CS LIFESCIENCES EUROPE Ltd

First and foremost, we understand you have a business to run so at CS Lifesciences Europe we balance that with the regulatory requirements that your business needs to be compliant.

Whether navigating the FDA or obtaining CE marks, Compliance Solutions will take you through the process in a way that minimises time and resources while meeting all the requirements of such standards.

Our hands-on practical approach is based on years of working with a vast range of different types and sizes of companies in the medical device industry, meaning you get good solid advice and clearly identified actions which lead to the approvals of your products.

Straight forward, practical and effective advice to guide you through the regulatory maze of quality affairs and regulatory approval processes.

Background

CS Lifesciences Europe has many years of experience within the life science industry (including blood establishments) advising on how to best meet the regulatory requirements of the MHRA, FDA, Notified Bodies and ICH, for the one man start up to multi-national companies.

CS Lifesciences Europe supports its clients by providing a risk-analysis based approach to meeting their quality and regulatory needs. We provide our clients with clear, hands on, cost-effective guidance to assist with the development, approval, manufacture, storage and distribution of their products.

Our consultancy services range from design, implementation and maintenance of quality management systems, preparation of technical files for regulatory approvals, part-time and interim management support, auditing, both internal and external, management reviews and presentations, training and mentoring.

- Expertise in Biological, Blood Establishment & Stem Cells industries
- A hands-on approach to achieving approvals
- Straight forward and successful regulatory routes to market
- CE, FDA, PMA, Pre IDE, IDE, NICE, MHRA experience
- International regulatory submissions

USA

- 510k Preparation & Submission
- Predicate Device Identification
- PMA
- IDE & Pre IDE
- Manufacturing site registration & device listing

Quality & Management systems design, development, implementation & maintenance to:

- ISO 13485 Quality System
- MDSAP
- QSR's (Part 820)

Europe

- Preparation of CE Marking Technical File / Design Dossier
- Technical and Design File Reviews
- Medical Device classification
- EU Authorised Representative
- Product Risk Assessment

The services offered include:

International Product Approval Processes (United Kingdom, Mainland Europe, USA) and International Regulatory Submissions, which includes activities such as:

Early stage Planning & development

- Regulatory strategy & steps / route to market Risk Management strategy
- Early stage regulatory support & guidance Training – GMP training with an FDA/ MHRA focus Clinical Trial Advice and Guidance
- Product Indications for Use and proposed labelling

Implementation & Management

- GMP and FDA Compliance Regulatory inspection Gap Analysis
- Design Control (New Product Development) strategy Pre-Audit Preparations (FDA, MHRA, Notified Body) Post Audit Advice and Guidance
- Validation of Equipment, Processes, Test Methods, Facilities, Product Software
- Business and Computer Systems validation including compliance to Part 11 (Electronic Records and Signatures)
- Commercialisation
- Medical Device Vigilance and Reporting Systems

Investor diligence

- Quality & regulatory due diligence (investor ready & for investors)

European and UK Authorized Representative Service:

CS Lifesciences Europe supports non-EU and non-UK based manufacturers to allow them to designate CS Lifesciences Europe as their single Authorised Representative within the European community for compliance with the MDD/ IVD and coming new MDR and IVDR Regulations

- Experienced consultants will review your Technical File/ Design Dossier, register your medical device or IVD, as required, and respond to any questions or concerns from the Competent Authorities.
- Our service conforms to EU/UKguidelines MEDDEV 2.5/10 and includes:
  - *The legal obligations for Medical Device and IVD regulations in Europe.*
  - *Registrations for Class 1 Medical Device and General/Class A IVD devices*
  - *Obtaining Certificates of Free Sales for contracted clients.*

CS Lifesciences Europe understand that your business will often have a varying requirement for consultancy support to meet the fluctuating needs of projects and activities. That is why we provide you with a flexible approach that is tailored to your requirements.

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