



Insourcing CMC Regulatory Services

Program Description



A large biopharmaceutical company approached us regarding specialist CMC Regulatory Leads in the UK.

These staff were to be responsible for established International brands, including neurology and immunology. They provided lifecycle maintenance including CMC variations, new indications and safety submissions for Asia Pacific, MENA and Latin America. They were also to be involved in pre-launch activities, GAP analysis of variations, and co-ordination with both QA and supply chain. They were also to manage regulatory agency questions by providing strategic guidance and support to client subject matter experts.

Staff Requirements



The Sponsor had very specific experience requirements and the candidates chosen were proven Regulatory Affairs Specialists with global and biologics experience, as well as experience in pharmaceutical manufacturing, analytical development and quality assurance/control.

Due to our recruitment strengths, we were able to present several candidates within the first 5 business days after receipt of the requirement. All with a strong background in the pharmaceutical industry and we were also able to head-hunt candidates from a Regulatory Authority in a CMC review capacity. The whole selection process was completed within a month and the candidates started shortly after.

Results



During the assignment our employees worked as integral members of the client team, with consistently positive feedback.

The CMC Regulatory Leads thoroughly enjoyed their Sponsor-based role and valued the benefits of working for a CRO, whilst being Sponsor-dedicated.

Key Learnings



The work was successfully completed. Contracts for staff were extended and additional staff were requested as time went on.

CROMSOURCE continues to place additional staff with this Sponsor in a variety of areas, including not only Regulatory, but also Clinical Project Management.

Partnership approach to relationship, transparency, integrity and shared goals was critical to the success of the program.

Experts Providing Experts

TalentSource Life Sciences is the dedicated flexible resourcing business unit within CROMSOURCE - a business started over 25 years ago when CROMSOURCE first entered the market.

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