

# Reports from the spring conference in Barcelona

## SECTION EDITOR



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We invited EMWA members to report on the medical device symposium and selected Expert Seminars during the spring conference in Barcelona, held in May 2018. We hope that this initiative will help to keep EMWA members up to date with our fast changing profession. Thank you to all the contributors.

## 6th EMWA symposium: Medical devices and technologies

Historically, medical devices were mostly limited to surgical tools, such as those for bloodletting and removing kidney stones. However, as modern medicine developed, doctors became equipped with more and more tools and treatment options. Today, medical devices span a wide spectrum of items from correction glasses, dental fixtures to insulin pumps and pacemakers. In fact, there are over 500,000 types of devices registered on the European market, with total annual sales reaching 110 billion euros.

To ensure patient safety, certification and registration of medical devices is tightly regulated. Similar to pharmaceutical products, the effectiveness and safety of a medical device must be properly documented before receiving approval for regulatory authorities. However, shorter developmental timelines and relatively short presence on the market poses several challenges for providing timely and accurate documentation. To harmonise the requirements and procedures for registration in the EU, new directives for medical devices and *in vitro* diagnostic medical devices have been introduced.

The objective of EMWA's 6th Symposium was to familiarise medical writers with the field of medical writing for medical devices and what changes lie ahead. Experts in the field, representatives of regulatory authorities, and manufacturers were invited to give participants a broad overview of the field, the required types of documentation and showed opportunities for medical writers to become involved.

### Introduction to medical devices

**Speaker:** Claudia Frumento

(International Communication in Medicine and Technology)

**Written by:** Gabriela Plucinska, PhD, communication and graphic design, Utrecht, The Netherlands

Medical writers may find themselves intimidated when faced with requests for preparing documentation for a medical device approval and certification. Claudia Frumento shared her experience. From the start, she emphasised that writing about medical devices requires not only comprehensive knowledge of the human anatomy, but also an understanding of physics and engineering related to the functionality of the product. This technical information is collected in the form of a product dossier, which contains all the data related to manufacturing and intended product use. This dossier is required to release a medical device to the market, as well as data confirming the device's safety. The type of documentation required for certification of a particular device is based on the European risk classification, which reflects the risk that the use of the device poses for the patient.

The EU has recently tightened control over high risk devices by introducing new regulations and adopting the certification process to meet higher transparency standards. Frumento emphasised that while new guidelines may extend overall approval time and prove challenging to adapt for smaller companies, at the same time they open unique opportunities for medical writers. As many of the policies are still being established, writers can become involved in the legislation process and, working alongside the authorities, help shape the field and set future standards.

### Writing for pharma versus medical devices – similarities and differences

**Speaker:** Gillian Pritchard (Sylexis Ltd.)

**Written by:** Gabriela Plucinska, PhD, communication and graphic design, Utrecht, The Netherlands

Medical writers associated with the pharmaceutical industry typically prepare a wide variety of documents, clinical study reports, pharmacovigilance documents, publications, lay summaries, and consent forms. This spectrum of documentation requires medical writers to develop an array of unique skills, which include: knowledge of clinical study design, ability to follow guidelines, language and communication skills, systematic approach to writing projects, and project management skills necessary for working with multiple partners and managing client expectations. As Gillian Pritchard took to the stage, she pointed out the high relevance of those skills when transitioning to writing about medical devices.

This is also reflected by the types of documents submitted for certification of a high risk medical device, which mirror the requirements for approval of new medications and treatments. Starting from articles about *in vitro* and animal studies, clinical investigation plans and clinical investigation reports, medical writers will find themselves working with familiar types of documents and templates that are similar to those required in pharma. In the certification process all of those documents are assembled into a clinical evaluation report (CER): a summary of the all available clinical information about the device. This information should be regularly updated.

The post-market surveillance (PMS) report may prove the most difficult to prepare for medical writers, Pritchard reflected. This is due to the fact that at the moment, some companies have not consistently gathered information about

a product once it was marketed. In such cases writers would first need to gather sufficient information about the product from literature searches, use the data that the company already has and then perform gap analyses.

### From a legislative perspective – new requirements for medical devices registration

**Speaker: Paul Piscoi**  
(European Commission)

**Written by:** Gabriela Plucinska, PhD,  
communication and graphic design, Utrecht,  
The Netherlands

Medical devices are typically present on the market for 18–24 months before improved versions become available. Such a fast turnover poses several challenges for regulatory authorities that are responsible for controlling safety. New EU regulations (2017/745 on medical devices [MDR]<sup>1</sup> and 2017/746 on *in vitro* diagnostic medical devices (IVDs)) are implemented to improve coordination mechanisms and risk management associated with use of medical devices. Specifically, medical devices will be subjected to higher scrutiny, including creating a clearer and more transparent certification process. This is accompanied by establishment of expert panels, reference laboratories, and development of an EU wide medical devices database – Eudamed – expected to go live in March 2020.

Paul Piscoi from the European Commission explained that among the most important changes are the enhanced criteria for the conformity assessment. This assessment will be in part based on the CER, which for the high risk medical devices should contain data sourced from the clinical investigations conducted with a specific product. Evidence based on a similar certified device will be considered admissible, provided manufacturers demonstrate equivalence and have sufficient access to the technical and clinical documentation. To allow companies adequate time to adjust to the new regulations, hire appropriate staff, and apply for re-certification, the legislators introduced a transition period until 2020 for medical devices

and 2022 for IVDs. During this time, certain clauses of the previous directives will remain in force.

As new regulations are starting to take effect and guidance documents are drafted, the European Commission is engaging in consultations with the public and stakeholders. Mr Piscoi encouraged EMWA to participate in this EU call and join the forefront of the upcoming changes.<sup>2</sup>

### MDR and MEDDEV – What notified bodies are looking for in Clinical Evaluation Reports (CER)

**Speaker: Itoro Udofia**  
(UL International UK Ltd.)

**Written by:** Malgorzata Paradowska, MPH,  
Proper Medical Writing, Warsaw, Poland

New MDR<sup>1</sup> forces notified bodies to focus more on solid information regarding device safety and performance under its normal intended use, which “shall be based on clinical data providing sufficient clinical evidence” to support compliance with essential requirements. The level of scrutiny will depend on the product risk, classification and novelty.

Technical documentation houses proof of compliance with essential requirements, and clinical evaluation is a key element. The sources of data for clinical evaluation are: clinical investigations, peer-reviewed scientific literature, and PMS regarding the device itself or an equivalent one. However, the clinical evaluation process does not end on finalising the CER before marketing. (Note: MEDDEV Guidance<sup>3</sup> was described as very supportive while writing CERs, but it does not cover all requirements from MDR.) A proactive PMS plan must also be provided. Apart from CERs, the following documentation will be scrutinised by notified bodies: risk management documentation; PMS plan and report; periodic safety update report (PSUR); post-market clinical follow-up (PMCF) plan and report; and summary of safety and clinical performance (SSCP, which will be available publicly on Eudamed). All these documents must be interlinked and constantly updated.

Notified bodies are expected to write Clinical Evaluation Assessment Reports (CEARs), which

are based on the CER itself (including methodology, authors’ qualifications, frequency of updates, demonstration of equivalence, conclusion on clinical benefit/risk analysis) and also, the following associated documents: device description and intended purpose; pre-clinical evaluation data; risk management documentation; clinical investigation plans, results, and justifications; PMS/PMCF plans and justifications; and conformance to the relevant essential requirements.

“The bars have been raised”, Udofia said. Professional medical writers will be extremely helpful in preparing high quality medical device documentation. Such medical writers need to: understand the product and its description, impact and relevant clinical data; apply up-to-date regulations; and write for the target audience, including notified bodies, competent authorities and expert panels.

### Patients as users: Apps, technologies, security, potential failures

**Speaker: Kyle J. Rose**  
(International Diabetes Federation, IDF)

**Written by:** Malgorzata Paradowska, MPH,  
Proper Medical Writing, Warsaw, Poland

People living with diabetes often struggle to balance their blood glucose concentrations as it is a tedious and challenging process. They make approximately 50 disease-related decisions every day. New mobile applications are specially designed to support diabetes patients. The most effective are able to provide a consumer-friendly user experiences and increasingly meet patients’ expectations of reducing the disease burden.

As certain diabetes apps affect disease management, these ones should be considered medical devices and thus be treated in a proper regulatory manner. The following groups of health apps, relevant to diabetes patients, were discussed:

1. **Logbook trackers.** Apps documenting daily events: blood sugar levels, exercise and medications
2. **Nutrition and exercise.** Apps that encourage people to be active, take care of nutrition and



facilitate carbohydrate counting.

3. **Motivation, education and coaching** programmes.
4. **Middleware & eHealthcare Solutions (EHS)**. Apps that serve as a medium to communicate with medical devices and health systems.
5. **Device manufacturer software**. Software made for devices such as insulin pumps, continuous glucose monitoring (CGM), and traditional blood glucose meters (BGM).
6. **DIY (do-it-yourself) apps** created by patients such as the NightScout Foundation for remote glucose monitoring.

For more information on diabetic software, please see the International Diabetes Federation (IDF) position paper<sup>4</sup> and a monograph on the digitalisation of healthcare.<sup>5</sup>

Rose presented directions for medical writers involved in the development of diabetic medical devices. Medical writers have the power to influence patients with diabetes through the written word, which can be accessed also via medical apps. Their message should present accurate information about the condition, dispel outdated stereotypes, and also be adjusted to the phase of the disease. Medical writers should use inspiring and motivational communication, and not always focus so much on complications (the diabetes “monster” can be scary at times). It is important to write a balanced argument to make the text realistic. In addition, any description on the use of a medical device should be supported by real-life examples. “Good communication and understanding patient expectations can help create medical devices people will love”, Rose concluded.

### Systematic reviews in medical devices

**Speaker:** Ivan Krstic  
(RELX Group, EMBASE/Elsevier)

**Written by:** Malgorzata Paradowska, MPH,  
Proper Medical Writing, Warsaw, Poland

EMBASE is a commercially available tool for peer-reviewed scientific literature searching that is recommended by the EMA, Cochrane Collaboration, WHO, and other institutions. The

European Commission recommends using EMBASE when performing literature searches for CERs.<sup>3</sup>

Although the Medline database is a good starting point, it is insufficient for systematic searching, as it has incomplete coverage of European journals. Therefore, other supportive data sources are recommended when conducting systematic reviews, including EMBASE and the Cochrane Central Database. The literature review should be performed by “applying objective, non-biased, systematic” searches and use PICO methodology, which splits the clinical question into four concepts: Patient, Intervention, Control, and Outcome.<sup>3</sup> The process of conducting a systematic review is described in detail in the Cochrane handbook.<sup>6</sup>

EMBASE ensures comprehensiveness by including Medline content and an additional ~3,000 non-US journals (mainly European journals, but also ones from Asia and the rest of the world). EMBASE content comes from peer-reviewed journals and conference abstracts. Indexing is based on the Emtree taxonomy, which focuses on drugs, diseases, and devices. Two search forms are available for medical devices: 1. a *medical device search form* that limits the search according to manufacturer or trade names, among others; and 2. a *PICO search form*.

For each of the PICO components, the most specific Emtree term should be used first, and then supplemented with as many synonyms as possible. The taxonomy synonyms (including trade names) are automatically proposed by EMBASE. The system records the search term and all synonyms, allowing the full search strategy to be documented. Results can be easily exported and packed into a reference management system. Furthermore, regular updates can be received automatically by setting

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### From bench to publication – A case example takes us through the life-cycle of a medical device

**Speaker:** Dipl.-Ing. Myriam Stieler  
(Director Medical Affairs at Biotronik)

**Written by:** Mariella Franker, PhD,  
Franker Medical Communications, Beinsdorp,  
The Netherlands

Myriam Stieler’s case example of a new bioresorbable scaffold nicely illustrates the development of a medical device throughout its life cycle. The first step to develop a novel product is defining key design requirements. The introduction of the permanent stent – and subsequently the drug-eluting stent – greatly improved treatment of coronary artery disease. However, other complications, such as restenosis and stent thrombosis, arose. Biotronik defined a solution: a stent that removes the blockage and then completely disappears. They developed a bioresorbable magnesium-based prototype. First, extensive testing in pre-clinical bench tests was done e.g. to assess the stent backbone flexibility. Subsequently, safety studies in animals were performed to assess restenosis rate and thrombogenicity. As pre-clinical data cannot be directly translated to humans, a clinical trial in humans was thereafter performed to assess safety.

The first-in-human trial PROGRESS and later the BIOSOLVE studies were to investigate safety and efficacy in humans. After the BIOSOLVE-I study, application for CE mark was rejected

because of the small sample size and lack of statistical analysis (which was not required by the old regulations). These issues were addressed in BIOSOLVE-II. Data from this trial showed that the stent dissolved too quickly after implantation, causing restenosis. Essential changes were made to increase the half-life of the stent in the body. The results of the following trial were greatly improved and CE mark was finally obtained in 2016. Pivotal and post-market studies are currently ongoing (BIOSOLVE-III and IV). Publishing validated data, both before and after the product is released to market, is essential to monitor performance of the device and for future developments.

“Ideally, you move through each developmental phase only once. In reality, several iterations and improvements are required at every stage before you come to the final product,” Dipl.-Ing. Stieler noted.

### New focus on clinical evidence: the added value of a publication strategy plan

**Speaker:** Patrice Becker, MSc, MBA  
(Global Director Scientific Communications at Sofradim/Medtronic)

**Written by:** Mariella Franker, PhD,  
Franker Medical Communications, Beinsdorp,  
The Netherlands

The new MDR 2017/745 increasingly requires peer-reviewed clinical evidence when applying for approval or re-approval of a medical device.<sup>1</sup> Clinical evidence must be obtained before and after a product enters the market: pre-clinical, clinical pre-approval and clinical post-approval studies. It is important to have a publication and communication strategy in place that covers the entire life cycle of a product. Such a strategy will aid manufacturers to be prepared for the new requirements either for market approval and post-market evidence generation.

A publication strategy “tells the story” of an invention and communicates important scientific data to the right audience at the right time. For example, publishing in peer-reviewed journals during the early phases of the product life cycle will support early awareness of key

opinion leaders and promotes the information dissemination of the product after approval. Of course, there are also challenges to face. The limited sample size of studies with medical devices, and the transferability of animal study data to humans are constant areas of debate. In addition, the objectiveness of publications about industry sponsored studies that originate solely from company authors may be challenged by authorities.

In post-market phase, medical writers will have a big role to play in supporting authors with the different types of clinical publications. During the panel discussion, Patrice Becker and Ito Udofia (Notified Body, Underwriters Laboratories) discussed that clinical evidence will become the new standard for medical devices. Becker emphasised that experts from many different areas, such as medical affairs, clinical, regulatory, marketing, R&D, and medical writers, must work together to create an effective publication strategy.

“[In the future] Medical affairs will have a preponderant role in evidence generation,” said Becker.

### Get your money's worth – Interesting opportunities for medical writers in market access

**Speaker:** Oleg Borisenko, MD, PhD  
(Director at European MedTech and IVD Reimbursement Consulting Ltd.)

**Written by:** Mariella Franker, PhD,  
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Reimbursement and funding are essential steps for market access and the success of a product. A value dossier contains all relevant data of a product, such as indication of the epidemiology and burden of disease, current treatment modalities and their limitations, systematic literature review for the procedure in scope, health economic analysis etc. Excerpts are often used for reimbursement and health technology assessment (HTA) submissions. Concepts of reimbursement and funding are complex and significant differences exist between countries. Nevertheless, there are clear opportunities for medical writers when it comes to creating the

value dossier and other reimbursement and HTA submission documents. Oleg Borisenko provided some useful and practical tips for writers who want to move into this field. He recommends: 1. seek collaboration with existing agencies and group your knowledge of different country systems, 2. take advantage of existing submission templates, and 3. increase your language skills to cater to demand in different countries.

“It is a complex world, but one that can provide a lot of opportunities [for medical writers] as well”, Dr Borisenko noted.

The key concepts in market access are reimbursements, funding and the HTA. Reimbursement is a system that provides payment for a procedure or technology. While in most EU countries, reimbursement is based on cost data, some countries demand evidence of efficacy, safety and sometimes cost-effectiveness (Austria, France, Belgium, Netherlands). Funding is the willingness to pay for a procedure and can be influenced by multiple stakeholders. Funding is decided at hospital level in some countries, contrary to pharma, different types of medical technologies compete for the same hospital budget. The key objective of the HTA is to advise policymakers. It includes systematic literature review of efficacy and safety of the product and a health economic analysis. HTA is typically performed by governmental or independent organizations and can have a large impact on reimbursement and funding policies.

### Conclusion

New EU regulations are introducing higher scrutiny standards to the field of medical devices. With requirements for more clinical data and close monitoring of device use come unique opportunities for medical writers in the field.

Speakers at the symposium highlighted the relevance of the transferable skills of medical writers including knowledge and understanding of regulatory procedures and objective writing. Thanks to those skills writers familiar with writing for pharmaceutical industry will easily adapt to medical devices field. At the same time this is a chance to expand writers portfolio by writing new types of documents, such as systematic reviews, market approval documentation and post-market surveillance reports.

Broad range of required documentation gives writers an opportunity to find the niche for themselves, whether it is with standard regulatory writing, scientific publications or patient oriented documents. Finally, as manufacturers take advantage of modern digital technologies writers can take roles of complex science translators to broad public.

In summary, medical writers willing to join the medical device field will find themselves working with familiar scientific concepts, while preparing new types of documentation and expanding their expertise to physics and engineering. Furthermore, as new regulations are taking effect writers will be working on the forefront of establishing new standards in the field.

### Acknowledgements

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## EMWA social events programme

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(with contributions from some of the team at Trilogy Writing & Consulting – Rachel Beeby, Elizabeth Millar, Jeffrey Fielhauer, Laia Pedro-Roig, and Bryan Greene)

The social programme for the 46th EMWA conference in Barcelona offered a diverse range of options for exploring the city, culture and cuisine of Barcelona. These included the annual dinner, a Spanish Cuisine cookery class, and both Gothic and Modernist walking tours.

The annual dinner, “Dinner with Friends”, took place at Mussol Caspe, where delegates

enjoyed a traditional Catalan meal. There were 10 small tapas courses including Montseny sausages (butifarra), coca bread with tomato, garden vegetables, and much more. Dishes were prepared with fresh regional ingredients, and accompanied by Catalan wine. Each course was served with a break in between, which allowed for a leisurely meal and an opportunity to catch up and to make new friends. The evening reflected some true elements of Spanish character: sociability and sharing!

The hands-on Spanish cuisine cooking class provided the opportunity to acquire new cookery skills in making gazpacho and also paella.

Delegates found the walking tours through Barcelona very informative, including immersion in Spanish history from excellent tour guides. Particular highlights were seeing the ruins, walls

and graves from an ancient Roman settlement the the older parts of Barcelona. Other highlights were the Mercat de la Boqueria market just off the main street of Las Ramblas, which had a variety of exotic fruit, chocolate and nougat. Las Ramblas was a diverse and vibrant street with lots of hustle and bustle, yet not far from this was the gothic quarter, the oldest part of the city, where there were small, quiet courtyards surrounded by tall buildings. Another stop was at the Sagrada Familia, the Roman Catholic church designed by Catalan architect, Antoni Gaudi. Here, the architecture amazed with so much detail. Incredibly, the designing and building of this church began over 100 years ago and is still ongoing. All in all, a memorable experience!