



Practical steps to a successful eIFU implementation

If you want to distribute your instructions for use online instead of on paper, there are many considerations to make.

This document provides a high-level overview of the steps you should take when moving towards eIFU.



Regulatory considerations

- Determine whether eIFU is accepted for your type of products.
- Requirements vary greatly across markets. Assess whether eIFU is accepted in the countries where you sell your products. If there are countries that require paper instructions, explore different options to deliver those paper copies to the user.
- The online platform to share your documents should be compliant to all regulations and should be developed in a controlled way with proper validation. You can develop this yourself or outsource it to a qualified supplier.
- Customers should be able to obtain a paper copy of your documents upon request.



Customers should
be able to obtain a paper
copy **of your documents**
upon request.

Impact on your Quality Management System

- Moving from paper to eIFU must follow the change control procedure you have in place within your company
- Perform an in-depth risk analysis: Are there additional risks for the patients when customers do not get a paper IFU, but instead obtain it online?
- The eIFU solution must be validated and kept in a controlled state according to written procedures. Identify the processes that are impacted:
 - Update impacted procedures, e.g. labelling control, packaging, logistics, ...
 - Create procedures for the specific operation of the eIFU platform
- If decide to outsource the development of your eIFU solution or use a complete outsourced solution:
 - Select and qualify the supplier as a critical supplier
 - Remember that the supplier selection should be justifiable towards your notified body. A supplier with ISO13485 and ISO27001 (for software development and maintenance according to IEC 62304) certificates is more easily justified
- Make sure to tell your Notified Body about switching to eIFU and prepare for an audit of your eIFU compliance project



Switching towards **eIFU**
represents a significant change.

Update labelling and instructions for use

- You should include clear instructions on the product's labelling how people can obtain their IFU.
E.g. add the eIFU symbol with the URL of the eIFU website to the outer package.
- Make sure your customers know how to request a paper copy, if needed.
E.g. if they can request the paper documents over the phone as alternative to the online IFU, make sure the relevant phone numbers are included on the labelling.
- Providing eIFU instead of paper IFU reduces the restrictions linked to printing. It is more user-friendly to enlarge the font used in your IFU. Moreover, you are now free to use colours, high-resolution images or you can even consider adding videos or other formats.
- It is more convenient for your users to obtain the IFU directly in their own language instead of having to browse through a multilingual file. Consider splitting your files in the different languages.
- Use a harmonized or easy-to-understand symbol to indicate the use of eIFU on your labelling.



Use a **harmonized** or **easy-to-understand** symbol to **indicate the use of eIFU.**

Improve the operational efficiency and logistic processes

- When switching to eIFU, you no longer need to print and handle the IFU yourself. Update the relevant processes and working instructions as such.
E.g. Employees no longer need to print IFU, there is no more stock management for IFU needed, update the process how people used to make sure to add the correct IFU in the correct product box...
- Write working instructions so people know how to upload IFU to the online platform and how they can keep the platform up-to-date.



Write working instructions
so people know **how to upload**
IFU to the online platform
and how they can keep **the**
platform up-to-date.



Communicate the implementation of eIFU to your customers

- Make sure your customers are informed in advance about your switch to eIFU and provide them with clear instructions so they know how to obtain the IFU in the future.





QARAD BV

HEADQUARTERS
Pas 257, 2440 Geel
BELGIUM
+32 14 49 04 22
info@qarad.com
www.qarad.com

