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EUROPEAN MEDICAL WRITERS ASSOCIATION



Barcelona Conference – 1-5 May 2018 at the Barceló Sants Hotel – check the conference [minisite](#) for the full programme and much more information

Medical Devices Symposium

- Is an App a medical device? What about security and data protection?
- Want to find the right information for Medical Device Clinical Evaluation Reports?
- Want to learn about the full life cycle of a medical device to understand clinical data obtained from medical device studies?
- Want to generate the necessary clinical evidence for medical devices through product life cycle communication strategy?
- Want to embark on a new area and learn about European Reimbursement strategies and the associated documents?

Then join us at EMWA's medical device symposium on **May 3rd in Barcelona**.

EMWA Photo Competition:

Have your photo sent to pr@emwa.org or tag it with **#EMWAphoto2018** in Twitter. Winners will be announced on Friday 4th May.

Internship Forum

Are you a prospective medical writer seeking practical experience in an established professional environment? Do you need career coaching or other related advice? Both?

Come join us at the next EMWA Internship Forum, to be held on **Thursday 3 May** at the next EMWA Spring Conference in Barcelona.

Don't forget to bring your EMWA badge to Barcelona and participate in the photo competition.

**Regulatory update**

- Brexit: Redistribution of UK's portfolio of centrally authorised products ([EMA news](#)).
- The EMA has released the updated Important Medical Event (IME) list in MedDRA version 21.0. The link is available [here](#).
- The EMA has set up an [inventory](#) of patient registries in the resources database of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP).
- The EMA has issued the European Union [recommendations for the influenza virus strains](#) that vaccine manufacturers should include in vaccines for the prevention of seasonal influenza from autumn 2018.
- The EMA has released for public consultation a [draft addendum](#) to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections to address paediatric-specific clinical data requirements - First version. This addendum to the Guideline has been developed to provide specific guidance on paediatric clinical development programmes that are required to support the authorisation of antibacterial agents for treatment of infectious diseases in paediatric patients.
- The Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh) has endorsed new measures to avoid exposure of babies to valproate medicines in the womb, because exposed babies are at high risk of malformations and developmental problems. The communication in full is available by clicking [here](#) and includes information to patients and healthcare professionals.
- The US FDA issued [draft guidance](#) on Scientific and Ethical Considerations in Including Pregnant Women in Clinical Trials.
- The US FDA issued [guidance](#) on how to comply with the final rule on post-marketing safety reporting requirements for combination products (issues on 20 Dec 2016; 81 FR 92603).
- A new CIOMS group has been established: [New Working Group XI - Patient Involvement in Development and Safe Use of Medicines](#). The task for the CIOMS group would be to develop criteria and guidelines on patient involvement in drug development, pharmacovigilance and risk management as well as several other areas where harmonized and pragmatic patient-centered approaches should be adopted.

**Education Committee**

The members of the EMWA education committee are looking forward to meeting you at the conference in Barcelona. If you've got any comments on the education programme, or suggestions for new topics for workshops or webinars, come and talk to us: Barbara Grossman, Lisa Chamberlain James, Laura Collada, Marian Hodges, Alison Rapley, Carolina Rojido, Kari Skinningsrud, Sarah Tilly, Thomas Wagner.

If you're attending a workshop at the conference, please fill in the evaluation form. The education committee looks at all of them and uses them to help monitor the programme and identify areas where new topics would be useful. Your views matter!

Marian Hodges
Education officer

Joint Position Statement

EMWA would also like to thank all of the following people for their excellent work in translating the Joint Positions Statement (JPS) on the role of medical communicators in the preparation of manuscripts for publication.

By joining with AMWA and ISMPP in both developing and publicizing the Joint Position Statement, EMWA has provided a valuable service to publication professionals around the world by enabling them to more easily read, understand, and apply the principles of the JPS.

German: Marion Alzer and Susanne Geercken
Italian: Tiziana von Bruchhausen and Andrea Rossi
French: Laurence Auffret
Spanish: Silvia Paz Ruiz and Eva Garcia Gonzalez
Romanian: Petronela M. Petrar
Hungarian: Petronela M. Petrar
Ukrainian: Oles Matyshenko

The Ukrainian translation of the JPS is now available and can be accessed at the following [link](#).

Ambassador's Program

We have initiated the Ambassador Program as part of EMWA's strategy to raise awareness about the medical writing profession and the benefits of joining our organization. The goal of the program is to recruit experienced EMWA members to give presentations at university career events, EMWA training organizations, and at medical conferences. So far we gave gotten off to a good start and the momentum is continuing.

Well received talks were given to inquisitive students on 18 April by **Anne McDonough** at Anglia Ruskin University Chelmsford, UK, and on 19 April by **Beatrix Doerr** (EMWA Honorary Secretary) at Ludwig Maximilian University, Munich.

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