MEDDEV 2.7/1 REV 4 & CERs

The new revision of MEDDEV 2.7.1 was published June 29, 2016. The changes from Rev 3 to Rev 4 are substantial. Most manufacturers who sell into the EU market will require significant effort to update CERs to meet the new requirements. Rev 4 is more prescriptive and requires manufacturers to provide greater quantity and quality of information for clinical evaluations. At the same time, the guideline now includes additional expectations in terms of equivalence and the data used to establish equivalence and adds increased requirements for the expertise of the evaluators.

SIGNIFICANT CHANGES

Significant changes to MEDDEV 2.7/1 Rev 4 include:

- Clinical Evaluation Plan
- Frequency of CER updates
- Evaluator qualifications
- Equivalence
- State of the art

R&Q CAN HELP

R&Q can help you meet the requirements of MEDDEV 2.7.1 Rev 4 with strategic planning and hands-on support. Our services deliver business-balanced solutions that are right for your business. Our services include:

- **CER Assessment**: Conduct an assessment between the company's device or family of devices and the requirements of MEDDEV 2.7/1 Rev 4 and develop a report that will define and prioritize the risks facing the company, and provide recommendations on when and how to mitigate the risks.
- **Clinical Evaluation Plan Strategy**: Create a Clinical Evaluation Plan (CEP) strategy outlining key elements to consider for the Clinical Evaluation Report to meet the requirements of MEDDEV 2.7/1 rev. 4 and EU MDR. This includes:
  - o Evaluation of options for equivalence
  - o Evaluation of options for State of the art
  - o Suggestions for potential sources of clinical data and when a clinical investigation may be needed
  - o Suggestions for sources and types of Post-Market Surveillance data
  - o Suggestion for sources of non-Clinical data
  - o General guidance.
- **Clinical Evaluation Plan**: Develop a Clinical Evaluation Plan for the Clinical Evaluation Report to outline the requirements for equivalency; state of the art; qualified evaluators; data sources to be used (e.g., literature search or clinical investigation); and post-market surveillance as recommended in MEDDEV 2.7/1 rev. 4 and EU MDR.
- **Clinical Evaluation Report**: Prepare a Clinical Evaluation Report to establish conformity to the essential requirements, a positive risk/benefit profile, post-market requirements, and frequency of updates.
- **Clinical Literature Review – Safety and Performance**: Safety & performance clinical literature review using multiple databases that includes a literature review protocol; identification, appraisal, and analysis of the literature to substantiate the clinical need, safety, and performance; and a report summarizing the findings.
- **Clinical Literature Review – State of the Art**: State of the art clinical literature review using multiple databases that includes a literature review protocol; identifying, appraising, and analyzing current technology and medical treatment alternatives; and a report summarizing the findings.

See back for specific CER experience...

CER EXPRIENCE

R&Q has supported a broad range of CER projects across many therapeutic areas and product types.

CLASS I ■ **CLASS IIa** ■ **CLASS IIb** ■ **CLASS III**

Therapeutic areas with CER projects:

- Cardiovascular - implantables, injection systems, syringes, catheters, LVADs, balloon pumps
- Respiratory - CPAPs, CPAP masks, respirators, tubing
- General hospital - wound care, infusion pumps
- Dental - orthodontics
- Orthopedic implantable - hips, spine, knees
- Obstetrical and gynecological - contraception aid
- Dermatology

CERs COMPLETED IN PAST THREE YEARS

R&Q Supporting Tools

- MEDDEV 2.7/1 Rev 4 Checklist
- Clinical Evaluation Report Procedure
- Clinical Evaluation Plan Template
- Clinical Evaluation Report Template

CONSULTANTS WITH CER EXPERIENCE COMPLIANT TO MEDDEV 2.7/1 REV 4 > >

R&Q APPROACH AND PROCESS FOR CERs

Based on the Six Sigma DMAIC process, R&Q uses the following process to ensure client success for CER projects:

- Understand client's "big picture" and ensure that the scope of the activity is clear to all those involved.
- Proactively request information to mitigate potential issues of data management early in the project.
- Understand clients' business needs and objectives, and consult in ways that will help clients' bottom line.
- Proactively escalate difficult or nebulous issues to R&Q program management leadership to avoid any future challenges.
- Plan and execute thorough reviews via a pre-determined schedule to keep everyone engaged and informed.

Unlike other regulatory consulting firms, the majority of R&Q's consultants are **trained engineers and scientists with direct experience in the medical device industry, product development, and Regulatory Affairs and Quality Engineering**. The benefits of having engineers developing CERs include:

- The device description section involves a technical description of the device and any design changes.
- The equivalence section includes a technical comparison of the specifications to another device.
- The majority of literature contains technical, design, and engineering information and statistical information.
- Understanding the design, Design History File, and engineering changes will be critical to this program.