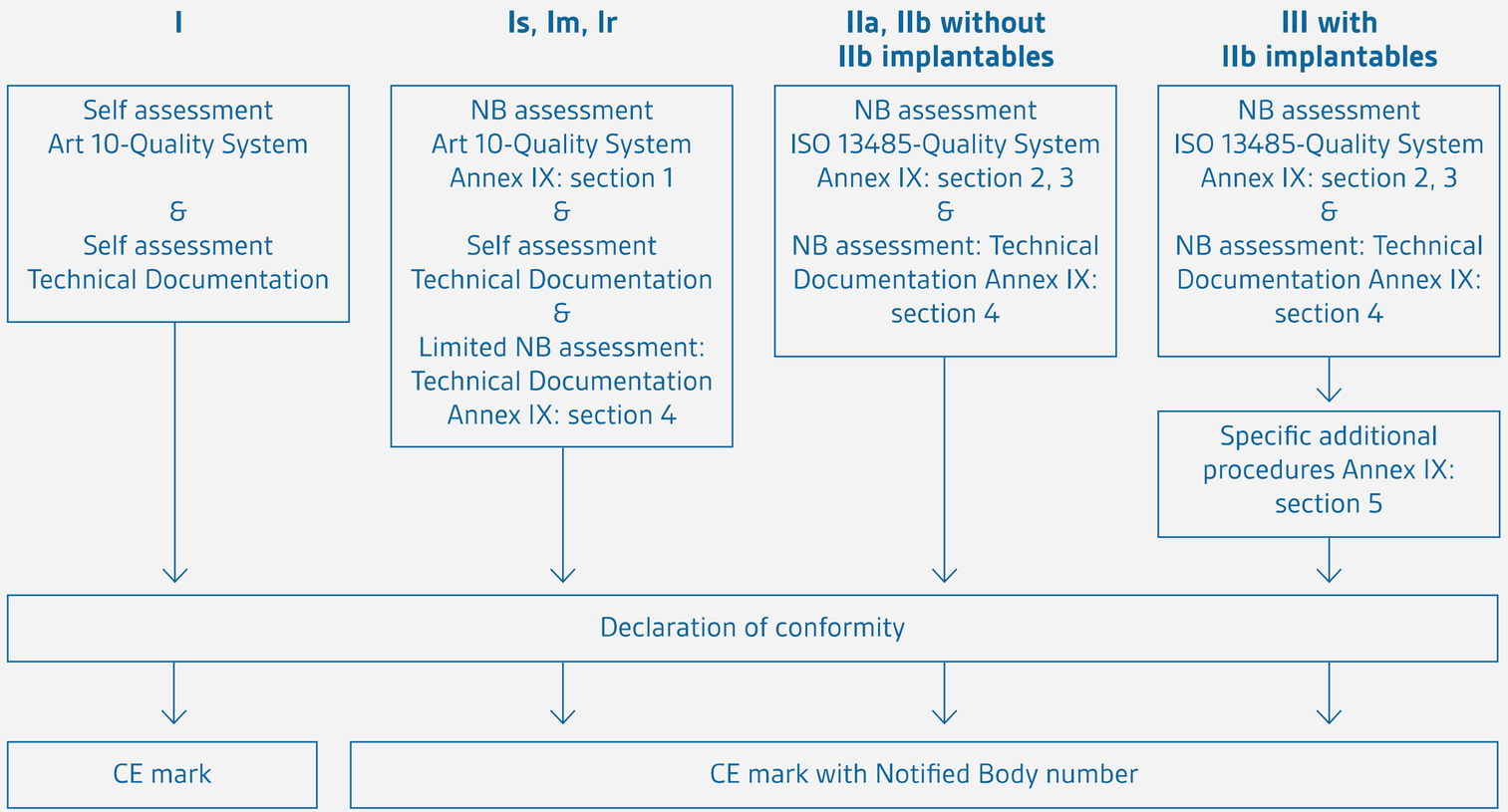
Step 7.- **Legal requirements and Standards. An example**

Non exhaustive list of some Standards:

- Medical Devices Regulation EU 2017/745
- Quality system according to Annex IX: ISO-EN 13485
- Risk Management: ISO-EN 14971
- Guidance on Qualification and Classification of Software in (EU) 2017/745-MDR: MDCG 2019-11
- Safety Reporting in clinical investigations of medical devices under the Regulation (EU) 2017/745: MDCG 2020-10
- Questions and answers on the UDI: MDCG 2022-7
-Clinical Investigation of Medical Devices for human subjects. Good Clinical Practice: ISO 14155

Step 8.- **Conformity Assessment Route**

Depending on the risk class of a Medical Device you can determine what is required to obtain your CE Mark, this is called Conformity Assessment route.



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Step 9.- **What documents do I need to do?**

TECHNICAL FILE

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Design of a Medical Device

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Design and development Input

The inputs must include:

the intended use, the applicable regulatory requirements, the use standards, the output of risk management activities, the experience from previous similar devices, and any other requirements for the product that you deem essential.

Design and Development Input.-

Documents to elaborate

a.-State of the art report

b.-GSPR (Annex I)

c.-Applicable Standards

d.-Risk Analysis (ISO 14971)

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Product Verification and Validation

Is there relevant pre-clinical data that supports the clinical performance claims?.

Evidence supporting scientific validity can be generated through:

- Literature Research
- Professional guidelines
- Proof of concept studies
- Clinical Performance studies

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Clinical Evaluation

Clinical Evaluation means the ability of a device to yield results that are correlated with a particular clinical condition or a pathological process in accordance with the target population and intended user.

The main objective is to demonstrate that the device can achieve clinically relevant outputs through predictable and reliable use.

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Clinical Evaluation

Potential sources of clinical peformance data:

- **Data from scientific peer-reviewed literatura**
- **Data from published experience gained by routine**
- **Data from clinical investigation studies**

A good regulatory strategy saves you time and gives you a significant competitive advantage

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Are you ready to take the next step?

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Don’t let your ideas get lost along the way.
We’re going to make it happen.

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Thanks!

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