SOLUTIONS SIMPLIFIED

Clinical Operations

Clinical Data Management

Medical Writing

Biostatistics & Statistical Programming

Clinical Trial Supplies

Pharmacovigilance

SIRO

Clinical development process can span up to 15 years and requires an investment of over $1 billion. As disease complexities increase, companies need to look for simplified solutions for their multi-geography clinical development plans

2 Decades Of Clinical Research Experience

SIRO

solutions simplified

SIRO Clinpharm, winner of Frost & Sullivan ***Clinical Research Organization*** of the year 2012 & 2011 India Healthcare award, is a drug development solutions provider to the global healthcare industry.

We help healthcare companies in bringing safe and effective innovations to the market with our deep domain knowledge, cutting edge technologies and dynamic & robust processes.

solutions simplified is our promise to our stakeholders of providing them with a solution that is efficient and succinct. In today's world of infinite choices, the hardest work is to understand what's important and what isn't.

We leverage our 4 pillars of *people*, *process, technology* and *solutions* to manage complexity and clutter. We believe that each client's requirements are unique; **solutions simplified** is our way of ensuring that our solution is tailor made for each client.

We focus on outcomes. Our in-house domain expertise is unparalleled in the industry, which focuses on knowledge and innovation. We leverage our technology advancements, an integral part of our success in service delivery, communication and customer management to design solutions that are flexible and apt.

As a full-service international clinical research organization, SIRO Clinpharm holds experience in all key therapeutic areas to drive clinical development by providing turnkey solutions. With global teams, integrated services, best-in-class technological infrastructure and extensive expertise at hand; our dedicated professionals help clients with high quality cost-efficient deliverables to bring safe and effective healthcare solutions to the market.

Our service delivery models are designed to help your strategic and tactical needs. Our flexibility allows us to offer you a delivery model which is optimized for your study.

We help healthcare companies in bringing safe and effective innovations to the market

Partnering With The Best

the SIRO journey

1996 - The Inception

Founded SIRO Clinpharm in Mumbai, India with clinical trial management as a key service

2001 - The Initiation

Started services in Data Management, Biostatistics and Medical Writing

2007 - The 1st Breakthrough

Awarded the Frost & Sullivan 'Partner of Choice' award for clinical trials in India

2009 - Widening Horizons

Extended operations in Europe

2010 - Increasing Footprint in Asia

Formed strategic alliances with leading CROs in South Korea and Taiwan to widen capabilities in Asia Pacific region

Expanded operations in Asia with our newly opened office in Malaysia

2011 - Emerging as a Winner

Won the Frost and Sullivan 'Clinical Research Organization of the Year' India Healthcare award

2012 - Winner, Twice in a Row

Frost and Sullivan chose us as the 'Clinical Research Organization of the Year', 2nd time in a row for their India Healthcare awards

Received the Life Science Leader award for capabilities in Regulatory, Productivity, Reliability and Accessibility

Launched Operations in North America

2013 - Medical Writing Champions

Became the largest medical writing service providers in Asia

2014 - Strengthening Local Presence

Expanded India operations with office in Hyderabad

Teams with deep domain knowledge, who have worked on various therapeutic areas provide valuable insights that help drive your project in the right direction

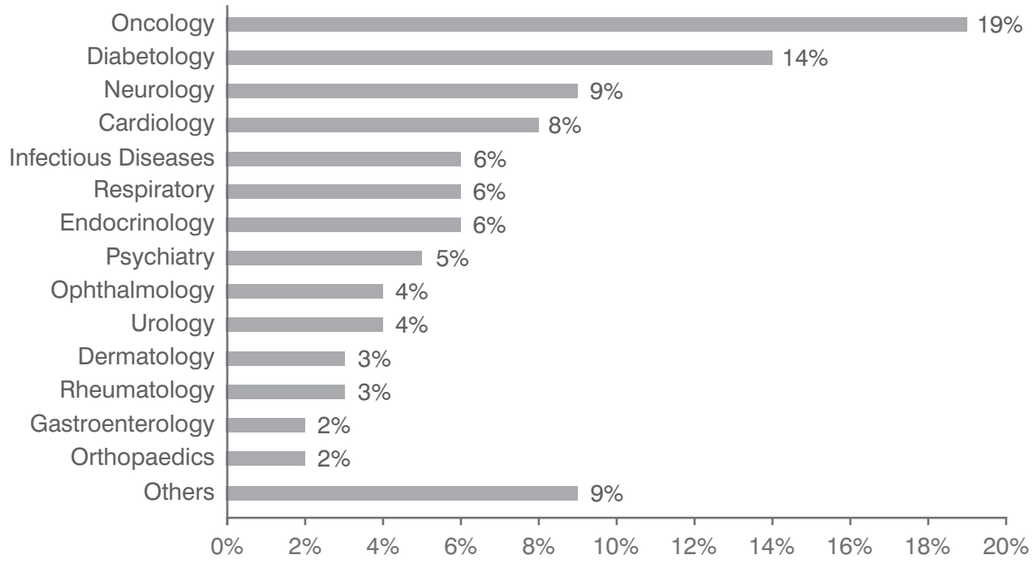
Wide Therapeutic Experience
Mapped With Disease Profiles

therapeutic insights

Our in-house experts and professionals have worked on various therapeutic areas including but not limited to oncology, diabetes, cardiovascular etc.

In depth knowledge coupled with experience in all key therapeutic areas enables our team to align resources to the client's study objective.

Snapshot of our experience in different therapeutic areas



No matter what phase of development your product might be in, we have the expertise to manage your study

Your Solutions Partner:
From Early Stage To Commercialization

phase-wise excellence

SIRO Clinpharm offers a full spectrum of services that suit your clinical development plans, right from early phase to post-marketing.

We have a track record of accelerated patient recruitment, using our SIRO expertise, for Phase II trials as well as conducting Phase III and IV studies for global regulatory submissions.

We have successfully conducted studies ranging from small Phase I trials to multinational Phase III and Phase IV programs, Registries, Proof of Concept and Observational studies.

Along with this, we help your product with its success in the market with pharmacoeconomic studies. In today's health care scenario, payers are increasingly asking for more evidence about the superiority of a new product. In such a scenario, pharmacoeconomic studies can help to emphasize important data points like quality of life or drug efficacy.

With our geographic experience stretching from the Americas, through Europe to Asia, we have the knowledge to support your development goals.

Specialized teams that manage every aspect of your clinical trial, strengthened by a robust governance structure

Your Partner in Clinical Development and more

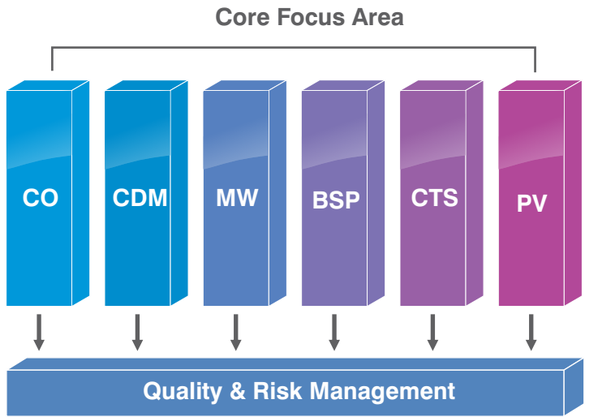
service portfolio

We are one of the few CROs, worldwide, with the capability to provide the full spectrum of services for clinical development of your product.

Right from protocol development & feasibility studies to clinical trial management, post marketing surveillance, epidemiology studies and drug safety, SIRO acts as your partner in clinical development needs.

SIRO promises customized business models in the fields of Data Management, Biostatistics & Statistical Programming and Medical Writing based on synergies arising out of globally integrated delivery teams.

We believe that you deserve the best. To ensure this, a well trained and devoted medical team from the industry constantly keeps abreast of all the drug developments happening globally.



CO: Clinical Operations
CDM: Clinical Data Management
MW: Medical Writing
BSP: Biostatistics and Statistical Programming
CTS: Clinical Trial Supplies
PV: Pharmacovigilance

SIRO has worked on more than 400 clinical trials across North America, Europe and Asia

End-to-end Clinical Operations Solutions
Presence in More Than 25 Countries

clinical operations

As drug pipelines narrow and the number of drugs that make it to the market reduces, it has become increasingly important to invest time and effort in the clinical development process. SIRO is your partner in getting the right resources on your projects to help crunch timelines and bring in cost efficiencies. A leading team of clinical operations experts, who have conducted more than 400 studies in various therapeutic areas, provide you with geographic insights for optimum patient recruitment strategies.

Our Clinical Operations Services

- Clinical Trial Feasibility
- Clinical Project Management
- Clinical Monitoring
- Medical Monitoring
- Clinical Documentation

Geographic Reach

- Operations in over 25 countries

Global Expertise

- Subject matter experts from Europe, Asia and North America

Broad Service Spectrum

- Dedicated feasibility team for high accuracy of recruitment rates
- Highly experienced resource pool with global project management experience

Customized Solutions

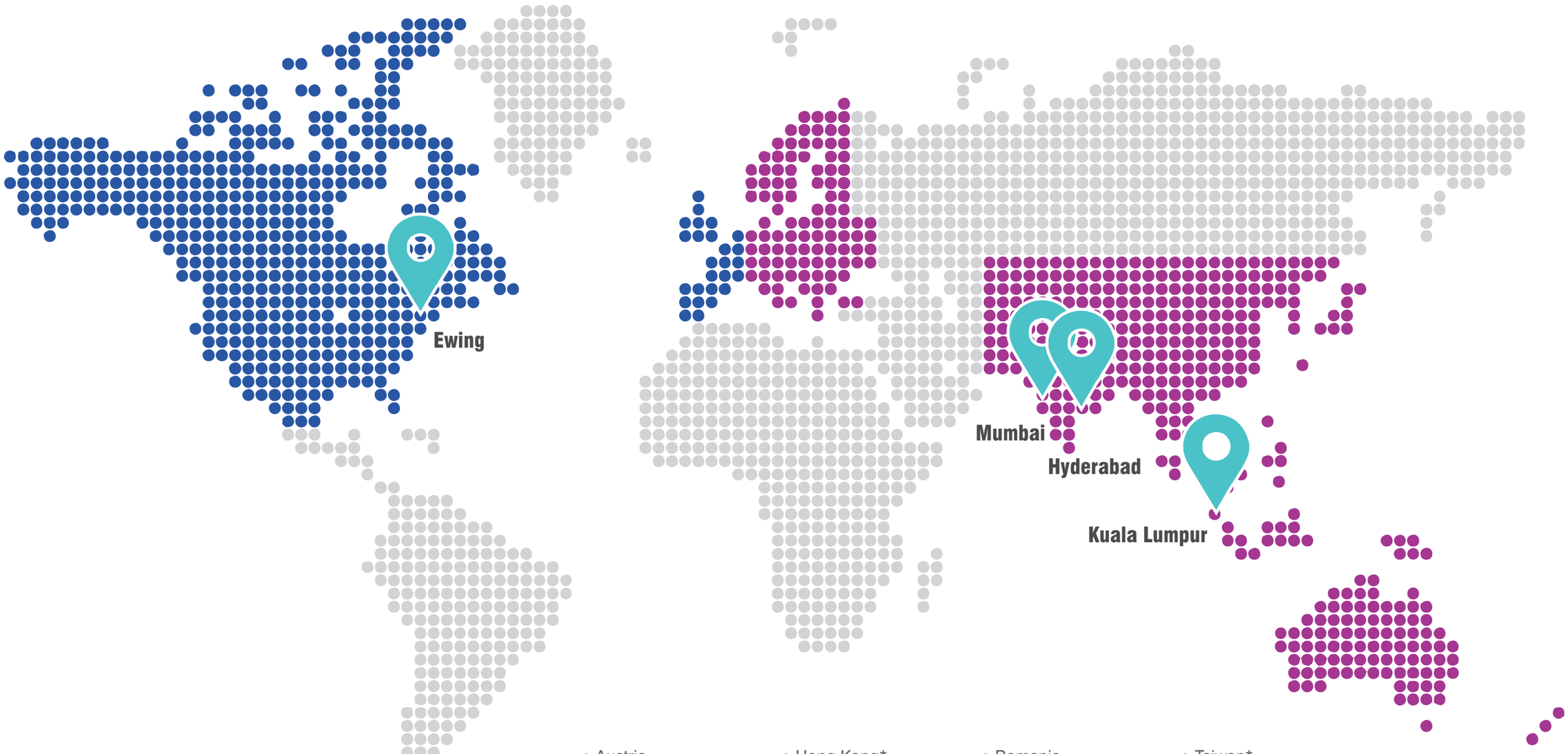
- Solutions Design team that understands your trial requirements and delivers customized solutions

Optimum output for your clinical trial

global teams to scale our resources

SIRO

Our clients are exploring different geographies. We're expanding our boundaries too.



- Offices
- Functional services
- Full scope services

- Austria
- Australia*
- China*
- Czech Republic
- France
- Germany
- Greece
- Hungary
- Hong Kong*
- India
- Israel
- Italy
- Malaysia
- New Zealand*
- Poland
- Philippines
- Romania
- Russia
- Singapore
- Spain
- Sri Lanka
- South Africa*
- South Korea*
- Switzerland
- Taiwan*
- Thailand*
- UK
- USA
- Vietnam*

*Through our alliance partners

SIRO Data Management team has experienced members who understand the special commitment it takes to contribute and make a difference to client needs

Implementing Cutting-Edge Technology to Deliver High Quality Data

clinical data management

With R&D costs spiraling, patents expiring on many molecules and stringent FDA requirements for new drug approval, it is imperative to reduce time-to-market and minimize costs. Accuracy of data, is, therefore, critical.

Our data management solutions integrate technology and clinical data expertise, supported by a robust quality management framework to deliver high quality data.

ORACLE Silver Partner

Our partnership with Oracle gives us access to cutting technology and support. Our IT capabilities in the region are second to none. By deploying Oracle Health Sciences InForm, we have upgraded our technology platforms to global standards.

The Technology Advantage

We offer flexibility, scalability and real-time access to trial data to streamline and accelerate large and complex international trials.

Our Data Management Capabilities

Study Start-Up

- Input to protocol design
- Data Management Operational project planning
- Creation of Data Management Plan & Data Validation Plan
- pCRF/eCRF Design
- Database Design & Edit Check Programming
- Database Testing & UAT
- Data Migration

Study Conduct

- Scanning and Indexing
- Data Entry
- External Data Loading
- Data Review & Query Management
- External Data Management
- SAE Reconciliation
- Medical Dictionary Coding
- Quality Control Activities
- 24X7 help desk to support investigators & site staff

Study Closure

- Project Documentation (Data Master File)
- Database Lock
- Submission Ready CRF PDFs
- Data Transfer
- Archival

One of the largest medical writing teams, providing full spectrum of medical and scientific communication services

Combining Your Experimental Expertise With Our Medical Writing

medical writing

The key to professional success for researchers is the precise presentation of scientific ideas and results, which helps maximize the accuracy and impact of written documents.

At SIRO, we have a team of dedicated medical writers experienced across all therapeutic areas including niche areas like vaccines and all phases of clinical research including bio-equivalence and pre-clinical.

All writers are trained on ICH-GCP principles, writing style guides, reference managers, medical dictionaries and specific writers on publication-related standards

Publications and MedComm
Manuscripts
Abstracts & Posters
Slide Decks
Training modules

Clinical Trial Disclosure
Protocol Registries
Report Registries
FDAAA Synopsis
PhRMA Web Synopsis

Drug Safety & Risk Management
Aggregate Reports (DSUR / PSUR / PBRER / PADER, SUSAR LL)
RMP and REMS

Regulatory Medical Writing

Start-up	*Conduct*	*Closure*
IB	Pre-DBL Narratives	Post-DBL Narratives
Protocols	Shell CSR with Mock Tables	CSR with Appendices
		eCTD Modules
		Summary Documents

Innovative biostatistical & SAS programming solutions leveraging knowledge on experimental design, statistical methodology and global regulatory requirements

Revisit your Project from the Perspective of Statistical Analysis

biostatistics and statistical programming

Biostatistics impacts a clinical study during all stages, therefore, periodically review your decisions as they will decide the success or failure of your study. SIRO Clinpharm, will enable you to make befitting decisions.

Our Biostatistics and Statistical Programming Services

Protocol & Design Support

- Sample size estimation
- Statistical planning – optimal design, end point selection
- Statistical selection of study protocol
- Generation of randomization schedule

Analysis & Reporting Services

- Statistical analysis plan
- Carrying out planned analysis
- Stand alone statistical reports

Statistical Programming Services

- Robust SAS programming module
- Customized displays
- CDISC standards

Statistical Consulting Services

- Protocol design, development and review
- Meta analysis
- Statistical support on adaptive design

One of the few CROs to have a clinical trial supplies facility in the Indian sub-continent

Establishing a Strong Supply Chain for your Products

clinical trial supplies management

One of the key drivers of an efficient clinical trial is the effective management of the supply chain. SIRO Clinpharm is one of the few clinical research organizations in the Indian sub-continent to offer clinical trial supplies (CTS) management services. Our fully equipped CTS facility, located in Mumbai is well equipped to store investigational products at ambient as well as cold temperatures. Our facility has been audited multiple times by regulatory bodies as well as by sponsors.

Our clinical trial supplies management services:

- IP management
- Obtaining regulatory approvals and import licenses for full-scope studies
- Customs clearance
- Receipt and storage
- Shipments management
  - Receipt of bulk shipments, pick and put away for storage
  - Shipments to investigator sites
  - Return & Destruction
  - Extension of expiry date (re-labeling)

SIRO offers comprehensive pharmacovigilance solutions including 24x7 call centre, triage, case processing, medical review and signal detection for spontaneous and clinical cases

Experienced Physicians On Board with Advanced Technology For Timely Processing and Electronic Submissions

pharmacovigilance

SIRO Clinpharm offers a comprehensive range of pharmacovigilance services essential for the conduct of clinical trials including study preparation, study conduct, medical coding, medical review and Drug Safety Officer (DSO) activities.

The medical affairs team is comprised of physicians and pharmacists with years of medical and pharmacovigilance experience and detailed knowledge in various therapeutic areas. This ensures key requirements within clinical trials are managed in line with regulatory demands. This includes not only the expedited reporting of Suspected Unexpected Serious Adverse Reactions (SUSAR) but also the appropriate handling of Serious Adverse Events (SAE) and Unexpected Adverse Event Information.

Our pharmacovigilance services

- Triage and case processing
- Medical contact center (AE, PC, MI)
- Case intake
- Experience with databases like Aris Global, Embase & Ovid
- Management and warehousing of safety database
- Individual case processing
- Literature case review
- Case submission (electronic and paper)
- Safety writing, risk management and signal detection
- Author periodic reports (IND AR, NDA PR, PSUR, PADER, ASR)
- Summary, bridging and ad-hoc reports
- Annual & ad-hoc safety signal evaluations
- Risk benefit assessments, lifecycle risk management strategy and authoring risk management plans (RiskMaps, EU-RMP)

SIRO believes in designing simple solutions even for the most complex of trials

Leveraging Resources, Technology and Processes
To Deliver Simplified Solutions

get the SIRO advantage

We have worked with most of the top 20 companies and have partnered with small and medium sized companies across the globe. For over 20 years, we have successfully executed projects for various Pharmaceutical, Biotechnology, Medical Devices, FMCG, Nutraceuticals and Cosmetics companies. Here's why:

Our 4 Pillars of Success

We leverage our 4 pillars of success: people, process, technology and solutions.

Partnering for Solutions

We provide end-to-end services for clinical studies with our unique delivery model. Our geographic spread and global expertise backed by local operations deliver excellence in our customized solutions.

- Customized governance and Delivery Models
- Quality and Risk Management
- IT Integration across services

Full spectrum of services

Clinical Operations | Clinical Data Management | Medical Writing | Biostatistics & Statistical Programming |Clinical Trial Supplies | Pharmacovigilance

flexible business models

We believe that each client's requirements are different and unique, and therefore must not be moulded into the traditional models. We, instead, work towards adapting the models to suit each client's needs. Our teams work towards crafting flexible models to deliver the right value.

Transactional models are designed to deliver the best on your project. With the **functional service provider (FSP) model**, we promise you depth of subject expertise, one that is the best in the industry, and trained resources to manage any unforeseen situations. **Full time equivalent (FTE) engagement model** ensures dedicated trained and experienced resources on your projects. We help clients in better co-ordination, risk mitigation through deeper understanding of project requirements, and time zone benefits through our **in-sourcing model.** Our **build-operate-transfer (BOT) model** makes way for any risks that may come your way, ensuring smoother functioning of your study. **Strategic alliances** help us in aligning our capabilities, resources and knowledge with your objectives with standardized processes and regular communication and provide time and cost efficiencies.

Asia
SIRO Clinpharm Pvt. Ltd.
Kalpataru Prime, 1st Floor
Unit Nos. 3 and 4 , Plot No. D-3
Road No. 16, Wagle Industrial Estate,
Thane (West) - 400604
India

Tel : +91 22 6108 8000

Asia
SIRO Clinpharm Malaysia SDN. BHD.
17th Floor Plaza Permata
6 - Jalan Kampar,
Opp. Jalan Tun Razak,
Kuala Lumpur
Malaysia

Tel : +603 4040 0063

North America
SIRO Clinpharm USA LLC.
850 Bear Tavern Road,
Suite 302
Ewing, NJ 08628,
United States of America

Tel: +1 609 530 1670
Fax: +1 609 530 1674

SIRO

For further information contact us at bd@siroclinpharm.com

www.siroclinpharm.com