Differences between writing for medical devices and pharmaceuticals: An update

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Abstract
Although the medical device and pharmaceutical industries are related, they are governed by distinct regulatory systems. Despite the similarities, the inherent differences between medical devices and drugs have implications for clinical research and medical writing. There has been a recent move to adopt more stringent regulatory requirements for the medical device industry, bringing the environment closer to what we have come to expect from the highly regulated pharmaceutical industry. The present article is a follow-up to a previous article published in *Medical Writing* in 2017, which introduced writing for medical devices and the challenges for medical writers coming from a pharmaceutical regulatory environment. In this article, we present our current knowledge about authoring documents for medical devices, the parallels with the pharmaceutical regulatory system, and the essential guidance documents.

Although the medical device and pharmaceutical industries seem intrinsically related, they are governed by distinct regulatory systems. An article published in *Medical Writing* by Beatrix Doerr and colleagues in 2017[1] discussed the inherent differences between drugs and medical devices and their implications for clinical research and medical writing in general. The article also noted parallels between the different phases of clinical trials for pharmaceutical drugs and studies assessing the feasibility, safety, and performance of medical devices (Table 1). The article served as a good introduction to the similarities and differences between the two regulatory environments, and it forewarned the move towards the more stringent regulatory environment that has governed medical devices since.

The pharmaceutical industry has long had the benefit of International Council for Harmonisation guidelines,[3] the CORE Reference manual,[4] and well-established, accessible document templates.[5] By comparison, the medical device regulatory environment is relatively young and not as well structured. In fact, medical writers with a pharmaceutical background may feel that the medical device regulatory environment only recently started to catch up with the clinical regulatory environment. The structural differences between the two regulatory environments were particularly evident in the early days of medical device trials and documentation, especially before the implementation of the European Union Medical Device Regulation (MDR) 2017/45 (see Table 2 for a list of key medical device-related terms and definitions).[6] However, with increasing experience, and as guidance documents and position papers have been published by the notified bodies, the medical device industry is becoming more structured and specific. This has inevitably made writing for medical devices more attractive for medical writers.

Guidance documents for medical device writing

As part of the transition from Medical Device Directive (MDD) 93/42/EEC to MDR in 2021, the previous guidance documents ("MEDDEVs") have gradually been replaced by newer ones issued by the European Commission and endorsed by the Medical Device Coordination Group (MDCG). These are aimed at providing a uniform application and interpretation of the MDR within the European Union.[7] Although not legally binding, the MDCG guidelines are considered to be the official interpretation of the MDR, and they will help move towards implementation of MDR Article 105 and the "effective and harmonised implementation of the Regulation".

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Like the MEDDEVs preceding them, the MDCG guidelines are broad and cover several

Table 1. Clinical studies for pharmaceuticals and medical devices

Pharmaceutical clinical study phase	Equivalent in medical device study	
	Pre-market	Post-market
Phase I	Pilot study • first in human clinical investigation • early feasibility clinical investigation	
Phase II	Pivotal study pivotal clinical investigation	
Phase III	Pivotal study pivotal clinical investigation	Post-market clinical investigation
Phase IV		Registry Observational study Real world data collection

Adapted from Doerr et al. (2017)[1] and ISO 14155 Annex I.[2]

topics, including classification of devices, clinical investigations, clinical evaluation, clinical evidence, post-market activities, and in vitro diagnostics. As of January 2022, 11 MDCG guidance documents were listed on the European Commission website as relevant to clinical investigations and evaluations.[7] Other guidance documents should be issued later in 2022, some of which will discuss post-market surveillance, vigilance, and Periodic Safety Update Report (PSUR) requirements under the MDR. Familiarisation with these guidance documents is thus important for the medical writer involved in writing for medical devices. Some of the guidance documents are discussed in Table 3.

A closer look at the documents required for drugs and medical devices

Although the regulatory environments for the early stages of clinical trial and medical device investigations are similar, differences start to become more pronounced once at the point of entry on the market. Table 4 lists some of the documents required for pharmaceutical products and medical devices throughout the various stages of the product lifecycle.

Documents for clinical trials and investigations

In the MDR, clinical trials are referred to as "clinical investigations" (Articles 2 (45), 62–82; Annex XV).[6] The requirements in the MDR regarding clinical investigations are based on BS EN ISO 14155:2011 (updated in 2020).[2] The MDR goes into much more detail than the MDD regarding clinical investigations. Specifically, Articles 62 through 80 of the MDR address:[6]

- General requirements regarding clinical investigations conducted to demonstrate conformity of devices
- Informed consent
- Clinical investigations on subjects requiring special consideration
- Application process and assessment by member states
- Conduct of the clinical investigation
- Electronic system on clinical investigations and other aspects

Clinical investigations to demonstrate conformity of devices (Article 62) can be considered pivotal clinical trials conducted to prove the intended performance, clinical benefits, and clinical safety of an investigational device. The MDR specifically states that pivotal clinical trials shall be performed in "a clinical environment that is representative of the intended normal conditions of use of the device in the target patient population" (Annex XV). The MDR does not, however, favour or specify particular trial designs but rather applies the principle of proportionality and a risk-based approach (see also ISO 14155:2020, Annex I).[2]

Required documentation includes a Clinical Investigation Plan (analogous to the Clinical Study Protocol in pharmaceutical trials), which must address safety for patients and users (see MDR Articles 2, 62, 72).[6] The requirements stated in MEDDEV 2.7.1/4 for the Clinical Investigation Plan are still relevant: the document must state the rationale, objectives, design, and proposed analysis, methodology, monitoring, conduct, and record-keeping of the clinical investigation.[8]

Similar to drug trials, medical device clinical investigations require informed consent in line with ISO 14155 and the Declaration of Helsinki (see MDR Article 63). The informed consent form should highlight and state potential risks, benefits, and treatment options, and it should contain information about the trial conduct in a language that is easily understood by the participants. This might require an additional "readability assessment" aimed at providing a document that can be easily understood by laypersons and the potential study population.

As for clinical trials, an Investigator Brochure is required for medical device investigations. It should contain clinical and non-clinical information on the investigational device relevant to the investigation and should be available at the time of application (MDR Annex XV, Chapter II).[6]

Table 2. Key medical device-related terms and definitions

Term	Abbreviation or acronym	Definition
Conformité Européenne mark	CE mark	Marking on a product to signify that it meets the legal requirements to be sold on the extended Single Market in the European Economic Area (EEA).
Clinical Evaluation Plan	CEP	The CEP can be considered as the road map for conducting a clinical evaluation process. It includes the scope, methodology and systematic approaches that will be used during the clinical evaluation, which will be documented in a CER. The CEP will identify the route for conformity as well as any clinical benchmarks and specific measurable outcomes for both clinical safety and performance.
Clinical Evaluation Report	CER	A document that collates all data proving the intended purpose of a device, its target groups, and its clinical benefits, along with the indications and contraindications. The CER will demonstrate safety and performance as well as the overall positive benefit-to-risk-ratio for a medical device through critical evaluation of all available data. A CER is required to show that a medical device is compliant to the Essential Requirements of the MDD/General Safety and Performance Requirements of the MDR.
Clinical Investigation Plan	CIP	A document that includes details on the rational, aims, objectives, design, and proposed methodology and analyses of a clinical investigation of a medical device.
Clarity and Openness in Reporting: E3-based	CORE	The CORE Reference is a user manual to help medical writers navigate relevant guidelines as they create content for clinical study reports.
European Databank on Medical Devices	EUDAMED	A secure, central, web-based portal for the exchange of information between national Competent Authorities and the European Commission. Under the MDR, this will be interoperable and publicly accessible. The new database is designed to be multifunctional, i.e. a registration, collaboration and notification system.
International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use	ICH	The ICH is an initiative that brings together regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of pharmaceutical product development and registration.
Medical Device Coordination Group	MDCG	The MDCG advises and assists the European Commission and Member States in ensuring a harmonised implementation of the new EU MDR. The Group publishes legally non-binding guidance documents in accordance with Article 105 of Regulation 745/2017 to help ensure uniform application of the relevant regulations within the EU.
Medical Device Directive	MDD (93/42/EEC)	The MDD (Council Directive 93/42/EEC) came into force in 1993 with the aim of harmonising the laws relating to medical devices within the EU. In order for a manufacturer to legally place a medical device on the extended EU Single Market (i.e. have the CE mark applied), the requirements of the MDD had to be met. This has been replaced by the EU MDR which comes into force in May 2020.
Medical Device Regulation	MDR 2017/745	The EU MDR is a set of regulations that govern the clinical investigation, production and distribution of medical devices in the Europe Unions. Compliance with this regulation is mandatory for medical device companies that want to sell their products in the European marketplace. The EU MDR replaces the previous Medical Device Directive (MDD) and Active Implantable Medical Devices Directive 90/385/EEC (AIMDD). Under the new medical device regulation, manufacturers need to provide more in-depth clinical data to demonstrate their safety and performance claims.
Revision 4 of the Clinical Evaluation Guidance Document MEDDEV 2.7.1	MEDDEV 2.7/1 rev. 4	A document that provides guidance for medical device manufacturers and notified bodies who must perform clinical evaluations for medical devices that fall under the MDD (93/42/EEC) and AIMD (90/385/EEC). This document, along with the MDR, forms the basis for clinical evaluation of a medical device. CE certifications under MDD were historically based only on product equivalency. The MEDDEV 2.7/1 rev. 4 and MDR now substantially tighten the requirements for equivalence justification compared to before.

The content of the clinical investigation report is described in ISO 14155:2020,[2] and the minimum requirements can be found in Chapter III point 7 of Annex XV of the MDR. Further guidance can be found in MDCG 2021-6.[9] The guidance documents MDCG 2020-10/1 (Safety reporting in clinical investigations of medical devices under the Regulation EU 2017/745)[10] and MDCG 2020-10/2 (Clinical Investigation Summary Safety Report Form v1.0)[11] are available on the European Commission website.

Trial disclosure and publications

Reporting of clinical results is discussed in the MDR Article 77. For clinical investigations carried out for conformity purposes (MDR Article 62) or for CE (*Conformité Européenne*)-marked medical devices (MDR Article 74), a clinical investigation report and summary should be submitted to all Member States in which a clinical investigation was conducted within 1 year of the end of the clinical investigation, although later may be justified for scientific reasons and specified in the Clinical Investigational Plan. In cases where the clinical investigation is terminated early or halted temporarily, publication of results should occur within 3 months. Study sponsors are expected to submit a risk analysis addressing any safety issues related to the temporary halt. The report and lay summary should become publicly available:

- Immediately after submission in cases of early termination or temporary halt.
- When the medical device is registered (Article 29) and before it is placed on the market.
- At the latest 1 year after submission of the report and summary if it is not registered before that time.

MDCG 2021-6 further details the requirements and timelines for reporting of clinical investigations.[9]

Common Technical Documents vs. Technical Documentation

For pharmaceutical products, the Common Technical Document was designed to provide a common format for the technical documentation included in an application for the registration of a human pharmaceutical product.[12] In essence, it

Table 2. *continued*

Term	Abbreviation or acronym	Definition
Post-market clinical follow-up	PMCF	This is a specific form of post-market surveillance that is required for devices of Class IIb and higher. The PMCF includes all clinical evidence such as literature publication on safety and performance as well as use and adverse events reports that should be gathered as part of post-market surveillance for all medical devices on a periodic basis.
Post-market surveillance	PMS	The MDR defines PMS as a proactive and systematic process that manufacturers must implement in order to take corrective and preventive action in accordance with information on medical devices and their performance. A PMS system should be used to actively gather and analyse data on the quality, performance, and safety of the device throughout its lifetime. The PMS should result in a PMS plan the results of the plan should generate a report.
Periodic Safety Update Report	PSUR	The PSUR is essentially an extension of a post-market surveillance report that is required only for moderate and high-risk devices (Class IIa, IIb, III, implantables). It summarises the results and conclusions from PMS data, provides a summary of post-market information, vigilance reporting, and current status of these devices on the market in the EU and a rationale and description of any corrective actions taken for product on the market. This is a new demand placed upon all manufacturers by the MDR. The PSURs are required at least every year for class III devices and class IIb implantable devices and at least every 2 years for class IIa devices and class IIb non-implantable devices.
Summary of Safety and Clinical Performance	SSCP	The SSCP in an important MDR requirement that is tied to PMCF activities for implantable and class III medical devices. The SSCP is intended to provide healthcare practitioners and relevant patients access to current clinical data and other information about the safety and clinical performance of the medical device. The SSCP needs to be updated when the PMCF and PSUR are updated as part of the ongoing lifecycle of these regulatory documents. The specific requirements of the SSCP can be found in Article 32 of the MDR, with further guidance released in MDCG 2019-9.
Technical document	TD	TD is a generic term for product documentation outlining the general safety and performance requirements of a medical device as evidence of conformity with the relevant legislation. The MDR provides a clear structure of the technical documentation required by manufacturers. In case of Class I self-certified products, technical documents are not always subject to review while in the case of Class I non-sterile up to Class III, the Technical Document is always subject to a review by the notified body.

Table 3. List of guidance documents to be considered during the clinical evaluation process

Guidance document	Description
EU MDR 2017/45 Article 61	Article 61 discusses clinical evaluation and the need for clinical investigations. Clinical investigations shall be performed for novel implantable and Class III medical devices to demonstrate that the device is compliant with the GSPRs set out in Annex I of the MDR. Article 61.6(a) also states that for a device cleared under the MDD with sufficient clinical data, it is not required to conduct a clinical investigation. A list of exempt devices is also provided in Art 61.6 (b).
MDCG 2019-9 Summary of safety and clinical performance	For Class III and implantable devices. Provides definition and templates.
MDCG 2019-11 Software as a medical device	MDCG 2019-11 is the guidance document that addresses medical device classification and includes software as a medical device.
MDCG 2020-5 Guidance on clinical evaluation – Equivalence	Covers equivalence in clinical evaluations. Defines technical, biological, and clinical requirements that need to be addressed when claiming equivalence to an already established device.
MDCG 2020-6 Guidance on sufficient clinical evidence for legacy devices	Defines "sufficient" clinical data for legacy devices and well-established technologies. Provides a hierarchy of clinical evidence (Appendix III) Also defines important terms such as: indication/indication for use; intended purpose/intended use;state of the art
MDCG 2020-7 Post-Market Clinical Follow-up Plan MDCG 2020-8 Post-Market Clinical Follow-up Report	The MDCG 2020-7 provides a template for the post-market clinical follow-up plan, while MDCG 2020-8 provides a template for the report. The MDR requires continuous post-market clinical follow-up activities, which will feed back and impact the Clinical Evaluation Report, Periodic Safety Update Report, and Summary of Safety and Clinical Performance, if relevant.
MDCG 2020-13 Clinical evaluation assessment report template	This is a document aimed at notified bodies, but manufacturers and writers should be familiar with the document as it defines what minimum amount of information will be sought by the notified bodies. There is also information on best practices for conducting literature searches
MDCG 2021-24 Guidance on Classification of medical devices	This guidance has brought about some further definitions and changes that particularly affect Class IIb implantable devices and spinal devices, which have now been up-classed to Class III.
International Medical Device Regulators Forum	IMDRF is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices and aims to accelerate international medical device regulatory harmonization and convergence. IMDRF provides working groups for specific topics (e.g., IVD medical devices, AI devices, adverse event terminology), support for documents, and even consultations.

is divided into five main modules:

- Module 1 – Administrative information and prescribing information
- Module 2 – Overviews and summaries of Modules 3–5
- Module 3 – Quality (pharmaceutical documentation)
- Module 4 – Non-clinical reports (pharmacology/toxicology)
- Module 5 – Clinical study reports (clinical trials)

Similarly, for medical devices, a Technical Document (TD) is required. The TD includes all the documentation providing evidence and supporting compliance with the general safety and performance requirements of the MDR (Annex I). The TD represents the entirety of the documents describing a device and includes the device's design, development, verification & validation (including clinical and performance validation), along with its regulatory status within target markets. Furthermore, the MDR now requires a closed-loop process, implemented with data from the post-market use of the device, to ensure that early warnings are captured, that the "General Safety and Performance Requirements" are continuously fulfilled, and that the benefits for the patient always outweigh the risks. The TD must be made available for all devices irrespective of device class and before placing a medical device on the European market, as it provides evidence of conformity with the relevant legislation.

In contrast to the MDD, the MDR Annex II and Annex II define the requirements and specify

criteria for the TD on post-market surveillance (Table 5).[6] Medical writers may occasionally be asked to assist in updating technical documentation in compliance with the MDR.

Most writers working in the medical device industry will have been involved in regularly updating Clinical Evaluation Plans and Clinical Evaluation Reports to meet and maintain MDR compliance. These documents are based on the TD. Depending upon the class of device, other documents may be required.[13] The clinical evaluation process aims to establish whether a CE-marked device meets the relevant general safety and performance requirements throughout its expected lifetime. The clinical evaluation process will draw conclusions about the clinical safety and performance of the device, with a focus on comparing its benefit-risk balance with the current state of the art.

Of note, starting May 26, 2024, all devices placed on the market must be in conformity with the MDR. MDD devices already on the market may continue to be made available until May 27, 2025. With deadlines fast approaching, medical device manufacturers have been increasingly requesting updates to their TDs and their Clinical Evaluation Plans and Clinical Evaluation Reports.

Documents related to pharmacovigilance, post-market surveillance and safety reporting

The MDR not only mandates post-marketing surveillance for all devices but also introduces new and expanded requirements that increase compliance efforts. Annex III of the MDR 2017/745 details the European Union requirements. Manufacturers of low-risk Class I devices must create a post-market surveillance report, while manufacturers of Class IIa, IIb, and III devices must submit a PSUR.

Moreover, manufacturers must prove that Post-Market Clinical Follow-Up (PMCF) plans have been carried out for their medical devices or provide a justification if it is omitted. The PMCF is one component of the post-market surveillance (PMS) activities and is required depending on the device's risk and novelty. Devices designated as high risk or first of their kind require a PMCF. Traditionally, PMS activities for medical device relied on reactive data gathering, but with the advent of the MDR, manufacturers are expected to take a more proactive approach to data collection and feedback of results into design, clinical evaluation, and technical documentation, with the intent of using real-time data to anticipate risks.

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Documents and information aimed at patients and users

Article 32 of the MDR introduces a requirement for a Summary of Safety and Clinical Performance (SSCP) for implantable device and Class III devices not custom-made or investigational. The SSCP is intended to provide an objective summary of the results obtained from the clinical evaluation. It should be seen not as a replacement to the Instructions for Use but rather as a supplement describing the end user of the device, whether they are healthcare professionals or patients, and the essential information related to the device.[14]

Information written for patients is mandatory for implantable devices for which patients will be given implant cards and for Class III devices intended to be used directly by patients. The SSCP will be available in the

Table 4. Documents within the lifespan of pharmaceutical products and medical devices

Document type	Pharmaceutical products	Medical devices
Study protocol	**Clinical study protocol** Including all information deemed necessary to conduct a clinical trial with pharmaceuticals (see ICH E6 Section 6)	**Clinical investigation plan** Equivalent document to pharmaceuticals with specific focus on safety not only for patients, but also for users (see EU MDR Article 2, 62, 72)
Informed consent	**Informed consent form** Stating all risks, benefits, treatment options, contains information about the trial conduct in lay language that all trail subjects have to date and sign themselves or a legal representative for e.g., minors, ICFs have to be updated in case of new trial findings that impact the risk/benefit evaluation (see ICH E6 Section 4.8)	**Informed consent** Medical device trial also requires a form as in pharmaceutical trials (as per EU MDR Article 63, follows the same principles as pharmaceuticals, i.e., the Declaration of Helsinki)
Investigator's brochure (IB)	The IB is a compilation of the clinical and nonclinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects (see ICH E6 Section 7).	The IB shall contain the clinical and non-clinical information on the investigational device that is relevant for the investigation and available at the time of application (see EU MDR Annex XV, Chapter II, content guidance also found in ISO 14155 Annex B).
Study report	Clinical study report – according to CORE and/or ICH E3 reports all outcomes and results from a clinical trial	Clinical Investigation Report – the content of the study report is described in ISO 14155:2020 and the minimum requirements can be found in Chapter III point 7 of Annex XV of the EU MDR; further guidance – MDCG 2021-6.
Patient information	**PIL, information sheets, etc.** ICH E6 does not state the form of patient information, other than the content of the ICF (see above)	Patient information is not directly described in the EU MDR. MDCG 2019-09 clearly states the Summary of Safety and Clinical Performance (SSCP) as a source for patient's information (see below)For implantable devices, the necessity of an implant card and information to be supplied to the patient is described in EU MDR, Article 18
Update reports	**Periodic Safety Update Report, PSUR** The study sponsor is required to submit regular safety update reports (see ICH E6 Section 5)	**PSUR** Manufacturers of class IIa, class IIb and class III devices shall prepare a PSUR for each device (see UE MDR Article 86). A finalised guidance for device PSURs is still outstanding, but an MDCG guidelines is expected sometime in 2022.
Results and clinical trial publication/s	Basic results must be posted 12 months after the date of last patient visit on clinicaltrials.gov There may be more than one publication arising from a clinical trial. Patient data must be protected/redacted. High level clinical trial publications are common courtesy. Regulation (EU) No. 536/2014 on clinical trials on human medicines (the Clinical Trials Regulation) provides a legal basis for the release of clinical trial results conducted in the EU and authorised under this Regulation. It entered into application on January 31, 2022.	The EU MDR states that the publication of study results shall be done in accordance with recognized ethical principles (see Annex XV Chapter I) Reporting of clinical results is discussed in the EU MDR Article 77 In general, publications of medical device trials are usually less rigorous designs and have lower level of evidence.

Table 4. *continued*

Document type	Pharmaceutical products	Medical devices
(Post-) Market access documents	**CTD modules** The Common Technical Document (CTD) contains 5 modules, whereas module 1 is not part of the CTD and entails regional administrative information. Module 2 is built up by summary and overview documentation. Module 3 contains the quality documentation, module 4 the non-clinical study reports, and module 5 all clinical study report about the investigational drug in question.	**Technical documentation (also technical file)** Contains all descriptions, documentation, classification, SSCP, labelling documents, GSPR evidence, about risks and benefits, pre-clinical and clinical evidence, the so-called Product verification, and validation, and as part of it the clinical evaluation and PMS with documents listed below, that might be of particular interest for medical writers: **CEP** Clinical evaluation plan (see Annex XIV Part A) **Systematic literature review** As per EU MDR Article 61, the systematic literature review is a procedural step of the clinical evaluation. There is no comparable methodological equivalent requirement for pharmaceuticals. Depending on the manufacturer's needs, the state-of-the-art literature review can lead to a stand-alone document, embedded in the clinical evaluation. The review and appraisal of clinical literature of not only the device under evaluation but also of the benchmark devices often presents as one of the major tasks for medical writers. **Clinical evaluation report** (see Annex XIV Part A) Summarises all information deemed necessary for market access or prolongment. Contains information from PMS, PMCF, Risk Management File, Instructions for Use, and other source documents (Medical writers are usually not involved in the preparation of those source documents but can be asked to assist). **Summary of safety and clinical performance** document intended to provide public access to an updated summary of clinical data and other information about the safety and clinical performance of the medical device (for guidance see MDCG 2019-9). Translations necessary for all languages where medical device is marketed. **Instructions for Use –** Technical document describing all information for the use of the device, including all precautions, warnings, and risks for both patients and users. (Medical writers may assist in writing Instructions for Use). Some of the content may resemble the setting of an SmPC (summary of product characteristics) for pharmaceuticals.

Table 5. Content required for Technical Documents per MDR Annex II & Annex III

Document	Required content
Annex II – Technical Documentation	1. Device description and specification, including variants and accessories Device description and specification 1.2 Reference to previous and similar generations of the device 2. Information to be supplied by the manufacturer 3. Design and manufacturing information 4. General safety and performance requirements (GSPRs) 5. Benefit–risk analysis and risk management 6. Product verification and validation 6.1 Pre-clinical and clinical data 6.2 Additional information required in specific cases
Annex III – Technical Documentation on Post-market Surveillance (PMS)	1. The post-market surveillance plan 2. The PSUR (Periodic Safety Update Report) 3. PMS Report

public domain and will eventually be available on the EUDAMED database of medical device. This introduces new challenges for manufacturers and medical writers because the documents will be more closely scrutinized. Moreover, the medical writer will need to write these documents with the intended user in mind and eliminate potentially confusing medical jargon.

Conclusion

Although regulatory guidance for pharmaceuticals has been well established and structured for some time, the guidance for medical devices is relatively young and unstructured. Medical writers need to be aware of the similarities and differences between regulatory documents for pharmaceuticals and medical devices. Guidance documents and feedback provided by notified bodies has been crucial in providing clarity to this field. A number of MDCG guidelines are to be issued this year, and medical writers will be expected to familiarise themselves with these new updates and interpretations of the MDR. Writers in the field of medical devices should also be on the lookout for position papers issued periodically by notified bodies that can shed further light on the grey areas of the medical device regulations.

The move towards a more structured medical regulatory environment and the increasingly detailed device documentation required by the MDR have brought about a number of challenges. However, this has also proved to be attractive to medical writers looking to work in a more fast-paced, technical environment. Luckily, demand is not expected to slow for skilled medical writers who can assist in compiling medical device technical documentation and who have sufficient clinical experience to produce sound reports for clinical evaluation and post-market activities.

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