L&T Technology Services

Clinical Documentation Services

Redefining Compliance

CLINICAL DOCUMENTATION

A Clinical Evaluation Report (CER) documents the conclusions of a clinical evaluation of your medical device. It consists of analyzed clinical data collected either during a clinical investigation of your device, or collated from the results of studies on substantially equivalent devices.A favorable CER demonstrates that your device achieves its intended purpose without exposing users and patients to additional risks.

STAGES OF CLINICAL EVALUATION

- Stage 0: Scope and plan
- Stage 1: Identification of pertinent data
- Stage 2: Appraisal of pertinent data
- Stage 3: Analysis of the clinical data
- Stage 4: Clinical evaluation report, including PMS/PMCF plan

CHALLENGES SHAPING THE CER LANDSCAPE

New, stringent classification norms

Stricter technical and clinical documentation requirements

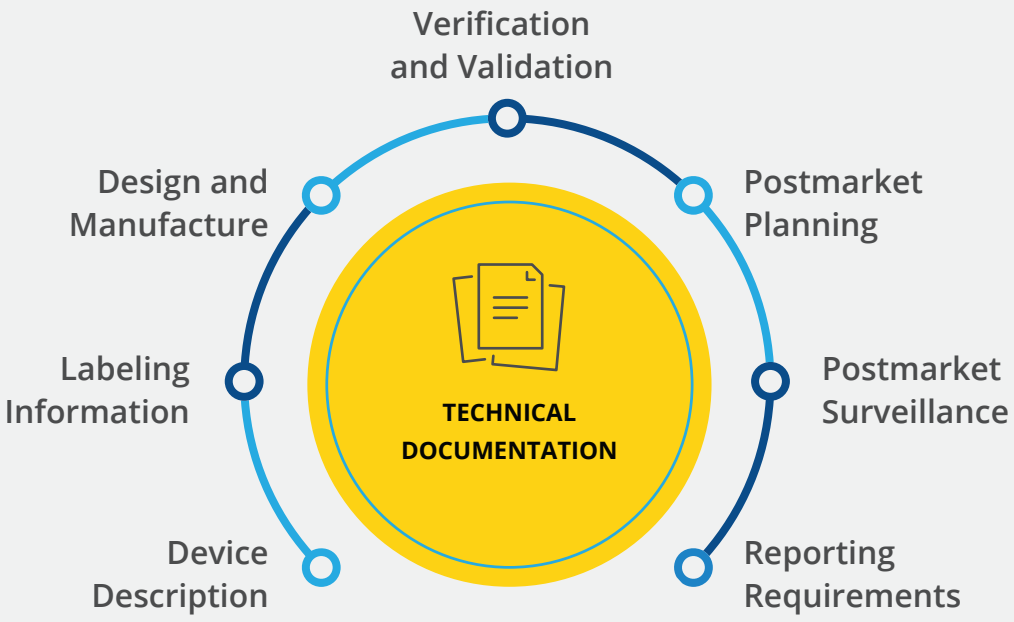
Regular reporting of PMS and vigilance

Increased need for QMS compliance and clinical data requirements

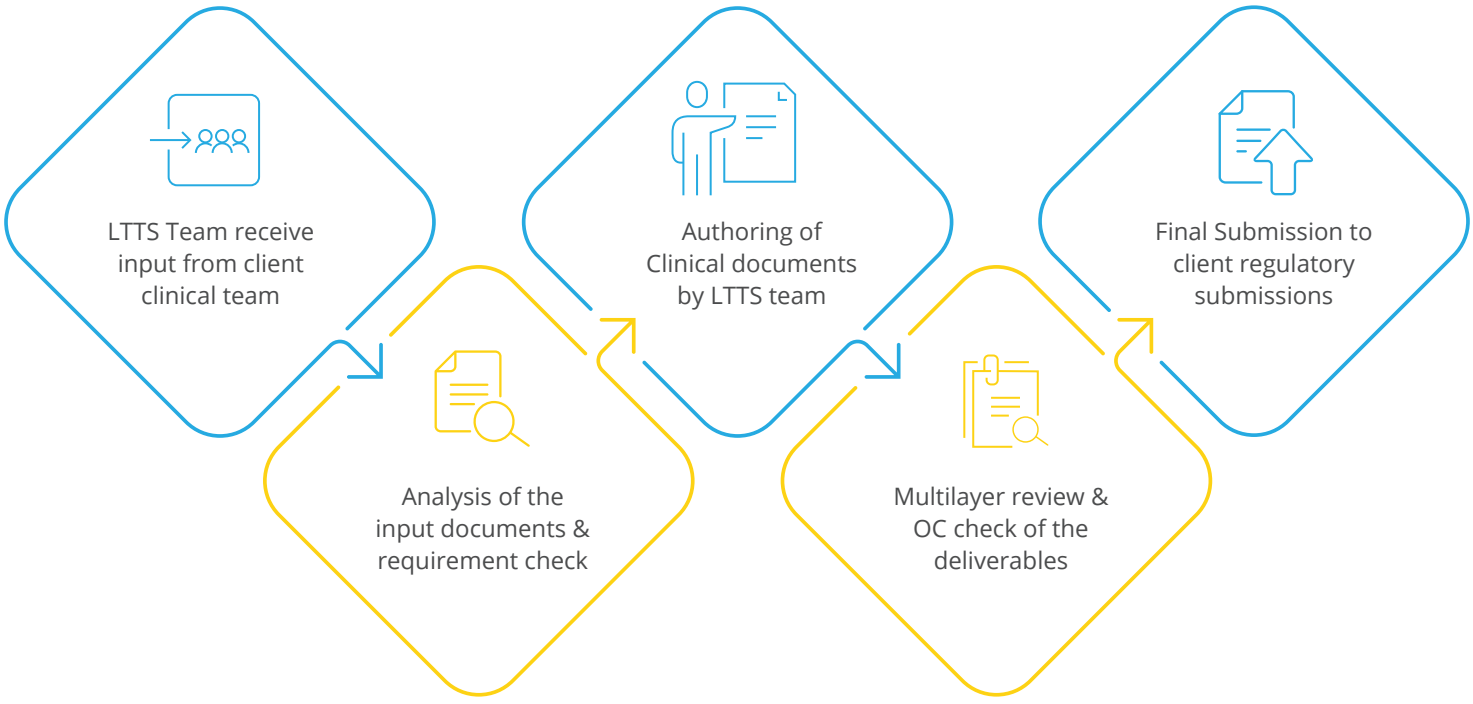
LTTS EDGE

Our team of engineers and experts help:

- Monitor, evaluate, and streamline the interface of the intended clinical evaluation with the risk management process, including an appraisal and analysis of the pre-clinical and clinical evaluation and their relevance for the demonstration of conformity with the relevant requirements
- Formulate, conduct, and ensure post-market surveillance, including any corrective and preventive actions involving the device
- Create, implement, and execute a post-market clinical follow-up plan, and where appropriate, generate a post-market clinical follow-up report.
- Define, develop, and deliver instructions for device use, providing adequate information on intended purpose, proper use, and warnings about potential risks to patients and healthcare practitioners



APPROACH


LTTS Team receive input from client clinical team
Authoring of Clinical documents by LTTS team
Final Submission to client regulatory submissions
Analysis of the input documents & requirement check
Multilayer review & QC check of the deliverables

KEY DIFFERENTIATORS

- 20+years of experience in managing compliance programs for multiple medical devices
- Establishing an optimized/streamlined workflow compliance programs using automation

BUSINESS VALUE DELIVERED

1050+ Device Labels
44+ Packaging projects

180 Tech Files Gap Assessment Completed

50 Tech Files under remediation

100+ RMF updated as per EN ISO **14971 : 2012**

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ENGINEERING **THE CHANGE**