Know your Instructions for Use Inside-Out

Input documents and writing recommendations

Tipologia	Data	Lingua	Location
Online Training - Numero chiuso	12 April 2022	Inglese	Online

INTRODUZIONE

Instructions for use (IFUs) are part of the labeling documentation for medical devices and, as such, are subject to MDR regulatory requirements.
Instructions for use are not required for Class I and Class IIa devices if such devices can be used safely without any such instructions and unless otherwise specified in the MDR. Still, all other devices do need to have their own IFUs.

Understanding where each piece of information in the IFUs comes from is not an easy task and newbies to the world of medical devices would benefit from learning the intricacies of this document before working on any other related documentation.

Also, as a medical device professional, you may even need to provide some of the content in the IFUs for their final version: such as ‘possible adverse events’ or ‘cleaning instructions’. Thus, you may also benefit from the writing recommendations targeting IFUs.
Finally, IFUs are subject to predefined review cycles and depend on several other input documents.

This workshop will give you profound insights into the regulatory requirements for IFUs, best practice recommendations on how to draft IFUs, and insights into common pitfalls and tips on how to avoid them.

PROGRAMMA

- Regulatory framework: EU MDR 2017/745 requirements and definitions
- Content and structure of the Instructions for Use
- Where do all those contents come from? Legacy devices vs new devices
- Recommendations for the writing process: Tips to improve writing of the IFUs
- Usability and readability
- Images, photos and symbols
- Where else is the content of the IFUs used and how it needs to be used

A CHI È RIVOLTO

This course is intended for medical device professionals with little or no experience in medical devices Instructions for Use, under the Medical Devices Directive 93/42/EEC (MDD) or under the Medical Devices Regulation 2017/745 (MDR).

Participant experience
We will assume that participants have basic knowledge of the directives and regulations governing medical devices, such as the MDD and MDR.

TECNICHE DIDATTICHE

Lecturers will deliver short presentations on the programme topics. Questions and subsequent discussions are welcome at any time during the workshop.

A series of polling questions will be used to illustrate participants' ideas and perceptions on the topics presented. In breakout rooms, small groups of participants will be given a common workshop-related 'problem' to discuss and suggest ideas to solve the proposed problem.

DOCENTE/I

Katharina Friedrich
MD – Freelance Medical Writing Consultant
Katharina Friedrich is a medical writer with experience in MDR regulatory writing. She is based in Heidelberg, Germany and works as a Freelance Medical Writing Consultant with focus on orthopedic and cardiovascular devices. She prepares Clinical Evaluation Plans and Reports, PMCF Plans and Reports and SSCPs in compliance with MDR 2017/745 for class I to class III devices. She also supports development projects and the conduction of PMCF activities. As medical doctor she has experience in the field of orthopedic and trauma surgery.

Laura C Collada Ali
Freelance Medical Writing Consultant, LS Academy Scientific and Medical Writing Coordinator
Laura is a medical writing consultant with more than 20 years of experience in delivering multilingual authoring services for leading pharmaceutical and medical device companies. She regularly prepares CEP, SSCPs, and PMCF related documents for medical devices in the fields of orthopaedics, cardiology, dermatology, and infectious diseases among others.

COSA SAPRAI FARE DOPO IL CORSO

- Know which regulations address Instructions for Use
- Improve your writing practice when dealing with Instructions for Use
- Identify the common pitfalls and avoid them

DURATA E INFORMAZIONI UTILI

This online training consists of 1 module:

12 April 2022 – from 9:00 am to 1:00 pm CEST

Some days before the online training you will receive all details about the connection.

The course will proceed with a minimum number of participants. Should this number not be reached the registered participants will be notified one week prior to the commencement of the course.

QUOTE ISCRIZIONE

Early Bird: **€ 495,00*** (until 15 March 2022)

Ordinary: **€ 625,00***

Freelance – Academy – Public Administration**: **€ 370,00***

* for Italian companies: +22% VAT

***Early Bird discount not applicable to Freelance – Academy – Public Administration fee*

The fee includes: tuitions, organizational office assistance, teaching materials and attendance certificate that will be sent after the training via e-mail.

SEDE DEL CORSO

Online interactive training on Zoom platform.
LS Academy will provide the access link to the virtual platform a few days before the training.