



EMWA's 25th Anniversary - Call for old photos

On the occasion of EMWA's 25th anniversary, we are looking to post some amusing pictures from past conferences on the website. If you have pictures that you would like to share, please send them to webmanager@emwa.org. Thanks for your help!

New members needed for the EPDC

Sadly, Laurence Auffret and Andrea Palluch have had to step down from the EMWA Pro-fessional Development Committee (EPDC). We are very grateful for all the work they have done to support the EMWA professional development programme (EPDP).

We are looking for 2 new members. One will be our lead on webinars, which will include leading the small team of volunteers who are working on webinar presentations and the forthcoming programme. The other member will focus on the workshops, including men-toring workshop leaders who are developing new topics.

To ensure we maintain a broad range of experience and expertise on the EPDC, we are particularly keen to recruit a member who has experience in med comms or medical de-vices, but we are open to applications from members with other experience.

If you are an EPDP workshop leader and/OR have experience and expertise relevant to the webinar programme and would like to help ensure the quality and further development of the education programme, we'd like to hear from you.

Please contact Marian Hodges at education@emwa.org for full details, including the terms of reference for the EPDC and an expression of interest form.

Now online:

AMWA–EMWA–ISMPP Joint Position Statement on the Role of Professional Medical Writers - Hear about the scope of the [AMWA–EMWA–ISMPP Joint Position Statement on the Role of Professional Medical Writers](#) and also find out how EMWA can help you meet your responsibilities as a medical writer, by Art Gertel

Upcoming webinar: **Introduction to Clinical Evaluation Reports for Medical Devices**

By Raquel Billiones, registration not yet open.



Barcelona Conference – 1-5 May 2018 at the Barceló Sants Hotel – Save the date

BELs Exam in Barcelona

The Board of Life Sciences (BELS) will be offering their editing proficiency certification exam on 1 May on the afternoon before the Spring Conference in Barcelona. Please check bels.org for more details on registration for the exam.



PV SIG Update

The **EMA information day on risk management planning** was held in London on 19th December. Presenters from EMA and PRAC addressed practical aspects of the im-plementation of the revised RMP guidance (GVP module V Rev. 2). The key message of the information day was that the principles of the revised guidance should enable a critical review over time of the list of safety concerns, pharmacovigilance activities, and risk min-imization measures. The transition of RMPs into the new format should represent the op-portunity to re-focus on selected safety concerns and reflect the new streamlined ap-proach. A deviation between the (selected) safety concerns in RMPs and the important risks in PSURs is expected.

The [FAQs](#) on risk management plans on the EMA website were updated in December 2017.

According to the annex to the excipient guideline published in October 2017, all prod-ucts that contain sodium salts have to include a statement in their package leaflet (guide-line [here](#)). This is particularly relevant to products used in special patients' populations, such as e.g. children or patients on a low sodium diet.

Regulatory update

The CMDh released for public consultation a guideline „on the Informal Work-Sharing procedure for follow-up for PSUSA for NAPs“. Further information on this new follow-up procedure (“PSUFU”) to address specific authority requests received within PSUSA pro-cedures for nationally authorised products is available [here](#).

A draft qualification opinion on PROactive in chronic obstructive pulmonary disease (available [here](#)) has been released for public consultation.

The EMA's second Awareness Session for international regulators, academia, and non-governmental organisations will take place in London on 8 9 March 2018. Further information is provided [here](#) (draft programme [here](#)).

MEDICAL WRITING –EMWA's Journal

The December issue of the Journal, on Preclinical studies will soon be at your mail box together with the EMWA 25th Anniversary buttons.

Upcoming issues of Medical Writing

March 2018 – Vaccines & immunotherapy – deadline is now closed
June 2018 – Public disclosure – deadline for feature articles March 12, 2018
September 2018 – Editing – deadline for feature articles June 11, 2018
December 2018 – Patient-reported outcomes – deadline for feature articles September 10, 2018

To be confirmed: Careers in medical writing (planned for March 2019) and Generics & biosimilars (planned for June 2019).

New Webeditorial

The latest EMWA Webeditorial is now available and is aimed at people new to the industry.

As you probably know, getting started as a medical writer can be tough. But fear not, Mariella Franker shares six pitfalls she has seen and that people starting out as medical writers should be aware of.

The Webeditorial archive is open to all. Feeling inspired? If you have something you would like to get off your chest about any aspect related to medical writing, please get in touch in touch if you would like to pen a webeditorial.



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