

EMWA Newsblast - September 2020



[MC:TOC]

EMWA Medical Devices SIG Meeting



The EMWA Medical Device SIG is meeting on **Friday, 4 September 2020 (11:00-12:00 CET)** for a virtual round table discussion. The main topic for this month is on the State of the Art (SoA) in clinical evaluation. In preparation for the call, please [download and read](#) the SoA white paper.

The discussion will be structured as follows:

1. Brief introduction
2. Discussion about the State of the Art in clinical evaluation
3. Other questions on medical devices
4. Survey on future topics for discussion

If you are interested to join the discussion, please do join us on Zoom via [this link](#).

EMWA Vet SIG Meeting



Next quarterly vet SIG social online meeting will take place on 30 October 2020, (15:00-16:00 German time).

If you are interested to join the discussion, please contact vets@emwa.org for more details.

Virtual Expert Seminar Series - Save the Date



Come and join us for EMWA's second virtual Expert Seminar on medical devices.

Life cycle safety and risk management for medical devices – an integrated approach
Wednesday, 07 October 2020, from 14:00 to 17:00 CET

This Expert Seminar covers the safety and risk management of the full life cycle of a medical device, from its development to post-marketing surveillance. More information [here](#)

Pharmacovigilance Special Interest Group - News

Dear members, we would like to draw your attention on the following:

- Do not miss the upcoming ESS that has been organized in collaboration by the PV SIG and the Medical Devices SIG
- The PV SIG has received several expressions of interest from members over the past months. We are going to organise a virtual networking meeting in Fall to get together with writers interested in pharmacovigilance and to launch a discussion and exchange platform. We will update you soon!

Regulatory News

- EMA's annual report 2019 available
- EMA's virtual workshop on benefit-risk of medicines used during pregnancy and breast-feeding on 22 September 2020
- Questions and answers on adverse event reporting in for veterinary medicine
- FDA's Risk Evaluation and Mitigation Strategies: Modifications and Revisions; Guidance for Industry

To read more, please click [here](#).

RPD Special Interest Group - News

- UK National Health Service Transparency Commitment
- Journal of Data Protection and Privacy
- Good Lay Summary Practice
- Clinical Trials Information System (CTIS) Webinar
- US CIVIL MONEY PENALTIES FOR VIOLATIONS RELATING TO CLINICALTRIALS.GOV DATA BANK

To read more, please click [here](#).

EPDC News

We are sad to report that Carolina Rojido has had to step down from the EPDC because of work and family commitments. Carolina has made a fantastic contribution, not only to the webinar programme but also to other EPDC activities. We are very sorry to see her go.

We are very pleased, though, to welcome Jules Kovacevic who is going to take over from Carolina as EPDC co-lead for the webinar programme, working with Laura Collada Ali. As Head of Medical Writing at Ergomed, Jules has experience of using online training to develop a global team of medical writers and is keen to contribute this to support the webinar programme and the EPDC.

Webinar Programme News

First experiences in the writing of Summaries of Safety and Clinical Performance (SSCPs) for medical devices

Presented by Laura C Collada Ali, Medical Writing & Translation Consultant & Katharina Friedrich, Medical Writer, Clinical Affairs, BD Interventional-Peripheral Intervention, Thursday 17 September, 14.00 CEST.

Join us in this webinar to hear about the first experiences of the two speakers with this challenging document. The webinar is aimed for writers with little or no experience with SSCPs.

To register, click [here](#).

Sustainability Demystified: An Introduction with Focus on the Healthcare Industry

Presented by Achim Schneider, PhD, Thursday 22 October, 14.00 CEST.

This webinar gives an introduction to sustainability, with focus on the healthcare industry. Several examples from the healthcare sector, especially the pharma industry, will be provided. Finally, the objectives of the EMWA sustainability SIG with regard to the SDGs will be presented for discussion.

November workshops

We are in the final stages of putting together an online workshop programme for November. Look out for further details this month.

Ambassador Programme News

As part of the [EMWA Ambassador Programme's](#) continuing efforts to reach out to new audiences to promote medical writing and EMWA, Abe Shevack gave a presentation on Medical Writing and the benefits of joining EMWA at the PAREXEL Academy in Berlin on 18 Aug.

If you are an experienced medical writer and EMWA volunteer and are interested in becoming an EMWA Ambassador or if you know of any upcoming career events in your locality please email [Abe Shevack](mailto:Abe.Shevack).

Arabic Translation of the Joint Position Statement on

the Role of Medical Writers

The position statement has now been translated into Arabic by Ahmad Nazzal and Chahira Katamesh. To access the translation please use the following [link](#).

Arabic Translation of the Joint Position Statement on

Predatory Journals

We are proud to announce the posting of the first JPS translation into Arabic by Chahira Katamesh and Nawal Benabbas. In order to access the translation please click [here](#).

We are currently looking for translators. If you would like to volunteer please contact [Abe Shevack](mailto:Abe.Shevack) or the [EMWA Head Office](#).

Three new editorials available online

Getting an EMWA certificate: investment and benefits

[Diana Ribeiro's summary](#) of both the practical and opinion-based aspects of EMWA certificates.

Of all bases some uncovered: Random observations and opinions on the Novel Corona Virus

"Medical writers have substantial contributions to make to efforts to learn and communicate about our pandemic". Read more [here](#).

O, Safety, quo vadis?

"We should not be deluded into believing that safety procedures can or will ever fully allay our fears".

Jack Aslanian muses on [keeping safe](#).

And last, but not the least, we all at EMWA wish you a nice return to work!