



Insourced Independent Quality Reviewers

Program Description



A small biopharmaceutical company approached us to work with them to find an International Team of Quality Reviewers in a niche therapy area.

The Sponsor requested either Medics or people with a very strong scientific background and experience of monitoring clinical trials.

The team were requested to have oversight of the monitoring that had already taken place with their CRO partner. Acting as a liaison between sites and Sponsor, providing feedback.

Staff Requirements



Field-based team in Russia, Romania, Bulgaria, Poland, Germany, Benelux, Spain, Italy and USA. Sponsor were experiencing a lot of GCP CAPAs at site and required individual visits. Undertaking identification of action areas – assessing the need to re-monitor, CAPA implementation suggestions, overview of work that was not reaching the required standards and facilitating patient retention strategies.

The role was to do a quality check of the CRA activities at site (site data verification discrepancies, management of pharmacy and drug accountability, frequency of interactions with the site staff, etc.), including some co-visits to address monitoring issues.

Results



Time to hire results:

Initial Request to CV submission – Average 4 days

From initial request to start date USA - 4 weeks; Europe 6-12 weeks.

Key Learnings



The project ran from 2010 to 2019 when the studies completed. The client was happy with the results that the team brought to their studies and it helped them to build their own processes around the work that the team did.

It was important to operate with a partnership approach, key to success is having transparency, integrity and shared goals. Also critical to have close oversight from line managers and a governance structure in place. We needed a very deep and detailed understanding for this niche service supply, along with an up-front investment in time to understand the client's way of working, in order to set up a clear communication plan.

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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Contact TalentSource now to discuss your needs!



European Headquarters

Mechelsesteenweg 455 Bus 5
1950 Kraainem - Belgium
Phone: +32 27680166

North American Headquarters

8000 Regency Parkway, Suite 575
Cary, NC 27518 - USA
Phone: +1 919 626 9882



www.cromsource.com

www.talentsourcelifesciences.com