The European Medical Devices regulations

What are the requirements for vigilance reporting and post-market surveillance?

Author – Eamonn Hoxey, Director, E V Hoxey Ltd
BSI White Paper Series

Updated March 2023

By Royal Charter

Contents

Introduction

The European Union (EU) Medical Devices Regulation[1] (EU 2017/745) (MDR) and the In Vitro Diagnostic Medical Devices Regulation[2] (EU 2017/746) (IVDR), now apply. Important terms used in the regulations are ‘entry into force’ and ‘date of application’. The publication of the text in the Official Journal of the European Union was on 5 April 2017. The ‘entry into force’ was the date when each regulation came into effect, twenty days after publication. The ‘date of application’ reflects the date from which the requirements apply and the Active Implantable Medical Devices Directive (AIMDD – 90/385/EEC), Medical Devices Directive (MDD – 93/42/EEC) and In Vitro Diagnostic Medical Devices Directive (IVDD - 98/79/EC) were repealed.

Since the publication of the legal texts, there have been corrigenda issued. These correct small errors and amendments that have been made to change the date of application and transitional arrangements. The changes in dates are in response to the challenges created or exacerbated by the COVID-19 pandemic impacting on manufacturers’ ability to undergo conformity assessment of technical documentation. These challenges include limited notified body capacity, particularly for the IVDR, and limited availability of guidance documents.

1 REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

2 REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

The transitional arrangements for the regulations allow for medical devices and in vitro diagnostic medical devices (IVDs), with valid certificates or declarations of conformity to the Directives, to continue to be placed on the market for finite periods. These periods depend on the classification of the device or IVD. For all classes of devices and IVDs, there are three provisos to the extension of validity of certificates or declarations of conformity.

- Firstly, that some requirements of regulations will apply to devices with valid certificates and declarations of conformity under the Directives. These requirements include those for post-market surveillance (PMS), vigilance reporting, market surveillance by national authorities and registration.
- Secondly, that no significant changes are made to the device or intended use.
- Thirdly, that the notified body that issued the certificate continues to be responsible for surveillance of devices it has certified.

For the MDR, the approved text of an amending regulation[3] was published on 24 April 2020. As well as postponing the date of application of the MDR to 26 May 2021, the amending regulation also delayed or extended, as applicable, dates or deadlines for:

- repeal of the AIMD and MDD;
- drawing up a declaration of conformity under the MDD for a class I device requiring notified body involvement;
- availability of the common specification of products without an intended medical purpose;
- availability of the common specification for reprocessing of single use devices;
- publication of the notice on the functionality of the EUDAMED database;
- Member States publishing their rules on penalties for infringements of the MDR;
- permission to designate notified bodies to the MDR whilst the AIMD and MDD remain in force;
- ongoing clinical investigations under the AIMD or MDD to continue;
- publication of guidance on the operation of expert panels established under the MDR.

3 Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions.

An amendment to the IVDR[4] changed the date of application for certain classes of IVDs. The amending Regulation did not change any requirements contained in the original IVDR, only the dates from which some of those requirements apply. There is no change for CE-marked devices that do not require notified body involvement under the IVDR, or for new devices that do not have either a notified body certificate or a declaration of conformity under the IVD Directive. For these types of devices, the IVDR applied from 26 May 2022 as planned. For other IVDs, there are staggered arrangements quite similar to that introduced for legacy devices under the MDR. IVDs that were lawfully placed on the market under the IVD Directive before 26 May 2022 can continue to be made available or put into service until 26 May 2025. IVDs that were self-certified or self-tested under the IVD Directives but require certificates from a notified body under the IVDR had the date of application changed to later years. The additional time increases as the risk associated with the devices decreases, as follows:

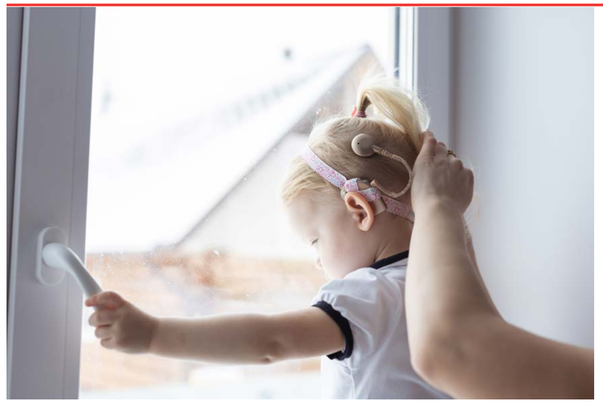
- 26 May 2025 for Class D;
- 26 May 2026 for Class C; and
- 26 May 2027 for Class B and Class A, sterile.

4 REGULATION (EU) 2022/112 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 January 2022 amending Regulation (EU) 2017/746 as regards transitional provisions for certain in vitro diagnostic medical devices and the deferred application of conditions for in-house devices.

The European Commission's Medical Device Coordination Group (MDCG) undertook a survey on notified body certification and application activities under the Medical Devices Regulation (EU 2017/745) (MDR) and In Vitro Medical Devices Regulation (EU 2017/746) (IVDR). Its findings revealed the following problems in the transition to the MDR[5].

- A significant number of certificates for legacy devices expire in 2024 for medical devices. At the current rate of certification, all existing products cannot be transitioned by the current deadline.
- The overall capacity of notified bodies remains insufficient to carry out the required conformity assessment tasks.
- Many manufacturers were not ready to meet the requirements of the MDR by the end of the transition period.

5 Notified Bodies Survey on certifications and applications (MDR/IVDR) https://health.ec.europa.eu/system/files/2022-10/md_nb_survey_certifications_applications_en.pdf.



The European Commission presented a proposal to further extend the transition period for the MDR in order to maintain patients' access to a wide range of medical devices while ensuring the transition to the new regulations[6]. The extension will be staggered depending on the risk class of the devices. There are conditions associated with these extensions, including that the manufacturer has to have taken steps to transition to the MDR in order to benefit from the additional time. It also proposes to delete the deadline in both the MDR and IVDR for making available of devices which are placed on the market before or during the transition period and which are still in the supply chain when the extended transition period is over.

6 Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices 2023/0005 (COD).

This proposal has been agreed by the European Council and the European Parliament and has been adopted as Regulation (EU) 2023/6077. This Regulation entered into force on 20 March 2023, the day of its publication in the Official Journal of the European Union.[8]

As a result, Article 120(2) of the MDR has been amended. This extends the validity of certificates issued under the Directives for active implantable medical devices and medical devices (90/385/EEC or 93/42/EEC) that were valid on the day of the MDR's date of application (26 May 2021) and have not been withdrawn by a notified body. The extension is directly applicable; notified bodies are not required to change the date on the individual certificates. For certificates that have already expired when the proposed amendment comes into force, the extension would be subject to the condition that, at the moment of the expiry, the manufacturer has signed a contract with a notified body for the conformity assessment of the device in question under the MDR.

7 REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

8 Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices (Text with EFA relevance).

In addition, it is proposed that the transition period is extended from 26 May 2024 until:

- 31 December 2027 for higher risk devices (class III and class IIb implantable devices except certain devices for which the MDR provides exemptions since considered to be based on well-established technologies); and
- 31 December 2028 for medium and lower risk devices (other class IIb and class IIa devices, and class I devices with a measuring function, are sterile, are reusable surgical instruments or software as a medical device, provided that the declaration of conformity was signed before 26 May 2021).

The extended transition is subject to the following proposed conditions:

- the devices continue to comply with the applicable Directives;
- the devices do not undergo significant changes in the design and intended purpose;
- the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to public health;
- no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with the MDR; and
- no later than 26 May 2024, a formal application has been submitted under the MDR for conformity assessment in respect of a 'legacy device' covered by a Directive's certificate or declaration of conformity, or in respect of a device intended to substitute that device under the MDR, and no later than 26 September 2024 the notified body and the manufacturer have signed a written agreement.

Notwithstanding the proposed extensions to the transitional periods, the requirements for PMS and vigilance apply to legacy devices placed on the market with certificates of conformity to the previous Directives.

BSI has published several white papers describing the MDR, the IVDR and how to prepare for them [9,10,11,12,13,14,15,16].

9 How to prepare for and implement the IVDR – Dos and don'ts – revised.
10 Planning for implementation of the European Union Medical Devices Regulations – Are You Prepared? – revised.
11 General Safety and Performance Requirements (Annex 1) in the New Medical Device Regulation: Comparison with the Essential Requirements of the Medical Device Directive and Active Implantable Device Directive.
12 Technical Documentation and Medical Device Regulation: A Guide for Manufacturers to Ensure Technical Documentation Complies with EU Medical Device Regulation 2017/745.
13 European Union Medical Device Regulation and In Vitro Device Regulation: unique device identification: What is required, and how to manage it.
14 Guidance on MDCG 2019-9: Summary of Safety and Clinical Performance.
15 Person responsible for regulatory compliance.
16 Clinical evaluation under the EU MDR.

One of the areas that has been emphasized substantially in the Regulations, compared to the Directives that preceded them, relates to the need for an ongoing oversight of marketed devices by the manufacturer of devices. This is exemplified in the gathering of information from the post-production phase referred to in BS EN ISO 14971[17]. BS EN ISO 14971 is the European adoption of the international standard for risk management that is harmonized and listed in the Official Journal as providing a presumption of conformance with requirements of the MDR and IVDR.

BSI published a white paper on MDR vigilance requirements in comparison to Australia, Brazil, Canada, Japan and USA[18]. This provides a detailed review on the requirements of MDSAP participating countries in comparison with the European Medical Device Regulation 2017/745.

PD CEN ISO/TR 20416:2020[19] provides guidance to manufacturers who are planning and executing their PMS activities. Other organizations, such as importers, distributors and reprocessors, that are connected to the manufacturer in the product lifecycle and who play a role in PMS activities can also utilize the guidance in PD CEN ISO/TR 20416. PD CEN ISO/TR 20416 is intended to be complementary to requirements in BS EN ISO 13485[20] and BS EN ISO 14971 for production and post-production activities. PD CEN ISO/TR 20416 is the European adoption of an international Technical Specification and is not specifically drafted to provide guidance on the requirements for PMS in the MDR or IVDR.

The MDCG have published guidance on Periodic Safety Update Reports (PSUR[21]) and their workplan includes development of a document titled Guidance on Post-Market Surveillance Requirements.

This paper focuses on vigilance and PMS requirements from the European context. PMS is undertaken as a responsibility of the manufacturer and is in contrast to ‘market surveillance’, a term used in the Regulations to describe activities undertaken by, and coordinated between, the national competent authorities.

17 BS EN ISO 14971:2019+A11:2021 Medical devices — Application of risk management to medical devices.
18 Do you know the requirements and your responsibilities for medical device vigilance reporting?
19 PD CEN ISO/TR 20416:2020 Medical devices - Post-market surveillance for manufacturers.
20 BS EN ISO 13485:2016+A11:2021– Medical devices. Quality management systems – Requirements for regulatory purposes.
21 MDCG 2022-21 Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745 - December 2022.

This paper addresses a number of areas, including:

- PMS as an element of the management of clinical evidence throughout the device lifecycle;
- the PMS system, which is the comprehensive process used to collect, analyze and take action on PMS information;
- the PMS plan, which describes the application of the PMS system to a device or device family;
- preparation of a summary report of PMS information;
- complaint handling;
- reporting of vigilance; and,
- electronic submission of vigilance data and summary reports of PMS to EUDAMED.

It is important to note that the dates of application of the MDR and IVDR have now passed. The vigilance and PMS requirements in these Regulations apply to i) all devices from the date that they were CE marked under the MDR or IVDR, and, ii) any devices CE marked and legally marketed with certificates or declarations of conformity under the AIMDD, MDD or IVDD after the date of application.

In many aspects the requirements of the IVDR parallel the MDR and the material presented here applies to both Regulations unless specifically indicated otherwise. An overview of the requirements for vigilance and PMS is summarized in Table 1.

Table 1: Summary of the main vigilance reporting and PMS provisions of the Medical Devices Regulation and the In Vitro Medical Devices Regulation

Element of the Regulation	Description	Medical Devices Regulation	In Vitro Medical Devices Regulation
Post-market surveillance system MDR – Article 83: Post-market surveillance system of the manufacturer MDR – Article 15: Person responsible for regulatory compliance IVDR – Article 78: Post-market surveillance system of the manufacturer IVDR – Article 15: Person responsible for regulatory compliance	Comprehensive system to gather experience from the use of devices	• Proactive and systematic • Allows cooperation on vigilance and market surveillance • Connects with corrective action or preventive action processes • Allows update of technical documentation, including the risk-benefit determination and clinical evaluation	
	Person responsible for regulatory compliance	• Fulfils minimum conditions of qualification • Within the manufacturer's organization, except small manufacturers • Permanently and continuously available to the authorized representative • Ensures the requirements for PMS and vigilance are met	
Post-market surveillance plan MDR – Article 84: Post-market surveillance plan MDR – Annex III: Technical documentation on post-market surveillance IVDR – Article 79: Post-market surveillance plan IVDR – Annex III: Technical documentation on post-market surveillance	Describes the implementation of the PMS system for collecting information and characterizing the safety and performance of the device, or family of devices, and the methods and processes to assess the collected information	• Part of the QMS and technical documentation • Defines indicators and thresholds for continuous reassessment of risk management and the risk–benefit analysis • Incorporates information from complaint investigation and market experience • Describes methods to monitor trends, identifies statistically significant increases in frequency or severity of incidents and provides trend reports • Defines methods of communication with competent authorities and notified bodies • Defines methods of communication with authorized representatives, importers, distributors, users and patients • Describes means of tracing and identifying devices • References the documented procedures for the: – PMS system – creation of the PMS plan – generation of the PSUR or PMS report, as applicable – processes for corrections, corrective actions or preventive actions	
Post-market surveillance report MDR – Article 85: Post-market surveillance report IVDR – Article 80: Post-market surveillance report	Summarizes the results and conclusions of analysis of the PMS data	• Includes rationale for, and description of, any preventive or corrective actions taken • Updated when necessary and made available to the competent authority upon request	
		Applicable to Class I devices	Applicable to Class A and Class B devices

Element of the Regulation	Description	Medical Devices Regulation	In Vitro Medical Devices Regulation
Period safety update report MDR – Article 86: Periodic safety update report IVDR – Article 81: Periodic safety update report	Summarizes the results and conclusions of the analysis of PMS data with usage data	• Kept up to date throughout the lifetime of the device • Part of the technical documentation • Includes: – conclusions to be used in risk–benefit determination – main findings of any PMCF evaluation report – volume of sales of devices with an estimate of the size of the population using the device – rationale for, and description of, any preventive or/and corrective actions taken	
		Class IIa devices • updated when necessary and at least every 2 years	
		Class IIb devices • updated when necessary and at least annually • made available to the notified body and, upon request, to competent authorities For implantable devices • submitted electronically by means of EUDAMED to the notified body • notified body evaluation added with details of any action taken • PSUR and the notified body evaluation available to competent authorities through EUDAMED	Class C devices • updated when necessary and at least annually • made available to the notified body and, upon request, to competent authorities
		Class III devices • to update when necessary and at least annually • submitted electronically by means of EUDAMED to the notified body • notified body evaluation added with details of any action taken • PSUR and the notified body evaluation available to competent authorities through EUDAMED	Class D devices • updated when necessary and at least annually • submitted electronically by means of EUDAMED to the notified body • notified body evaluation added with details of any action taken • PSUR and the notified body evaluation available to competent authorities through EUDAMED
Vigilance MDR – Article 87: Reporting of serious incidents and field safety corrective actions MDR – Article 88: Trend reporting MDR – Article 89: Analysis of serious incidents and field safety corrective actions IVDR – Article 82: Reporting of serious incidents and field safety corrective actions IVDR – Article 83: Trend reporting IVDR – Article 84: Analysis of serious incidents and field safety corrective actions		• Exclusion in the need to report events is for expected side-effects that are clearly detailed in the product information and contained in the technical documentation • Trend reporting required • The timelines for reporting: – serious public health threats – maximum 2 days – death or unanticipated serious deterioration in health– maximum 10 days – all other events – maximum 15 days	

01 Definitions

As the Regulations introduce some new terms or modify others from the previous Directives, some key terms for vigilance and PMS are provided in Table 2.

The definitions in Table 2 are definitions in the Regulations or, in the absence of a definition, the explanatory text in an article in the Regulations. The Regulations do not use the term ‘family of devices’ but refer to a ‘category or group of devices’ without a definition. BS EN ISO 13485 defines ‘medical device family’, and that definition has been included in Table 2; the term is used as ’device family’ in this document.

Table 2: Key terms and their definitions

Term	Definition
Post-market surveillance (PMS)	All activities carried out by the manufacturer, in cooperation with other economic operators, to institute and keep up to date a systematic procedure to proactively collect and review experience gained from their devices placed on the market, made available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions
Market surveillance	Activities carried out and measures taken by competent authorities to check and ensure that devices comply with the requirements set out in the relevant legislation and do not endanger health, safety or any other aspect of public interest protection
Post-market clinical follow-up (PMCF)	Continuous process that updates the clinical evaluation of a device and is addressed in the manufacturer’s PMS plan
Post-market performance follow-up (PMPF)	Continuous process that updates the performance evaluation of an IVD and is specifically addressed in the manufacturer’s PMS plan
Periodic safety update report (PSUR)	Summary of the results and conclusions of the analyses of the gathered PMS data for each device or, where relevant, for each category or group of devices
Vigilance	Process of collection, assessment, reporting to the relevant competent authorities of serious incidents and field safety corrective actions (when needed) as well as the identification of trends by manufacturers of devices, made available on the Union market
Device family	Group of medical devices manufactured by or for the same manufacturer and having the same basic design and performance characteristics related to safety, intended use and function
Incident	Any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side effect
Serious incident	Any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person (b) the temporary or permanent serious deterioration of a patient’s, user’s or other person’s state of health or (c) a serious public health threat

02 Clinical evidence and the device life cycle

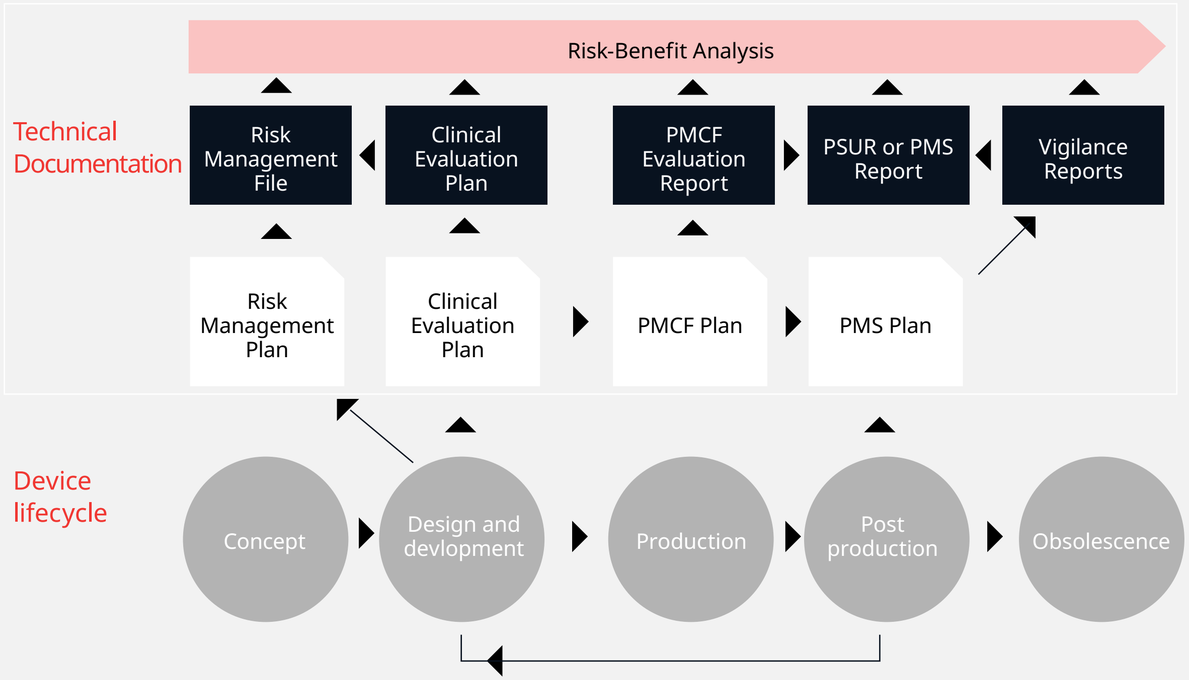
The Regulations emphasize the responsibilities of the manufacturer to update and maintain the clinical evaluation of their device and the resulting documentation throughout the device life cycle. While these responsibilities were also a feature of the AIMDD, MDD and IVDD and the guidance in MedDev 2.7/1 Revision 4[22], the Regulations provide significantly more detail and require the creation of specific plans and summary reports as well as, for certain classes of device or IVD device, submission of a Summary of safety and (clinical) Performance (SS(C)P) to the notified body. The life cycle activities associated with clinical evidence for a medical device include:

- establishing clinical or performance evidence through pre-market clinical evaluations or clinical investigations, or performance evaluations
- preparing and maintaining clinical or performance evaluation reports
- planning and conducting post-market clinical or performance follow-up (PMCF/PMPF), or documenting a justification why it is not applicable
- planning and conducting PMS
- documenting periodic safety update reports (PSURs) for:
- Class II and Class III medical devices
- Class C or D IVD devices
- documenting PMS reports for:
  - Class I medical devices
  - Class A or B IVD devices
- publishing a summary of safety and clinical performance (SS(C)P) for medical devices or safety and performance (SSP) for IVDs
- maintaining the risk–benefit analysis up to date based on the latest information

Figure 1 illustrates how key stages in the device life cycle and the ongoing risk–benefit analysis connect with the collection and monitoring of clinical evidence and the requirements for PMS and vigilance.

22 MEDDEV 2.7/1 Revision 4 – June 2016 – Guidelines on medical devices – Clinical evaluation: A Guide for manufacturers and notified bodies under Directives 93/42/EEC and 90/385/EEC.

Figure 1: Illustration of the relationship between device life cycle, ongoing collection and monitoring of clinical evidence and requirements for vigilance and PMS



As a critical element of monitoring the safety and performance of the device, PMS data are used as an input into a number of processes used by the manufacturer to ensure the safety and performance of their device throughout its life cycle. In particular, PMS data are intended to be used to:

- input into risk management, including maintaining the risk–benefit determination
- update design and manufacturing information, the instructions for use and the content of the labels
- update the clinical evaluation report
- update the SSCP or SSP
- identify the need for preventive action, corrective action or field safety corrective action
- identify improvements in usability, performance and safety of the device
- contribute to PMS of other devices
- detect and report trends indicating a statistically significant increase in the frequency or severity of (i) incidents that do not meet the criteria for classification as serious incidents, or (ii) expected undesirable side effects that could have a significant impact on the risk–benefit analysis

Initial activities to implement the requirements include:

- reviewing the life cycle activities and their connections in the quality management system (QMS), in particular the connections between risk management, generation of clinical or performance evidence, PMS and the maintenance of the technical documentation
- establishing the linkage mechanisms between the risk management plan, clinical or performance evaluation plan, PMCF or PMPF plan, PMS plan and their associated reports, how they feed into the technical documentation and how they are maintained to be consistent throughout the life cycle of the device

03 Post-market surveillance system

A comprehensive PMS system needs to be established, through which the manufacturer gathers experience from the use of their devices. The Regulations are explicit that this gathering of experience is proactive, involving actions to seek information, not simply reactive to complaints or other feedback received from the market.

The PMS system has to allow:

- systematic and active gathering of information
- cooperation with the competent authorities responsible for vigilance and market surveillance
- connection with the system for corrective or preventive action to incorporate lessons learned
- update of the technical documentation, including the risk–benefit determination and clinical or performance evaluation

The PMS system needs to be part of the manufacturer's QMS to allow an integrated, systems approach to be employed and connect with other processes of the QMS, including connections with the processes for risk management. This is consistent with the requirements in BS EN ISO 14971 on risk management and the requirements on measurement, analysis and improvement in BS EN ISO 13485 to:

- document procedures for a feedback process including gathering data from post-production activities as input into risk management to maintain product requirements
- gain specific experience from post-production activities and review this experience in the feedback process
- identify and implement any changes necessary to ensure continued safety and performance of the device through the use of PMS

As part of the manufacturer's QMS, PMS is subject to all the general QMS requirements including establishing, documenting and maintaining procedures that are implemented by competent personnel; providing adequate infrastructure and resources; subjecting PMS processes to internal audit and management review and implementing correction, corrective action or preventive action to QMS processes or devices when necessary.

Post-market clinical/performance follow-up (PMCF/PMPF) is a continuous process to update the clinical/performance evaluation. Whilst the Directives mentioned PMCF but provided little detail, the Regulations introduce specific PMCF/PMPF requirements. PMCF/PMPF is part of the PMS system and is described in a specific PMCF/PMPF plan that is in turn an element of the PMS plan. When conducting PMCF/PMPF, the actions of the manufacturer include collecting and evaluating clinical data proactively from the use of a CE marked device to i) confirm the safety and performance throughout the expected lifetime of the device, ii) ensure the continued acceptability of identified risks, and iii) detect emerging risks.

PMCF is an element of clinical evaluation that forms a bridge from clinical evidence collected in the premarket stage with PMS collected when the device is in regular use.

The Medical Device Coordination Group (MDCG) is composed of representatives of Member States and chaired by the EU Commission. The MDCG has endorsed guidance notes on a PMCF plan template[23] and a PMCF evaluation report template[24]. As with all the MDCG guidance, it cannot be regarded as reflecting the official position of the European Commission, or as being legally binding. PMCF is a broad topic closely connected with clinical evaluation and is not discussed further in detail here. A separate White Paper discussing PMCF is in preparation[25]. Similarly, PMPF is not discussed further here.

The Regulations require that, within the manufacturer's organization, a person responsible for regulatory compliance, who fulfils minimum conditions of qualification, is responsible for ensuring that the requirements for PMS and vigilance are met. The qualifications of this person are demonstrated by either (i) formal qualification such as a diploma or certificate awarded on completion of a university degree, or equivalent course of study, in law, medicine, pharmacy, engineering or other relevant scientific discipline with at least one year of professional experience in regulatory affairs or QMS relating to medical devices or IVD devices as applicable; or (ii) four years of professional experience in regulatory affairs or in QMS relating to medical devices or IVD devices as applicable. Small manufacturers[26] are not required to have this person within their organization, but the person has to be permanently and continuously available to them; this implies a contractual relationship that defines responsibilities and ensures availability to carry out these responsibilities. Where the manufacturer is located outside the EU, their authorized representative also has to have a similarly qualified individual with the defined responsibilities for ensuring the requirements for PMS and vigilance are met either within their organization, or permanently and continuously available if they are not within their organization.

The responsibilities and authority of the person responsible for regulatory compliance should be documented in their job description and their interrelationships within the organization (shown in the organization charts). The person responsible for regulatory compliance should not be disadvantaged by the proper fulfilment of his or her responsibilities, regardless of whether or not they are employees of the organization. This implies that their independence should be guaranteed and their remuneration or career progression not limited by correctly fulfilling their responsibilities. The name, address and contact details of the person responsible for regulatory compliance are elements of the information to be submitted with the registration of the manufacturer or authorized representative. An MDCG guidance document[27] and separate White Paper[12] discuss the role of the person responsible for regulatory compliance in more detail.

23 MDCG 2020-7 Post-market clinical follow-up (PMCF) Plan Template - A guide for manufacturers and notified bodies

24 MDCG 2020-8 Post-market clinical follow-up (PMCF) Evaluation Report Template - A guide for manufacturers and notified bodies

25 Requirements of EU-GDPR and PMCF studies, registries and surveys under the MDR

26 As defined in Commission Recommendation of 6 May 2003 concerning the definition of micro-, small- and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

27 MDCG 2019-7 Guidance on Article 15 of the Medical Device Regulation (MDR) and in vitro Diagnostic Device Regulation (IVDR) regarding a 'person responsible for regulatory compliance' (PRRC).

Activities to implement the requirements include:

- reviewing PMS activities against the requirements of the Regulation and identifying any gaps that need to be filled
- documenting an overview of the future PMS system and the links to specific documented procedures for executing its elements
- including the documented overview of the PMS system within the QMS
- identifying the role that will act as the person responsible for regulatory requirements and the requirements for that position
- updating the job description and job requirements for the person responsible for regulatory requirements

04 Post-market surveillance plan

Under the Regulations, a PMS plan has to be established for each device or device family. The PMS plan describes the implementation of the PMS system for collecting information and characterizing the safety and performance of the device, or device family, with similar devices in the market, together with the methods and processes to assess the collected information. Potential information for use in PMS comes from a number of sources, including (see also Annex III: Technical Documentation on PMS):

- investigations of serious incidents
- investigations of incidents not meeting the criteria for classification as serious incidents
- data on undesirable side effects
- trend analysis and reporting
- field safety corrective actions
- reports in specialist or technical literature
- reports or outputs from databases or registries
- complaints provided by users, distributors and importers
- other feedback including customer surveys, information provided as input into manufacturer's websites and reports in social media
- publicly available data on events with similar devices provided by other manufacturers

The PMS plan includes a description of indicators and thresholds for continuous reassessment of risk management and the risk–benefit analysis together with the means to:

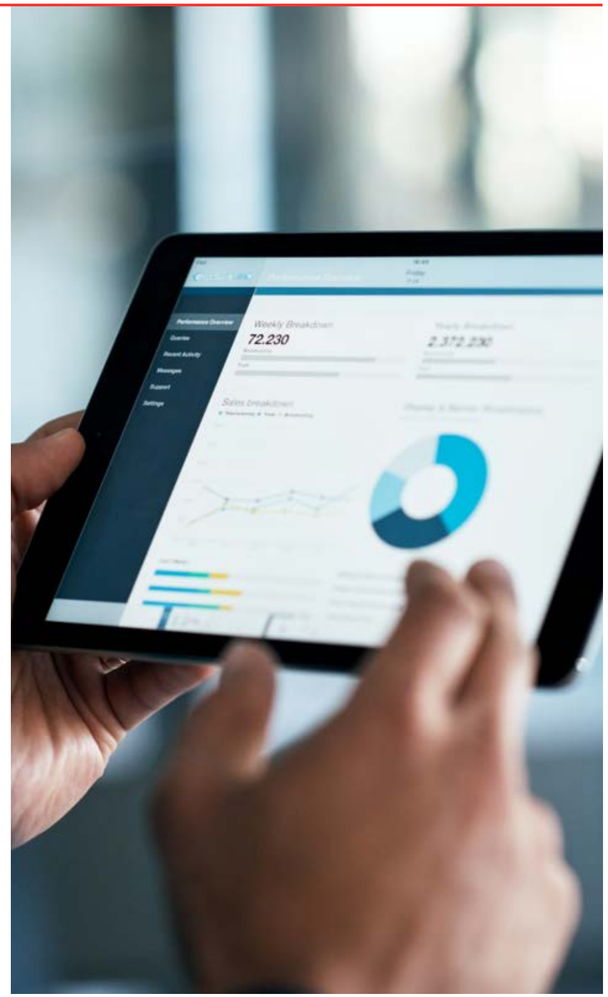
- investigate complaints and market experience from the field
- monitor trends, identify statistically significant increases in frequency or severity of incidents and provide trend reports
- communicate with competent authorities and notified bodies
- communicate with authorized representatives, importers, distributors, users and patients
- trace and identify devices for which correction or corrective action might be necessary

The PMS plan should also reference the documented procedures describing (i) the PMS system, (ii) the creation of the PMS plan, (iii) the generation of the PSUR or PMS report, as applicable, and (iv) the processes for identification and implementation of corrections, corrective actions or preventive actions.

The PMS plan is an element of the technical documentation and so should be in place before the declaration of conformity to the applicable Regulation is drawn up and before the device is CE marked under the Regulations.

Activities to implement the requirements include:

- establishing a template for future PMS plans
- identifying a sequence for creating or updating PMS plans into the new template for the portfolio of devices
- creating or updating PMS plans and incorporating the plans into the technical documentation



05 Reports of post-market surveillance

The Regulations contain new requirements to prepare summary reports of PMS information for all classes of devices.

5.1 Medical devices in Class I

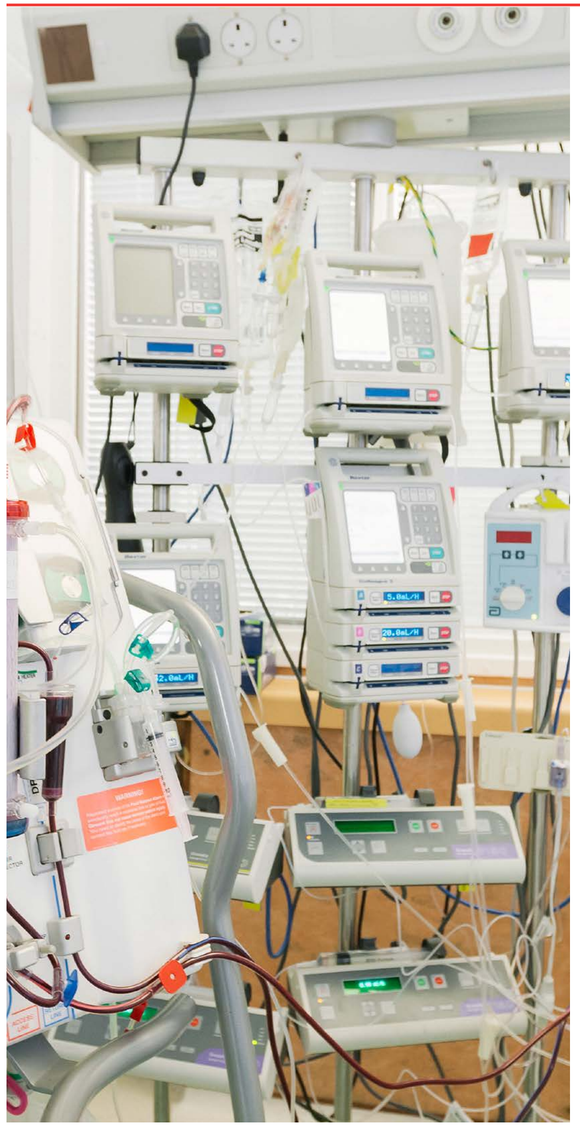
The manufacturer prepares a report summarizing the results and conclusions of analysis of the PMS data together with a rationale for, and description of, any preventive or corrective actions taken. The report is updated when necessary and made available to the competent authority upon request.

5.2 Medical devices in Classes IIa, IIb and III

The manufacturer has to prepare a PSUR for each device (or each device family) summarizing the results and conclusions of the analysis of PMS data together with a rationale for, and description of, any preventive or/and corrective actions taken. The PSUR needs to be kept up to date throughout the lifetime of the device and contain the:

- conclusions to be used in risk–benefit determination
- main findings of any PMCF evaluation report
- volume of sales of devices, an estimate of the size of the population using the device involved and, where practicable, the frequency of use of the device
- The PSUR forms part of the technical documentation.

The PSUR has to be updated when necessary but minimally the manufacturer of Class IIb or Class III devices is required to update the PSUR at least annually, whereas the manufacturer of Class IIa devices updates the PSUR at least every two years. For Class III devices or implantable devices in Class IIb, the manufacturer submits the PSUR electronically by means of EUDAMED to its notified body. The notified body reviews the report and adds its evaluation to EUDAMED with details of any action taken. The PSUR and the notified body evaluation are available to competent authorities through EUDAMED. For non-implantable Class IIb devices, the manufacturer has to make the PSUR available to its notified body and, upon request, to competent authorities.



5.3 IVD devices in Classes A and B

As for Class I medical devices, the manufacturer prepares a report summarizing the results and conclusions of the analyses of the PMS data together with a rationale for, and description of, any preventive or corrective actions taken. The report is updated when necessary and made available to the notified body and the competent authority upon request.

5.4 IVD devices in Classes C and D

The requirements for Class C and Class D IVD devices parallel Class II and Class III medical devices. The manufacturer has to prepare a PSUR for each device or each device family summarizing the results and conclusions of the analysis of PMS data together with a rationale for, and description of, any preventive or/and corrective actions taken. The PSUR is kept up to date for the lifetime of the device and forms part of the technical documentation, the content of the PSUR is the same as for medical devices. The manufacturer updates the PSUR when necessary and at least annually.

For Class D IVD devices, the manufacturer submits the PSUR electronically by means of EUDAMED to its notified body. The notified body reviews the report and adds its evaluation to EUDAMED with details of any action taken. The PSUR and the notified body evaluation are available to competent authorities through EUDAMED. For Class C IVD devices, the manufacturer has to make the PSUR available to its notified body and, upon request, to competent authorities.

The MDCG have published guidance on Periodic Safety Update Reports (PSUR28).

Activities to implement the requirements include:

- reviewing current reports of PMS activities against the requirements of the Regulations and identifying any gaps
- creating template(s) for PSUR or PMS reports, as applicable
- creating documented procedure(s) for creation of PSURs or PMS reports, as applicable, together with the associated roles and responsibilities
- estimating the number of PSURs or PMS reports that will need to be prepared and the frequency at which they will need to be updated
- establishing a timeline for creating or updating PSURs or PMS reports, as applicable
- confirming the availability of the necessary resources

28 MDCG 2022-21 Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745 - December 2022.

06 Complaint handling and vigilance reporting

The process for reporting of incidents is an element of the manufacturer's QMS as required by the regulations. BS EN ISO 13485 has separate, identified subclauses for the activities of complaint handling and reporting incidents.

The manufacturer is required to establish, implement and maintain documented procedures for handling complaints in a timely manner. These procedures need to include requirements and responsibilities for:

- receiving and recording information
- evaluating information to determine if the feedback constitutes a complaint
- investigating complaints
- determining the need to report to the appropriate regulatory authorities
- handling complaint-related devices
- determining the need to initiate corrections or corrective actions

When the need to report to an appropriate regulatory authority is identified, the manufacturer is required to implement documented procedures for i) reporting individual adverse events that meet reporting criteria or, under certain conditions, providing periodic summary reports, ii) providing trend reports, and iii) reporting field safety corrective actions to regulatory authorities. They also need to keep records of such reports.

Notified Bodies are required to review vigilance data to which they have access in EUDAMED in order to estimate its impact, if any, on the validity of existing certificates.

In regard to the requirements for vigilance, information previously contained in guidance[29] has been included in the Regulations themselves. The only exclusion in the need to report events is for expected side-effects that are clearly detailed in the product information and contained in the technical documentation. Furthermore, there is a requirement for trend reporting of incidents that are exempt from reporting, that is to report any statistically significant increase in the frequency or severity of incidents that do not meet the reporting criteria but could have a significant impact on the risk–benefit analysis and present or may present unacceptable risks to the health or safety of patients, users or others. Consequently, the manufacturer has to:

- specify how to identify, record and analyse these incidents
- document the foreseen frequency or severity of such incidents
- decide the criteria for identifying a statistically significant increase from this foreseen frequency or severity over a specific period of time

Additionally, the scope of reporting has been increased as temporary serious deterioration in health is now reportable.

29 MEDDEV 2.12-1 – Revision 8 – Guidelines on a medical devices vigilance system.

The maximum timelines for reporting events that are considered serious public health threats or death or unanticipated serious deterioration in health are two and ten days respectively, but the maximum timeline for reporting all other events is 15 days. This restricts the time available to determine whether an event meets the reporting criteria. This could lead to submission of initial reports if all the necessary information is not available and follow-up reports to provide additional information.

It is useful to note the change in terminology found in the Regulations: what were previously called reportable events are now called serious incidents, whereas incidents or non-serious incidents refer to what were previously called non-reportable events.

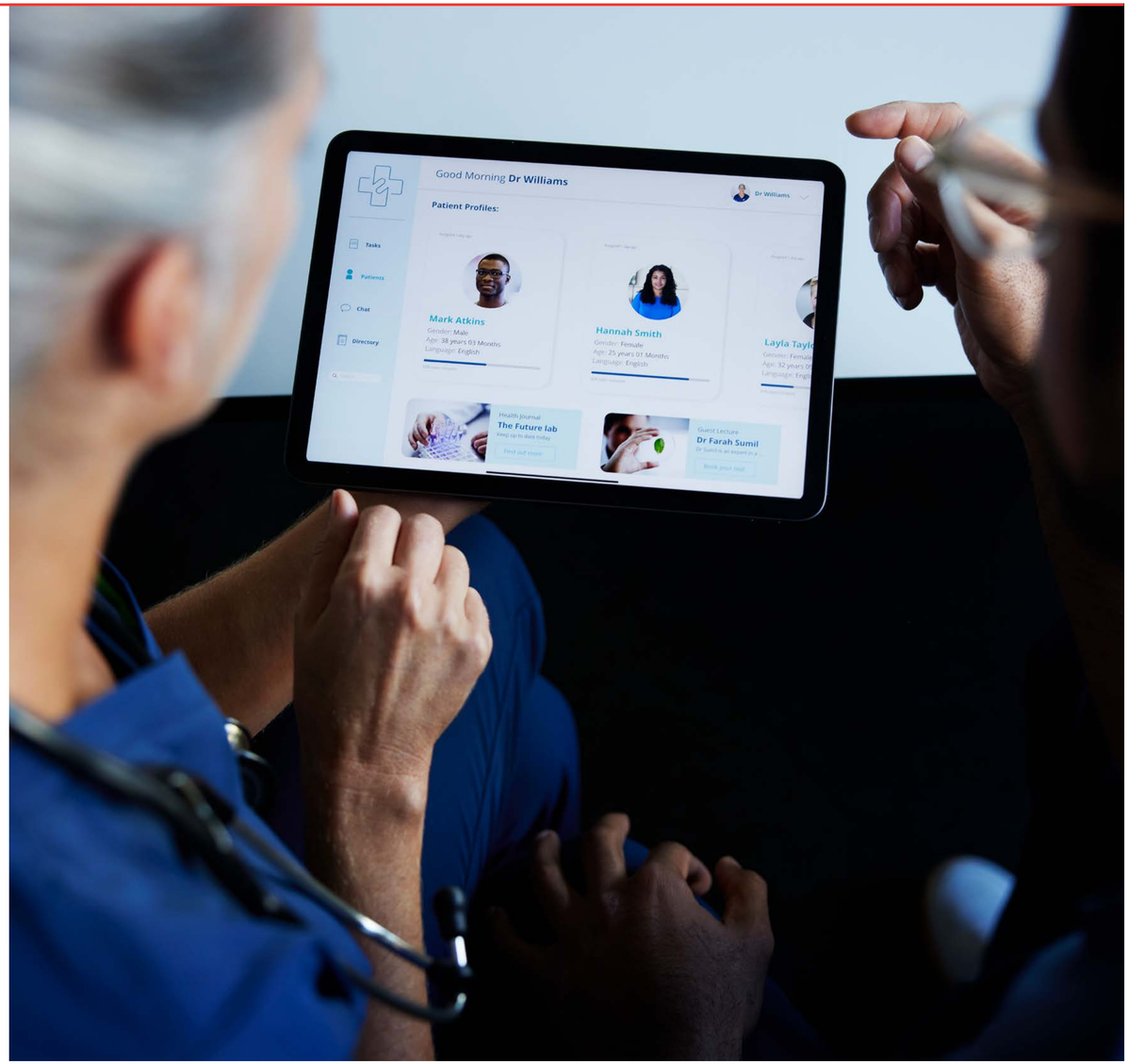
In addition to the changes in the requirements for vigilance reporting, the Regulations include an explicit requirement that, when conducting a field safety corrective action, the manufacturer has to inform the competent authority before implementing the action, unless this would cause a delay that could present a consequent risk to health.

Taken together, these changes are likely to lead to an increase in the number and types of reports submitted.

The MDCG workplan includes development of documents covering (i) Q&A on vigilance terms and concepts, (ii) Q&A document on Articles 87 to 90 on vigilance requirements, and (iii) development of harmonized reporting forms for incidents.

Activities to implement the requirements include:

- reviewing the procedures for vigilance against the requirements in the Regulations and identify any gaps
- determining the methods to establish statistical increases in frequency and severity for trend reporting
- reviewing a sample of previous vigilance reports against the revised exemption rules and timelines to estimate the likely increase in reporting that could result
- reviewing resources for vigilance reporting against the projected future workload
- identifying the changes needed to processes for complaint handling and vigilance reporting and the timeline for their implementation



07 Electronic submissions

Several aspects of the PMS system envisage electronic submission of information into EUDAMED. Vigilance and PMS information intended to be submitted into EUDAMED include:

- vigilance reports
- field safety corrective actions and field safety notices
- periodic summary reports
- trend reports
- PSURs for Class III devices or implantable devices and for Class D IVD devices
- notified body evaluation of submitted PSURs

EUDAMED was intended to be fully functional by the date of application of the Regulations, but this has not happened. Consequently, the Commission has to publish a notice when functionality has been verified, and the requirements relating to EUDAMED start to apply at set intervals after that publication date. With delay in the availability of EUDAMED, the text of the Regulations indicates that those elements of the requirements relating to EUDAMED are postponed, not the full provisions of the affected Articles. The MDCG published two guidance documents related to alternative solutions until Eudamed is fully functional[30] [31].

The implementation of EUDAMED for vigilance and PMS will establish a centralized reporting process to replace reporting to the competent authority in which an incident occurs. It also establishes a consistent means of information exchange with notified bodies on PMS. In order to benefit from this standardization, the manufacturer will need to establish processes for review and approval of documents for electronic submission and an interface between their internal systems and EUDAMED. The detailed technical solution for these enhancements will depend upon the specification for EUDAMED, and the development of standardized templates for the data to be exchanged will be a key milestone.

30 MDCG 2021-1 Rev. 1 Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional May 2021.

31 MDCG 2022-12 Guidance on harmonised administrative practices and alternative technical solutions until Eudamed is fully functional (for Regulation (EU) 2017/746 on in vitro diagnostic medical devices) July 2022.

As well as acting as the electronic system for collecting and sharing information on vigilance and PMS, EUDAMED is the electronic system for:

- registration of devices
- unique device identification
- registration of economic operators (manufacturers, authorized representative, importers, and producers of systems or procedure packs)
- certificates issued, suspended or withdrawn
- clinical investigations/performance studies
- market surveillance by competent authorities

Activities to implement the requirements include:

- establishing mechanisms to remain informed of development of EUDAMED, including the timelines and interface requirements
- reviewing procedures to establish internal processes, including responsibility and authority for preparation and review of electronic submissions

Conclusion

The dates of application of the MDR and IVDR have now passed. The vigilance and PMS requirements in these Regulations apply, including to devices that continue to be placed on the market with certificates or declarations of conformity to the Directives. Understanding the requirements is essential to your ability to provide the EU market with safe medical devices that perform as intended and comply with the Regulations.

Manufacturers should watch out for promised MDCG guidance documents covering PMS and vigilance.

Author

Eamonn Hoxey is a technical author, trainer and consultant on a range of life science areas including regulatory compliance, quality management, sterility assurance and standards development. Eamonn worked for Johnson & Johnson (J&J) for 17 years in positions of increasing responsibility for Quality and Regulatory Compliance for medical devices, pharmaceuticals and consumer products including Vice President of Compliance, Vice President of Market Quality and Vice President of Quality & Compliance Strategic Programs leading quality implementation for the EU MDR for J&J's Medical Devices companies. Prior to joining J&J, Eamonn spent 16 years with the UK Medical Devices Agency, including six years as Head of Device Technology and Safety.

Reviewers

Laure-Anne Thieren, Senior Manager, Quality Assurance EMEA, Biosense Webster

Laure-Anne has been working for J&J over the last 10 years, in positions of increasing responsibility for Quality and Compliance for medical devices, mostly in the fields of vigilance, PMS and quality systems. She is currently senior quality manager for Biosense Webster, a J&J company. In addition, Laure-Anne serves as vice-chair in the PMS working group of MedTech Europe trade association for medical devices. Prior to joining J&J, Laure-Anne worked as a registered nurse in various institutions.

Jane Edwards, Head of Communications, Global Product Management, BSI

Jane holds a BSc in Chemistry and an MBA from Durham University. She has over 13 years' experience in the medical device industry, having previously worked for Coloplast in their ostomy and continence business. Jane's experience includes working within the pharmaceutical, chemical and telecoms industries for Glaxo Wellcome, ICI and Ericsson, allowing her to bring depth of knowledge from across many industries and technologies. Her current role in BSI allows her to work with technical reviewers across all disciplines ensuring that all BSI communications are accurate and relevant. She is a member of the European Medical Writers Association.

Paul Sim, Medical Devices Knowledge Manager, BSI Standards

Paul has worked in the healthcare industry for over 35 years, joining BSI in 2010 to lead the organization in Saudi Arabia where it had been designated as a Conformity Assessment Body. Later, he managed BSI's Unannounced Audits programme. Since October 2015, he has been working with both the Notified Body and Standards organizations looking at how best to use the knowledge, competencies and expertise in both. Previously he held senior RA/QA leadership positions at Spacelabs Healthcare, Teleflex Medical, Smiths Medical and Ohmeda (formerly BOC Group healthcare business). Paul is a member of the Association of British Healthcare Industries (ABHI) Technical Policy Group and Convenor of the ABHI ISO TC 210 Mirror Group. He is Convenor of the BSI Committee that monitors all of the work undertaken by ISO TC 210, and Convenor of the BSI Subcommittee dealing with quality systems. As UK Delegation Leader to ISO TC 210, he is also actively involved in the work of national, European and international standards' committees.

Anette Sjorgren, Consultant, Preventia

Anette has over 30 years' experience in the medical device and pharma industries, as QA, RA, QP and the tasks within the medical fields such as quality and risk management, clinical affairs, toxicology and biocompatibility. She is a member of the Swedish (TK355) and the international technical (TC210) committees since 2010. Anette has been a consultant with PRENENTIA since 2003. She holds an MSc in Biomedicine.

Published white papers

The growing role of human factors and usability engineering for medical devices: What's required in the new regulatory landscape? Bob North

The differences and similarities between ISO 9001:2015 and ISO 13485:2016: Can we integrate these quality management standards? An update, Mark Swanson

Planning for implementation of the European Union Medical Devices Regulations – Are You Prepared? Eamonn Hoxey

Cybersecurity of medical devices: Addressing patient safety and the security of patient health information, Richard Piggin

General Safety and Performance Requirements (Annex 1) in the New Medical Device Regulation: Comparison with the Essential Requirements of the Medical Device Directive and Active Implantable Device Directive, Laurel Macomber and Alexandra Schroeder

Do you know the requirements and your responsibilities for medical device vigilance reporting? A detailed review on the requirements of MDSAP participating countries in comparison with the European Medical Device Regulation 2017/745, Cait Gatt and Suzanne Halliday

Technical Documentation and Medical Device Regulation: A Guide for Manufacturers to Ensure Technical Documentation Complies with EU Medical Device Regulation 2017/745, Dr Julianne Bobela, Dr Benjamin Frisch, Kim Rochat and Michael Maier

Nanotechnology: What does the future look like for the medical devices industry? Professor Peter J Dobson, with Dr Matthew O'Donnell

Developing and maintaining a quality management system for IVDs. An update, Melissa Finocchio

Recent advancements in AI – implications for medical device technology and certification, Anil Anthony Bharath

The impact and potential for 3D printing and bioprinting in the medical devices industry, Kenny Dalgarno

Sterilization – Regulatory requirements and supporting standards, Eamonn Hoxey

Medical device clinical investigations – What's new under the MDR? Maria Donawa

The convergence of the pharmaceutical and medical devices industries: Navigating the innovations and regulations, Barbara Nasto and Jonathan Sutch

Phthalates and endocrine disruptors – An overview of their safety requirements and evaluations and the standards that support them, Benjamin Seery

European Union Medical Device Regulation and In Vitro Device Regulation: unique device identification: What is required, and how to manage it, Mary Gray

Person responsible for regulatory compliance (PRRC) – MDR/IVDR Article 15: An overview of the requirements and practical considerations, Anne Jury and Maddalena Pinsi

Guidance on MDCG 2019-9: Summary of Safety and Clinical Performance, Amie Smirthwaite

Clinical evaluation under EU MDR, Amie Smirthwaite

Medical device clinical investigations — What's new under the MDR? An update, Maria Donawa

Using Standards to Demonstrate conformity with Regulations, Eamonn Hoxey

Performance Evaluation for IVD, Fiona Gould

How to best implement the EU IVDR – dos and don'ts. An update, Steve Lee

Risk management for medical devices and the new BS EN ISO 14971. An update, Jos van Vroonhoven

Implementing the European Union Medical Devices Regulations – Are You Prepared? Eamonn Hoxey

Forthcoming white papers

Requirements of EU-GDPR and PMCF studies, registries and surveys under the MDR

EUDAMED: an overview of how it is being developed and deployed by the European Commission

Symbols and information to be provided with medical devices

The regulation of AI

bsi.

Read more about our services and products on our website
bsigroup.com