Client Input Checklist for CEPs/CERs

What to ask from your client before initiating a CEP/CER

- ✓ Name of the device / Trade names
- ✓ Detailed Scope of the requested CER
- ✓ Intended medical field
- ✓ Intended use
- ✓ CE marking
  - Date the device was first marketed
  - Copy of the current EC certification / Declaration of Conformity
  - Countries the device is marketed in
  - Legal Manufacturer details
- ✓ Device classification in EU/FDA and/or any other countries this device is marketed in
- ✓ Identification of equivalent devices and/or similar devices (including devices names/trade names & manufacturer names)
- ✓ Previous MDD-compliant Clinical Evaluation Reports
- ✓ A confirmation whether this will be the first CER under MDR
- ✓ Incomplete or complete previous MDR-compliant CERs
  - A list of changes/modifications since the last incomplete or complete MDR-compliant CERs (if applicable)
  - A list of any planned changes/modifications that could have a clinical impact on the device
- ✓ Summary of Technical Documentation contents or
- ✓ STED file

If not available, the Manufacturer **should** be able to provide **in separate files all the following documentation:**

- A technical overview of the device including description, principles of operation and outline of accessories (if any) and components/specifications
- Clinical Development Plan

- IFUs and all available labelling material (including Operative Techniques if applicable)
- Sales data for the last five years (at least)
- PMS and PMCF plans and reports; latest PSUR (if available and applicable)

  Important Note: *explain to the Manufacturer the requirement to provide complaint data by date and country/region*

- CAPAS (if any)
- Up to date Risk files including Residual Risk Reports

  Important Note: *explain to the Manufacturer the requirement to cross-check the identified residual risks with the literature and external vigilance data*

- Non-clinical data; Verification/Validation data including biocompatibility data and data on packaging, usability and shelf-life
- Device-specific Clinical data (e.g. manufacturer-initiated clinical investigations)

❖ **Go through the provided files together!**

❖ **Identify any gaps and/or missing information and escalate them to the Manufacturer. It will be much more time-consuming to wait for pending information during the writing process**

❖ Ask the Manufacturer to approve your search terms BEFORE executing any literature and vigilance searches

❖ Discuss the intended clinical benefits and identify safety and performance claims along with the Manufacturer.

❖ Frame the performance and safety endpoints you will be discussing in the clinical evaluation and confirm them before starting the writing process

❖ Clarify the intentions of the Manufacturer with respect to potential requirements for additional PMCF activities