# Articles Relevant for Safety Writers from the “Medical Writing” Journal (MEW) - PV section articles

**2023**

Ecopharmacovigilance: Cause, impact, and remedies, a review. Ernest Dela Dzidzornu, Jerin Jose Cherian, Joan D’souza, Diana Radovan, Jayesh M Pandit, Melissa Bernal; Volume 32, Number 1 (March, 2023) pp.90-93

## 2022

[Accelerated regulatory submissions: Less haste, more speed!](https://journal.emwa.org/medical-devices/pharmacovigilance/) Arthur Jarov; Volume 31, Number 2 (June, 2022) pp. 128-130

[Guidance impact on Development Safety Update Reports.](https://journal.emwa.org/sustainable-communications/pharmacovigilance/) Stefanie Rechtsteiner; Volume 31, Issue 1 (March, 2022) pp.94-97

## 2021

[What to expect from the revision to GVP Module XVI](https://journal.emwa.org/medical-journalism/pharmacovigilance/). Samuel Ramsden; Volume 30, Issue 4 (December, 2021) pp.72-75

# Articles Relevant for Safety Writers from the MEW - Feature articles and other section articles

## 2021

EMA guidance meets reality: An evolving [story](https://journal.emwa.org/medical-journalism/regulatory-matters/). Joan D’souza, Tiziana von Bruchhausen; Volume 30, Issue 4 (December, 2021) pp.56-58

## 2020

[Risk management plans in the EU: Managing safety concerns.](https://journal.emwa.org/eu-regulations/risk-management-plans-in-the-eu-managing-safety-concerns/) Tiziana von Bruchhausen, Sven Schirp; Volume 29, Issue 3 (September, 2020) pp.30-35

## 2019

[The 360° approach to authoring risk management plans](https://journal.emwa.org/trends-in-medical-writing/the-360-approach-to-authoring-risk-management-plans/). Sushma Materla; Volume 28, Issue 3 (September, 2019) pp. 56-61

[Lay summaries and writing for patients: Where are we now and where are we going?](https://journal.emwa.org/trends-in-medical-writing/lay-summaries-and-writing-for-patients-where-are-we-now-and-where-are-we-going/) Lisa Chamberlain James and Trishna Bharadia; Volume 28, Issue 3 (September, 2019) pp. 46-51

[Same but different: Basic tools for biosimilar and generic pharmacovigilance writing.](https://journal.emwa.org/generics-and-biosimilars/same-but-different-basic-tools-for-biosimilar-and-generic-pharmacovigilance-writing/) Tiziana von Bruchhausen, Kerstin Prechtel, and Stefanie Rechtsteiner; Volume 28, Issue 2 (June, 2019) pp. 45-52

[Medical writing for generics throughout the life cycle.](https://journal.emwa.org/generics-and-biosimilars/medical-writing-for-generics-throughout-the-life-cycle/) Sandra Götsch-Schmidt; Volume 28, Issue 2 (June, 2019) pp. 39-44

[Writing biosimilar clinical study reports and submission documents – what to expect and](https://journal.emwa.org/generics-and-biosimilars/writing-biosimilar-clinical-study-reports-and-submission-documents-what-to-expect-and-what-to-consider/) [what to consider.](https://journal.emwa.org/generics-and-biosimilars/writing-biosimilar-clinical-study-reports-and-submission-documents-what-to-expect-and-what-to-consider/) Katharina Brauburger and Sabrina Heisel-Stöhr; Volume 28, Issue 2 (June, 2019) pp. 33-38

[Biosimilar development – an overview.](https://journal.emwa.org/generics-and-biosimilars/biosimilar-development-an-overview/) Radovan Diana; Volume 28, Issue 2 (June, 2019) pp. 20-27

[Regulatory pathways for development and submission activities](https://journal.emwa.org/generics-and-biosimilars/regulatory-pathways-for-development-and-submission-activities/). Yousuf Mohiuddin Mohammed; Volume 28, Issue 2 (June, 2019) pp. 8-17

## 2018

Expert seminar: The new EU RMP guidance and template in daily pharmacovigilance practice. Diana Radovan (Reports from the spring conference in Barcelona. Section editor: Amy Whereat); Volume 27, Issue 3 (Sep, 2018) pp. 46

[In the Bookstores: An Introduction to Pharmacovigilance (Second Edition](https://journal.emwa.org/authors/stephen-gilliver/)). Section editors:

Alison McIntosh and Stephen Gilliver; Volume 27, Issue 2 (June, 2018) pp. 89-90

*(this article is a book review)*

[Clinical trial disclosure and transparency: Regulation EU No. 536/2014 Public disclosure at](https://journal.emwa.org/public-disclosure/clinical-trial-disclosure-and-transparency/) [the clinical trial level.](https://journal.emwa.org/public-disclosure/clinical-trial-disclosure-and-transparency/) Kathy B. Thomas; Volume 27, Issue 2 (June, 2018) pp. 7-17

*(this article presents disclosure requirements for clinical safety data)*

[Pharmacovigilance for vaccines and immunotherapies: What does the medical writer need](https://journal.emwa.org/vaccines-and-immunotherapies/pharmacovigilance-for-vaccines-and-immunotherapies/) [to know?](https://journal.emwa.org/vaccines-and-immunotherapies/pharmacovigilance-for-vaccines-and-immunotherapies/) Justina Orleans-Lindsay; Volume 27, Issue 1 (March, 2018) pp. 35-38

[Allergen immunotherapy in the European regulatory environment.](https://journal.emwa.org/vaccines-and-immunotherapies/allergen-immunotherapy-in-the-european-regulatory-environment/) Ulrike Lehnigk; Volume 27, Issue 1 (March, 2018) pp. 30-34 *(this article presents safety collection and reporting requirements for allergen immunotherapies)*

[HIV vaccine clinical trials: An overview.](https://journal.emwa.org/vaccines-and-immunotherapies/hiv-vaccine-clinical-trials-an-overview/) Jackline Odhiambo; Volume 27, Issue 1 (March, 2018) pp. 23-29

*(this article includes safety considerations in vaccine development)*

## 2017

[EMA releases the revised Good Pharmacovigilance Practices Module V - updated guidance](https://journal.emwa.org/observational-studies/ema-releases-the-revised-good-pharmacovigilance-practices-module-v-updated-guidance-on-risk-management-plans/) [on risk management plans.](https://journal.emwa.org/observational-studies/ema-releases-the-revised-good-pharmacovigilance-practices-module-v-updated-guidance-on-risk-management-plans/) Tiziana von Bruchhausen and Sven Schirp; Volume 26, Issue 3 (September, 2017) pp. 48- 51

[Reporting non-interventional post-authorisation safety studies (NI-PASS).](https://journal.emwa.org/observational-studies/reporting-non-interventional-post-authorisation-safety-studies-ni-pass/) Gregory Morley; Volume 26, Issue 3 (September, 2017) pp. 38-41

[Regulatory submissions of non-interventional post-authorisation safety studies: Challenges](https://journal.emwa.org/observational-studies/regulatory-submissions-of-non-interventional-post-authorisation-safety-studies/) [for data interpretation and comparisons with clinical data.](https://journal.emwa.org/observational-studies/regulatory-submissions-of-non-interventional-post-authorisation-safety-studies/) James Visanji; Volume 26,

Issue 3 (September, 2017) pp. 35-37

[Odd cases and risky cohorts: Measures of risk and association in observational studies.](https://journal.emwa.org/observational-studies/odd-cases-and-risky-cohorts-measures-of-risk-and-association-in-observational-studies/) Tom Lang; Volume 26, Issue 3 (September, 2017) pp. 12-16

## 2016

[Patient education in clinical trials and throughout the product lifecycle](https://journal.emwa.org/medical-education/patient-education-in-clinical-trials-and-throughout-the-product-lifecycle/). Susan M. Harris and Christopher G. Kelly; Volume 25, Issue 4 (December, 2016) pp. 23-29

RMP public summary reloaded: Revision 2 of GVP Module V. Tiziana von Bruchhausen and Stefanie Rechtsteiner (Medical Communications; Section editor: Lisa Chamberlain James); Volume 25, Issue 3 (September, 2016) pp. 65-68

[Study design made easy](https://journal.emwa.org/statistics/study-design-made-easy/). Diogo Bruno; Volume 25, Issue 3 (September, 2016) pp. 26-30 [Regulatory Matters: The growing need for drug safety documents](https://journal.emwa.org/medical-communication/regulatory-matters/). Section editor:

Greg Morley; Volume 25, Issue 2 (June, 2016) pp. 46-47

[Writing for pharmaceutical or medical device companies: A survey of entry requirements,](https://journal.emwa.org/medical-communication/writing-for-pharmaceutical-or-medical-device-companies-a-survey-of-entry-requirements-career-paths-quality-of-life-and-personal-observations/) [career paths, quality of life, and personal observations.](https://journal.emwa.org/medical-communication/writing-for-pharmaceutical-or-medical-device-companies-a-survey-of-entry-requirements-career-paths-quality-of-life-and-personal-observations/) Steven Walker, Jane Opie, Sophia Whitman, Wendy Critchley, Kristin L Hood, Vicki M Houle, Michael Todd, Tahin Manjur, Yvonne Anderson, and John Gonzalez; Volume 25, Issue 2 (June, 2016) pp. 21-29

## 2015

[In the Bookstores: Statistical Thinking for Non-Statisticians in Drug Regulation (Second](https://journal.emwa.org/writing-for-lay-audiences/in-the-bookstores/) [Edition).](https://journal.emwa.org/writing-for-lay-audiences/in-the-bookstores/) Section editors: Alison McIntosh and Stephen Gilliver; Volume 24, Issue 4 (December, 2015) pp. 245-247 *(this article is a book review; it includes details about Chapter 19 of the book, which deals with various aspects of safety data analysis and the*

*role of Data Monitoring Committees, including quantification of the benefit-risk balance for regulatory submissions, the importance of pharmacovigilance, and the use of proportional reporting ratios in evaluating safety signals)*

[Layperson summaries of clinical trial results: Useful resources in the vacuum of regulatory](https://journal.emwa.org/writing-for-lay-audiences/layperson-summaries-of-clinical-trial-results-useful-resources-in-the-vacuum-of-regulatory-guidance/) [guidance.](https://journal.emwa.org/writing-for-lay-audiences/layperson-summaries-of-clinical-trial-results-useful-resources-in-the-vacuum-of-regulatory-guidance/) Claire L. Gillow; Volume 24, Issue 4 (December, 2015) pp. 205-209

*(this article provides information on suitable lay safety language)*

[Medical writing for two audiences – The RMP public summary](https://journal.emwa.org/writing-for-lay-audiences/medical-writing-for-two-audiences-the-rmp-public-summary/). Kerstin Prechtel, Stefanie Rechtsteiner; Volume 24, Issue 4 (December, 2015) pp. 200-204

‘Safe’, ‘safety’, and ‘potential risk’: Examples of euphemisms used by the pharma industry. Laura C. Collada Ali (Gained in Translation; Section editor: Laura C. Collada Ali);

Volume 24; Issue 2 (June, 2015) pp. 101-104

[The Webscout: Risk Management](https://journal.emwa.org/risk-management/the-webscout/). Marc Briele (Section editor: Karin Eichele); Volume 24, Issue 2 (June, 2015) pp. 93-94

[Using social media as the patient's voice in the benefit-risk assessment of drugs: Are we](https://journal.emwa.org/risk-management/using-social-media-as-the-patients-voice-in-the-benefit-risk-assessment-of-drugs-are-we-ready/) [ready?](https://journal.emwa.org/risk-management/using-social-media-as-the-patients-voice-in-the-benefit-risk-assessment-of-drugs-are-we-ready/) Massoud Toussi, Lisa Chamberlain James, Sir Alasdair Breckenridge; Volume 24, Issue 2 (June, 2015) pp. 77-81

[A shot at demystifying the risk management plan for medical writers](https://journal.emwa.org/risk-management/a-shot-at-demystifying-the-risk-management-plan-for-medical-writers/). Sandra Götsch; Volume 24, Issue 2 (June, 2015) pp. 72-76

[Pharmacovigilance medical writing: an evolving profession.](https://journal.emwa.org/risk-management/pharmacovigilance-medical-writing-an-evolving-profession/) Tiziana von Bruchhausen and Kerstin Prechtel; Volume 24, Issue 2 (June, 2015) pp. 66-71

[The changing face of (benefit-)risk management.](https://journal.emwa.org/risk-management/the-changing-face-of-benefit-risk-management/) Lesley Wise; Volume 24, Issue 2 (June, 2015) pp. 62-65

Writing for a Public Audience. Wendy Kingdom (Medical Communications, Section editor:

Lisa Chamberlain James); Volume 24, Issue 1 (March, 2015) pp. 43-45

*(this article addresses the growing importance of writing for a lay audience and the requirement that companies nowadays face, namely to include a lay summary of safety concerns in the RMP and to provide lay summaries of clinical study results)*

## 2014

[Non-interventional Post-Authorisation Safety Studies (NI-PASS): A different type of report](https://journal.emwa.org/post-approval-regulatory-writing/non-interventional-post-authorisation-safety-studies-ni-pass-a-different-type-of-report/); [Gregory Morley](https://journal.emwa.org/authors/gregory-morley/). Volume 23, Issue 4 (December, 2014) pp. 273-276

[Strategic medical writing in the post-authorisation phase](https://journal.emwa.org/post-approval-regulatory-writing/strategic-medical-writing-in-the-post-authorisation-phase/); Sarah J. Richardson. Volume 23 Issue 4 (December, 2014) pp. 267-272

[Post-approval regulatory writing – How different is it from writing pre-approval documents](https://journal.emwa.org/post-approval-regulatory-writing/post-approval-regulatory-writing-how-different-is-it-from-writing-pre-approval-documents/); Sunil Modali. Volume 23, Issue 4 (December, 2014) pp. 262-266

[Responding to concerns over the PSMF: inspectors offer key insights.](https://journal.emwa.org/post-approval-regulatory-writing/responding-to-concerns-over-the-psmf-inspectors-offer-key-insights/) Dakshayini Kulkarni;

Volume 23, Issue 4 (December, 2014) pp. 259-261

*(this article focuses on the feedback provided by the inspectors during their assessment of*

*the Pharmacovigilance System Master File [PMSF] with an emphasis on areas for improvement)*

[Adverse event reporting: a brief overview of MedDRA.](https://journal.emwa.org/regulatory-writing-basics/adverse-event-reporting-a-brief-overview-of-meddra/) Gregory Morley; Volume 23, Issue 2 (June, 2014) pp. 113-116

[An overview of the Common Technical Document (CTD) regulatory dossier.](https://journal.emwa.org/regulatory-writing-basics/an-overview-of-the-common-technical-document-ctd-regulatory-dossier/) Debbie Jordan; Volume 23, Issue 2 (June, 2014) pp. 101-105

[The Investigator’s Brochure: a multidisciplinary document.](https://journal.emwa.org/regulatory-writing-basics/the-investigators-brochure-a-multidisciplinary-document/) Douglas Fiebig; Volume 23,

Issue 2 (June, 2014) pp. 96-100

*(this article addresses how to approach the IB section: Effects in Human: summary of safety information)*

[Effective authoring of clinical study reports: a companion guide](https://journal.emwa.org/regulatory-writing-basics/effective-authoring-of-clinical-study-reports-a-companion-guide/). Sam Hamilton; Volume 23,

Issue 2 (June, 2014) pp. 86-92

*(this article discusses requirements for clinical safety narratives compared with PV safety narratives)*

[A guide to pre-approval regulatory documents.](https://journal.emwa.org/regulatory-writing-basics/a-guide-to-pre-approval-regulatory-documents/) Raquel Billiones; Volume 23, Issue 2 (June, 2014) pp. 84-85

*(this article presents a broad overview of the whole range of documents to be prepared pre- approval, including those involving clinical safety aspects)*

## 2013

*No relevant article identified*

## 2012

[The MHRA perspective on the new pharmacovigilance legislation](https://journal.emwa.org/medical-writing-in-paediatrics/the-mhra-perspective-on-the-new-pharmacovigilance-legislation/). Mick Foy; Volume 21, Issue 2 (June, 2012) pp. 128 – 130

[Some considerations on the safety evaluation section of clinical study reports for studies with](https://journal.emwa.org/medical-writing-in-oncology/some-considerations-on-the-safety-evaluation-section-of-clinical-study-reports-for-studies-with-anticancer-drugs/) [anticancer drugs](https://journal.emwa.org/medical-writing-in-oncology/some-considerations-on-the-safety-evaluation-section-of-clinical-study-reports-for-studies-with-anticancer-drugs/). Vincente Alfaro; Volume 21, Issue 1 (March, 2012) pp. 23-25

# News from the EMA published in MEW on PV and safety

## 2019

[News from the EMA. Section editor](https://journal.emwa.org/trends-in-medical-writing/news-from-the-ema/): Anuradha Alahari; Volume 28, Issue 3 (September, 2019) pp. 79-82

[News from the EMA. Section editor](https://journal.emwa.org/generics-and-biosimilars/news-from-the-ema/): Anuradha Alahari; Volume 28, Issue 2 (June, 2019) pp. 94-97

[News from the EMA. Section editor](https://journal.emwa.org/careers-in-medical-writing/news-from-the-ema/): Anuradha Alahari; Volume 28, Issue 1 (March, 2019) pp. 78-81

## 2018

[News from the EMA](https://journal.emwa.org/patient-reported-outcomes/news-from-the-ema/). Section editor: Anuradha Alahari; Volume 28, Issue 4 (December, 2018) pp. 60-63

[News from the EMA.](https://journal.emwa.org/authors/monika-benstetter/) Section editor: Anuradha Alahari; Volume 28, Issue 3 (September, 2018) pp. 47-50

[News from the EMA](https://journal.emwa.org/public-disclosure/news-from-the-ema/). Section editor: Anuradha Alahari; Volume 28, Issue 2 (June 2018) pp. 76-79

[News from the EMA](https://journal.emwa.org/vaccines-and-immunotherapies/news-from-the-ema/). Section editor: Anuradha Alahari; Volume 27, Issue 1 (March, 2018) pp. 68-72

## 2017

[News from the EMA](https://journal.emwa.org/preclinical-studies/news-from-the-ema/). Section editor: Anuradha Alahari; Volume 26, Issue 4 (December, 2017) pp. 52-54

[News from the EMA](https://journal.emwa.org/authors/anuradha-alahari/). Section editor: Anuradha Alahari; Volume 26, Issue 1 (March, 2017) pp. 50-51

## 2016

[News from the EMA](https://journal.emwa.org/medical-education/news-from-the-ema/). Section editor: Anuradha Alahari; Volume 25, Issue 4 (December, 2016) pp. 44-46

[News from the EMA](https://journal.emwa.org/authors/anuradha-alahari/). Section editor: Anuradha Alahari; Volume 25, Issue 3 (September, 2016) pp. 55-57

[News from the EMA](https://journal.emwa.org/medical-communication/news-from-the-ema/). Section editor: Anuradha Alahari; Volume 25, Issue 2 (June, 2016) pp. 38-41

## 2015

[News from the EMA](https://journal.emwa.org/writing-for-lay-audiences/news-from-the-ema/). Section editor: Monika Benstetter; Volume 24, Issue 4 (December, 2015) pp. 236-239

News from the EMA. Section editor: Monika Benstetter; Volume 24, Issue 3 (September, 2015) pp. 145-147

[News from the EMA](https://journal.emwa.org/risk-management/news-from-the-ema/). Section editor: Monika Benstetter; Volume 24, Issue 2 (June, 2015) pp. 86-90

[News from the EMA](https://journal.emwa.org/plain-language-and-readability/news-from-the-ema/). Section editor: Monika Benstetter; Volume 24, Issue 1 (March, 2015) pp. 30-33

# Other Recent MEW Articles Relevant for PV (Safety) Writers

## 2019

[Clinical trial disclosure landscape and awareness in Japan](https://journal.emwa.org/careers-in-medical-writing/clinical-trial-disclosure-landscape-and-awareness-in-japan/). Hiroko Ebina and Jocelyn Colquhoun; Volume 28, Issue 1 (March, 2019) pp. 74-77

*(this article mentions clinical safety requirements in Japan)*

[The next medical device scandal: Medical device files – my personal view (Part 1).](https://journal.emwa.org/careers-in-medical-writing/medical-devices/)

Section editor: Beatrix Doerr; Volume 28, Issue 1 (March, 2019) pp. 86-89

*(this article addresses changes in post-market surveillance and safety reporting for medical devices over the last 10 years)*

[Career opportunities in medical device writing: Employee and freelance perspectives](https://journal.emwa.org/careers-in-medical-writing/career-opportunities-in-medical-device-writing-employee-and-freelance-perspectives/); Sarah F. Choudhury and Gillian Pritchard; Volume 28, Issue 1 (March, 2019) pp. 46-50 *(the article addresses the ways in which PV writing experience is beneficial for switching to medical device writing, for which safety/surveillance is also an important topic)*

## 2018

[Estimands – closing the gap between study design and analysis](https://journal.emwa.org/patient-reported-outcomes/estimands-closing-the-gap-between-study-design-and-analysis/). Helen Bridge and Thomas

M. Schindler; Volume 27, Issue 4 (December, 2018) pp. 52-56

*(this article addresses the efficacy and safety information provided by estimand analysis)*

[Medical devices: Useful links for medical device writing](https://journal.emwa.org/editing/medical-devices/). Section editor: Beatrix Doerr.

Volume 28, Issue 3 (September, 2018) pp. 57

*(this article mentions the sponsor’s obligation to provide Periodic Safety Update Reports)*

MDR and MEDDEV – What notified bodies are looking for in Clinical Evaluation Reports (CER). Itoro Udofia (Reports from the spring conference in Barcelona. Section editor:

Amy Whereat); Volume 27, Issue 3 (Sep, 2018) pp. 38

*(this article mentions the sponsor’s obligation to provide Risk Management [and other post- approval safety] documentation)*

## 2017

[Introduction to the legal implications of medical writing.](https://journal.emwa.org/preclinical-studies/medical-communications/) Joanne Flitcroft (Section editor: Lisa Chamberlain James); Volume 26, Issue 4 (December, 2017) pp. 67-68

*(this article discusses the legal implications of defending product safety issues)*

[Nonclinical studies in the Russian Federation: Problems, regulatory norms, and](https://journal.emwa.org/preclinical-studies/nonclinical-studies-in-the-russian-federation-problems-regulatory-norms-and-harmonisation-with-international-standards/) [harmonisation with international standards.](https://journal.emwa.org/preclinical-studies/nonclinical-studies-in-the-russian-federation-problems-regulatory-norms-and-harmonisation-with-international-standards/) Anna Buryakina and Natalie Merkulova;

Volume 26, Issue 4 (December, 2017) pp. 33-37

*(this article presents nonclinical safety requirements in the Russian Federation versus ICH requirements)*

[An introduction to little-known aspects of nonclinical regulatory writing](https://journal.emwa.org/preclinical-studies/an-introduction-to-little-known-aspects-of-nonclinical-regulatory-writing/). Alexander Nürnberg and Hélène Pierre; Volume 26, Issue 4 (December, 2017) pp. 9-19

*(this article offers insight into the range of safety assessments in the nonclinical setting)*

Preclinical research in drug development. Jennifer Honek; Volume 26, Issue 4 (December, 2017) pp. 5-8

*(this article covers toxicity study aspects)*

[French breast implants, the Medical Device Regulation, and a theoretical case study.](https://journal.emwa.org/medical-devices/french-breast-implants-the-medical-device-regulation-and-a-theoretical-case-study/)

Claudia Frumento. Volume 26, Issue 2 (June, 2017) pp. 39-40

*(this article addresses the need for patient and user safety in medical device development)*

[Medical devices in the disclosure era and the role of medical writers.](https://journal.emwa.org/medical-devices/medical-devices-in-the-disclosure-era-and-the-role-of-medical-writers/) Raquel Billiones.

Volume 26, Issue 2 (June, 2017) pp. 32-34

*(this article summarizes recent MDR updates in safety requirements for medical devices)*

[Medical Device Regulation: A necessary step towards more patient and user safety](https://journal.emwa.org/medical-devices/medical-device-regulation-a-necessary-step-towards-more-patient-and-user-safety/).

Claudia Frumento; Volume 26, Issue 2 (June, 2017) pp. 25-28

*(this article addresses the need for patient and user safety in medical device development)*

[New EU medical device regulations: Impact on the MedTech sector](https://journal.emwa.org/medical-devices/new-eu-medical-device-regulations-impact-on-the-medtech-sector/). Robert Behan, Mark Watson, and Abhay Pandit; Volume 26, Issue 2 (June, 2017) pp. 20-24

*(this article presents how the need for better safety and quality requirements for medical devices will be better met in light of the updated regulatory framework in the EU)*

[Clinical Evaluation Reports from the medical writer’s perspective!](https://journal.emwa.org/medical-devices/clinical-evaluation-reports-from-the-medical-writer-s-perspective/) Gillian Pritchard;

Volume 26, Issue 2 (June, 2017) pp. 14-19

*(this article presents the objective of Clinical Evaluation Reports, i.e. to support the conformity of a medical device with the essential requirements and the safety performance required by the MDR)*

[Writing for medical devices compared to pharmaceuticals:](https://journal.emwa.org/medical-devices/writing-for-medical-devices-compared-to-pharmaceuticals-an-introduction/) An introduction. Beatrix Doerr,

Sophia Whitman, and Steven Walker; Volume 26, Issue 2 (June, 2017) pp. 8-13

*(this article presents differences and similarities between [writing in] the medical device industry and in the pharmaceutical industry, including in terms of safety requirements)*