

# Medical Devices

## Editorial

Welcome to the world of medical devices! Increasing regulatory requirements lead to an increasing demand for medical writers. EMWA is acknowledging this emerging field in several ways:

- It is organising a medical device symposium at the next Spring conference in Barcelona, flanked by two medical device workshops.
- A medical device track/certificate is in preparation.
- A medical device special interest group has been founded.
- This section will become a regular contribution to MEW.

*Do you have anything particular you would like to see in this section? Or do you want to contribute to it? We would love to hear from you!*

Beatrix

## SECTION EDITOR



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## EMWA's Medical Device Symposium "Medical Devices and Technologies Emerging Opportunities for Medical Communicators"

The 6th EMWA symposium day will focus on medical devices in general, the recent changes in the European legislations, and opportunities for medical writers. The symposium is for regulatory writers and medical communicators alike, and will provide the perspectives of different stakeholders, including legislators, notified bodies, medical device companies, patient representatives, and reimbursement professionals.

The preliminary programme is as follows:

### Introduction to the medical device world

**Claudia Frumento, ICiMT – International Communication in Medicine and Technology**

The field of medical devices is a broad one: wheelchairs, contact lenses, X-ray machines and implantable cardioverter defibrillators are all medical devices, but they have completely different uses and pose different risks to the patient, the user and the environment. Thus, medical devices are classified based on their risk profile, affecting the processes required for their market release. Medical writers play a key role in this process: they write some of the most important documents required for market approval such as the Clinical Evaluation Report, Clinical Investigational Plan, and Clinical Investigation Report. This introductory session gives an overview of the terminology used, the classification system, the regulatory pathways and the role of MW in preparing the documents required.

### Medical writing and transferable skills: From pharmaceuticals to medical devices

**Gillian Pritchard, Sylexis Ltd.**

The idea of writing about medical devices might seem daunting—after all, there are so many of them, ranging from the simplest wound dressing to the most sophisticated imaging equipment. However, typical “pharmaceutical” documents such as clinical study protocols, clinical overviews and summaries, and summaries of product characteristics have their equivalents for medical devices. Just as “pharmaceutical” writing is governed by guidelines and directives, the same is true for medical devices. Similar skills are needed for pharmaceutical and medical device writing, namely the ability to follow guidelines, use templates, evaluate medical literature, and write clearly and objectively. So a writer accustomed to writing about pharmaceuticals may discover that they can just as easily write about medical devices.

### The new Medical Device Regulation (MDR) and its implications for medical writers

**Paul Piscoi, Scientific Policy Officer, Unit Cosmetics and Medical Devices, European Commission**

In May 2017, two new regulations were published namely Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices, foreseen to enter into application 26 May 2020 and 26 May 2022 respectively. The presentation will start by outlining the key new features of these regulations with a focus on the clinical/performance aspects, which represent one of the

major overhauls of the legislative framework for medical devices. This section will be supplemented with an outline of implementation priorities as well as the transitional timelines and measures. An overview of the existing guidance will follow along with plans for its updating in order to bring it in line with the requirements of the new regulations. The core of the presentation will cover sections on the clinical/performance requirements relevant to medical writers along with the latest novelties brought about by the activities of the Clinical Investigation and Evaluation Working Group. This will include information regarding the development of guidance on the Summary of Safety and Clinical Performance, various templates, an addendum to MEDDEV 2.7/1 rev 4 and EUDAMED as the future database for medical devices. The importance of scientifically sound and well written clinical sections of the medical devices technical files and the role of medical writers will be covered at the end.

### MDR and MEDDEV; what notified bodies are looking for in clinical evaluation reports

**Ito Udofia, Head of Medical Device Notified Body, Underwriters Laboratories**

The clinical evaluation is an essential part of the technical documentation, which manufacturers require to document their compliance with the general safety and performance requirements. The new Medical Device Regulations places greater emphasis on the use of clinical data to demonstrate compliance with the general safety and performance requirements. With the increased scrutiny expected with the new

regulations, the guidance document, MEDDEV 2.7.1 (rev 4) was published in July 2016, to prepare manufacturers and notified bodies for the key requirements of clinical evaluation. Although compliance with Revision 4 of the MEDDEV does not mean compliance with the new regulations, it brings manufacturers closer to compliance. This presentation focuses on the key requirements and what notified bodies will be looking for when reviewing clinical evaluation reports. By understanding what the notified bodies are looking for, clinical evaluation reports can be better written and presented for assessment.

### Panel session:

#### Impact of new regulations

**Panel led by Jane Edwards, Head of Global Communications – Medical Devices, BSI Group**

**Panelists: Claudia Frumento, Gillian Pritchard, Paul Piscoi, Itoro Udofia, Raquel Billiones, Beatrix Doerr**

#### **Apps, technologies, security, potential failures** **Kyle J. Rose, International Diabetes Federation (IDF)**

Thousands of health apps are available today, often using different approaches for different audiences. They range from fitness/nutrition trackers to apps connected with existing medical devices, such as blood monitors and complex medication infusion systems. Using diabetes as an example across chronic disease, this talk will propose a framework to think about apps, potential classification categories, and important differences such as primary use cases, medical content/nature, as well as software development infrastructure. Also discussed will be: (a) the impact of apps on patients, health care professionals, and other healthcare stakeholders; (b) the potential role of apps in our health systems; and (c) current limitations and progress (including clinical evidence, data ownership and safety).

#### **Systematic reviews: Finding the right information for medical device clinical evaluations and post-market surveillance for biomedical searching**

**Ivan Krstic, Senior Product Development Manager at RELX Group, EMBASE/Elsevier**

Information found in the biomedical literature strengthens every stage of the medical device life cycle, from concept and design through clinical trials to commercial release and reimbursement, as well as post-market surveillance. Embase provides all the relevant information and essential evidence for creating high-quality systematic reviews that support medical device development and post-market surveillance. In this session, Senior Product Development Manager Embase Dr Ivan Krstic will discuss:

- European Medical Device Clinical Evaluation Report guidelines (MEDDEV 2.7/1)
- the importance of biomedical literature in preparing successful Clinical Evaluations and in remaining compliant with post-market surveillance requirements
- a case study on how to design effective literature searches for CER to identify:
  - device clinical performance
  - comparisons of device with existing device(s)
  - device safety – finding adverse device effects

#### **From bench to publication: All you need to know about medical devices based on a case example**

**Myriam Stieler, Director Medical Affairs, Biotronik**

This presentation will build on the previous ones and will show the complete life-cycle of a medical device based on the practical example of a novel scaffold technology. It includes possible pitfalls, setbacks, and considerations in data interpretation. The aim is to provide a robust overview of the device development that will facilitate understanding clinical data obtained from medical device studies.

#### **Generating the necessary clinical evidence through product life cycle communication strategy**

**Patrice Becker, Global Director Scientific Communications, Medical Affairs, Medtronic**

With the current changes in the medical device industry, with new regulations, and with a move from a traditional customer base of health care professionals to health care administrators, it is more important than ever to have peer-reviewed

clinical evidence and to tell a “story” of a medical device throughout its lifecycle. This session will discuss the variety of studies worthwhile to publish (from pre-clinical animal models to post-approval studies), the regulatory context of publications, how to create an evidence-based strategy throughout the lifecycle of the product, possible challenges, and an example of an effective publication strategy.

#### **European reimbursement strategies and associated documents**

**Oleg Borisenko, CEO MedTech Reimbursement Consulting**

Market access is extremely important for the success of innovative technologies. This includes obtaining reimbursement (ability to pay for procedure/device) and funding (willingness to pay). To establish reimbursement and funding, multiple activities might be needed, including application for procedure code and change of the Diagnosis-Related Group (DRG) system, applications for reimbursement review, and health technology assessment. In this presentation, one of the leading European market access experts, Oleg Borisenko, will outline some of the specifics of the market access processes and how medical writers can contribute to these processes. In particular, the following questions will be addressed:

- What are the typical reimbursement barriers for medical devices in Europe?
- What are the typical requirements to overcome reimbursement barriers?
- What can be a role for a medical writer to support reimbursement activities?
- What is the concept of the value dossier?

### Panel session:

#### Medical devices 10 years from now

**Panelists: Jane Edwards, Kyle J Rose, Myriam Stieler, Patrice Becker, Oleg Borisenko, Ivan Krstic**

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## Medical device workshops in Barcelona

The medical device symposium will be flanked by two medical device workshops held on May 2 and 4:

### Basics of writing for Medical Devices under the MEDDEV rev. 4 and new MDR

**Claudia Frumento, ICiMT – International Communication in Medicine and Technology**

The objective of this workshop is to provide an introduction to the field of medical devices and associated document requirements. Areas covered include: classification of medical devices; basic regulatory issues regarding the approval and marketing of medical devices; recent changes in regulatory requirements and how these impact the medical writer's role; and some of the most common medical communication documents.

A syringe, a knee prosthesis, a computerised tomography (CT) scanner, an external defibrillator, and a pacemaker are all medical devices, but they belong to different risk classes. The new regulations (MEDDEV 2.7/1 rev.4 and Medical Device Regulation) define a core documentation set required for regulatory compliance of these

devices. And this can be challenging for the industry and the Medical Writer.

Focusing on a set of different medical devices, the main elements of the workshop will introduce:

- what a medical device is and why and how devices are classified
- key documentation for regulatory compliance and market release of a medical device
- medical communication texts: particularities for medical devices

### Literature review for medical devices

**Gillian Pritchard, Sylexis Ltd.**

The aim of this workshop is to understand how to write a literature review as part of a Clinical Evaluation Report. Participants will learn how to prepare a literature review to current MEDDEV 2.7/1 rev. 4 requirements. The workshop will explain:

- the role of the literature review in the clinical evaluation of a medical device

- the scope of the literature review
- literature search strategies for the subject device and state of the art (current knowledge)
- how to write the state of the art section
- how to screen and appraise the literature
- data extraction
- the analysis and presentation of the literature in the CER
- literature disposition
- reference citation and the listing of excluded references

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## EMWA's medical device special interest group (MD-SIG)



The MD-SIG was founded in November 2017 in Cascais. It consists of following members:

- Chairs: Raquel Billiones and Beatrix Doerr
- Committee members: Jane Edwards, Claudia Frumento, and Gillian Pritchard
- SIG supporting members: Diarmuid De Faointe, Helen Frampton, and Iain Colquhoun

### The objectives of the MD SIG are:

- to provide a forum for EMWA members to

discuss and share information in the area of medical devices and in vitro devices

- to ensure focus is given to this rapidly evolving medical communication speciality
- to support the implementation of the new EU Medical Device Regulation (MDR

2017/745) and the In Vitro Device Regulation (IVDR 2017/746)

- to act as a resource and support group for medical communicators interested in getting into this field
- to increase the educational offerings of EMWA relevant to this field

Current and upcoming activities of the MD-SIG are:

- The EMWA Symposium on "Medical Devices

and Technologies – Emerging Opportunities for Medical Communicators" will be held on May 3, 2018.

- Medical devices has been added as an area of expertise covered by for-credit workshops under the EMWA Professional Development Programme. More workshops will be offered in future conferences.
- Raquel is presenting a webinar on medical devices in 2018.
- Claudia and Gillian are spearheading the development of a standard Clinical Evaluation Report (CER) template.
- A regular medical device section has been established in *Medical Writing*.
- Topics pertaining to medical devices will be included in the Expert Seminar Series (ESS) starting 2019.

We would like to hear your thoughts and ideas!

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