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Site Start-Up Manager, SSO

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Company: Randstad

Location: Hong Kong

Category: other-general

job details

about the company.

Our client, a world-class leading pharmaceutical manufacturing company, is currently looking for an enthusiastic Site Start-up Manager to join their expanding team.

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about the job.

Collaborate with SSO Study Start-Up Team Lead, SSO Country Head Portfolio/SSO Cluster Head Portfolio to support country SSU strategy and ensure SSU timelines and deliverables are met

Accountable for timely start-up activities from country allocation until Green Light in assigned projects, including preparation of IRB/IEC submission packages, review of Informed Consent Forms, and engaging Regulatory Affairs/CTA Hub for Health Authorities submissions

Prepare and finalize local submission packages for submission to IRB/IEC, CTA Hub, and Health Authorities as applicable, and coordinate timely response to deficiency letters and reportable events

Ensure timelines, accuracy, and quality of country TMF documents in study start-up to ensure TMF inspection readiness

Support study feasibility and lead site selection in collaboration with Feasibility Manager and Site Partnership Manager and the global study team

Ensure sites are prepared for Green Light and oversee local SSU team activities in assigned studies to achieve start-up timelines and quality execution.

Lead/chair local SSU team meetings and participate in global study team meetings as required

Lead the development of country site initiation and patient enrollment plans together with SSU CRA, CPM, and SSU Lead

skills & experiences required.

Degree in scientific or health discipline required, advanced degree with clinical trial experience and/or project management is preferable

Minimum 5 years' experience in clinical operations overseeing and/or monitoring clinical trials

Capable of leading in a matrix environment without direct reports

Understanding of all aspects of clinical drug development, particularly trial set-up, execution, and monitoring

Strong project management capabilities with demonstrated ability to problem-solve and mediate complex issues

Thorough understanding of international drug development processes, including knowledge of international standards (GCP/ICH), health authorities (FDA/EMA), local/national health authority regulations, and Novartis standards

Strong interpersonal, negotiation, and conflict resolution skills

Effective communication in a local/global matrixed environment

Fluent in both written and spoken English, local language as needed

Interested individuals can click apply now and send through an updated resume in WORD format. For a more comprehensive list of current opportunities, please visit https://www.randstad.com/jobs/q-hong-kong/ or contact Jessica Cheung at + 852 6285 6991 or email jessica.cheung@randstad.com.hk

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skills

no additional skills required

qualifications

no additional qualifications required

education

Bachelor Degree

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