Scientific/CMC Writing and Regulatory Support

CMC Regulatory Services

With in-depth understanding of scientific writing, CMC documentation requirements, and regulatory processes, Ardena fast-tracks your product towards authority approval on a global basis. We ensure the preparation and negotiation of your applications, from the initial scoping, through drafting of source documentation, towards compilation of quality dossiers, and post approval. Acting as the accountable expert within your team, we keep track of compliance and add regulatory insights into the decision-making process. Striving for a seamless flow of information in quality documentation such as Module 3, we reduce the risks and timelines of our clients.

Navigating you through drug development

ARDENA

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Scientific/CMC Writing and Regulatory Support

Ardena provides CMC and scientific writing services throughout the entire drug development process. Our dedicated team provides regulatory advice to improve quality, lower risks, and stay within budget, fast-tracking your product to authority approval on a global basis.

Our expertise covers

Scientific/CMC Report Writing

Ardena's team consists of experts in writing scientific/CMC reports using a dossier-centric approach and keeping in mind the latest ICH, EMA, FDA, or other relevant guidelines. Our expertise covers drug substance, drug product, and analytical development.

Strategic Regulatory Advice

During all clinical phases and commercial phase, our team provides strategic regulatory advice. Our strategic advice focuses on aspects such as specification setting, stability design, product classification, etc.

Clinical Trial and Marketing Application

When writing clinical trial and marketing applications, we focus on CMC sections. Ardena applies a phase-appropriate writing strategy to reduce unnecessary delays in the approval of your application. We take care of the preparation of the application, address Health Authority questions, and follow up your application until approval is received.

Post-Approval Support

Post-authorization, we maintain your marketing authorization by efficiently overseeing post-approval activities (e.g., renewals, variations, etc.). Considering the dynamic and complex environment of pharmaceutical legislation, we harness our global experience to guarantee product conformance.

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