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White Paper

MEDICAL DEVICES

# Clinical Evaluation of Medical Devices: The Increasing Responsibilities of Clinical Evaluators

CROMSOURCE is an international provider of outsourced services to the medical device pharmaceutical, biotechnology and industries, specialised in clinical development and staffing solutions.

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## Setting out clinical evaluation in EU legislation

The requirement for clinical evaluation of medical devices was originally set out by EU legislation in the early 1990s, with the clinical evaluation being defined in Annex X of the Medical Devices Directive (MDD) 93/42/EEC[1] and Annex 7 of the Active Implantable Medical Devices Directive (AIMDD) 90/385/EEC[2].

The transitional period allowing a gradual implementation of the directives ended back in in March 2010, over eight years ago. In December 2009, Revision 3 of MEDDEV 2.7/1 guideline[3] on clinical evaluation for manufacturers and notified bodies recommended that:

"The clinical evaluation should be conducted by a suitably qualified individual or individuals. A manufacturer must be able to justify the choice of the evaluator(s) through reference to qualifications and documented experience. As a general principle, evaluators should possess knowledge of the following: the device technology and its application; research methodology (clinical investigation design and biostatistics); and diagnosis and management of the conditions intended to be treated or diagnosed by the device."

## How MEDDEV 2.7/1 Revision 4 clarified the clinical evaluation process

In June 2016, Revision 4 of MEDDEV 2.7/1 was published[4]. This revision provides much more detailed and clearer guidance to manufacturers and notified bodies, and makes significant changes to the clinical evaluation process. Manufacturers are expected to improve the quality of their Clinical Evaluation Reports (CERs) and notified bodies are to be much more critical of the data presented. The revised guidance was prepared in anticipation of Regulation (EU) 2017/745, known as the Medical Device Regulation (MDR)[5], which was in the final stages of development. It represents a useful first step towards compliance with MDR's more stringent clinical evidence requirements.

Although not entirely aligned with MDR and not legally binding, the guideline presents a uniform, state of the art, scientific method to conduct a clinical evaluation.

Revision 4 of MEDDEV 2.7/1 provided clarification of recommendations which had previously been vague and also introduced new recommendations.

The key changes are highlighted below:

- A new requirement for initial scoping and preparation of the Clinical Evaluation Plan, facilitates clear definition of objectives of the clinical evaluation and links them to specific safety, performance and risk-benefit endpoints (Section 7). Clinical evaluation is heavily emphasised as an ongoing process that needs to be effectively planned and revisited throughout the lifecycle of a medical device.

- Details on literature searching to establish and document current knowledge/ the state of the art and available treatment options as well as the risks and benefits of other available treatment options (Clause 8.2). A clinical expert's involvement is anticipated.

- Much more discussion of factors which determine the scientific validity of data, including statistical considerations (Clause 9.3.1). Guidance is provided how to ensure scientific validity of data at different stages of the clinical evaluation process: literature search and retrieval methods (Section 8 and Appendix A5); data appraisal and weighting (Section 9 and Appendix A6); and the analysis of data and demonstration of conformity (Section 10 and Appendix A7).

- Strict requirements for establishing equivalence. Each individual device with which equivalence is claimed must meet all three equivalence criteria: clinical, technical and biological. Design differences should be highlighted and their impact on clinical safety and performance discussed (Appendix A1). There is a new requirement of demonstrating sufficient access to data for equivalent devices and the manufacturer's notified body is directed to challenge this claim (Appendix A12.2.3).

- An improved process for benefit risk assessment is described with a list of key considerations relating to device risk and determination of sufficient clinical evidence (Appendix A2). The evaluation and quantification of benefits and risks, and the evaluation of the overall benefit risk profile is discussed (Appendix A7.2).

- The importance of post market surveillance (PMS) and post market clinical follow-up (PMCF) is reinforced. The requirement for notified bodies to ensure that PMCF studies are always considered and any decisions made appropriately justified is highlighted in Appendix A12.

Data derived from literature, data from clinical investigations, PMS and PMCF, and other clinically relevant data are analysed and appraised in the clinical evaluation and must be used to regularly update the CER.

## Clinical data and clinical evidence requirements under MDR

A fundamental revision of MDD and AIMDD was needed to establish a robust, transparent, reliable and sustainable regulatory framework for medical devices. This effort led to the EU Medical Device Regulation (EU 2017/745)[5], which entered into force on May 26, 2017. The official Date of Application for the MDR was May 26, 2021, but certificates to the MDR can be issued from a designated notified body during the transition period, and will have validity of five years. Manufacturers will need to carefully plan ahead for the transitioning of their devices to new certificates as all devices currently on the market will need to be re-evaluated and certified under MDR when their existing certificates under the current directives expire.

While the approach to clinical evaluation described in MEDDEV 2.7/1 Rev. 4 is similar to that described in the MDR, the requirement for demonstrating clinical benefits of a medical device has been added to the MDR definition of "clinical evaluation": "a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer" (Chapter I, Article 2 (44)).

The MDR definition of "clinical evidence" also stresses clinical benefits with MDR defining it as: "clinical data and clinical evaluation results pertaining to a device of a sufficient amount and quality to allow a qualified assessment of whether the device is safe and achieves the intended clinical benefit(s), when used as intended by the manufacturer" (Chapter I, Article 2 (51)).

One of the greatest challenges for manufacturers under MDR will be putting together sufficient clinical data to satisfy the MDR's more stringent clinical evidence requirements. MDR therefore emphasises the importance of early planning. The contents of a Clinical Evaluation Plan are described in more detail than in MEDDEV 2.7/1 Rev. 4; these should include, among other requirements: consideration of clinical benefits with clinical outcome parameters; methods to examine safety with reference to determination of residual risks and side effects; and parameters to determine benefit-risk ratio acceptability based on state of the art and a clinical development plan (Annex XIV, Part A1).

Stricter rules will apply to clinical data requirements. For implantables and class III devices, **clinical investigations** that have been carried out under the responsibility of a sponsor should, as a general rule, serve as the source of clinical data (Article 63). Manufacturers may only base the clinical evaluation on data from an equivalent device under very strict conditions - for implantables and Class III devices, only if it is the same manufacturer or if there is a contract for full access to technical documentation (Chapter VI, Article 61(5)). Manufacturers of non-implantable and non-class III devices who wish to use clinical data relating to equivalent devices will not require a contract but will need to demonstrate "sufficient levels of access" (Annex XIV, Part A3).

Manufacturers will also face increased PMS requirements.

Both MEDDEV 2.7/1 Rev. 4 (Section 4) and MDR (Article 2 (48)) state that clinical data should be sourced from:

- Clinical investigation(s) of the device concerned;
- Clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated; or
- Reports on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated. However, MDR specifies: "reports published in peer-reviewed scientific literature".

The MDR adds an additional key source:

- "Clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up" (PMCF).

PMCF must be proactive and appropriately planned (Annex XIV, Part B(5)): "PMCF shall be understood to be a continuous process that updates the clinical evaluation. When conducting PMCF, the manufacturer shall proactively collect and evaluate clinical data".

PMCF must be documented in the form of a PMCF plan and the outcomes assessed in a PMCF evaluation report which should be included in the CER, the post-market surveillance report and, if applicable, findings should be included in the summary of safety and clinical performance and Periodic Safety Update Report (PSUR).

The MDR does not discuss who should perform clinical evaluation. However, the increased stringency and scope of clinical evaluation under MDR will place additional demands on the clinical evaluators.

PMCF must be documented in the form of a PMCF plan and the outcomes assessed in a PMCF evaluation report which should be included in the CER, the post-market surveillance report and, if applicable, findings should be included in the summary of safety and clinical performance and Periodic Safety Update Report (PSUR).

The MDR does not discuss who should perform clinical evaluation. However, the increased stringency and scope of clinical evaluation under MDR will place additional demands on the clinical evaluators.

## What is expected of clinical evaluators?

The discussion below refers mainly to the current situation under MEDDEV 2.7/1 Rev. 4. This discussion will almost entirely be applicable to MDR as well with a few changes which are highlighted.

MEDDEV 2.7/1 Revision 4 brought clarification of what is expected of clinical evaluators. ”Evaluator” or “evaluators” is mentioned 55 times throughout the document. Specific requirements for the expertise and experience of evaluators are introduced, including a relevant higher education degree and five years’ related professional experience, or ten years’ professional experience if a degree is not considered a prerequisite for the task. Deviations from these requirements should be documented and duly justified. For every device under evaluation the manufacturers are required to define requirements for the evaluators and justify the choice of the evaluators through reference to their qualifications and experience.

Clause 6.4 states “The clinical evaluation should be conducted by a suitably qualified individual or a team” and goes on to specify a wide range of required competencies (listed in Table 1).

| As a general principle the evaluators should possess knowledge of the following: |
| --- |
| **Research methodology** (including clinical investigation design and biostatistics); |
| **Information management** (e.g. scientific background or librarianship qualification; experience with relevant databases such as Embase and Medline); |
| **Regulatory requirements** |
| **Medical writing** (e.g. post-graduate experience in a relevant science or in medicine); |
| **Training and experience in medical writing** |
| **With respect to the particular device under evaluation the evaluators should in addition have knowledge of:** |
| **The device technology and its application;** |
| **Diagnosis and management of the conditions** intended to be diagnosed or managed by the device, knowledge of medical alternatives, treatment standards and technology (e.g. specialist clinical expertise in the relevant medical specialty). |

**Table 1: Required competencies for evaluators**

## A team-based approach to clinical evaluation is advisable

The number of requirements placed upon the evaluator(s) indicates that a team-based approach is advisable. Finding one person with experience, expertise and knowledge to fulfil every aspect of the evaluators' role is highly unlikely in most circumstances. Anyone who undertakes the identification, appraisal and analysis of a data set included in the clinical evaluation should be considered an evaluator.

The guidelines tend to describe either the manufacturer or the evaluator(s). It has been assumed that the clinical evaluation is performed by both the manufacturer and evaluator(s). There is no requirement for evaluators to be employed by the manufacturer - only that a CV and declaration of interest for each evaluator is provided. However, it is not clear whether anyone who is involved in performing the clinical evaluation, but is not the manufacturer, must be an evaluator by default.

The most appropriate team to perform the clinical evaluation should be considered by the manufacturer as early as possible as it may take time to identify the individuals best placed to perform the tasks required and secure their time accordingly. Not everyone involved has to be an evaluator, but experts should be consulted and, in some circumstances, it may be appropriate for them to be an evaluator. Manufacturers and evaluators must be aware of the requirements placed upon them and work to fulfil these requirements wherever possible. Referring to the guidelines when planning to perform clinical evaluation and throughout the process itself is essential.

Clinical evaluation may be performed anywhere providing the evaluators have access to the necessary information and documentation. It can be performed in-house solely by the manufacturer with involvement from employees at one or more sites. However, it is often performed in conjunction with external parties (e.g., medical writers, consultants). Ultimately, clinical evaluation remains the responsibility of the manufacturer and the CER is part of the technical documentation.

Figure 1 illustrates inputs into a typical clinical evaluation. These inputs are discussed in more detail below.

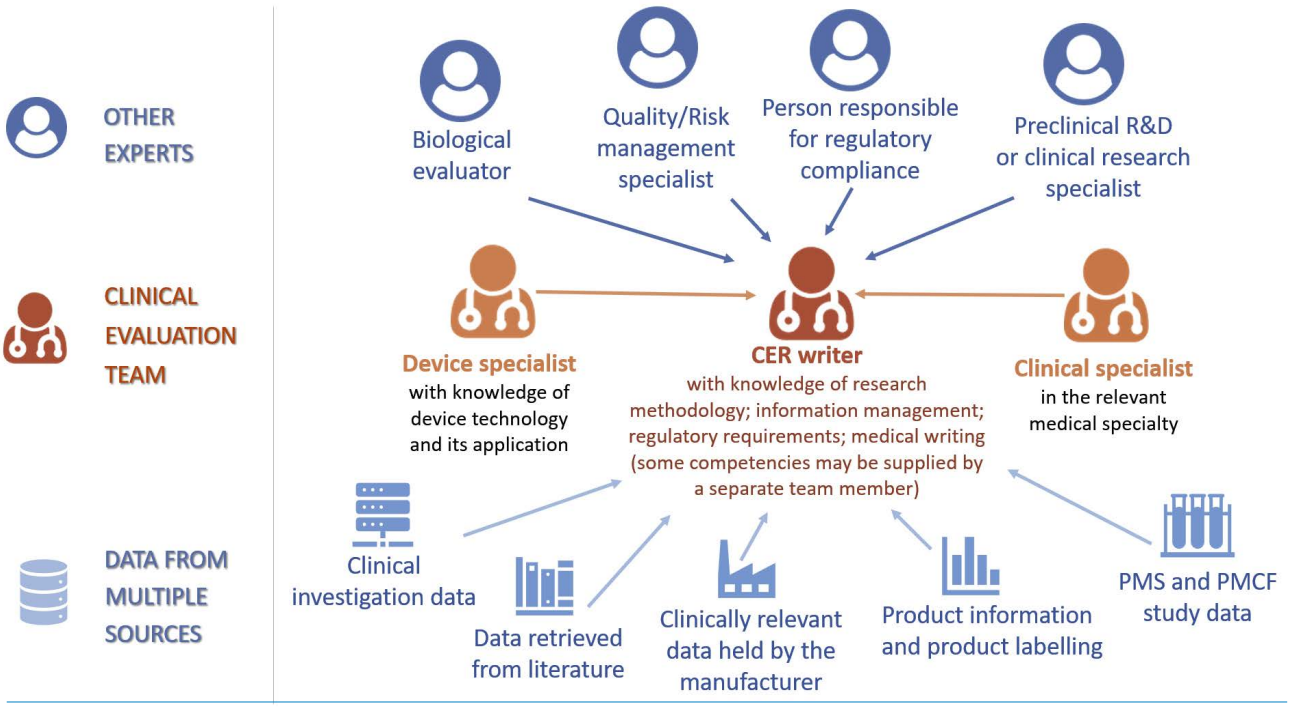


**Figure 1: Inputs into a typical clinical evaluation**

The CER writer often assumes a coordinating role within the **clinical evaluation team** which typically also includes a device specialist and a clinical specialist; these individuals will almost always act as signatories to the CER. **Other experts** help to inform the clinical evaluators; these individuals may or may not acts as signatories to the CER, depending on the circumstances. **Data from multiple sources** provide an input into the clinical evaluation.

## Evaluators who act as signatories to the CER

Evaluators who sign the CER are responsible for its contents and may include a CER writer, a device specialist and a clinical specialist. Table 2 outlines the roles of the evaluators who may act as signatories to a CER. Table 3 provides real-life examples of CERs prepared by a team of evaluators (signatories).

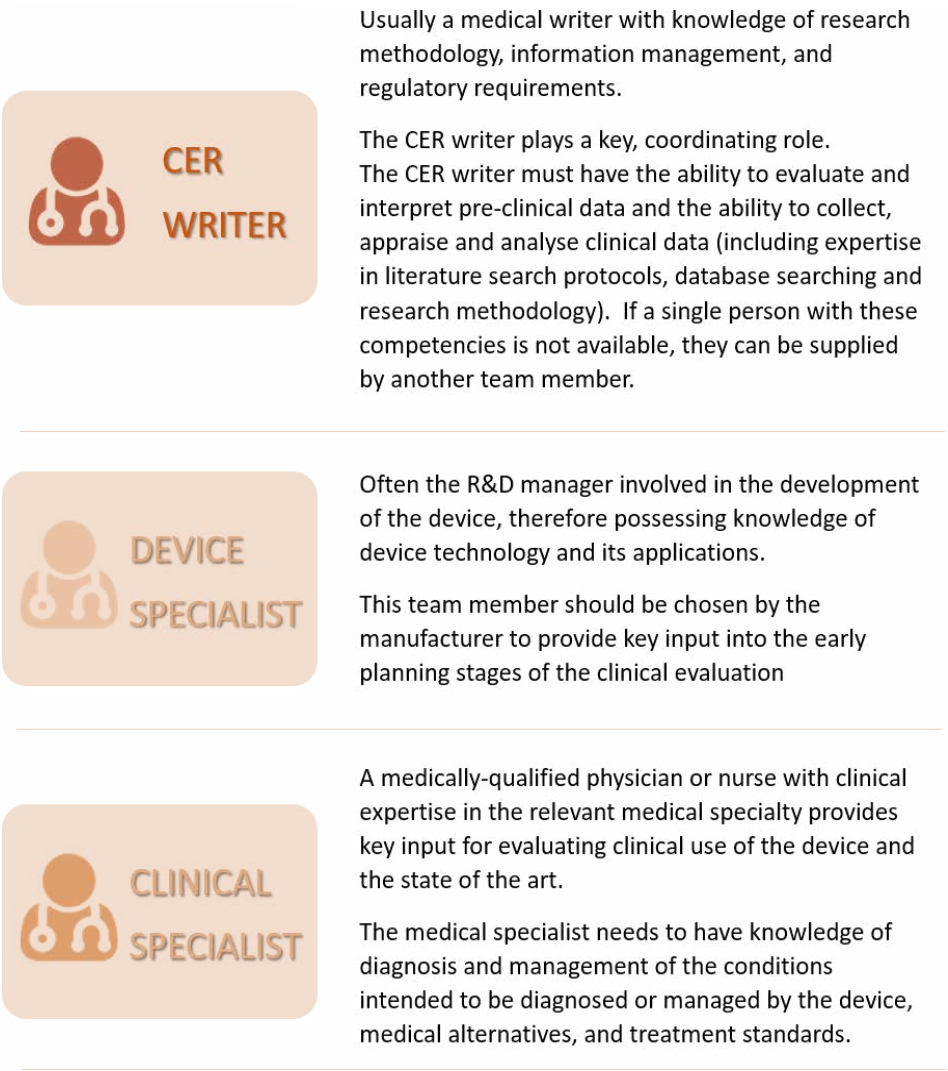


**Figure 2: Evaluators who may act as signatories to a CER**

| Device | Class | Reason for clinical evaluation | Signatories to the CER and their experience [1] |
|---|---|---|---|
| Endotracheal tube | IIa | Updated due to material change | CER writer/clinical specialist: Internal, Clinical Affairs Specialist (6 years);<br>Device/regulatory specialist: Internal, Regulatory Affairs Manager (>5 years);<br>Clinical specialist: External, Anaesthetist (25+ years) |
| Ophthalmic laser | IIa | Updated to revision 4 | 2 x CER writers: External, Medical Writer (25 and 20 years);<br>Clinical specialist reviewer: External, MD (13 years);<br>Clinical specialist reviewer: Internal, Clinical Affairs Manager (12 years);<br>Device specialist: Internal, R&D Manager (>5 years);<br>Regulatory specialist: Internal, Regulatory and Clinical Affairs Director (4 years) |
| Percutaneous Transluminal Coronary Angioplasty (PTCA) catheter | III | Rejection of CER by notified body prior to CE-marking | CER writer: External, Report Writer (5 years);<br>2 x device specialists: Internal, R&D Manager; Manager (>5 years);<br>Clinical specialist: External, MD (20 years+) |

**Figure 3: Examples of CERs prepared by a team of evaluators (signatories)**

[1] All signatories listed have higher education degrees. "Internal" refers to individuals employed by the manufacturer.

## Experts who provide an input into clinical evaluation

The clinical evaluators (signatories to the CER) receive an input from various experts. Experts who may be involved are listed in Table 4, together with a description of their roles. In some circumstances, it may be appropriate for an expert to act as a signatory to a CER.

### Biological evaluator

An individual involved in performing biological and biocompatibility evaluation.

### Quality/Risk management specialist

A professional with an understanding of risk management principles. The MDR (item 33) stipulates that "the risk management system should be carefully aligned with and reflected in the clinical evaluation for the device.. The risk management and clinical evaluation processes should be inter-dependent and should be regularly updated".

### Person responsible for regulatory compliance

One of the new requirements of MDR is that every manufacturer should appoint at least one person responsible for regulatory compliance (Chapter I, article 15).

Clinical evaluation of devices is not listed as a responsibility, but responsibilities include checking the conformity of the devices before a device is released; drawing up the technical documentation; and fulfilling post-market surveillance obligations – activities that intersect with activities involved in clinical evaluation.

In particular, the regulatory specialist has an important role in checking device labelling requirements, claims made about the device, and PMS and PMCF requirements.

### Preclinical R&D specialist

A biomedical scientist with knowledge of pre-clinical studies, implementation and interpretation.

### External expert panels

Under MDR, for class III devices and for active devices intended to administer and/or remove a medicinal product, a manufacturer should be able to consult voluntarily an expert panel, prior to initiating clinical evaluation. The consultation will relate to clinical development strategy and proposals for clinical investigations. The manufacturer should document its consideration of the views expressed by the expert panel in the CER (item 57).

### Clinical research specialist

A clinical scientist with knowledge of pre- and post-market clinical investigations (design, conduct, analysis).

### Usability engineering specialist

An engineer with an understanding of usability engineering. The specialist knowledge must be relevant to the particular device (e.g. medical software, electrical components).

**Figure 4: Experts who may provide input into clinical evaluation**

## Conclusion

MEDDEV 2.7/1 Rev. 4 and the MDR place an increasing number of stringent requirements upon clinical evaluator(s). These are best met by a team consisting of core clinical evaluators (who appraise and analyse clinical data and act as CER signatories) and supporting experts. A carefully assembled and well-functioning team will be needed to meet the additional clinical evidence requirements of the MDR, in particular the requirement to demonstrate clinical benefit, in addition to safety and performance, of devices based on data derived predominantly from clinical investigations and PMCF studies.

Clinical Evaluation Reports (CERs) and CE certifications under the EU's previous Medical Device Directive 93/42 EEC (MDD) were historically based only on product equivalency. However, new expectations under MEDDEV 2.7/1 Rev. 4 now present challenges for EU medical device manufacturers provided that clinical data expectations under the new Medical Device Regulation (MDR) require more in-depth assessments and increased expectations of Notified Bodies (NBs).

The EU Medical Device Regulation 2017/745 (MDR) substantially tightens the requirements for equivalence justification compared even to MEDDEV 2.7/1 Rev. 4, and makes it now almost impossible to leverage a competitor's clinical data. Although there remains significant uncertainty regarding the MDR – with many implementing and delegating acts to be drafted and approved – in the case of clinical evidence, MEDDEV 2.7/1 Rev. 4 provides clear expectations for MDD compliance with Annex X and Annex 7 of the Active Implantable Device Directive 90/385/EEC (AIMD), as well as Art 61 and MDR Annex XIV.

For most CERs, a writer with broad content experience, a knowledge of the therapeutic area, a familiarity with devices with the same general type of technology, and knowledge of MEDDEV 2.7.1 will be quite up to the task. Someone with a solid knowledge of MEDDEV 2.7.1 is a must. Knowledge of the current version, an understanding of the EU regulatory framework for devices, especially the role of the notified bodies in review of a CER, would be pluses indeed.

Although the new revision is longer and more detailed, in practice most of the differences are to provide helpful guidance and examples, and to clarify existing requirements, rather than to introduce new requirements. Much more explicit guidance is provided to manufacturers on how to undertake a robust and systematic clinical evaluation, and how to demonstrate the scientific validity of their data and conclusions.

While this White Paper places focus on the clinical evaluators, it is also incumbent upon the evaluators to be aware of the key changes and some clarification considerations with MEDDEV, not only qualifications of report authors and evaluators, but including, but not limited to frequency of updates to the Clinical Evaluation Report (CER); specific and measurable objectives for the CER; establishing the state of the art; scientific validity of data; device equivalency; access to data for equivalent devices; clarification with Post Market Surveillance (PMS) and Post Market Clinical Follow-up (PMCF), risk-benefit; and certainly when is a clinical investigation required and assessing sufficient clinical evidence, and more.

Since the date of application for MDR and release of MEDDEV 2.7/1 Rev. 4, medical device regulatory professionals are craving clarity on issues related to clinical data that supports new global submissions and ongoing regulatory compliance. Late in 2019, the International Medical Device Regulators Forum (IMDRF) issued three updated guidance documents that clear up confusion and harmonize the guidance with the EU MDR for additional consultation. The Medical Device Coordination Group (MDCG) has released additional guidance as well about the provisions that must be addressed for the implementation of the MDR and certainly information on the interpretation and execution concerning the clinical evaluation and investigation. Yes, MEDDEV Rev. 4 is approximately 50% larger than its predecessor because of the level of detail. Fortunately, the document was written by many of the same people who wrote the latest MDR requirements published in May of 2017, so we hope to see these documents aligned. Industry should be aware and not surprised that there could be a Revision 5 in the future. Stay tuned.

## Q&A

Q: What is the definition of an “Evaluator”?

A: Evaluator isn’t specifically defined in the MEDDEV. We interpret this as the person (or persons) who is ultimately responsible to appraise and analyze the clinical data and determine whether it is sufficient to show compliance. In general, the clinical evaluation needs to be performed by “a suitably qualified individual or a team.” If any members of that team are making the final judgement about the data, we would call them evaluators.

Q: Will devices already on the market be required to show equivalence?

A: This depends on whether you are relying on clinical data that was generated on equivalent devices. If so, requirements for equivalence in Rev. 4 must be met, even if the device is already CE marked (the CER is an ongoing process). You may also replace the original clinical data on equivalent devices with PMS data gathered on the device itself.

Q: How will the new European Medical Devices Regulation (MDR 2017/745) impact CER requirements?

A: MDR 2017/745 and a revised CER guidance (MEDDEV 2.7/1 Rev. 4) were released. Both documents reflect more stringent requirements for clinical data. There will be a three-year transition period to the MDR, which became effective on May 26, 2021.

Q: How should manufacturers of small, simple, and safe devices (e.g., a thermometer) comply with the guidance if their product does not require a clinical investigation and/or does not have appropriate or available literature?

A: If you device is already on the market, PMS data should be available to support it. It’s important to clearly identify aspects of safety and performance that can only be addressed by clinical data and focus the CER on that data. A good review of the state of the art will also set the relative risks and benefits in context, as well as identify any standardisation of the device design that may help identify equivalent devices. However, even for lower classification devices, it may be necessary to conduct a clinical study if clinical data is not available in the published literature, or if the device has a novel feature.

Q: Who should perform clinical evaluations?

A: Many device manufacturers are receiving nonconformities and findings, because the evaluators are not sufficiently qualified or the qualifications are not documented or there is no evidence to support this. It’s vital that the qualifications must follow 6.4 of the new guidance and the qualifications set by your company should be documented in your procedure for clinical evaluations. You must document these qualifications with more than an abstract, but you will also need to present a declaration of interest for each evaluator. Evaluators need knowledge in clinical study design, information management, regulatory requirements, biostatistics and medical writing. Evaluators also need knowledge specific to the device, its technology and its application. Evaluators must also have a higher education degree in the field and at least sufficient number of years, like 5 years of experience or 10 years of experience if they do not have a higher education degree. Yes, it’s quite likely you will need to assemble a team to perform the evaluations due to the breadth and depth required of meeting the criteria and expectations.

## References


1. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
2. Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical device.
3. The Council of the European Communities (2009) MEDDEV 2.7/1 revision 3. December 2009, Guidelines on Medical Devices: Clinical Evaluation: A Guide for Manufacturers and Notified Bodies incorporating changes introduced by Directive 2007/47/EC amending Council Directive.
4. The Council of the European Communities (2016) 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.
5. 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.


## About the Author


**David R. Dills** - Regulatory Services Department Director, CROMSOURCE


David joined CROMSOURCE in 2018 as Regulatory Services Department Director. He has more than 30 years of leadership experience in the pharmaceutical and medical device industry within the regulatory affairs and compliance space.

He has held positions of increasing responsibility with sponsors and service providers of various sizes, including large, global OEM's/sponsors, consultancies and a global CRO, as well as virtual, small, mid and large-sized enterprises.

He has worked with clients in ASEAN/APAC, EMEA and The Americas, and certainly with FDA and the global Health Authorities with product portfolios covering multiple therapeutic areas and medical specialties.

He is providing the global regulatory capabilities and regulatory intelligence support for clients and collaborating with our internal stakeholders. In addition, to being a professional member with industry associations, advisory boards, prolific speaker at industry events, he navigates the regulatory landscape throughout the product life cycle and regulatory crisis management. In addition, David is responsible for the development and launch of new services in the regulatory and strategic consulting space.

## About CROMSOURCE

**CROMSOURCE** is an ISO-certified international provider of outsourced services to the pharmaceutical, biotechnology and medical device industries, specialising in clinical development and staffing solutions. CROMSOURCE was founded in 1997, more than 25 years ago. Its successful growth has been built on stability, integrity, and high levels of customer satisfaction, all of which contribute to a high rate of repeat and referral business. We have grown steadily, but responsibly, to become an organisation of over 350 organised and well-trained experts.

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**European Headquarters**
Via Giorgio De Sandre, 3
37135 Verona - Italy
Direct: +39 045 8222811

**North American Headquarters**
8000 Regency Parkway, Suite 575
Cary, NC 27518 - USA
Direct: +1 919 626 9882


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