Venn Life Sciences

part of Open Orphan plc

CMC regulatory team capabilities with Medical Devices

The CMC regulatory team has 20+ years' experience supporting several pharma (small and large molecules) and medical device companies to ensure the continual manufacture and supply of high-quality products to patients in licenced global markets.

The support we provide you from concept to licence approval includes:

- Objective, independent, advice on regulatory activities for each development stage, to ensure that your **combination drug-device** product adheres to applicable laws, regulations, and international guidelines
- Sound definition of device extractable and leachable requirements, materials and performance testing activities for product confirmation
- Planning and managing successful health authority and notified body interactions
- Preparation and review of device technical file and regulatory documentation for a range of regulatory procedures
- Due diligence review of device-related CMC sections for potential in-licensing assets

With this support we enhance your asset value and your company profile. We provide robust concept definition, development planning and technical regulatory strategy.

Expertise provided throughout the Drug-Device development lifecycle

Phase I	Phase II	Phase III	Post-approval
• Strategy definition • Risk management • Preparation of Clinical Evaluation study documentation	• Requirement assessment – Risk assessment Validation documentation review	• Product confirmation • Performance specification definition • Technical file writing • Inspection support	• Lifecycle management Change assessment • Post-approval submissions

Over 20+ years, the team has supported 10+ companies in developing robust plans and CMC regulatory documentation for Class IIa and Class III devices:

- Developed regulatory strategies for >5 device lifecycle products leading to several progression in most cases (5) to licencing approval
- Prepared high quality technical files to support EU and USA registrations
- Supported 10+ audits and inspections for human medicines and medical devices

CMC regulatory team capabilities with Medical Devices

Therapeutic areas supported

- oncology
- haematology
- cardiovascular
- diabetes
- implantation
- ophthalmology
- inflammatory disease

Drug type

- monoclonal antibodies
- small molecules
- human blood proteins
- human hormones
- animal hormones for human use

Case study medical device technical file remediation for EU MDR

EU Medical Device Regulation came into effect in May 2021. A medium sized device manufacturer needed technical documentation remediation for it's products to meet the new EU requirements. Support was given to assess gaps in the existing documentation and revision. Working with a multi-disciplinary team, assessment of requirements for: material specifications, product technical assessment, clinical evaluation, product performance specifications and testing, and the ability to meet product essential criteria to retain the CE mark was made. The product programme team decided which actions to take and the extent of activities required. This was done with reference to product experience, the risk presented by the gaps and the product strategy.

The technical file was updated according to the confirmed remediation plan. The files were submitted to the notified body, leading to timely and successful issuance of the CE mark.

Case study post-market alternate primary packaging selection

Our client, a global pharma company required a change to an approved drug product to accommodate an alternate primary package, a pre-filled syringe, (PFS). Advice was given to advise on the change, including technical requirements for the replacement applying to EU and USA. The change involved updated user needs requirements for the PFS, which translated into updated performance and labelling specifications. In addition to assessment, drug CMC dossier and technical documentation were prepared. The activities also lead to preparation of clinical trial applications (CTAs) for the product using the alternative PFS.

The information prepared was subsequently adapted for use with other client products. This change to accommodate the alternate PFS allowed the client increased flexibility across it's supply chain while meeting evolving customer needs.

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