

## SHOWCASE

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### Quality Assurance

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#### 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.

## Highlights/Philosophy of our Quality Assurance Services

At CROMSOURCE we have quality in our DNA. The company's certification according to the quality system ISO 9001 was initially achieved when few other CROs considered such accreditation important. It was first implemented in 2002, while in November 2017 we successfully completed the certification transition to the newly revised ISO 9001:2015 standard.

This standard is reflected and embedded throughout all our departments, equally applying to the whole range of TalentSource processes from recruitment and onboarding to project management and regular customer satisfaction review, both towards pharmaceutical and medical device customers.

Our employees operate on a 'Quality by Design' principle having a quality focus and commitment from the very first steps in our assignments, aiming to proactively identify and prevent quality issues and operational threats through our tools and processes. We identify with the philosophy of Quality Assurance through smart, correct and flexible process design.

As much as it is critical to the success of any Clinical Study, Quality Assurance is also a very broad area, encompassing not only SOP management, internal and external auditing or

CAPA management, but also BCDR approaches, risk management, Data Protection and vendor management. The quality professionals you can hire from TalentSource are ready to support or offer guidance in the areas of: general Quality Assurance, Compliance, Auditing, Audits of Investigators/Sites, Audits of Vendors, Internal System Audits, Regulatory Inspection Assistance, and more.

The TalentSource team of CROMSOURCE has a proven track record of successfully providing dedicated experts to work for our sponsors in all the above fields.

Yet another service we have successfully extended with our clients is Regulatory Training, both online and in person. The Regulatory Training content is based on our solid 25 years of know-how and its daily implementation on behalf of our sponsors and towards authority bodies.

Our experts, especially individuals recommended by TalentSource division which operates flexibly, most often on tailor-made basis, will respond to your quality related challenges worldwide, implementing both the internationally required standards, as well as local expertise.



## Training

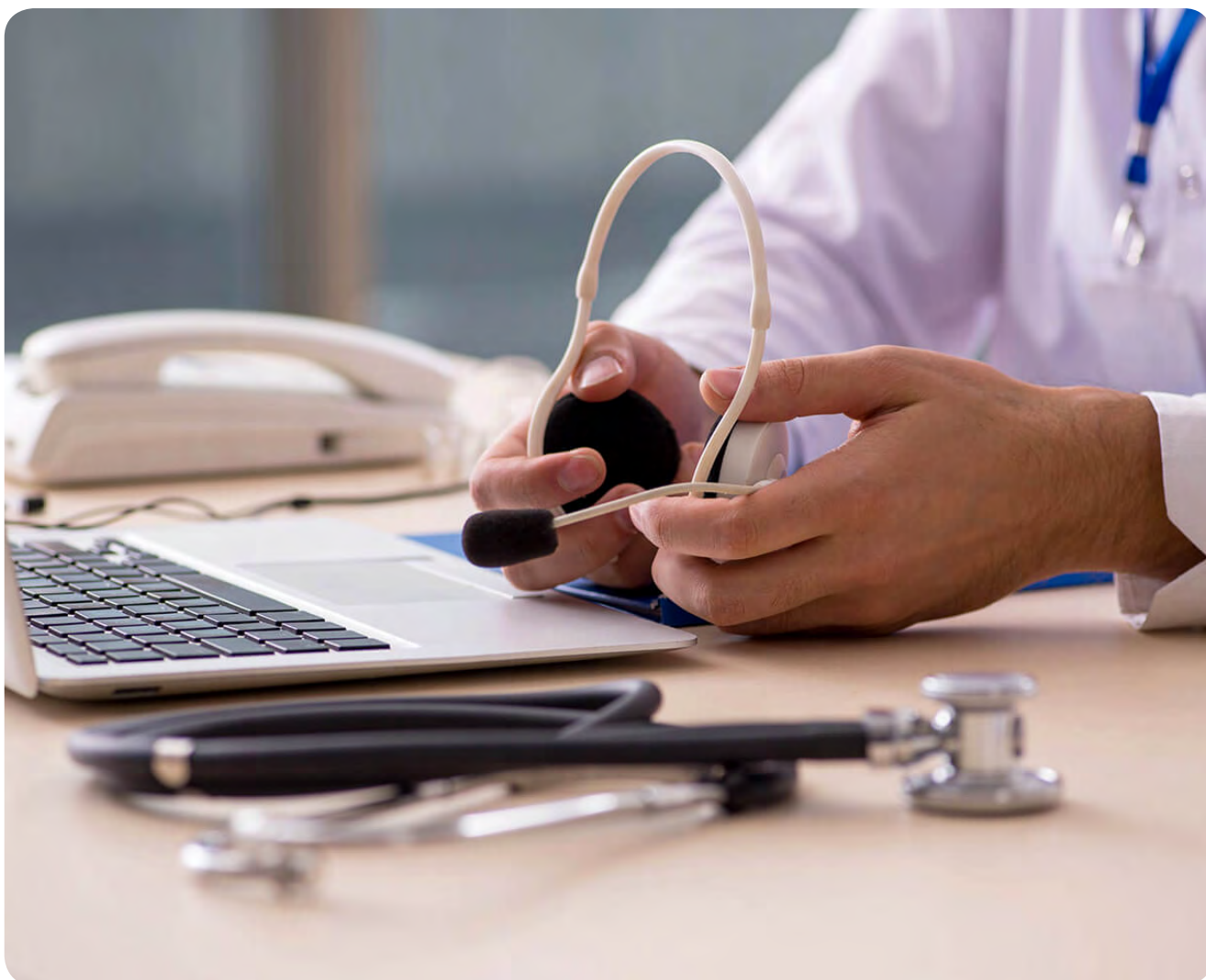
Generally, our sponsors are responsible for staff training on their SOPs, systems and therapeutic areas assigned. Nevertheless, TalentSource being part of a CRO, have a full set of Quality Assurance SOPs and Working Instructions available that all our staff can follow, including our externally based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

Our in-house training portfolio includes dedicated courses on the following range of topics: Hosting Audits and Inspections, Quality Assurance Service Audits and Consulting, comprehensive aspects of Data Protection or Computer System Validation.

In addition, our professionals benefit from access to our internal Quality and Auditing Teams 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.



## Case Study

Recently we completed a long-term project initiated with a biopharmaceutical company that approached us to work with them as supplier of an International Team of Quality Reviewers in a niche therapy area.

Excelling at recruitment, we were able to present the matching CVs within 4 days on average, the first Quality Reviewers starting on the project within 4 weeks (US) and 6 weeks (Europe).

Throughout nearly 10 years of collaboration we were not only regularly receiving positive feedback from the client, but we were also happy to see that the effort, knowledge and input CROMSOURCE's team brought to the Sponsor's studies helped them to build their own internal quality review processes. Please look at some more details in the below case study:

### Case Study – 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 MDs or people with a very strong scientific background and experience of monitoring clinical trials.

Sponsor were experiencing a lot of GCP CAPAs at sites and required individual visits. 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 to the Project Manager.

#### Staff Requirements



Field-based team in: Romania, Bulgaria, Poland, Germany, Benelux, Spain, Italy and USA.

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 (SDV discrepancies, management of pharmacy and drug accountability, frequency of interactions with the site staff, etc.), including some co-visits to address issues.

Results: Initial request to CV submission – average 4 days. Initial request to start date – USA 4 weeks; Europe 6-12 weeks.

#### Key Learning



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 in a partnership approach, key to success being 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.

## Functions covered by CROMSOURCE/TalentSource in the area of Quality Assurance:

- Auditor
- CAPA Investigator and Manager
- Clinical Quality Assurance - Associate to Manager
- Compliance Associate, Manager, Officer
- Governance and Performance Manager
- Medical Devices QA Lead
- Project Quality Lead II
- QA Expert (Device)
- QA Product Complaint Specialist
- QS Specialist
- Quality Assurance Customer Service and Complaints Specialists
- Quality Assurance Process Specialist
- Quality Review Specialist
- Quality Risk Area Manager
- Quality Vendor Manager
- SOP Coordinator
- Computerized System Validation Specialist

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 can 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

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

### 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  
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ITALY  
KAZAKHSTAN  
LATVIA  
LITHUANIA

NETHERLANDS  
NORWAY  
POLAND  
PORTUGAL  
ROMANIA  
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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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