

FACT SHEET



Medical Devices Strategic Resourcing

Experts Providing Experts

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

Medical Devices Strategic Resourcing

TalentSource Life Sciences (TalentSource) is proud of our heritage as pioneers of life sciences staffing solutions, which started nearly 25 years ago as MSOURCE. We specialise in supporting clients of all sizes, from global giants to virtual biotechs. Whatever the size of your company, TalentSource will work with you closely, drawing on the clinical experience of CROMSOURCE, to provide experts who are ready to make a difference to your work.

We have seen many trends in our industry come and go, and the introduction of many 'new' models of staffing support. Our success is, however, mainly attributed to our focus on what may seem more basic but fundamental factors, including the ability to provide a fast ramp-up of staff for projects, appreciated, well trained, valued employees and dedicated, experienced Line Managers, providing fast problem resolution.

At CROMSOURCE we have vast experience with Medical Devices studies and we leverage this experience to establish an optimal solutions for our clients. The most valuable assets in the industry are well-qualified, experienced and expert resources. That's why we invest heavily in training and development to ensure our resources are learning all the time and always up-to-date with regulations.

Over 30% of all CROMSOURCE projects as a CRO are the medical devices trials. In the past 5 years we have completed over 150 Class II & III medical devices, multiple countries clinical investigations, involving 5,000+ patients & 300+ sites.

In particular, we are very experienced in the following medical device therapeutic areas:

- **Respiratory and Cardiovascular**
- **CNS - Including Pain & Psychiatry**
- **Dermatology**
- **Endocrinology / Diabetology**
- **Gastrointestinal**
- **Oncology**
- **Ophthalmology**
- **Orthopaedics**
- **Women's Health**



Let us advise you on the best model to fit your business needs

We listen to you and propose a solution that fits your needs so you do not receive a standard 'FSP Model' or 'Retained FTE Model', you receive your own model, custom designed to suit you perfectly - and because we take time to get to know you and how you work, the experts we select are perfectly suited both to your needs and to your working culture. We can supply single individuals or fully flexible, tailor-made resource teams, with management oversight - allowing you to concentrate on your core competencies, while maintaining control over your studies and enhancing productivity & cost efficiency. We have been involved in supporting preferred provider partnerships for many years, some multiple country relationships, as well as many local relationships in the area of human capital in the medical devices industry. This experience has allowed us to deliver resources in a short time frame and add value to our partners through our customised resourcing models:

Contract Placement - Flexible Resourcing

Providing our resources, contracted to work directly under your direction and control. Enabling temporary increase in capacity, while maintaining complete oversight. Offering long- and short-term placements, interim vacancy cover, cover for workload peaks, headcount freezes, maternity leave etc.

Functional Solutions (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. With an FSP structure, our clients have a higher level of service than with traditional staffing models, providing teams of experience staff across a specific functional area. This approach can reduce the operational cover by our clients with our teams taking the responsibility of the function. Benefits of FSP model include, cost efficiencies, streamlining processes (flexibility on use of CROMSOURCE or your SOPs), working with fewer vendors and reducing contracts and invoices.

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.

This model combines the seamless cooperation between TalentSource and CROMSOURCE Clinical Operations and the dedicated CROMSOURCE Team acts as an extension of your team. It offers full scalability to the clinical project team in regards to duration of resources, commitment and location.

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

This service can be used as a transition from traditional insourcing/staff augmentation to a full FSP model as your business grows.

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.

Providing flexible resources through the TalentSource unit, coupled with additional add-on services from the CRO business, this model is particularly suited for Sponsors to extend their global reach but who wish to retain project management oversight.

Permanent Placements

For finding qualified & competent candidates for permanent employment. Using our extensive database for filling client internal roles.

Our Life Sciences Services

We'll make sure that the staff we deliver:

- Know and understand medical device and diagnostics regulations;
- Are trained on the all required guidelines: MDD, AIMDD, MEDDEV, ISO EN norms and National Laws; have experience with the regulatory process for clinical investigations and product approval EU / US;
- Understands the IPM regulatory implications of its actions and decisions, so your clinical study or regulatory submission is in qualified hands;
- Can meet your requirements from simple pilot studies to large and complex medical device trials, from pre to post-market;

Regardless of the differences in regulatory requirements of drug vs medical devices, the detail is in the understanding of these differences and addressing them appropriately and therefore, leading to success. CROMSOURCE has this depth of knowledge from our own experience as a CRO.

Roles Covered:

- Project Assistants
- Site Mangers/Clinical Research Associates/Field Clinical Engineers
- Project Managers
- Clinical Data Managers
- Clinical Trial Submissions Specialists
- Project Managers
- Medical Writers
- Materiovigilance Specialists
- Regulatory Affairs Specialists
- Clinical Affairs Specialists

So when your medical device study requires clinical research professional with specialist experience in medical devices, think TalentSource.



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Contact TalentSource now to discuss your needs!



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