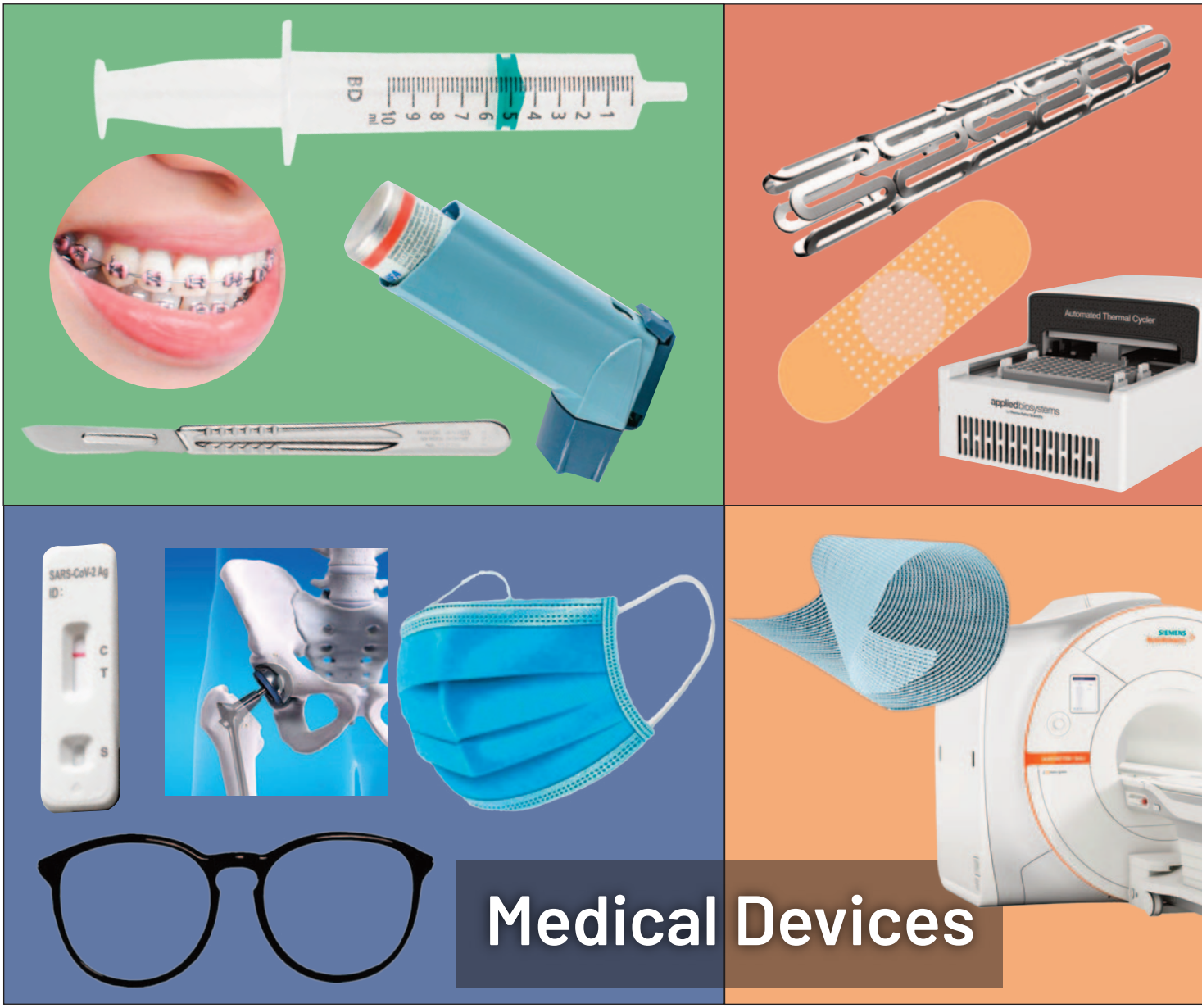

Medical devices are at the core of healthcare forming a large share of the global healthcare market. With consistent advances in technology, MedTech is enhancing our lives more so now than a few decades ago owing to accelerated digitisation and software development.

The contributions made by the MedTech industry during the COVID pandemic must also be emphasised where a plethora of devices were mass-produced and delivered globally in a short span of time to those in dire need. This journal issue is dedicated to all those who made this possible and helped save thousands of lives during these unprecedented times.

Also coinciding with the COVID pandemic has been the implementation of the EU medical device regulations (EU MDR 745/2017), which has been an uphill battle for most involved in this industry. With the uncertainties involved, either due to the remote working models owing to COVID 19, or the lack of prompt clarifications – be it with the number of notified bodies available to handle the workload or the insufficient guidelines to support with the interpretation of the regulation – the medical device industry has nonetheless presented itself victorious on the other end.

This issue presents a glimpse into this tumultuous yet unbreakable world of MedTech presenting to you several articles on its inner workings.

Roderick Mallia and Beate Walter open the issue with an introduction to the differences between medical writing in the pharmaceutical industry and the medical device industry. This is a follow up to the first article written in 2017 by Beatrix Doerr et al on the differences between writing for pharmaceuticals and for medical devices.

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This issue presents a glimpse into this tumultuous yet unbreakable world of MedTech presenting to you several articles on its inner workings.

They seamlessly define the parallels between both these worlds and present the variety of documentation involved, from a medical writing perspective, in both domains.

With pre-clinical testing being one of the first steps towards medical device production, it is apt to introduce the article by **Monica L. Meyer** on preclinical testing of implantable medical devices (IMDs) during new product development. The article walks us through the various stages in a device's product life cycle and facilitates our understanding of the multiple pre-clinical stages involved in device development with corelations also made from a regulatory perspective between US FDA and European submissions.

An important distinction made in the world of MDR is whether a device contains animal derived tissue or not. The article by **Russell T. Kronengold** caters to the intricacies of regenerative medical products derived from animal tissues and the regulatory requirements to be fulfilled with emphasis on the ISO 22442 standard.

With the pre-clinical testing stage complete, the device officially enters the clinical planning stage where one essential development under the MDR is that of defining the Clinical Development Plan. **Namrata Upadhyay** shares with us the essential content of a clinical development plan for medical devices and how a manufacturer can leverage it as a useful tool to enhance the quality of their overall clinical evaluation and technical documentation.

A well executed clinical development plan culminates into a medical device clinical investigation based on the risk classification of the device. **Jessica Norberg** introduces the clinical investigation plan and the reporting of the post-investigation results in the clinical investigation report. She helps readers to understand the differences between clinical studies conducted in pharma with those run for medical devices, emphasising the crucial role of a medical writer at this stage of device development.

With the pre-market clinical investigations completed, the next stage is in the creation of the clinical evaluation report (CER). **Gillian Pritchard** introduces the current trends in the writing of the clinical evaluation report 6 years after the introduction of MEDDEV 2.7/1 revision 4. The reader may walk through the various stages of CER writing with due diligence to the current challenges faced with the introduction of the MDR to the writing of this complex document.

Following market approval, the manufacturer is obliged to demonstrate a robust post market clinical follow up (PMCF). **Laura Collada Ali et al** provide valuable insights to the PMCF stage of device development – a welcome discussion owing to the stringency now placed by the MDR on the PMCF stage.

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All manuscripts should be submitted to mew@emwa.org.

Adding to the post market stage is an article by **Karelia Tecante** and **Andre Sokija** that introduces the periodic safety update report (PSUR) and post market surveillance report (PMSR) documentation requirements under the MDR. The lack of a final guidance for creating these documents has been a challenge for everyone tasked with creating PSURs, even 1 year after MDR implementation.

With all the stages of device development covered, we then look towards the future of the MedTech domain which brings us back to the digitisation within the field over the past decade. When speaking of digitisation, one cannot ignore the introduction of artificial intelligence (AI). The last article by **Kirsten Dahm** introduces to us the new rules governing AI for devices in Europe owing to the limited guidance documents available to this rapidly growing and popular field.

We would like to thank all the authors for their contribution towards this issue of *Medical Writing* and welcome our readers to enhance their understanding of the inner workings of the medical device world. We hope that our readers enjoy this medical device focused journal issue as much as the authors and editorial team have enjoyed putting it together for them.

Happy reading!

Namrata & Kelly

About the Guest Editors

Kelly Goodwin Burri has a background in biomedical engineering and epidemiology with 20 years of professional experience in medical writing, clinical research, and project management in both the pharmaceutical and medical device industries. She currently serves as the co-chair of EMWA's Medical Devices Special Interest Group (MD-SIG) and a workshop leader.

Dr Namrata Upadhyay is a dental surgeon and a certified Clinical and Regulatory Medical Device professional. She is currently the Team Manager of Medical Writing and Safety Reporting at MD-Clinicals, Switzerland. She is also section editor of the EMWA *Medical Writing* journal and manages her freelance business NamNR, where she provides MedComms services to the Medical Device and Pharma sector. She has authored multiple regulatory and clinical documents for all classes of medical devices and supports regulatory submissions for CE mark approval.

The first year of application of the Medical Devices Regulation:

Foreword from the European Commission

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Already 1 year has passed since the date of application of the new Medical Devices Regulation (EU) 2017/745 (MDR), replacing the previous Directives 90/385/EEC and 93/42/EEC from 26 May 2021, while for the new *In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR) the date of applicability is 26 May 2022, replacing the previous Directive 98/79/EC.

The medical devices sector is essential to the provision of healthcare to citizens and is an important player in both the European and global economy. As such, medical devices and *in vitro* diagnostic medical devices play a fundamental role in saving lives by providing innovative healthcare solutions for the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease. Keeping this in mind, on 5 April 2017, two new Regulations were adopted, establishing a modernised and more robust EU legislative framework for medical devices to ensure better protection of public health and patient safety and improve the functioning of the internal market in medical devices.

Both Regulations require particularly far-reaching changes in the way the sector operates and important efforts for adaptation.

Both Regulations require particularly far-reaching changes in the way the sector operates and important efforts for adaptation. This was made even more difficult with the COVID-19 pandemic in 2020-2021, seriously affecting the ability of the different actors involved to prepare for these changes.

The European Commission has been very active during these years and working closely with national competent authorities, notified bodies, and European associations representing health professionals, patients, and industry to ensure the smooth and effective implementation of the Regulations. This has included the adoption of a number of key implementing acts for designation of notified bodies, the availability of harmonised standards and common specifications, the ongoing development of the new European database on medical devices ("Eudamed"), the assignment of Unique Device Identifiers (UDI), the European Medical Device