CATALENT

Booth 1831

Corporate Description

Catalyst + Talent. From drug and biologic development to delivery technologies to clinical and commercial supply, we are the catalyst for your success.

As a worldwide clinical supply services leader, Catalent has the scale, expertise, and innovative solutions to improve efficiency and reduce your trial timelines. Our customer-centric project management and integrated solutions will help accelerate your project and provide peace of mind.

Markets Served

Catalent serves thousands of innovators, large and small, in over 100 markets, including 41 of the top 50 biotech companies and 48 of the top 50 pharmaceutical companies.

Catalent Clinical Supply Services has 8 facilities in the US, Europe, and Asia, with over 50 depots on 6 continents. We provide about 150,000 clinical trial shipments a year to more than 80 countries with 99.9% on-time delivery.

Major Services

Clinical Supply Services: Our clinical expertise and offerings span all facets of clinical trials, including:

- Clinical supply management
- Direct global comparator sourcing
- Clinical packaging and labelling
- Clinical storage, distribution, and returns management

Development and Analytical Services: With our broad range of expert services — including analytical, biologics, preformulation, formulation, and world leading drug delivery technologies — we drive faster, more efficient development timelines and produce better products.

With broad analytical services for both small and large molecule drugs, we design creative solutions to complex problems to produce market ready results that you can rely on for virtually any dose form.

DIA Information

VIPs and Spokespersons attending: Lucy Sha, Strategic Marketing Director – Development and Clinical Services.

New Products and Services launching: ADVASEPT™ technology, for the advanced aseptic filling of injectable drugs, provides a glass-free, aseptically filled, primary container that reduces or eliminates many concerns associated with traditional glass vials, including the risk of injuries to treatment providers and patients, the potential for glass particulate contamination and accidental breakage in transit and subsequent product wastage.

Cocktail Receptions and Parties: Catalent offers a light continental breakfast, including Coffee and a selection of pastries, on days Monday, June 16, and Tuesday, June 17, at their booth number 1831.

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NUMBER OF EMPLOYEES
8,500

DATE FOUNDED
2007

CROMSOURCE

Booth 710

Corporate Description

CROMSOURCE is an ISO-certified international provider of outsourced services to the pharmaceutical, biotechnology, and medical device industries, specialized in clinical development and staffing solutions. A well-established full-service CRO, CROMSOURCE is unique in offering an End-to-End Guarantee covering trial timelines, enrollment, and contract price. This guarantees our clients that their trials are delivered on time and within the contract price with no CRO initiated change orders. CROMSOURCE operates through offices across all regions of Europe and North America and delivers a comprehensive breadth of services.

Services

CROMSOURCE seamlessly moves biopharmaceutical products from first-in-human conducted in an exceptional early phase unit, through all subsequent phases of pre- and post-approval research internationally.

Clinical Development Services

- Feasibility/site selections
- Clinical operations: project management and monitoring
- Regulatory affairs and medical monitoring
- Medical writing
- Quality assurance
- Pharmacovigilance/vigilance
- Data management and statistics
- Drug management
- Vendor management
- Legal representative
- IT: Customized tools and resources
- Staffing solutions

Early Phase Services

- ADME studies
- Bioavailability
- Bioequivalence
- Dose ranging/multiple dose tolerance
- Drug-drug interactions
- First-in-human (SAD, MAD)
- Food effect studies
- Patient studies
- Pharmacokinetics/pharmacodynamics
- Proof of concept
- QTc studies

Strategic Services

End-to-End Guarantee. It's a simple concept, really. Quality data. On time. On Budget. Guaranteed. A unique concept in an environment where change orders and delays are commonplace with other service providers.

One Trial One Price. The CROMSOURCE guarantee is our unique pledge that the price agreed at contract signature is the only price that the sponsor will pay.

Expert Trial Rescue. CROMSOURCE regularly rescues projects for clients dissatisfied with the progress of on-going studies. The experienced CROMSOURCE team quickly assess the situation and implement tailored solutions which get such trials back on track.

Feasibility Plus. Feasibility Plus is provided without obligation at the proposal stage. Through direct contact with potential investigators, Feasibility Plus provides accurate country and site selection data, and allows precise budget and timeline forecasts.

DIA Information

CROMSOURCE will be at the 50th DIA Annual Meeting from June 15-19, 2014. Please visit us at booth 710. We would be delighted to hear about your work and perhaps suggest how CROMSOURCE can support you to reach your clinical development goals.

CROMSOURCE

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NUMBER OF EMPLOYEES
550

DATE FOUNDED
1994

Spectra Clinical Research

Booth 2238

Nicholas Brownlee, PhD, President

We pride ourselves in working side-by-side with our customers to understand their specific needs and move their trial toward success.

Corporate Description

Spectra Clinical Research provides central laboratory services to pharmaceutical companies, academic institutions, and other medical organizations conducting Phase I–IV clinical trials. Backed by over a decade of clinical trial expertise and nearly 30 years of central laboratory services to the dialysis community, we are able to support diverse clinical trials of all sizes.

Spectra Clinical Research acts as a unique resource for organizations conducting clinical trials. As a division of Spectra Laboratories, we leverage the capacity and technology of a large organization while maintaining the flexibility and responsiveness of a small specialty laboratory. We continually review and streamline our processes to ensure timely, accurate results. Furthermore, our advanced testing platforms, specimen management, online data management application, and dedicated team of service specialists help move each trial toward a successful outcome.

Markets Served

Spectra Clinical Research provides central laboratory services to pharmaceutical, biotechnology, research, government, and academic organizations. We have participated in trials spanning a wide range of therapeutic areas including nephrology, gastroenterology, women's health, anemia, cardiovascular disease, depression, diabetes, endocrinology, GERD, menopause, nephrology, microbiology, oncology, and central nervous system (CNS) disorders. Our global support network ensures continuous, reliable service for clinical trials in locations worldwide including North America, Israel, South America, Europe, Australia, South Africa, Asia, and India.

Products and Services

- A dedicated project manager prepares all study-specific documents, coordinates activities with partner laboratories, and attends investigator meetings.
- Specially trained personnel shepherd each sample through the laboratory.
- Designated customer service representatives assigned to each study ensure personalized assistance throughout the trial.
- Support for numerous esoteric tests includes soluble transferrin receptor, aluminum, zinc, I-PTH, and others.
- Microbiology department offers 24/7 testing services for bacteriology.
- ELISA and EIA tests can be set up and validated.
- Advanced web-based reporting and data management.

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UBC

Booth 923

Corporate Description

United BioSource Corp. (UBC), a subsidiary of Express Scripts Holding Company, leads the market in providing integrated, comprehensive clinical, safety, and commercialization services for pharmaceutical and biotechnology companies.

UBC brings together renowned scientific research and operations experts with leading-edge technologies, allowing for the best patient and healthcare provider experience. Comprehensive, end-to-end services cover product and patient population characterization during development and market entry, as well as a focus on the patient experience, safety, and adherence.

Working with Express Scripts' specialty pharmacy and specialty distribution organizations, UBC is uniquely positioned to seamlessly integrate best-in-class services throughout the lifecycle of a product.

Markets Served

UBC is now part of Express Scripts. Our goal to support manufacturer sponsors with the best possible team of recognized scientific and industry experts and leading technology is backed by a parent company that manages more than a billion prescriptions a year for tens of millions of patients.

By combining insight from data, understanding patient behavior, and the science behind clinical specialties, we can help our clients make informed decisions and optimize the care given to patients using their therapies and products.

Major Services

- Clinical development & late stage research
- Risk management & pharmacovigilance
- Reimbursement & patient assistance
- Nursing & adherence
- Product access & channel management

DIA Information

VIPs and Spokespersons attending:
Patrick Lindsay, President; Sandra Lottes, PharmD, Global Clinical Development; Annette Stemhagen, DrPH, FISPE, Safety & Risk Management; Kevin Cast, Global Pharmaceutical Business Development; Véronique Basch, PharmD, Global Pharmacovigilance; Jess Sohal, MSc, Clinical Operations

Workshop: *Preparation of REMS Assessment Reports*
Sunday, June 15, 1:00pm - 4:30pm
Annette Stemhagen, DrPH, FISPE, Senior VP; Catherine Sigler, PhD, MPH, Senior Epidemiologist

Abstract Poster Presentations:
Monday, June 16
Evaluating Risk Evaluation and Mitigation Strategies Effectiveness Using Existing Tools
Annette Stemhagen, DrPH, FISPE, presenting for author Gretchen Dieck, PhD

Tuesday, June 17
Rock and a Hard Place: Mandated Multi-National Drug Utilization Studies in the Absence of Suitable Secondary Sources of Dataoduct Safety Statistical Analysis Plans
Krista Payne, Executive Director, Sr. Research Scientist

Retrospective Chart Review Studies: Key Considerations for Fulfilling Safety Reporting Requirements
Dara Stein, Sr. Research Scientist

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NUMBER OF EMPLOYEES
2,000+

DATE FOUNDED
2003