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Using Standards to Demonstrate Conformity

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1. Overview

Standards are developed to provide a way to share common expectations on the characteristics of products, services or processes. Standards are literally as old as civilization. From the original pharmacopoeia developed by the ancient Egyptians to the documented specifications for the columns on Greek temples, various versions of standards have been used by developed cultures to convey important information and codify knowledge. Specific standards development organizations (SDOs) started to be established in the industrial revolution by professional societies particularly to share common expectations and best practices, initially in mechanical and civil engineering.

It is widely accepted that developing standards internationally is the most effective and economic mode of standards development. The development of international standards can have an important role in establishing the current technical capability or, for standards in the healthcare sector, clinical practice. This is also known as the state of the art. In addition, standards can have a role in supporting alignment of technical requirements for products across different regulatory jurisdictions. International standards can then be adopted regionally and nationally, preferably without modification. However, it might not always be feasible to achieve international consensus in a short timescale, and standardization through regional or national standards can be undertaken, sometimes as a precursor to international work.

One important characteristic of standards is that they are voluntary – there is no obligation to apply them or comply with them, except in those few cases where their application is directly required by regulations. However, the application of standards in the medical devices sector has undoubtedly been accelerated by their use to support regulation by providing a voluntary means to demonstrate conformity with regulatory requirements.

Regulatory authorities around the world not only use standards to support their regulations but use different approaches to apply or recognize standards. For example, the USA, the European Union (EU) and United Kingdom have specific mechanisms in place to create and maintain lists of standards that support their regulatory requirements.

Organizations that use standards to demonstrate conformance with regulatory requirements for their products or processes, or need to understand the current state of the art, should monitor the development on new or revised standards that affect their operations. Establishing efficient and effective processes to monitor standards developments and to implement changes when new standards are introduced, or existing standards are revised, can provide critical information and a competitive advantage.

2. Introduction

The purposes of standards can be summarized1 as:

a) facilitating trade, particularly reducing technical barriers and obstacles to international trade

b) providing a framework for achieving economies, efficiencies and interoperability

c) enhancing consumer protection and confidence and

d) supporting public policy objectives and, where appropriate, offering effective alternatives to regulation

The formal definition of a standard is that it is a

> *document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.*[2]

The definition is supported by a note recommending that 'standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits'.

Standards represent development of a consensus. Consensus is defined as

> *general agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments.*[2]

It is important to recognize that consensus need not imply unanimous agreement.

3. Use of standards to support regulations for medical devices

3.1 International Medical Device Regulators Forum guidance

The International Medical Device Regulators Forum (IMDRF) is a voluntary group of medical device regulators from around the world. IMDRF aims to accelerate international medical device regulatory harmonization and convergence. The members of IMDRF are the regulatory authorities from:

- Australia
- Brazil
- Canada
- China
- European Union
- Japan
- Russia
- Singapore
- South Korea and
- the USA

[2] ISO/IEC Guide 2:2004, Standardization and related activities — General vocabulary.

The World Health Organization (WHO) and the UK Medicines and Healthcare products Regulatory Agency (MHRA) are official observers. The Asia-Pacific Economic Cooperation (APEC) Life Sciences Innovation Forum, Asian Harmonization Working Party (AHWP) and Pan American Health Organization (PAHO) are affiliate organizations.

The IMDRF has undertaken several projects looking at the role of standards developed in a formal, consensus approach, in support of medical devices regulation, including:

- looking at the role of standards in the assessment of medical devices[3]
- surveying international standards recognized by IMDRF members[4] and
- developing recommendations for optimizing standards for regulatory use[5]

The IMDRF has concluded that reliance on standards is a key element of a robust regulatory framework. Standards have a significant role throughout the life cycle of medical devices by:

- providing tools for conformity assessment
- allowing objective assessment of device safety and performance
- facilitating and supporting innovation
- helping ensure that devices are safe and perform as intended and
- offering a means to streamline and harmonize regulatory processes around the world through:
    - streamlining the device review process
    - improving the efficiency of regulations and
    - establishing productive dialogue among regulatory authorities, manufacturers, conformity assessment organizations (including accreditation and testing professionals), clinicians and the public

All the member regions of IMDRF use standards for regulatory purposes but they differ in how they apply and/or recognize them. The IMDRF encourages the use of appropriate standards in regulatory regimes and recommends that all regulatory authorities assess standards and publish a list of recognized or approved standards.

3.2. European harmonized standards

The European Medical Device Regulation (MDR)[6] and In Vitro Diagnostic Medical Devices Regulation (IVDR)[7] specify General Safety and Performance Requirements (GSPRs) in Annex I of each Regulation. The GSPRs are product-related safety and performance requirements that have to be complied with irrespective of the regulatory classification of the device. Regulatory classification is based on the perceived risk associated with the device and is used to allocate available routes of conformity assessment applicable for that device. The primary focus of the GSPRs is the protection of health and safety of patients and users, although they can also have implications in other areas such as environmental considerations. GSPRs fulfil the role previously given to essential requirements in the new legislative framework (new approach), namely to 'define the results to be attained, or the hazards to be dealt with, but do not specify the technical solutions for doing so[8]. The detailed explanation of the requirements can normally be found in standards, common specifications and to some extent in guidance documents.

The MDR and IVDR have specific roles for European standards that are designated as harmonized. Article 8 in each Regulation indicates that harmonized standards are those adopted based on a request from the European Commission to support legislation. Devices in conformity with relevant harmonized standards, or applicable parts of standards, are presumed to be in conformity with the requirements of the Regulation covered by those standards when the standard is accepted by the European Commission and cited in the Official Journal of the

[6] 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.

[7] 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.

[8] The 'Blue Guide' on the implementation of EU products rules 2016.

European Union. Additionally, the presumption of conformity also applies to system or process requirements, including those requirements relating to quality management systems (QMSs) and risk management.

European standards that are intended to be harmonized include a European foreword and Annex Zs that describe the relationship between the requirements of the standard and the regulatory requirements in the European Regulations that are applicable to the scope of that standard. A harmonized standard that has been developed under a standardization request and includes an Annex ZA (or ZZ) does not automatically provide a presumption of conformity until it is accepted by the European Commission and listed in the Official Journal.

The Directives for medical devices (Medical Devices Directives (MDD), Active Implantable Medical Devices Directive (AIMDD) and In Vitro Diagnostic Medical Devices Directive (IVDD) 98/79/EC) that preceded the MDR and IVDR also had specific roles for harmonized standards in demonstrating conformity. A number of standards were harmonized against these Directives and listed in the Official Journal. Three Commission Implementing Decisions for harmonized standards were adopted in April 2021 and published in the Official Journal.[9,10,11] These implementing decisions gave the final updates to the list of harmonized standards that give a presumption of conformity for the Directives for medical devices. These updates leave the final numbers of standards harmonized under the Directives for medical devices as:

- 47 for the AIMDD
- 268 for the MDD and
- 43 for the IVDD

As the date of application of the MDR was May 2021, and for the IVDR is May 2022, no further updates to the harmonized standards lists are planned.

A standardization request from the European Commission to the European Standards Organizations, CEN and CENELEC, provides the legal basis for harmonizing standards. Agreement of this request allows publication of references to harmonized standards that provide a presumption of conformity under the MDR and IVDR to start. In May 2021, the European standards organizations, CEN and CENELEC, formally accepted the standardization request[12] from the European Commission for standards to support the MDR and IVDR. This initiates steps to revise or develop more than 200 harmonized standards for medical devices. The standardization request includes lists of the first standards to be developed and harmonized under the MDR and IVDR. The lists of standards to be developed will be updated and enlarged periodically.

Acceptance of the standardization request started the process to amend or revise many standards for devices. Standards that were harmonized for the Directives for medical devices will not automatically be added to the lists of standards supporting the Regulations. In some cases, a European amendment to change the European foreword and replace the Annex Zs for the Directives with annexes showing the relationship between the standard and the MDR and IVDR, as applicable, will be required. In other cases, an amendment or revision of the standard that is already underway can be used to update the foreword and Annex Zs. There is a common deadline of 27 May 2024 for all the requested standards to be in place.

The European Commission has published lists of the first standards to be harmonized under the MDR and IVDR.

[9] Commission Implementing Decision (EU) 2021/609 of 14 April 2021 amending Implementing Decision (EU) 2020/439 as regards harmonized standards on packaging for terminally sterilized medical devices and sterilization of healthcare products.

[10] Commission Implementing Decision (EU) 2021/610 of 14 April 2021 amending Implementing Decision (EU) 2020/437 as regards harmonized standards on medical vehicles and their equipment, anaesthetic and respiratory equipment, biological evaluation of medical devices, packaging for terminally sterilized medical devices, sterilization of healthcare products, clinical investigation of medical devices for human subjects, non-active surgical implants, medical devices utilizing animal tissues and their derivatives, electroacoustics and medical electrical equipment.

[11] Commission Implementing Decision (EU) 2021/611 of 14 April 2021 amending Implementing Decision (EU) 2020/438 as regards harmonized standards on biological evaluation of medical devices, packaging for terminally sterilized medical devices, sterilization of healthcare products and clinical investigation of medical devices for human subjects.

[12] M/575 Commission Implementing Decision C(2021) 2406 of 14.4.2021 on a standardization request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards medical devices in support of Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices in support of Regulation (EU) 2017/746 of the European Parliament and of the Council.

The first list of harmonized standards for the MDR[13] is a short one, containing only five entries. The first list of standards harmonized for the IVDR[14] is even shorter with just four standards included. However, these initial lists are just the start. Further Commission decisions added a further nine standards to the list for for the MDR (EU 2022/6) and five for the IVDR (EU) 2022/15). More standards are expected to be included over time.

3.3. US FDA recognized standards

US government agencies are directed to use voluntary consensus standards rather than developing their own, unique standards, except where voluntary consensus standards are inconsistent with law or otherwise impractical.[15,16] Furthermore, the US FDA is directed to

recognize all or part of an appropriate standard established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity in order to meet a premarket submission requirement or other requirement.[17]

A list of consensus standards that FDA has recognized or decided to recognize is available on the FDA Recognized Consensus Standards database.[18]

Standards can be used to meet premarket submission requirements and support the premarket review process. However, in most cases the standards would only satisfy part of the submission requirements. Standards can be used to support different types of premarket submissions to the FDA, such as:

- any 510(k)-submission including abbreviated premarket notifications 510(k)s
- De Novo requests
- investigational device exemption (IDE) applications
- premarket approval (PMA) applications
- product development protocols (PDPs)
- humanitarian device exemptions (HDEs) application
- investigational new drug (IND) applications or
- biologics license applications (BLA) for those devices that are regulated by the Center for Biologics Evaluation and Research (CBER) as biological products

There are two appropriate uses of consensus standards in the premarket process – in a declaration of conformity and in general use.

[13] Commission Implementing Decision (EU) 2021/1182 of 16 July 2021 on the harmonized standards for medical devices drafted in support of Regulation (EU) 2017/745 of the European Parliament and of the Council.

[14] Commission Implementing Decision (EU) 2021/1195 of 19 July 2021 on the harmonized standards for in vitro diagnostic medical devices drafted in support of Regulation (EU) 2017/746 of the European Parliament and of the Council.

[15] The National Technology Transfer and Advancement Act (NTTAA).

[16] Office of Management and Budget (OMB) directive, Circular A-119, Federal participation in the development and use of voluntary consensus standards and in conformity assessment activities.

[17] 21 U.S.Code. 360d – Performance standards (c)(1)(A).

[18] Recognized Consensus Standards.

3.3.1 Declaration of conformity

A declaration of conformity can refer only to standards for which FDA has assigned a recognition number. These standards are recognized by a notice published in the Federal Register or that the FDA has decided to recognize but for which recognition is pending because a periodic notice has not yet appeared in the Federal Register. The FDA database for Recognized Consensus Standards can be consulted to determine whether a declaration of conformity can refer to a particular standard. The database provides the most up-to-date list of suitable standards because the database is updated even before recognition of the standard appears in the Federal Register. The database includes a recognition number and a supplemental information sheet for each decision, including for cases for which recognition is pending. The supplemental information sheet contains essential information on the standard and its recognition including:

- date of publication of the standard in the Federal Register
- recognition number
- standard designation number
- title of the standard
- information on US adoption of the standard
- extent of recognition (e.g. wholly or in part)
- rationale, including basis, for recognition (technical, scientific, regulatory or another basis)
- transition period (if any)
- relevant FDA guidance
- FDA technical contact or contacts
- SDO publishing the standard
- history of recognition declaration of conformity to a consensus standard can be used to certify that a device conforms to all of the requirements of a recognized standard – there can be no deviation from the standard

3.3.2. General use

General use of a standard in premarket submissions is a choice to conform to a standard, in whole or in part, without submitting a declaration of conformity. This approach can be used, for example, because a standard that the FDA has not recognized or decided to recognize has been used or there is a deviation from an FDA-recognized standard.

4. UK designated standards

It is important to be aware that the MDR and IVDR will not be implemented in England, Scotland and Wales. In this context, the distinction between Great Britain (GB) – England, Scotland and Wales – and the United Kingdom, which comprises Great Britain and Northern Ireland, is relevant. Northern Ireland will have a special status as EU rules will continue to apply there. The Northern Ireland Protocol is a key part of the agreement on the UK withdrawal from the European Union. The effect of the Northern Ireland Protocol is that products on the Northern Ireland market, including medical devices, are required to comply with EU Regulations and Directives as well as with UK law. Separate requirements regarding CE marking will apply in Northern Ireland.

The UK Medical Devices Regulations[19] implement the EU Directives for active implantable medical devices,[20] medical devices[21] and in vitro diagnostic medical devices[22] (IVDs) in the UK and continue to apply in Great Britain. These Directives have specific roles for harmonized standards in demonstrating conformity (see 3.2).

Therefore, the UK Medical Devices Regulations have a similar role for standards to support the regulatory requirements. With the UK leaving the EU, the link with the publication of the list of harmonized standards published in the Official Journal has been broken. As a result, the UK has published its own list of standards that support UK Regulation. These have been termed 'designated standards'.

Three lists of designated standards for medical devices have been published. These lists of standards apply to medical devices,[23] active implantable medical devices[24] and in vitro diagnostic medical devices,[25] respectively.

At the time of publication, the lists of UK designated standards reproduce the harmonized standards in the Official Journal of the European Union for the respective Directives for medical devices. The listed standards are all European standards and not identified as the UK adoptions of those standards by BSI. Harmonized European standards include a European foreword and Annex Zs that describe the relationship between the requirements of the standard and the regulatory requirements in the Directives that are applicable to the scope of that standard. As the UK Regulations currently mirror the requirements in the EU Directives for medical devices, the Annex Zs currently also link the requirements of the standard with the requirements of the UK Regulations.

The process by which the lists of designated standards will be maintained has not yet been made available publicly. As no further standards will be harmonized in Europe for the Directives for medical devices, future European Standards will not be published with Annex Zs for these Directives. In addition, the UK Regulations will be updated and the Medicines and Medical Devices Act [26] has been adopted. If the regulatory requirements in Great Britain start to diverge from those in the EU, the relationship between the UK Regulations and a particular standard might not be reflected by a European Annex Z. Therefore, adoptions of European standards in the UK might also contain a national annex that is the equivalent of a European Annex Z showing the relationship between the standard and the regulatory requirements in Great Britain. The European Annex Zs, with the relationship between the standard and the MDR or IVDR, will be relevant for Northern Ireland.

[19] The Medical Devices Regulations 2002 (SI 2002 No 618, as amended).

[20] Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices.

[21] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

[22] Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

[23] Notices of publication and a consolidated list for designated standards for medical devices.

[24] Notices of publication and a consolidated list for designated standards for active implantable medical devices.

[25] Notices of publication and a consolidated list for designated standards for in vitro diagnostic medical devices.

[26] Medicines and Medical Devices Act 2021.

5. Standards and the state of the art

The requirements for medical devices in the EU, in both the MDD and Regulations, refer in a number of places to the need to 'take into account the generally acknowledged state of the art' in relation to safety and performance of medical devices.

The Medical Device Coordination Group (MDCG) has issued a guidance document on standardization for medical devices.[27] The MDCG is composed of representatives of member states and chaired by the EU Commission. As with all the MDCG guidance, it cannot be regarded as reflecting the official position of the European Commission, or as being legally binding.

The guidance covers a range of topics on standardization and the harmonization of standards to provide a presumption of conformity with European regulatory requirements. One interesting area of the document relates to the frequently discussed relationship between standards and the state of the art.

The guidance stresses that 'taking into account' is different from a requirement to 'comply with'. The guidance goes on to indicate that the state of the art is not legally defined and is difficult to express in a single, clear definition. This is because the term involves several complex aspects. The guidance indicates that it is useful to consider different sources where the term is defined or explained, even if the definition is not legally binding. Two such definitions of 'state of the art', with a lot of similarity, are:

- developed stage of current technical capability and/or accepted clinical practice in regards to products, processes and patient management, based on the relevant consolidated findings of science, technology and experience – IMDRF[28]
- developed stage of technical capability at a given time in regards to products, processes and services, based on the relevant consolidated findings of science, technology and experience – BS EN ISO 14971:2019+A11:2021.[29]

The MDCG has also indicated that the most recent published editions of standards should be considered as reflecting state of the art, regardless of whether they are referenced in the Official Journal. The guidance extends this discussion to indicate compliance with the most recent version of a standard does not automatically imply compliance with the requirements of the applicable EU legislation. Furthermore, the use of standards is voluntary. Therefore, the use of a specific standard in the conformity assessment of a product cannot be imposed, not even based on 'compliance with the state of the art'. The manufacturer needs to have evidence of how the device meets the regulatory requirements in the technical documentation of the product. The guidance clearly states that while a notified body has to check whether device complies with the requirements of the Directives or Regulations on medical devices, it cannot make conformance with any particular standard mandatory. Manufacturers can find it useful to discuss with their notified body how they will review technical documentation regarding the state of the art and references to standards.

The manufacturer has the choice whether to use a standard within its responsibility for compliance of products intended to be placed on the market. The manufacturer also needs to be able to demonstrate how they have 'taken into account' the state of the art. This suggests that manufacturers should be aware of, and consider, the latest version of a relevant standard, even if it is not yet cited in the Official Journal.

[27] MDCG 2021-5, Guidance on standarisation for medical devices.

[28] IMDRF/GRRP WG/N47 FINAL:2018, Essential principles of safety and performance of medical devices and IVD medical devices.

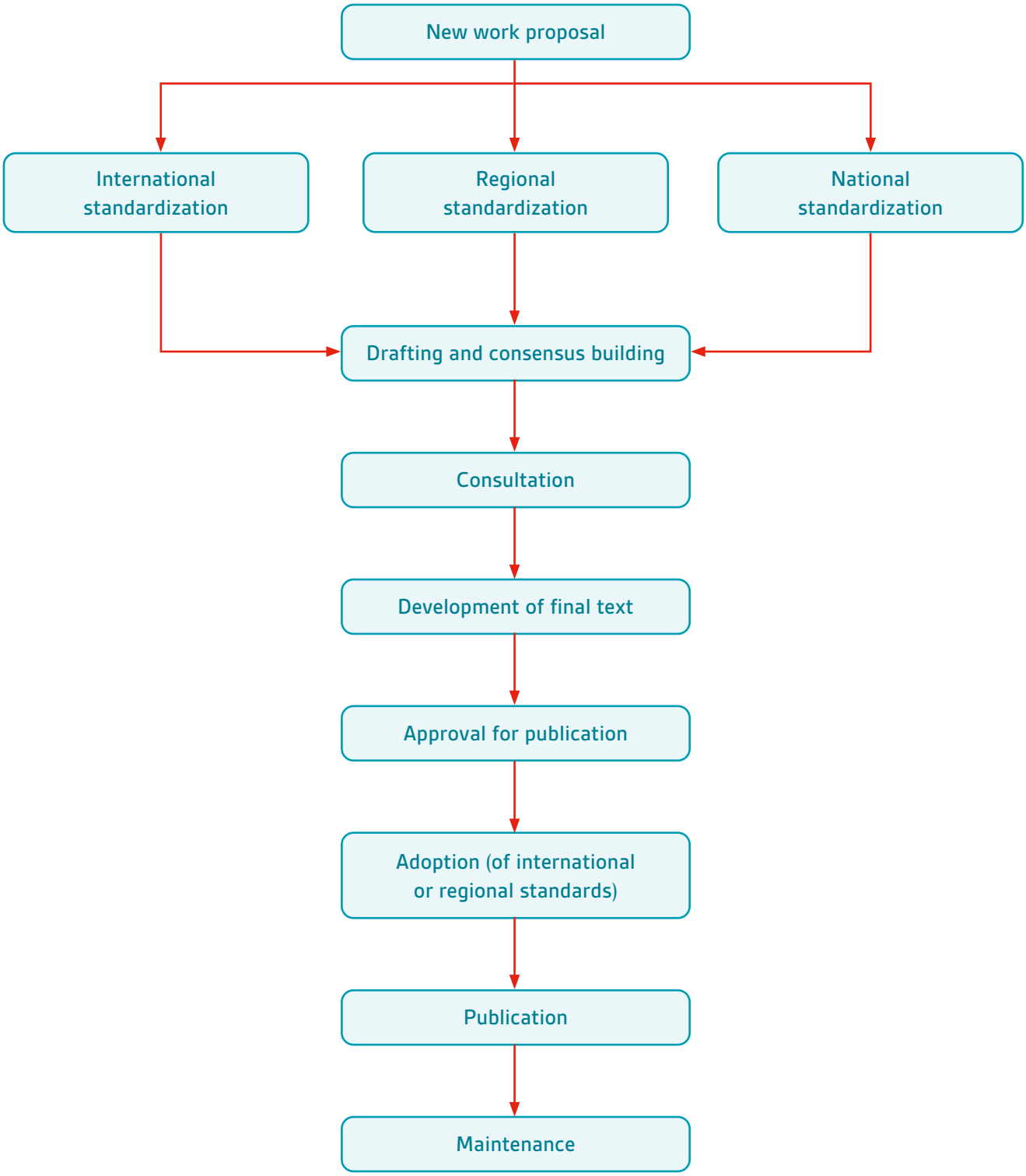
[29] BS EN ISO 14971:2019+A11:2021, *Medical devices — Application of risk management to medical devices.*

6. Development of standards

Standards are used to support the regulatory process because they are developed in accordance with set principles of transparency, openness to participation by interested stakeholders, balance of representation and due process. The way that standards are developed is intended to assure that, while many interests are considered, no single party wields disproportionate influence.

The process and description of stages in the development of standards can differ between SDOs. Figure 1 gives a general description of the common elements involved.

Figure 1 Stages of standards development, publication and maintenance[30]



[30] Adapted from BS 0:2021, *A standard for standards — Principles of standardization.*

The process for developing a standard starts with a proposal for new work. This gives the intended scope and purpose of the standardization project. The proposal is subject to review to determine if the proposed project is feasible and should go ahead.

Whether the standard is developed at an international, a regional or a national level, approved projects go through a process of drafting and building a consensus on the technical content. This can take place in a variety of different settings such as project teams, task groups, working groups, subcommittees or committees. When the group has reached an agreement, there is a period of consultation when the text is made widely available for comment from stakeholders. All these inputs are considered and there can be several consultations on iterations of the draft as it evolves. After consultation, the inputs are addressed and the final text developed. This text generally goes through an approval process, such as a ballot. However, in some cases if the requirements for consensus are met during the consultation stage, the approval stage may be omitted.

Standards developed internationally or regionally go through a process to be adopted as national standards. Members of the European Standards organizations, such as the UK, are obliged to adopt and publish European Standards without change when they are approved.

For standards listed in the EU standardization request (see 3.2), the European foreword and Annex Z that describe the relationship between the standard and the European regulatory requirements are developed at the same time as the standard. These parts of the standard go through the development process, and associated consensus building, as the text of the standard itself. There are specific additional reviews, however, where the foreword and Annex Z are considered by consultants engaged on behalf of the European Commission. A consultant is assigned to assess the standard, European foreword and Annex Z against criteria set by the European Commission, to provide comments and recommendation on the suitability of the standard to support the regulatory requirements. These assessments can take place at the working draft stage but are most important at the consultation and approval for publication stages. When any comments from the consultants are addressed by the standards drafters, the European standard, or European adoption of an international standard, can be published with the European foreword and Annex Z included. On publication, the standard is proposed to the European Commission for inclusion in the list of harmonized standards. The final decision on whether to cite the standard in the Official Journal rests with the European Commission. There have been instances when, even if the consultant has given a positive assessment, the European Commission has not accepted some standards for citation. That stage of review by the European Commission only occurs once the standard has been published, which means that to correct this, the standard has to be subsequently amended or revised.

Unfortunately, the process of resolving comments from the consultants has, in some instances, led to:

- delays in the publication of international standards
- delays in adoption of international standards as European standards or
- formally de-linking the standard from the European legislation and adoption of international standards as European standards without the inclusion of required information in the European foreword or Annex Z, making the standard unsuitable for harmonization under the MDR or IVDR

Hopefully, with the successful publication of the first lists of harmonized standards for the MDR and IVDR establishing precedents for the process, such delays or disconnections between international and European standards can be avoided in future.

Following citation of a standard in the Official Journal, a formal objection can be raised against the citation if the standard is considered not to support European legislation adequately.[31] Updates to the lists of harmonized standards in the Official Journal are made periodically.

[31] Article 11 of Regulation 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council Text with EEA relevance.

Published standards have established processes to make sure that they remain current. Revisions can be triggered by identification of a specific need, such as a change in technology, the state of the art, user needs and expectations or regulatory requirements. Standards are also reviewed on a set frequency – generally the default is a 5-year interval of systematic review. The outcome of the systematic review can be that the standard is confirmed without change, identified for revision or withdrawn.

Participating actively in the development of standards is a time-consuming process. Organizations nominating individuals to undertake standards development activities need to be aware of the time that needs to be allocated and be prepared to dedicate that level of resource. The precise amount of time that is needed will vary at different stages of the development process. Not only it is necessary to review text and prepare comments, but also to prepare text for working drafts and to support comments. Comments from other stakeholders need to be reviewed and addressed. Participating in standards development is a significant commitment and a strategic decision of a nominating organization. Participating in the standards development process can provide organizations with information on the rationale behind the requirements and that insight provides some element of competitive advantage.

7. Monitoring standards development and implementing new or revised standards

7.1. Process approach

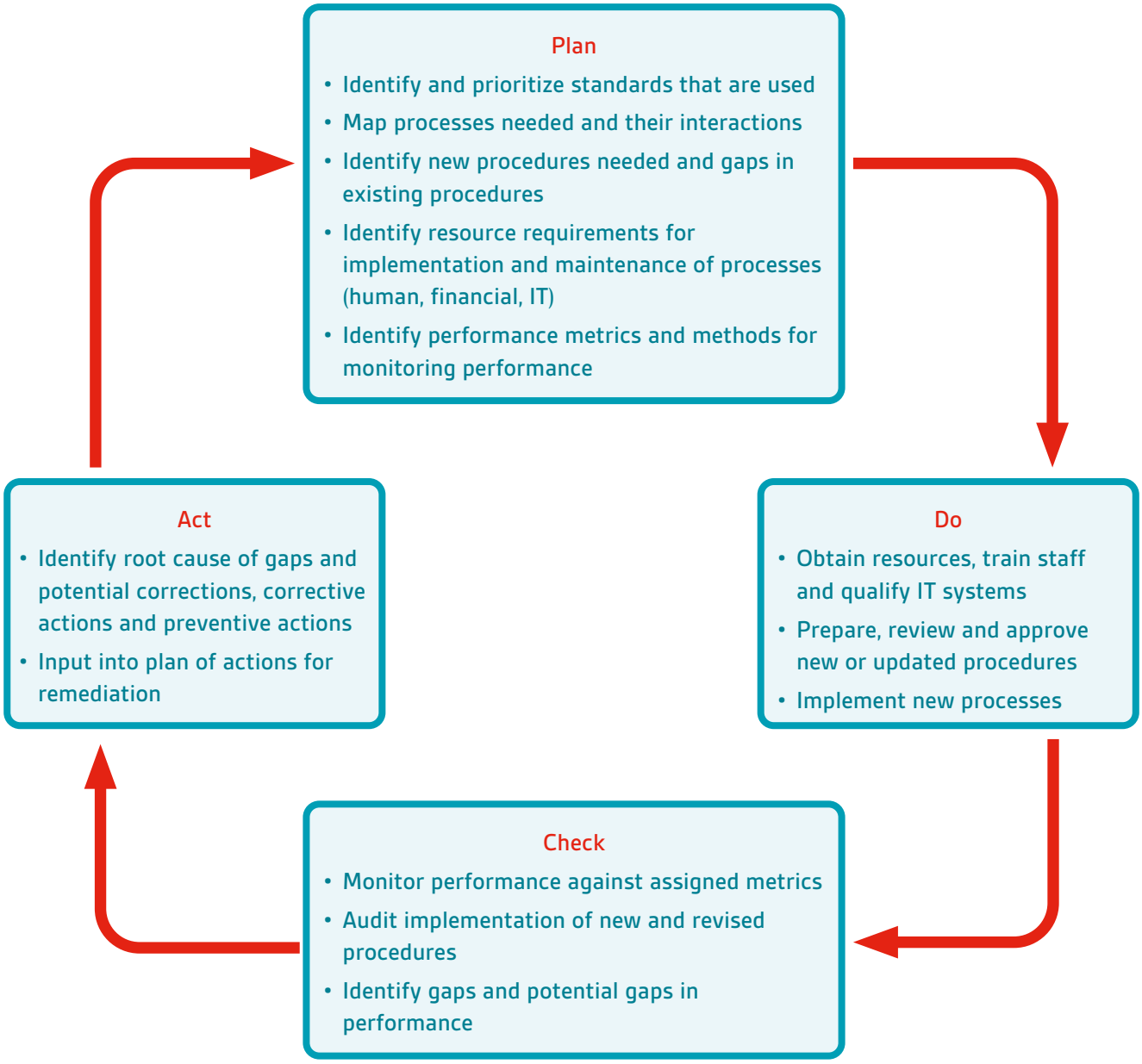
The standards for a QMS, including BS EN ISO 13485:2016+A11:2021,[32] are based on adopting a process approach to developing, implementing and improving the effectiveness of the QMS. Understanding and managing interrelated processes as a system contributes to the effectiveness and efficiency in achieving its intended results. Controlling the interrelationships and interdependencies among the processes of the system allows the overall performance of the organization to be improved. Management of the processes and the overall system can be achieved using a plan-do-check-act (PDCA) cycle with risk-based approach to take advantage of opportunities and prevent undesirable results. The PDCA cycle consists of four stages:

- plan – define what needs to be done and the resources to do it
- do – implement the planned actions and monitor their effectiveness
- check – analyse the results of monitoring and other feedback on the process
- act – identify actions to prevent potential failure to achieve intended results, correct any failures that have occurred and take action to prevent their recurrence

Monitoring developments in standards effectively, or implementing a new or revised standard successfully, requires processes to be put into place. The processes need to be maintained over time. A PDCA approach can be used for each of these processes. Figure 2 illustrates a general PDCA cycle that could be applied to monitoring developments in standards (see 5.2) or implementation of a new or revised standard in an organization (see 5.3).

[32] BS EN ISO 13485:2016+A11:2021, Medical devices — Quality management systems — Requirements for regulatory Purposes.

Figure 2 Illustrative PDCA cycle monitoring standards developments or implementing new or revised standards



7.2. Monitoring standards development

The manufacturer has responsibility for the legal compliance of products intended to be placed on the market. Within this responsibility, the manufacturer has the choice of whether or not to use a particular standard. The manufacturer also needs to be able to demonstrate how they have 'taken into account' the state of the art.

Manufacturers of medical devices should monitor developments in the standards that are relevant to them. They can do this by:

- participating in the development of a standard in the relevant technical committee, subcommittee, working group or task group at an international, a European or a national level
- monitoring the revision of a standard from reports provided to committees doing the work or shadowing work undertaken at an international or a European level
- checking the work programmes of relevant technical committees made available through publicly available websites
- participating in or receiving reports from industry and professional associations that monitor standards developments or
- subscribing to information services that provide information and analysis of standards developments

The extent of involvement that a manufacturer wishes to commit to monitoring or participating in standards development can depend on the importance of the standard project to that manufacturer's business. Therefore, effective prioritization is an important part of the monitoring process.

Some key aspects of using the PDCA cycle for monitoring standards development include:

Plan

- identify standards used to support regulatory compliance
- prioritize standards for importance
- allocate responsibility for monitoring developments in each applicable standard
- determine the method of monitoring developments depending on the criticality for the standard to the business
- determine resources needed to monitor developments
- establish methods to share information on standards developments
- identify performance metrics for the process

Do

- implement the planned arrangements for monitoring standards developments

Check

- review performance against metrics
- audit implementation of the monitoring process
- identify gaps in performance

Act

- identify root cause of performance gaps and actions to address them

Once the process to change a relevant standard is initiated, it is useful for manufacturers to follow the change through the various stages of development. This allows the implications of the change to be identified at an early stage and planning to implement the change to begin. Such intelligence gathering also allows input to be provided on the proposed change as it goes through the development process.

7.3. Implementing changes to standards

For organizations that use standards in their activities, deciding when to start the process to implement a change can depend on a variety of factors. The process for monitoring standards developments should identify when new standards are being developed or existing standards are being revised. The PDCA cycle can then be used to implement any necessary changes to products or processes.

Plan

- carry out a gap analysis:
  - the gap analysis considers the importance of the standard to the organization; the magnitude of the change; the effect of the change on existing devices, including devices in the supply chain and the interchangeability of spare parts and the impact on devices at different stages of development. This analysis will inform the decisions needed in all subsequent steps of the implementation process
- develop an action plan with timelines, responsibilities and costs:
  - based on the gap analysis and the significance of the change, an action plan can be developed. This should address what needs to be done, by whom and by when. This will inform priorities as well as allow the required resources to be estimated
- inform senior management:
  - senior management will need to be informed on any implications of the change on business strategies, market access and product approval or registration. In addition, senior management engagement will facilitate the implementation of the action plan. The information developed in the gap analysis and action planning can give key points to brief senior leaders and gain their support. Reviewing the implications of new or revised standards can be an element of the management review of the QMS

Do

- update operating procedures:
  - the gap analysis will identify what changes need to be made. These could be changes to the manufacturer's QMS, risk management process, device specifications, labels or instructions for use, or test methods. These changes are likely to be included in procedures or documents that are controlled in the manufacturer's QMS. Such changes need to be introduced in accordance with formal change control procedures
- review training needs:
  - the individuals who need to perform any new or revised procedures can require training to execute the procedures effectively
- update any technical documentation:
  - the change triggered by a change to a standard can also need to be captured in the technical documentation for the device. In some instances, notified body review of changes to this technical documentation will need to be addressed

Check

- review effectiveness of implementation:
  - this can be a check on the performance or output of the revised process or conformance for revised products. This could be done by monitoring performance against metrics, auditing process implementation and documentation or reviewing results of product inspections. Identify any failures to meet requirements and their causes

Act

- remediate or improve the process:
  - identify the causes of performance gaps or nonconformances, or potential performance gaps or nonconformances, and move to plan corrections, corrective actions or preventive actions

8. Conclusion

Standards are developed in accordance with an established process to assure transparency, openness to participation by interested stakeholders, balance of representation and due process. Participation stakeholders, with a range of interests, are important to maintain that balance.

Standards provide an important, voluntary means of demonstrating conformance with regulatory requirements. Regulatory Authorities differ in the way that they use standards within their regulatory regime but are encouraged to assess and publish lists of standards that they recognize. The USA, EU and UK have specific systems in place to recognize, harmonize or designate standards that support their regulatory requirements. However, even standards that are not formally recognized can have an important role in establishing the current technical capability or clinical practice, also known as the state of the art.

Organizations that use standards or need to know the state of the art should monitor the development of new or revised standards that affect their activities. They should also have an established process to prioritize standards development activities and implement new or revised standards. The effective monitoring and implementation of standards requires resources, but efficient processes can provide competitive advantage.

9. Further reading

BS 0:2021, *A standard for standards — Principles of standardization*

GHTF-SG1-N012R10, 2000, *Role of standards in the assessment of medical device*

IMDRF/Standards WG/N51 FINAL:2018, *Optimizing standards for regulatory use*

IMDRF/GRRP WG/N47 FINAL:2018, *Essential principles of safety and performance of medical devices and IVD medical devices*

MDCG 2021-5, 2021, *Guidance on standardisation for medical devices*

Author

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Technical reviewers

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Published white papers

- The proposed EU regulations for medical and in vitro diagnostic devices: An overview of the likely outcomes and consequences for the market, Gert Bos and Erik Vollebregt
- Generating clinical evaluation reports: A guide to effectively analysing medical device safety and performance, Hassan Achakri, Peter Fennema and Itoro Udofia
- Effective post-market surveillance: Understanding and conducting vigilance and post-market clinical follow-up, Ibim Tariah and Rebecca Pine
- What you need to know about the FDA's UDI system final rule, Jay Crowley and Amy Fowler
- Engaging stakeholders in the home medical device market: Delivering personalized and integrated care, Kristin Bayer, Laura Mitchell, Sharmila Gardner and Rebecca Pine
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- How to prepare for and implement the upcoming IVDR — Dos and don'ts, Erik Vollebregt and Gert Bos
- 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
- The European Medical Devices Regulations: What are the requirements for vigilance reporting and post-market surveillance? Eamonn Hoxey
- 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
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- 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
- Software as a medical device — A comparison of the EU's approach with the US's approach, Pat Baird and Koen Cobbaert
- 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
- Guidance on MDCG 2019-9: Summary of Safety and Clinical Performance, Amie Smirthwaite, RMQ+
- CER generation, Amy Smirthwaite, RMQ+
- Medical device clinical investigations — What's new under the MDR? - An update, Maria Donawa, Donawa Lifesciences
- European Union Medical Device Regulation and In Vitro Device Regulation: unique device identification: What is required, and how to manage it, Mary Gray, Johnson and Johnson Medical Device Companies (JJMDC)

Forthcoming white papers

- *Requirements of EU-GDPR and PMCF studies, registries and surveys under the MDR (working title),* Richard Holborow
- *Performance evaluation under IVDR*, Fiona Gould

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BSI is keen to hear your views on this paper, or for further information please contact us here: julia.helmsley@bsigroup.com

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