6th EMWA Symposium – Thursday, 3rd May 2018
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 symposium program is:

- Introduction to medical devices
- Transferrable skills: from drugs to medical devices
- The new Medical Device Regulation (MDR) and its implications for medical writers
- MDR and MEDDEV: What notified bodies are looking for in Clinical Evaluation Reports (CERs)
- Patient user, apps, technologies, security, and potential failures
- Databases and tools: systematic reviews
- From bench to publication: All you need to know about medical devices based on a case example
- Publication planning during device life cycle
- European medical devices reimbursement strategies and associated documents

We look forward to welcoming you to our EMWA Symposium.

Fourth EMWA Expert Seminar Series – Wednesday 2 May and Friday 4 May 2018

EUROPEAN MEDICAL WRITERS ASSOCIATION

The target audience for the ESS is experienced medical writers, heads of medical writing departments, and industry leaders from other disciplines interested in the latest developments affecting the medical writing industry and playing a role in shaping the world of medical writing. This ESS will feature developments in the field of regulatory, pharmacovigilance and medical communications writing, led by invited speakers, all leaders in their field.

The ESS programme will be held either side of Symposium Day, and will comprise paired sessions in a common area of medical writing. The 3-day content package will appeal to our more experienced members. The provisional programme includes:

Regulatory

- Disaster recovery plans: a case study of a regulatory medical writing department's response to a cyber attack.
- Requirements and writing tips for clinical documents (Modules 2.5 and 2.7) for hybrid, mixed and fixed combination applications.
- Cochrane Working Group insights: the use of clinical study reports in systematic reviews.

Orphan drugs and rare disorders

In this comprehensive integrated session focusing on medical and patient-targeted publications, and regulatory document requirements, regulators (EMA), research and patient organisations, and the pharmaceutical industry will present their perspectives on collaboration with medical writers.

Pharmacovigilance

- Major revision of guidance and template on Risk Management Plans (RMPs): impact of the revision from a regulator, assessor, and industry perspective
- How the life cycle of a medicinal product should be reflected in RMPs and Periodic Safety Update Reports: the medical writer´s perspective
- Impact of the RMP guidance revision on patients´ safety

Medical Journalism

This session will discuss the skills needed for good medical journalism; including ethics; training opportunities; sources of information; and will explore different professional paths. The session will conclude with medical and scientific journalists sharing their experiences.

We look forward to welcoming our experienced EMWA members to the Barcelona ESS.