Introduction - Capabilities

RegKarya Consultancy
United Kingdom
https://regkarya.co.uk/

Introduction

- Offer Regulatory Services to Life Sciences Industry
- Established in 2018 in the UK
- Works globally with network of local affiliates

CMC Authoring

At RegKarya we understand the complexity of different molecules and streamline the information based on the type of application. We provide high-quality authoring by adhering to good documentation practice with attention to detail. We perform CMC authoring of Cell and Gene Therapy (CGT) products, biological products, small molecules and Active Pharmaceutical Ingredients (API).

Clincal Development	Pre-authorisation	Post-authorisation
➢ Clinical Trial Applications ➢ Investigational Medicinal Product Dossiers ➢ Investigational New Drug Applications ➢ Scientific Advice meetings	➢ Active Substance Master File ➢ Biological License Applications ➢ Marketing Authorisation Applications ➢ EU centralised procedures ➢ Decentralised procedures ➢ Mutual recognition procedures ➢ National procedures	➢ ASMF amendments ➢ Renewals ➢ Variations

Reg-Resource

RegKarya is an expert in providing talent acquisition services. We have our own updated talent pool and assist our clients to accomplish their requirements/demands of highly specialized and dedicated candidates. More precisely, we can support our clients in filling roles for regulatory, CMC, research, pharmacovigilance, production, and marketing.

Talent Acquisition Facilities

Helping clients to identify, approach and evaluate local and global talent from junior to senior positions

Diverse Employment Services

Supporting clients to fulfil various job requirements like contracts (short term or long-term) and seasonal recruitment

Current Ongoing Projects

Post-approval life cycle mgmt. for global market	Regulatory Intelligence for Biologicals for Development of Reg Intel Tool	PV and CT documentation requirements for global market	Dossier Writing and Labelling support for MAA
Newsletter updates Country-Specific Regulatory Intelligence Reports	Clinical Trial Applications, IMPD Authoring	Dossier audit for in-license applications	Regulatory intelligence for Excipients and API

Contact us

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