EMWA Newsblast- July 2021

Delivering Vaccines and Profiling the Veterinary Medical Community: vetSIG On-line Meet&Share, July 30th

At the vetSIG's next Meet&Share, Jen Bell will give a talk related to her co-authored paper on distributed vaccine manufacturing, an area with great potential for improving both human and animal health and highly relevant to the issue of "One Health". We will then hear about a survey of the veterinary medical writing community aiming (amongst other things) to define "veterinary medical writer", before opening the meeting to further discussion.

The meeting will be held at 3 pm CEST on Friday, July 30th. Please e-mail vets@emwa.org for a Zoom invitation or further details.

Do animals feature in your medical writing?

If so, then please try the 10-second, one-question/one-comment survey here and tell the vetSIG what species you write about.

The results—together with those from our earlier six-question survey —will be presented at our next Meet&Share (July 30th). Please e-mail vets@emwa.org for more details.

Medical Device SIG Meet & Share

Save the dates for our upcoming Meet & Share sessions:

Claims Identification and Substantiation, 6 August

In August the discussion will focus on how to identify claims and ensure they are substantiated with clinical data. What is a claim? Which claims must be addressed in the clinical evaluation report and how? What has been the feedback from Notified Bodies related to clinical claims? If you are interested in the answers to these questions, join us for what is sure to be a lively discussion!

How to Respond to Notified Body Review Questions, 3 September

Are you interested in optimizing your response to review questions from Notified Bodies? Then you should not miss this Meet & Share session.

The points for discussion will include:

- Organisational management, including cooperation between different expert teams
- Frequently asked questions by Notified Bodies and how to best handle them
- Writing-related aspects (e.g. formulation of claims)

Both sessions start at 11:00 CET on the respective dates. All EMWA members are welcome to join our Zoom call using this link.

You can also join the MD-SIG as a supporting member and receive regular updates and meeting invitations by contacting us at MD-SIG@emwa.org.

Business Development SIG

We are delighted to announce the formation of another new EMWA SIG. This group will aim to:

- provide a professional space for EMWA members who want to take the next step from freelancing to grow their business
- collectively help each other grow our businesses in a collaborative environment
- address common problems and provide group support to help pull each other up the next rung of the ladder

We will reach out to those EMWA members who have already asked to be involved, but if any other EMWA member would like to be part of the SIG, please contact Allison Kirsop via email or through LinkedIn. We hope that many more EMWA entrepreneurs will join us in our journey into business development.

EPDC News

Thank you to all of the workshop leaders who ran workshops at the May conference. There were 35 workshops in all and the overall feedback from delegates indicated that it was another successful virtual programme.

We value all the responses to the end-of-workshop Zoom polls and the Survey Monkey questionnaires because they help the committee and workshop leaders see what works well and where improvements could be made

Congratulations ...

to Thomas Schindler and Uma Swaminathan who have each presented 20 EMWA workshops, and to Raquel Billiones and Sarah Tilly who have now run 10 workshops each.

Badges are on their way to you, as a small thank you for your commitment to the EMWA education programme.

Webinars

Many EMWA members joined the very successful June webinar on EndNote. Don't worry if you missed it: it's now available in the members-only Webinar Archive.

The topic of the next webinar, on Thursday 22 July, is The role of Quality Tolerance Limits (QTLs) in Clinical Development, presented by Andy Lawton. Register on the EMWA website.

Getting into Medical Writing (GIMW) group

We are delighted to announce that we are taking the Getting into Medical Writing (former Internship Forum) session to another level with the recent formation of the GIMW group. The aim of this group is to support new EMWA members in smoothly and successfully starting their career path as medical writers.

Group activities:

- Private LinkedIn discussion group
- Monthly meet & share calls
- Organization of the GIMW session at EMWA conferences
- Creating a starting resource package for new EMWA members
- Supporting new EMWA members and aspiring medical writers
- Working in collaboration with the Ambassador's programme

The GIMW group will meet virtually every month. If you are interested in joining our discussions, please contact Evguenia Alechine via email at gettingintoMW@emwa.org

Your input is extremely valuable to all new members! :)

Spanish translation of the Joint Position Statement on Medical Publications, Preprints, and Peer Review

We are proud to announce the posting of our first translation of the JPS into Spanish by Almudena Pardo Mateos and reviewed by Sabrina Silano. 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 (aspscientist@gmail.com) or the EMWA Head Office (info@emwa.org).

Medicines and Vaccines

Guidance for RCTs

Real World Data

Clinical Trials Information System Update

EMA 2020 Annual Report

Course on Improving Clinical Trial Reporting

Requesting your help

On 22 June, I attended the PHUSE Summer Data Transparency Meeting Day 1 and heard Lora Chavis Killian (Pfizer T&D Lead) speak on the challenges of meeting transparency and disclosure requirements when preparing COVID vaccine regulatory documentation for EMA, CDP and HC PRCI submissions. I would like to ask her to write an article for the RPD Section in Medical Writing (MEW), but have been unable to reach her, even via LinkedIn. If you know Lora, please encourage her to be in touch with me.

MedDRA to SNOMED and vice versa – data exchange to support public health

CSRs provide most detailed primary source data

Devices

EUDAMED Module on Economic Operators

European Medical Device Nomenclature (EMDN)

Unique Device Identification (UDI) System Help Desk

Layman's Report on Joint Action on Market Surveillance of Medical Devices

Newly Released Guidance Documents on Clinical Investigations

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