CaligorRx.com

caligor RX
Beyond Compare

Clinical Trial Services

TrialAssist™

For pharmaceutical and biotechnology companies lacking large, in-house clinical resources, the complex task of selecting and managing clinical trials can be overwhelming. With our TrialAssist services, you can stay focused on the success of your clinical trial while Caligor handles the countless details.

Easing the burden of managing clinical trials

Comprehensive Assistance

TrialAssist provides a complete solution to help manage your clinical trials–from sourcing and procurement to local language labeling, comparator programs, warehousing, and distribution–with a trusted, single point of contact.

Our flexible, on-demand service model helps ensure that you receive the right comparators when you need them, while minimizing the risk of costly excess.

Our custom labeling service localizes comparator labeling for specific languages and countries, helping protect patient safety and ensure regulatory compliance.

Expert Guidance

Caligor's experienced professionals serve as an extension of your team, providing expertise and advice whenever you need it.

With pharmacists on staff, Caligor can provide expert guidance on comparator selection and dosing to help your clinical team make informed decisions. We monitor your progress at every step, providing advice to improve your program–from recommending comparator alternatives to calculating quantities.

Caligor's TrialAssist service can help keep your clinical trial on schedule and on budget, while reducing your staffing requirements.

GMP Controlled Temperature Storage

Caligor offers long and short term storage for clinical trial materials, APIs, and commercial products in our dedicated facilities. We offer a flexible approach to storage, from single samples to entire pallets at continuously monitored and controlled temperatures from +15C to +25C and +2C to 8C. We can also offer split-site, GMP storage of critical materials from one-off samples through to commercial supplies at temperatures ranging from -20C to -196C.

We are responsive to urgent shipping requests to meet your needs for timely material delivery.

Qualified experts at your service

Key to our consulting services is the expertise of our team, including our in-house, licensed Qualified Persons (QPs). Their knowledge and experience can help ensure compliance at every step, freeing your team to focus on the business of product development.

We help you deal with the complexity of clinical trials, assisting with a range of value-added services, including:

- **QP certification**–All non-EU pharmaceutical products destined for use in the European Union must be certified by a licensed Qualified Person (QP). Caligor's team of QPs can provide the required clearances you need in a timely manner.
- **Trial application review**–We provide expert review of your Investigational Medicinal Product Dossier (IMPD) and other applicable regulatory documents to ensure they are accurately and optimally completed, helping streamline regulatory review and avoid trial delays.
- **Batch manufacturing records review**–We review manufacturers' investigational product records to ensure accuracy, acceptability for the trial, and GMP compliance. We can also assist with batch expiry extensions.
- **Audits of manufacturing facilities**–We perform audits of primary and secondary production facilities to ensure that they conform to GMP guidelines.
- **Trial optimization consulting**–We can help support your success with a range of expert consulting services, from helping select the most appropriate product form for your trial to managing third-party vendors.
- **Customized solutions**–We can provide tailored solutions for a wide range of requirements–from packaging and labeling to storage, distribution, and logistics.

Caligor's team of consultants is completely dedicated to helping you achieve a smooth, efficient and successful clinical trial. Let us show you the difference expertise can make.

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