

How the EU Medical Device Regulation is affecting the medical device landscape

An interview with Suzanne Halliday,
the Regulatory Head of BSI, Medical Devices Notified Body

Carmen Giefing-Kröll, Geneviève Laumen
MED-EL Elektromedizinische Geräte
Innsbruck, Austria

Correspondence to:

Carmen Giefing-Kröll
Carmen.Kroell@medel.com
Geneviève Laumen
Genevieve.Laumen@medel.com

Abstract

Suzanne Halliday, D.Phil., is the Vice President for Regulatory within the Notified Body BSI with extensive experience in compliance to the Medical Devices Directive (MDD), ISO 13485, risk management, clinical evaluations and investigations, meeting essential requirements with harmonised standards, post market surveillance, and vigilance. She has a Bachelor's and Master's in Science (University of Waterloo) and a Doctorate in Engineering (University of Oxford). Prior to working for BSI, she has designed orthopaedic implants and conducted post market clinical investigations on these products.

The EU Medical Device Regulation (MDR) has drastically changed the regulatory environment for medical devices and reinforced the requirements on clinical evidence and the post-market surveillance. We are glad to have interviewed Suzanne Halliday for this issue of MEW with special focus on medical devices.

Medical Writing (MEW): The EU Medical Device Regulation (MDR) entered into force on May 25, 2017, and it has applied since May 26, 2021. What are your impressions as a Notified Body (NB) now 1 year after implementation?

Dr Halliday (DH): BSI has issued our first few hundred MDR and IVDR (In-vitro Diagnostic Device Regulation) certificates. Our teams of quality management system (QMS), microbiology and technical specialists have now implemented the processes that were developed for designation. After actually assessing conformity to the Regulations, people have gained confidence in their abilities and manufacturers' applications have started to flow more smoothly.

MEW: Could you please explain what you mean by "...have now implemented the processes that were developed for designation".

DH: When the NBs applied to be designated to the new EU Regulations, the applications consisted of process flow diagrams and procedures and forms and templates; however none of these had actually been used to assess conformity of any medical device. None of the NBs were allowed to take on any actual conformity assessment work until they were designated. What has happened recently is that technical specialists and QMS teams have used the documents in combination with their expertise. Nothing was perfect when it was based on theory and so our processes, procedures, forms and IT systems now are improving based on hundreds of people completing hundreds of reviews.

MEW: What were the biggest challenges that you experienced as a NB to ensure BSI was MDR ready?

DH: BSI was the first NB to be designated to the MDR and the second to be designated to IVDR. The Regulations are more prescriptive; however, BSI was already doing many of the activities required by Annex VII. The greatest challenges remain how to interact with EUDAMED (European Database for Medical Devices) and trying to keep up with training our teams on the thousands of pages of MDCG (Medical Device Coordination Group) guidance that have been developed.

MEW: How do you foresee the MDR changing the medical device landscape? Do you expect any negative effect on the availability of legacy and niche products or the development of new devices?

DH: Many articles have been written about the increased requirements for clinical evidence.

If manufacturers were writing their clinical evaluation reports in line with MedDev 2.7.1 Rev 4 (2016), there are only a few additional requirements to reach the requirements of the EU MDR.

The regulation has a prescriptive frequency of update for new documents including periodic safety update reports (PSUR) and summary of safety and clinical performance (SSCP). The regulation also has a prescriptive sample size and frequency of technical documentation reviews. These increased numbers of reviews will increase costs to

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manufacturers. Unfortunately, this may result in some manufacturers choosing not to place a product on the market in the EU.

MEW: Are you able to estimate the increased effort required for submissions for CE marking under MDR compared to MDD /AIMDD (Active Implantable Medical Device Directive), both from a manufacturer's point of view and from a NB's perspective?

DH: Conformity assessment from the NB must be considered an initial assessment for devices to be listed on MDR certificates. This is true even of safe devices that have evidence of performing as intended for 10, 20, and 30 years. The initial assessment is taking time that used to be spread over many years in the past.

MEW: Could you please elaborate on this?

DH: When there were legislation changes in the EU in the past there were a few extra new things to check. The M5 amendment (Directive 2007/47/EC) moved Essential Requirement (ER) #14 to ER#6a, which means that a clinical evaluation was required for all devices. This amending regulation also required the review of specific risks of single use devices, specific justifications for clinical investigations not being performed for high risk devices and specific justifications for not completing post-market clinical follow-up (PMCF); however we did not re-review all of the technical documentation. The EU Regulations require all technical documentation to be re-reviewed.

MEW: What are some of the most common problems for manufacturers that you have seen as a NB with the transition to the MDR?

DH: There is an acute lack of resources in the competent authorities who complete reviews of ancillary medicinal substances. MDCG 2020-12 requires that these are initial assessments (which can take 210 days to complete), despite the pharmaceutical legislation not changing. Time is running out for manufacturers to make these submissions and have them completed by May 2024.

MEW: "Sufficient" clinical evidence seems to be the main topic for clinical evaluators under the MDR. What is your interpretation of "sufficient" for different risk classes of devices?

DH: EU Directives clarified the requirements for PMCF on the actual devices covered by CE certificates if those devices were placed on the market based on equivalence to another device. These clarifications were published in 2007 and should have been fully implemented by 2010. That should mean that actual data have been collected for more than 10 years. That could be "sufficient" to meet initial MDR requirements and then build on that manufacturer's evidence for all subsequent changes.

MEW: As a follow up to the previous question, there seems to be more value placed on small investigator-initiated studies that gather patient-reported outcomes over survival data from national registries; what hierarchy of evidence do you follow? How would you suggest addressing the challenges of obtaining sufficient clinical evidence for low volume and short life expectancy products where it is not feasible to obtain data on a sufficiently powered sample of patients?

DH: There are strengths and weaknesses from information learned in proactive study collection and strengths and weaknesses from information learned in registry data. The NB consider all sources of information. PMCF study data can ensure that data are gathered on subpopulations, extreme sizes of devices or rare severities of disease. Registry data can ensure that data are gathered from many different sites, many different medical

professionals, and across the most and least compliant patients. We would encourage a mixture of data to meet the “sufficient” expectation.

MEW: What MDCG guidances can be expected in the future? When can we expect guidance on the PSUR and updated guidance to replace the MedDev 2.7/1 Rev 4 for clinical evaluations?

DH: The Commission has indicated that they will not replace all MedDev guidances that were generated for the Directives. They are trying to prioritise the guidances necessary to successfully implement the Regulations.

Each MDCG workgroup (WG) publishes a work programme. The 2022 programme for MDCG WG #3 Clinical does not include a replacement for MedDev 2.7.1. The 2022 programme for MDCG WG #4 PMS & Vigilance includes PSUR guidance, although no guidance for the NBs to complete their review of the PSUR. Unfortunately, despite the NB working on these requirements for more than 1 year, this will be developed separately by MDCG WG#1 NBO (notified bodies oversight).

MEW: Have you witnessed increased demand and new opportunities for medical writers under the MDR, and are there opportunities for medical writers to work for NB?

DH: BSI are seeing manufacturers hire temporary employees to support the peak in workload required by initial EU Regulation submissions.

MEW: How have manufacturers demonstrated sufficient training and professional experience required for clinical evaluators in the broad areas of clinical research methodology, information management, regulatory requirements, medical writing, and the device technology and application as defined in MedDev 2.7/1 Rev 4? How would you advise medical writers to gain sufficient training and experience to prepare a clinical evaluation?

DH: BSI try to contribute to the whole system by delivering our own webinars and roadshow presentations. We also try to deliver other presentations at Regulatory Affairs Professionals Society (RAPS), The Organisation for Professionals in Regulatory Affairs (TOPRA), Association of British HealthTech Industries (ABHI), the British In Vitro Diagnostic Association (BIVDA), etc., where there is wide attendance from manufacturers, consultancy firms, and other service providers to the manufacturers trying to place product on the market.

MEW: Could you please elaborate on this? Do the clinical evaluators in general have the required expertise or are deficiencies regarding the qualification frequent? What kind of expertise would you see crucial? Is there an optimal way to get prepared for this task?

DH: MDCG 2020 6 indicates that MedDev 2.7.1 Rev 4 is still applicable for review of devices under the MDR with respect to who should perform the clinical evaluation.

MedDev 2.7.1 Rev 4 indicates:

- The clinical evaluation should be conducted by a suitably qualified individual or a team.
- As a general principle, the evaluators should possess knowledge of research methodology (including clinical investigation design and biostatistics); information management (e.g. scientific background or librarianship qualification; experience with relevant databases such as Embase and Medline); regulatory requirements; and medical writing (e.g. post-graduate experience in a relevant science or in medicine; training and experience in medical writing, systematic review, and clinical data appraisal).
- There are also requirements for specific knowledge of the device technology, diagnosis and management of the conditions intended to be managed by the device, and medical alternatives to the device under review.

Our Clinical Masterclass webinar series provides lots of additional information.

<https://www.bsigroup.com/en-IN/medical-devices/resources/webinars/2022/mdr/clinical-masterclass/>

Disclaimers

The opinions expressed in this article are the authors’ own and not necessarily shared by their employer or EMWA.

Disclosures and conflicts of interest

The authors are employed by the medical device industry. The interviewee is employed by a NB.

Author information

Carmen Giefing-Kröll, Dr. nat. tech., has been a Clinical Evaluations Manager at MED-EL since 2016 and is responsible for clinical evaluations.



Geneviève Laumen, Dr. rer. nat., has been a Clinical Evaluations Manager at MED-EL since 2019 and is responsible for clinical evaluations.