





Barcelona Conference – 1-5 May 2018 at the Barceló Sants Hotel – Save the date –registration open – take advantage of the early bird registration price!

Workshops for Barcelona

Workshops are filling up quickly!

We will be running 52 workshops in Barcelona, including 5 new topics. They cover a broad range of topics, with about one third of workshops at the advanced level.

As well as workshops, there will be lots of other opportunities for learning, including 4 Expert Seminar Series sessions on a range of topics and the 1-day Symposium on medical devices.

You can check the workshops running at the May conference at our dedicated

<u>mini-site</u>.

EMWA Expert Seminar Series

The EMWA Expert Seminar Series (ESS) is for experienced medical writers, heads of medical writing departments, and industry leaders from other disciplines who want to learn about the latest developments affecting the medical writing industry and play a role in shaping the world of medical writing.

This year, EMWA's ESS comprises a range of topics led by international experts. The topics are:

- Pharmacovigilance
- Orphan drugs and rare disorders

• General Data Protection Regulation and Regulatory update: Clinical Trial Registries and Public Databases, and use of Clinical Study Reports for Cochrane Reviews

Medical journalism

BELS exam

The Board of Editors in the Life Sciences (BELS) exam that tests proficiency in manuscript editing is again being offered in parallel with the EMWA conference at 12:00 on 1 May. The deadline for applying is 10 Apr. For more information please check <u>bels.org</u>

EMWA Anniversary photo competition

As you already know we have been celebrating our 25th Anniversary as an organization and have sent out a specially designed button with the Dec issue of the MEWs. We are having a contest for the best pictures of delegates wearing these buttons so go out and take some pictures and send them to our PR Officer Maria Almeida at <u>pr@emwa.org</u>



Regulatory updates

1) EMA issued the following publications:

<u>Strengthening standards, transparency, and collaboration to support medicine</u> <u>evaluation: Ten years of the European Network of Centres for</u> <u>Pharmacoepidemiology and Pharmacovigilance (ENCePP)</u>

<u>The impact of parallel regulatory-HTA scientific advice on clinical development.</u> <u>Assessing the uptake of regulatory and HTA recommendations.</u>

2) The European Medicines Agency has released for public consultation a <u>draft</u> <u>guideline</u> on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus - Revision 2.

3) The EMA publishes a monthly "Human Medicines Highlights" Newsletter, which is addressed primarily to patients, consumers, healthcare professionals and their organisations. The latest edition of the Newsletter is available by

clicking <u>here</u>. Previous editions can also be found on this <u>page</u>.

4) Following the safety recommendation and the public hearing on valproate, PRAC <u>recommends new measures</u> to avoid valproate exposure in pregnancy.

5) The Ukraine now accepts RMPs written according the EU format as per GVP V Rev. 2.

6) The EMA has published a question-and-answer document addressing common misunderstandings about the meaning of orphan designation and other aspects pertaining to orphan medicines. The Q&A document is available by clicking <u>here</u>. For more information about orphan designation please click <u>here</u>.

Education

Our first LIVE webinar of the year will take place on Tuesday 13th of March at 2 pm!

Raquel Billiones will talk about "Medical Devices: Key Regulations and Guidelines that Medical Writers Should Know". The medical device industry is undergoing a major revamp with new regulations, guidelines, and requirements. In this environment, the role of medical communicators in the medical device industry has gained in importance.

This webinar provides regulatory medical writers a short introduction to the key regulations and guidelines, the new requirements and documents, and the challenges and opportunities. Registration will open on the 1st of March on https://www.emwa.org/training/emwa-webinars-programme/



Upcoming issues of Medical Writing

Here's a list of the upcoming issues of Medical Writing and the deadlines for submitting articles:

June 2018: Public disclosure (deadline March 12, 2018)

September 2018: Editing (deadline June 11, 2018)

December 2018: Patient-reported outcomes (deadline September 10, 2018)

March 2019: Careers in medical writing (deadline December 10, 2018)

June 2019: Generics and biosimilars (deadline March 11, 2018)

If you are interested in contributing an article, short text, or news item related to one of these themes or any other topic relevant to medical writers, please contact our editorial office at mew@emwa.org



Opportunity to Vote for Your Next EMWA Executive Committee (EC) Members!

Voting for the next EMWA Executive Committee (EC) Members is now open. Meet Successful Candidates in Barcelona on 2 May 2018. Check here to view the elections page.

Ambassador's program

EMWA President Abe Shevack has given a talk on medical communication and EMWA at the Winter School career event at the Leibniz Institute of Molecular Pharmacology in Buch, Berlin. This was well received by over 30 PhD candidates, many of whom had never heard of the field of medical communication before.

Alison Rapley will be holding an interactive course on Improving your writing skills" and the role of EMWA training as part of the Health and Life Sciences Careers event at the University College London on 6 March. Alison also gave a talk on the 27th of February at the Imperial College London during their Focus on Science Communication and Policy week.

The Ambassador's program group will be having a lunch time roundtable discussion on Thursday 3 May at 12:15 during the EMWA conference in Barcelona. Anyone interested in finding out more about this program are welcome to attend.



 OPEAN
 Registered Office: Chester House, 68 Chestergate, Macclesfield, Cheshire SK11 6DY

 ICAL
 Tel: +44(0)1625 664534
 Fax: +44(0)1625 664510
 E-mail: info@emwa.org

 rERS
 DCIATION
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