



Position Description: Senior Regulatory Affairs Associate/Manager Switzerland

POSITION DETAILS

Title	Senior Regulatory Affairs Associate/Manager Switzerland
Upward Reporting	Vice President, Scientific Affairs
Company Location	Hauserstrasse 14, 8032 Zürich Switzerland
Core Responsibilities	Management of regulatory and ethics committee submissions to support Clinuvel's clinical trials program
Working Hours	8.30am – 5.00pm, Monday to Friday. Some overtime as required
Travel	Some travel (domestic and/or international) required for trial monitoring

PURPOSE OF THE ROLE

To prepare regulatory and ethics committee submissions to ensure timely approval of clinical trials in accordance with applicable local and international regulations and company objectives

MAIN INTERFACES

Internal: Regulatory Affairs Director, Clinical Research Director, Clinical Research Team, VP Scientific Affairs, Chief Scientific Officer and Clinical Staff in European and United States Offices

External: Regulatory agencies, clinical trial investigators, CROs, clinical trials material manufacturers and distributors, regulatory consultants

KEY RESULT AREAS

Clinical Trial Applications	<ul style="list-style-type: none"> Prepare and/or collate all documentation to support clinical trial applications in Australia, Europe and United States
Ethics Committee Documentation	<ul style="list-style-type: none"> Prepare required HREC/IEC/IRB applications
Document Management	<ul style="list-style-type: none"> Assist with the maintenance of the Investigational Medicinal Product Dossier for European agencies Update documentation as required in response to Ethics or Regulatory comments/questions Implement quality systems to ensure that a complete history of updates is maintained
Investigational Medicinal Product and Study Supplies	<ul style="list-style-type: none"> Ensure investigational medicinal product is supplied to the study sites in compliance with regulatory approvals, including labeling, import permits Arrange adequate storage and distribution of investigational medicinal product to the investigational sites
Regulatory	<ul style="list-style-type: none"> Assist in the development of a global regulatory strategy Assist in the preparation and review of briefing documents to support meetings with the relevant regulatory bodies Develop and maintain relationships with the regulators
Pharmacovigilance	<ul style="list-style-type: none"> Report adverse events in compliance with regulatory requirements and company SOPs



COMPETENCIES (KNOWLEDGE, SKILLS AND ATTRIBUTES)

- Ability to plan, organise and follow up
- Excellent attention to detail
- Prepare high quality documents for HRECs and regulatory agencies
- Plan and track regulatory activities to meet agreed timelines
- Establish and maintain relationships with internal/external customers
- Deliver high quality customer services to internal/external customers
- Effective verbal and written communication in individual and group settings
- Ability to create and maintain relationships with internal/external customers
- Ability to work in a team environment
- Maintain a current awareness of ethical and regulatory requirements
- Ability to analyse and interpret data
- Problem solving skills
- Effective time management of multiple tasks
- Ability to source information, research skills
- Negotiation skills
- Presentation skills, personality to engage
- Computer literacy

QUALIFICATIONS / EXPERIENCE REQUIREMENTS

Required Qualifications:	<ul style="list-style-type: none"> • Graduate qualifications in Biological Sciences, Nursing, Pharmacy or related discipline • Post-graduate qualifications desirable
Required Experience / Knowledge:	<ul style="list-style-type: none"> • At least 2 years experience as a Regulatory Affairs Associate
Desirable Experience / Knowledge:	<ul style="list-style-type: none"> • Preparation of CTAs to support clinical trials in Europe • Preparation of marketing authorization applications in CTD format • Working knowledge of ICH GCP guidelines and key ICH Quality, Safety and Efficacy Guidelines