mi CE
CONSULTANCY

mi-CE consultancy

Your regulatory compliance consultant for Medical Devices, In Vitro Diagnostics, CE marking, Clinical Evaluation and Clinical Trial Design reviews.

As a starting or experienced company in the Medical Device or In Vitro Diagnostic field you want to enter the EU market as soon as possible. However, you are not fully aware of all the regulatory requirements necessary to start selling your medical device tomorrow.

mi-CE consultancy

We offer complete (including clinical) consultancy services for medical device and IVD manufacturers for CE marking compliances according to the MDD and IVDD.

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mi-CE Services:

Consultancy for Design History Files/ Technical dossiers and regulatory compliance audits for Medical Device and In Vitro Diagnostic Device companies:

CE-Marking compliance:

- MDD full scope compliances; from low risk Class Im, Class Is to high risk Class III design history file/ technical file reviews and regulatory compliance audits (including Annex II).
- IVDD full scope compliances; design history file/ technical file reviews (including self-testing, Annex III.6) and regulatory compliance audits (including Annex IV).

Audits:

- MDD Annex II, Annex V.
- IVDD Annex IV , Annex VII.
- QMS audits: ISO 9001, ISO 13485; ISO 13485 under CMDCAS necessary for Canadian regulatory compliance.
- Internal audits.
- Subcontractor, Supplier audits; including clean room/ CEA audits and production and validation audits.

Technical dossiers/ Design History Files:

- Full Design History File/ Technical Dossier set-up/ writing and maintenance, with extensive experience in for example biocompatibility, sterilisation, packaging, labelling, pre-clinical and clinical regulatory and international standards compliances.
- Risk Analysis according to ISO 14971.
- Regulatory pathway strategy analysis,
  - With specific experience in the so-called “Borderline” products and in vitro diagnostics.

Clinical:

- Clinical Pathway strategy and reviews.
- Clinical Trials design and evaluation.
- Wide broad access to several clinical departments in leading hospitals.

Fully qualified contractors for Notified Bodies to execute Notified Body MDD/ IVDD compliance audits and to execute full scope MDD design history file reviews and list B IVDD technical dossier reviews.

- Full scope MDD, including Annex II and design dossier reviews.
- Full scope IVDD, including Annex IV and Annex III.6, for List B technical file reviews and self-testing devices.

mi-CE offers:

Experienced senior consultants/ notified body auditors (university degrees and PhDs), with background in the medical technology and medical device field; Medical Doctors (MD) with experience in the clinical evaluation and trial design, and direct relations with leading hospitals.