



Position Description: Vice President, Clinical Research (EU)

POSITION DETAILS

Title	Vice President, Clinical Research (Europe)
Upward Reporting	Vice President, Scientific Affairs
Company Location	Zürich
Core Responsibilities	Management of Clinuvel's clinical development program
Working Hours	8.30am – 5.00pm, Monday to Friday. Some overtime as required
Travel	International travel required

PURPOSE OF THE ROLE

To manage the clinical development program in accordance with applicable local and international regulations and company SOPs to ensure the timely delivery of clinical study reports within budget.

MAIN INTERFACES

Internal: Chief Scientific Officer, CEO, VP Scientific Affairs, Clinical Research Project Team Members

External: Clinical opinion leaders, trial investigators and other trial staff, regulatory agencies

KEY RESULT AREAS

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| General | • Manage clinical development activities to meet agreed timelines |
| Study Feasibility Assessments | • Identification, assessment and selection of appropriate investigators/sites and other service providers according to project requirements and company SOPs |
| Study Set-up | • Manage preparation and execution of site initiation and associated meetings |
| Clinical Site Management | • Manage all aspects of study site management from site selection, site initiation to study execution and study report finalization (according to ICH GCP guidelines and company SOPs) |
| Pharmacovigilance | • Manage the pharmacovigilance function in compliance with regulatory requirements and company SOPs |

COMPETENCIES (KNOWLEDGE, SKILLS AND ATTRIBUTES)

- Ability to lead and inspire a team of clinical research professionals
- Establish and maintain relationships with internal/external customers
- Maintain a current awareness of ethical and regulatory requirements
- Effective verbal and written communication in individual and group settings
- Ability to work in a team environment
- Problem solving skills with the ability to analyze and interpret data
- Negotiation skills
- Presentation skills
- Excellent attention to detail
- Ability to plan, organise and follow up



QUALIFICATIONS / EXPERIENCE REQUIREMENTS

Required Qualifications:

- Medical qualification with registration to practice as a medical practitioner

Required Experience / Knowledge:

- Post-graduate qualifications desirable
- Minimum of 5 years' experience managing clinical research programs within the pharmaceutical industry
- Working knowledge of ICH GCP guidelines and European regulatory requirements as they apply to clinical research

Desirable Experience / Knowledge:

- Management of a team of clinical research professionals
- Management of clinical research programs in the United States