TALENT SOURCE LIFE SCIENCES

SHOWCASE

Regulatory Affairs

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 resourcing market.

Experts Providing Experts

TalentSource Life Sciences is the dedicated flexible resourcing department within CROMSOURCE. Our commitment to providing the right services to support our clients has seen us at the forefront of developments in the Industry; from pioneering the provision of contract staffing solutions in Northern Europe in the mid-90's, to being early adopters of the ISO Quality Management certification in 2000. Our successful growth has been built on stability, integrity, high levels of customer satisfaction and we have grown steadily to open offices across Europe and North America and have activities running on a global scale.

The Essence of our Regulatory Resourcing Services

The key to fast regulatory approvals for clinical trials is based on having an in-depth understanding of the ever-changing global and local regulatory landscape, combined with ongoing professional relationships with regulatory personnel in each country. Flexibility, experience in multidisciplinary projects and deep knowledge of legislation and the regulatory environment are the major strengths that we look for in our resources.

Our regulatory experts provide integrated services to pharmaceutical, biotechnology, and medical device companies, working with our clients to develop comprehensive and customised solutions to optimise product development, minimise costs and time to market for novel therapies and medical devices. They constantly monitor the regulatory environment and keep track of changes in local legislation, guidelines, and regulations. We maintain high quality standards in preparation of regulatory documents and when required, support our sponsors during communications and submission to the regulatory bodies.

The CROMSOURCE resources who are fully dedicated to work on our client projects are highly experienced and committed to study success, from inception to final deliverable. We are able to assign local staff in each major market, who have a deep understanding of the local regulatory framework. They are able to support development of strategic regulatory plans for products, identify the best countries for clinical trials, and assist our sponsors in obtaining advice from regulatory authorities, including the FDA, where necessary.

Our professionals support sponsors in complying with vigilance and safety monitoring requirements for pre- and post-market trials in all territories.

Training

Generally, our sponsors are responsible for staff training on their SOPs, systems and therapeutic areas assigned. Nevertheless, TalentSource being part of a CRO, have a full set of Regulatory Services SOPs and Working Instructions available that all our staff can follow, including our externally based employees.

In addition, our professionals can benefit from access to our regulatory services team and our various leaders in Regulatory Affairs, Regulatory & Scientific Writing and in Regulatory Intelligence, to capitalise on their knowledge and experience. All our resources are trained in ICH/GCP and local regulations.

We also work closely with our Clients to identify development needs during our staff´s assignments and offer support and training to ensure enhanced performance in the role, as well as development opportunities.

Scalable and Flexible Solutions

A comprehensive range of fully flexible solutions from insourcing/staff augmentation to full-service outsourcing and Functional Solutions (FSP) and permanent recruitment for our clients.

Being an experienced CRO, we have a wealth of experienced regulatory professionals working with us and more importantly, our recruitment experts know what they are looking for in the regulatory affairs arena!

Case Study

In 2016, a large biopharmaceutical company approached us for the resourcing of specialist CMC Regulatory Leads in the UK.

Due to our recruitments strengths we were able to present several suitable candidates within a week after receipt of the requirement and the candidates were onboarded after just over a month.

The assignments were successfully concluded, enhancing our partnership with the client.

Please read more in the below case study:

Case Study – Insourcing CMC Regulatory Services

Requirement Description	Selected Applicant	Role & Responsibilities	Collaboration to Date
A large biopharmaceutical company approached us in 2016 regarding specialist CMC Regulatory Leads in the UK. 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 even found 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.	Responsible for established International brands, including Neurology and Immunology. Lifecycle maintenance including CMC variations, new indications and safety submissions for Asia Pacific, MENA and Latin America. Pre- launch activities in MENA, GAP analysis of variations, and co-ordination with both QA and Supply Chain. Managing regulatory agency questions by providing strategic guidance and support to SMEs.	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. CROMSOURCE continues to place additional staff with this Sponsor in a variety of areas, including not only Regulatory, but also Clinical Project Management and Site Engagement Management. Partnership approach to relationship, transparency, integrity and shared goals.

Functions Covered in this area:

Regulatory Affairs

- Regulatory Affairs Specialists from Associate to Director level
- Regulatory Affairs Process Managers
- Regulatory Affairs Registration Managers
- Regulatory Strategy & Intelligence Leaders
- Regulatory Project/Programme Managers
- Data Disclosure Leads
- Regulatory Database Managers

CMC Regulatory Affairs

- CMC Managers/Directors

Regulatory & Scientific Writing

- Regulatory and Scientific Writers
- Regulatory Publishing Specialists
- Regulatory Documentation Scientists
- Regulatory Labelling Specialists

Other Regulatory Functions

- Regulatory Chemists
- Regulatory Toxicologists

Choose the right Flexible Resourcing model that suits you or let us advise you on the best fit for your business:

Insourcing/Staff Augmentation

Providing our resources, contracted to work directly under your direction and control. Enabling temporary increase in capacity, while maintaining complete oversight.

Functional Resourcing (FSP)

For clients who want to outsource complete functions across multiple projects. Full leverage of CROMSOURCE's global capabilities, infrastructure, and functional expertise. This approach gives speed, flexibility, efficiency, innovation and a potential for reduced cycle times.

Hybrid Delivery Model

Creating a more flexible model is key to success for many clients, with our Hybrid Model, we are able to provide clients with full, multi-disciplined teams, utilising the project management and core strengths of CROMSOURCE. Ideal for clients who need to start projects quickly where they do not have their own structure in place.

Services can be bundled together for increased flexibility in allocation of internal and/or external resources to quickly ramp-up or down.

Combined Services

For a combination of development services, we will work with you to design a model that suits your specific needs for quality, geographic coverage and speed of delivery. By offering an option to our Sponsors to have control but also be able to ramp-up a large team of staff to support a single study or studies, the combined service model is ideal.

Permanent Placements

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Staff Recruitment Expertise

TalentSource's dedicated staff recruitment team allows our clients to capitalise on the state-of-the-art technology and database within CROMSOURCE. Recruitment and acquisition of talent is a corporate core competency at CROMSOURCE and one of the reasons why we can support our clients with a fast ramp-up of resources for their studies. Our recruiting process is established to attract and hire qualified candidates and utilises a variety of methods to recruit new hires including: direct sourcing, outsourcing and retained searches.

We place major emphasis on direct and clear communication lines between CROMSOURCE and clients at the start-up phase of any relationship and clients can be closely involved with the selection of resources assigned, if required.

Why work with CROMSOURCE?

- Commitment to Clients: Critical to program success, we have a dedicated Account and Line Management Team. Formal communication/Governance for fast issue resolution. High level of client control and regular interaction at all levels.
- Resource Availability: TalentSource has the ability to quickly ramp-up resources, either via our existing employees or finding the best matched people externally. We have a database of pre-identified resources, who can quickly start on your projects.
- Training: Our own internal training structure, with dedicated trainers and electronic training system, covering both Medical Device and Pharmaceutical regulations.
- Client and Employee Support Infrastructure: We have robust management oversight, IT, HR, Finance, Legal, Quality, etc.
- Employee Retention: Robust management structure for performance and problem resolution, career development to give us a stable workforce. Offering reward and recognition programs and long-term retention techniques. We are proud that our employee turnover rate is less than 15% per year.
- Management Structure: Formal communication/Governance with high level interaction and fast resolution

Countries Served

AFRICA
EGYPT
SOUTH AFRICA

ASIA
AUSTRALIA
CHINA
NEW ZEALAND
SINGAPORE

EUROPE
AUSTRIA
BELGIUM
BULGARIA
CROATIA
CZECH REPUBLIC
DENMARK
ESTONIA
FINLAND
FRANCE
GERMANY
GREECE
HUNGARY
IRELAND
ISRAEL
ITALY
KAZAKHSTAN
LATVIA
LITHUANIA
NETHERLANDS
NORWAY
POLAND
PORTUGAL
ROMANIA
SERBIA AND MONTENEGRO
SLOVAKIA
SLOVENIA
SPAIN
SWEDEN
SWITZERLAND
TURKEY
UK

LATIN AMERICA
ARGENTINA
BRAZIL
CHILE
MEXICO
PERU

NORTH AMERICA
CANADA
USA

Contact TalentSource now to discuss your needs!

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