



NEWS FROM THE PRESIDENT

EMWA's President, Abe Shevack was invited to speak at the National Congress of Clinical Re-search in Bucharest Romania on 19 Oct. This was the first time that a representative from EMWA had held a presentation in Romania. The conference was attended by over 200 participants including healthcare professionals from industry, CROs, academia, and officials from the Romanian ministry of health. There were also speakers from Switzerland, Poland, and Bulgaria.

Abe introduced the participants to the field of medical writing and the importance of EMWA in setting high professional standards in medical communication. His talk was well received as communicated by the organizers:

"Please accept our sincere appreciation for the outstanding presentation you made to the 2nd Edition of the National Congress of Clinical Research in Bucharest, Romania. It was very interesting to hear about your expertise. The slides you showed gave us a close look at the environment, process, and methods of Medical Writing that we couldn't have gained in any other way."



Call for Abstracts - 46th EMWA Conference, Barcelona 2018

The Scientific Organising Committee calling for abstract submissions for the 46th Annual EMWA Conference in Barcelona, Spain, [until the 15th December 2017](#).

Posters based on accepted abstracts will be displayed at the conference from 2nd to 4th May 2018. More info [here](#)



Love Webinars? What works for you?

Help develop the webinar programme by telling us what you think makes a good webinar - one that is truly memorable and gives you answers you are looking for? Let us know at webinar@emwa.org

Online now & coming up!

EMWA's October webinar is now online. Beatrix Doerr's [Writing clinical study reports for medical devices](#) is an informative and dynamic presentation followed by a Q&A session. If you still have questions, feel free to contact [Beatrix](#) for further info.

Next? Let's hear from Art Gertel about the scope of the [AMWA-EMWA-ISMP 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.

This session will be pre-recorded. Interested, or any questions, please contact Laurence Auffret at webinar@emwa.org before 22nd November.



EMWA WORKSHOPS

Going to be in Cascais? Have you got an idea for an EMWA workshop or webinar, or would you like to know what's involved in developing one? Any member of the education committee would be pleased to hear your ideas, answer your questions or listen to your feedback.

Come and see us at the conference, or email education@emwa.org or webinar@emwa.org. Your education committee members are: Laurence Auffret, Lisa Chamberlain James, Barbara Grossman, Marian Hodges, Andrea Palluch, Kari Skiningsrud, Sarah Tilly and Thomas Wagner.

EMWA Webeditorials are back!

What is a webeditorial? As the name suggests, it is an opinion piece published online which touches on a topic related to medical writing. It may be serious or light, descriptive or opinion led. The most recent webeditorial is by Jane Edwards and examines the impact of the new Medical Device Regulations on medical writers. You can read it [here](#).

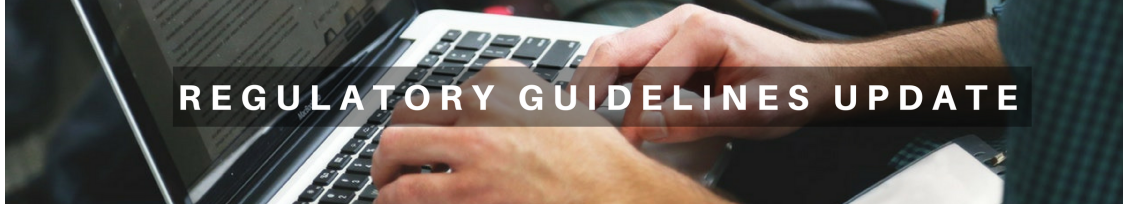
The webeditorial archive is still online. Feeling inspired? If you have something you would like to get off your chest about any aspect related to medical writing, please get in touch if you would like to pen a webeditorial.

Have you checked out the Resources section of the EMWA website lately?

[In this section](#), you can find job listings, useful reading lists, book reviews and the medical writers career guide. There is also a comprehensive collection of useful links covering everything from regulatory guidance, to reporting requirements for publishing clinical studies, to grammar and languages reference sites, as well as sites on medical background, statistics, and software just to name a few. This is definitely worth a look.

Dec issue of the MEWs

And last, but not the least: the December Issue of the MEW will cover Preclinical studies and also the results of the EMWA Salary Survey



ICH Guidance on CTD M4 Organization

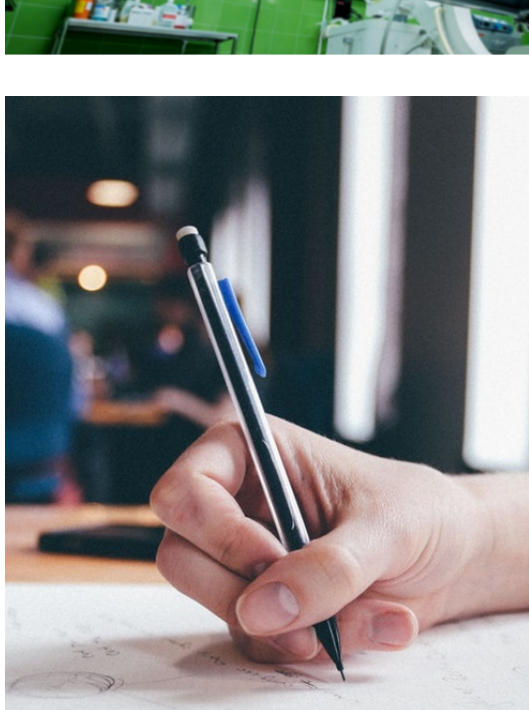
The ICH Guidance on "M4 Organization of the Common Technical Document for the Registration of Pharmaceuticals for Human Use" dated October 2017 is available now at:

<https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm073257.pdf>

Pharmacovigilance Special Interest Group Updates

The [PV SIG webpage](#) was updated with regard to news, sources, and links relevant for pharmacovigilance writers (status: September 2017). Visit the tabs "[News](#)" and "[Resources](#)"!

[Draft updated guidance on REMS](#) format and content has been published in early October by the US FDA. The draft revises 2009 draft guidance for industry known as "Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Pro-posed REMS Modifications." You can find further information [here](#).



FRENCH TRANSLATION NOW AVAILABLE

EMWA has now undertaken to translate the Joint Position Statement on the Role of Medical Writers.

This statement was prepared together with our colleagues at AMWA and ISMP in order to set out ethical standards for medical writers in developing scientific and medical publications. We are now spreading the word among non-native English speakers in Europe and beyond.

The German and Italian translations and PDF versions have already been posted and can be accessed by clicking on the "Deutsch" or "Italiano" language tab from the English language Joint Position Statement page.

The French translation and PDF version is now available and can be accessed by clicking [here](#).

