

## EMWA Newsblast - March 2019



### 48th EMWA Conference, Vienna 7th - 11th May 2019

**Registration is now open and workshop spaces are filling up fast!**

To help you plan for the EMWA Spring conference, you can access the dedicated conference mini-site.

[Visit Conference mini-site](#)

#### Call for volunteers

We are looking for volunteers to participate in the Getting into Medical Writing event. If you want to share your expertise as a speaker, please write to [gettingintoMW@emwa.org](mailto:gettingintoMW@emwa.org).

You are also very welcome to come into the event and network with future medical writers

#### Medical Devices Special Interest Group

Following the 2018 Symposium in Barcelona, the Medical Devices SIG has received requests to continue building up EMWA's offerings focused on medical devices.

We are happy to announce the following medical device-related events at the 48th EMWA Conference in Vienna in May this year:

**Expert Seminar Series (ESS) on Medical Devices on Friday, 10 May 2019, 9:00 to 12:15, covering the following topics:**

\* Drug-device combination products: regulations and documentation, by Beat U. Steffen (confrinis)

\* Medical device approval in Europe, US and Japan: similarities and differences, by Myriam Stieker (Biotronik)

\* Clinical evaluation, PMS/PMCF - requirements for plans and reports requirements with impact on medical writing, by Susanne Gerbl-Rieger (TÜV Süd)

**Workshops as part of the EPDP Medical Device track:**

\* Writing Clinical Evaluation Reports (New, Advanced), Wednesday 8:45 to 12:15, by Claudia Frumento

\* Literature Reviews for Medical Devices (Advanced), Wednesday 13:30 to 17:00, by Gillian Pritchard

\* Going from Pharma to Medical Devices: Transferrable Medical Writing Skills (Foundation), Thursday 13:30 to 17:00, by Gillian Pritchard and Raquel Billiones

**Medical Device SIG meeting on Friday, 12:30 to 13:15**

#### Exciting news from the Pharmacovigilance Special Interest Group!

The PV SIG are delighted to announce their ESS session at the May conference, entitled 'RMPs and new format PSURs (PBRERs): what the regulators really want and how to give it to them'. The session will be on Wednesday 8th May at 13:30 and will feature two Regulators from the MHRA, plus a very experienced speaker giving the Industry perspective.

This is a fantastic opportunity to really hear 'from the horse's mouth' how to improve our RMP and PSUR submissions and how to avoid the common errors seen by Regulatory Agencies.

If anyone has any questions they would really like the speakers to address, please let us know ahead of time ([Lisa@trilogymwriting.com](mailto:Lisa@trilogymwriting.com) or [rohith.pushparajan@accenture.com](mailto:rohith.pushparajan@accenture.com)). See you all there!

#### Hot topic: lunch seminar on predatory publishing in Vienna

Join the dedicated lunch seminar on Thursday 09 May (12:30 – 13:15) in Vienna and learn more about this topic and EMWA's initiatives! Medical communicators need adequate training to recognise good publishing: besides planning EMWA-specific seminars, trainings, and articles, our subject matter experts (SMEs) are going to discuss the possibility of a joint position statement together with SMEs of AMWA and ISMPP. See you in Vienna!

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#### Be a part of the Veterinary Medical Writing Special Interest Group

EMWA is going to deepen a new area with high potential for development: veterinary writing, which spans across medical communications, scientific publications, and regulatory writing.

If you are working in the veterinary field please join us in Vienna to establish a "veterinary medical writing" SIG, strengthen the veterinary writers The meeting is scheduled

network, and define which EMWA activities can better support the professional development of our veterinary members. We would be delighted to meet you and hear your voice! on Thursday 9 May (12:30 - 13:15).

#### Photo contest!

Get inspired and prepare your EMWA merchandise for the "Bring EMWA to Vienna" photo contest!

#### Ambassador's Program Update!

The Ambassador Programme has gotten off to a good start in the New Year. As you know EMWA's strategy is 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, professional training organizations, and at medical conferences.

The Ambassador's program group is planning to have a lunch time roundtable discussion on 9 May (Thursday) from 12:00 to 13:15 during the EMWA conference in Vienna at the Intercontinental Hotel restaurant.

We will be discussing the status of the program and any new ideas to keep the momentum going. Everyone interested in finding out more about this program are welcome to attend.

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#### BELS Exam Update

For the convenience of our members attending the May 2019 EMWA Conference in Vienna, the Board of Editors in the Life Sciences (BELS) is planning to hold its examination on **7 May at 12:00 before the conference at the Austria Trend Hotel Savoyen**. This hotel is within walking distance of the conference venue.

The exam is offered world-wide and tests proficiency in manuscript editing. Candidates who pass this certification exam are allowed to add the initials "ELS" after their names (Editor in the Life Sciences). Delegates wishing to register for the BELS exam should contact BELS via [www.bels.org](http://www.bels.org).

Delegates should note that while EMWA and BELS are co-ordinating the timing of these events, the BELS examination is a separate event, and not part of the EMWA conference.

EMWA accepts no liability arising from registration for, the conduct of, or potential cancellation of the BELS examination event, and is not able to provide assistance with BELS registration, or authorised to answer any queries regarding the BELS examination.

#### Webinars

PerfectIt is an MS Word add-in that offers a fast and accurate way to check for consistency errors.

This 14th of March at 4 pm CET (please note the time is 4 pm and not 2 pm as usual) we will have a private company webinar on "Checking Consistency: An Introduction to PerfectIt" by Daniel Heuman (CEO & Founder of Intelligent Editing Ltd). Here's a brief summary:

EMWA Webinar Programtext. It's designed for professionals and used by more than 500 members of the Society for Editors and Proof-readers. The workshop is primarily for complete beginners who have never used PerfectIt before. It will cover what the software can and cannot find, with an overview of all the styles and checks that it can run. It will show how suggestions vary by location, and every location and suggestion need to be checked for context. It's open for users on Mac or PC.

Please click [HERE](#) to register for this webinar.

In April 11th, we will expand on this subject with "Checking House Styles: Customizing PerfectIt for Advanced Users" also by Daniel Heuman.

## NEWS OF INTEREST

### Regulatory News

#### Regulatory News

- EMA relocation in Amsterdam: EMA London offices will close on 1 March 2019 and re-open on 4 March in Amsterdam, The Netherlands
- Updated "Questions & answers on signal management" available on EMA webpage
- Heads of Medicines Agencies (HMA) - EMA Joint Big Data task force published a summary report on the acceptability of evidence derived from "Big data" in support of the evaluation and supervision of medicines by regulators
- EMA's PRAC recommended EU-wide suspension of fenspiride medicines, used in children and adults to relieve cough caused by lung diseases
- EMA's review of cancer medicine Lartruvo has started
- EMA's review of study on bleeding risk with direct oral anticoagulants has started
- Swissmedic published information sheet "Drug Safety Signals"

#### Resources

1. Does anonymization or de-identification require consent under the GDPR?
2. "Opinion" on the interplay of the CTR and GDPR
3. "Big Data" - consultation on the acceptability of evidence
4. UK government national strategy to boost clinical trial reporting

Read more [here](#)

#### Professional Indemnity Insurance - 20% Discount for EMWA Members!

Did you know that EMWA members get a 20% discount on their Professional Indemnity Insurance?

Established in 1992, PIA Commercial works closely with their clients to provide a tailored range of specialist insurance products for both individuals and businesses.

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Keep up to date with their business news and industry insights by following them on LinkedIn, by searching 'PIA Commercial'

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