Practical (Pharma) Quality Research (PQR CRO)

Powerful service from

Shanghai DrJ Medical Development Co., Ltd.

DrJ

PQR CRO - Helping pharmaceutical companies safeguard the Quality of clinical research and regulatory submissions in China.

Keep Quality up!

One CRO just focus on helping your Quality in China.

Practical (Pharma) Quality Research (PQR CRO) belongs to Shanghai DrJ Medical Development Co. Ltd. It is a trademark registered by Shanghai DrJ Medical in China. It has been helping pharmaceutical companies safeguard the Quality of clinical research and regulatory submissions in China.

The core strength of PQR is its local unique expertise and local resources. PQR have consultants in Beijing, Shanghai, Guangzhou locations. PQR have established good relationships with State Food Drug Administration Bureau (SFDA) experts and some of SFDA certificated GCP research bases. PQR have in-depth knowledge and expertise of the regulatory requirements and process of SFDA, and have rich experience in clinical research operations in China.

PQR's key Project Director is Dr. Jack (Juncai) Xu, who has more than 15 years experience in China's regulatory submission and clinical research field. His unique experience of working in China State Research Institute (Shanghai Institute of Materia Medica, Chinese Academy of Science), Multinational Pharmaceutical companies (Upjohn, Pharmacia, Ranbaxy), and international leading CROs(Loudon, Quintile) has given him the chance to handle all kinds of regulatory issues(Import Drug application, New Drug development, and Mimic Drug development) and all phases of clinical research(from Phase I to Phase IV) in China. In particular his ICH GCP studies operational experience in China will help the customers' remove roadblocks, compress timelines, and ensure smooth success in China.

With any research project, PQR starts with a Practical detailed plan, uses a reasonable budget, and will deliver a Qualified result. PQR in China currently focus on the following

services:

1: Quality assurance of clinical research in China;
2: Regulatory submission and consultation in China;
3: Clinical research training;
4: Clinical research.

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Quality Assurance of Clinical research in China

The study quality is crucial for the success of any clinical research. The increasing clinical trial activities in China call for ever-increasing emphasis on compliance with Good Clinical Practice (GCP) in order to safeguard the rights of human participants and to protect the integrity and validity of clinical research data. PQR's experienced clinical quality assurance professionals can help you conduct in-depth audits of your systems, your investigator sites and your documents/reports to ensure that your system and on-going projects are GCP-compliant.

For example, PQR can help you do "Mock China SFDA Inspection" and Mock FDA inspection" practice to train your staff. The Mock inspection will reveal your gaps, help you know your team's performance, fine-tune your systems and be prepared for the real inspection from regulatory agencies and audits from your headquarters.

From individual site audits or system audits to multi-site quality assurance audit programs, PQR Mock inspection designs and delivers the QA services you need to meet China, USA, Europe and Japan's increasingly stringent requirements.

PQR's Quality Assurance services:

1. GCP compliance audits
2. System validation audits,
3. Mock China SFDA and USA FDA Inspections (Complete range of clinical auditing capabilities)
4. On-site Clinical Investigator Audits
5. In-house Central File Audits & System Audits
6. Database Audits & Clinical Study Report Audits
   Clinical Laboratory Audits (Good Laboratory Practice [GLP])

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Regulatory service

PQR understands the complexities and time associated with obtaining a product registration in China. PQR's practical plan will help you to prepare and complete China document submission. The qualified document will save you traditional timelines by an average of 20% or more. PQR offer services as the following:

1. Consultation on the Strategic regulatory, scientific, and safety planning in China
2. IND, NDA, Import license application
3. Strategic regulatory advice & Drug development plans for the China market
4. Liaison with regulatory authorities e.g: Direct interactions with China SFDA: Regulatory intelligence; SFDA meeting planning, preparation, and presentation; Consultation on SFDA Pre-meeting briefing packages
5. Expert Reports and summaries (Medical writing) & Product information preparation

Clinical training service

Dr. Jack (Juncai) Xu's 15 years - practical experience can help provide you the following training service:

1. New CRAs training
2. Project Management training to Senior CRAs or new Project Managers
3. On-site ICH GCP training to investigators
4. Quality Assurance Training - Audit

- How to prepare for an audit
- Common audit problems

5. SFDA and FDA inspection brief and how to prepare for SFDA and FDA inspection

Clinical Research

PQR takes practical & innovative approaches to provide quality data on time and within budget. Beijing, Shanghai, Guangzhou located-alliance CRAs will ensure that clinical trial procedures are conducted timely and accurate data collection are upheld. Well trained staff with SOP are able to maintain the highest standard of clinical trial monitoring, since PQR,s monitors routinely meet ICH-GCP guidelines.

PQR are also be flexible for meeting your needs in any of part of clinical trials as following:

- Protocol design, CRF Design
- English to Chinese, or Chinese to English Translation services
- Investigators' meeting
- Sites Monitoring services
- Project management
- Medical report writing, Chinese Medical report writing,
- Pharmaco-economic Studies
- Safety Surveillance Services
- SAE reporting
- Safety Surveillance and Reporting
- SAE form and safety database development
- Data entry into safety database
- Patient Recruitment

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