COMBINATION PRODUCTS
DEVICE SPECIALISTS®

Combination Products Technical Documentation (Regulatory Service)

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The technical documentation (TD) of the device component in combination products must demonstrate compliance with the relevant General Safety and Performance Requirements (GSPRs) outlined in the Medical Device Regulation (MDR)

Be the best & save money

CPDS has developed a coherent series of trainings and services to meet the diverse needs of the Pharma combination product manufacturers and their suppliers. The methods used are proven and mature (30 years of experience).

Key features of TD gap assessments by CPDS:

- Holistic Approach: CPDS takes a comprehensive approach to gap assessments, evaluating all aspects of your TD and QMS processes that govern the TD
- Custom Solutions: CPDS provides tailored solutions based on the specific needs and challenges of your combination products, ensuring a customized and effective compliance strategy
- Streamlined Evaluation: CPDS streamlines the gap assessment process, saving you time and resources while ensuring no critical aspect is overlooked.
- Detailed Reporting: We offer detailed reports that highlight gaps and provide clear, actionable recommendations to address any deficiencies
- Ongoing Support: Beyond the initial assessment, CPDS provides ongoing support to help you implement and sustain compliance practices

Read more in the recent published white paper (+ link)

1. Conformity Assessment
The TD undergoes conformity assessment by a notified body (NoBo). This involves detailed review of Device documentation to ensure it meets the General Safety and Performance Requirements (GSPRs) of the MDR

Certification
If the documentation meets all necessary requirements. NoBo issues a CE-certificate or opinion report demonstrating that the device component complies with the GSPRs. Resulting CE-certificate or NoBo opinion report can be included in the Drug Master File for submission to the European Medicines Agency (DIA)

Obtain CE-Certificate or NoBo opinion report
>
Include in Drug Master File
>
Submite to EMA for approval

2. Feedback and Corrections
Any gaps or issues found during the review. will result in NoBo feedback. The manufacturer will then need to address these issues and resubmit the documentation for another review

Continuous Monitoring
Even after certification, the manufacturer must continuously monitor the product and maintain the TD. Periodic audits and updates to the TD might be necessary to ensure ongoing compliance with regulations and standards

Technical Documentation Gap Assessment

Depending on the chosen conformity assessment routes, this involves either:

1. Reviewing the technical documentation of at least one device component of your DDC products for submission to a notified body to obtain a CE-certificate for the CE-mark of conformity* or:
2. Reviewing the technical documentation for a notified body opinion report for submission to the Regulatory Authority (EMA)*.

*If the device bears the CE mark of conformity, obtaining a copy of the CE-certificate will suffice for submission to the EMA.

Custom

CPDS may review the technical documentation of all your medical device component types or medical device component family (see Definitions in ISO 13485:2016) or a limited number when you feel confident to complete the task yourself.

Availability and Costs

The review and reporting of the gap assessment is off site and is completed within five days following submission. Our assessment fee depends on the number of technical documents you agreed to submit.
Please check availability and competitive pricing!

Duration

Gap assessment of a typical TD including reporting may take several up to eight hours. In case of NoBo feedback and required corrections, the revised TD may be submitted to CPDS for supplementary review. Upon request, CPDS may participate in reworking the TD. The total number of euros to be invoiced is based on post-calculation.

Languages and Communication

TDs are expected to be written in English as will be the gap assessment report. It is advised that you appoint someone in your company responsible for communication. Communication may also be in Dutch.

What a Pharma manufacturer of a combination product will understand

Upon completion of the gap assessment of a representable device technical documentation, your will have a perfect understanding of:

- The format and contents of the required technical documentation
- The documentation structure of and way of working with GSPRs
- Correct classification of the device component
- The latest regulations, standards and guidelines
- From a NoBo point of view, the manufacturer's pitfalls
- The importance of providing only the required information
- TD change management
- Documentation consistency

Support

Beyond the initial assessment, CPDS provides ongoing support to help you implement and sustain compliance practices

The TD should cover

- Device Description: Detailed information about the device
- Manufacturer Information: Instructions and information provided by the manufacturer
- Design and Manufacturing: Details on design and manufacturing processes
- GSPRs Matrix: How the device meets safety and performance requirements
- Risk Management: Analysis and management of risks
- Pre-clinical Data: Relevant pre-clinical study data
- Clinical Evaluation and Plans: Clinical evaluation, post-market surveillance, and follow-up plans
- Special Substances: Information on any medicinal, biological or other substances in the device
- Sterilisation Information: If applicable, details on sterilization processes
- Declaration of Conformity: Statement that the device meets GSPRs

GSPRs Matrix

A GSPRs matrix helps per device or device family demonstrate that your device complies with the GSPRs of the MDR, Annex I. Here is a simplified approach:

- List the 23 GSPRs: Start by listing all 23 requirements as stated in Annex I of the MDR
- Applicability: For each requirement, mark it as:
  - Applicable (A): The requirement applies to your device
  - Not Applicable (N/A): The requirement does not apply to your device
  - Justification for N/A: If a requirement is marked as N/A, provide a clear justification explaining why it does not apply
- Method of Compliance for A: For each applicable requirement, describe how you demonstrate compliance. This could include:
  - Reference to a standard or common specification
  - Reference to FDA or EU guidance documents

Maintaining the TD

To ensure compliance with ISO 13485:2016, QMSR, and MDR, the TD must be maintained and updated through three key routes

➢ Periodic Review

- Frequency: Conduct a review of the TD and the GSPRs annually
- Scope: Update the GSPR Checklist, Risk Management Report, post-production information (including CAPA, Post Market Surveillance and Post Market Clinical Follow-up report and plans where appropriate and Periodic Safety Update Reports as per Articles 83–86 of the MDR), Clinical Evaluation (Annex XIV), and the list of applicable standards and specifications

- Process: Document the review and any decisions in the appropriate document's Revision History. Update and internally accept the TD by the responsible internal authority. Approved revised TD is included in the design and development file

➢ New or Revised Standards or Legislation

- Assessment: Evaluate the impact of new or revised standards or legislation on the TD, particularly regarding the device's compliance with GSPRs
- Impact Analysis: Subject matter experts assess the impact on, e.g., labeling, product requirements, risk management or biocompatibility
- Change Orders: New or revised standards may necessitate a Change Order for design or re-evaluation of compliance with GSPRs. Document decisions in the Revision History and prepare, assemble, and submit the required documentation for internal approval
- Approval and Inclusion: Approved revised TD is included in the design and development file

➢ Change Order

- Assessment: Determine if the change to the device part of the combination product is substantial, meaning it could affect safety or effectiveness and needs to be notified to external authorities
- Notified Body Approval: Substantial changes require notified body approval before market implementation. The changed design is not available on the market until approval is confirmed
- Implementation: Upon approval, apply the design change process and update the design and development file and technical documentation accordingly
- Where necessary, update dedicated sections of the design and development file

By following these strategies, manufacturers can ensure their TD remains compliant with the relevant regulations and standards, maintaining the safety and performance.

Risk Mitigation and Building Trust

- Proactive Management: By identifying potential compliance gaps early, CPDS helps you proactively manage risks, reducing the likelihood of regulatory issues and associated costs
- Quality Improvement: Our assessments contribute to continuous improvement of your products and processes, enhancing overall quality and reliability
- Regulatory Confidence: Partnering with CPDS builds confidence with regulatory authorities, customers, and stakeholders, showcasing your commitment to compliance and quality
- Competitive Advantage: Demonstrating a robust compliance strategy can provide a competitive edge in the market

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