

JOB DESCRIPTION – Product Safety Expert (Toxicology)

Note: This job description does not necessarily itemise all activities which the jobholder may be required to do

POSITION TITLE:	Product Safety Expert (Toxicology)
REPORTING TO:	Business Unit Manager Regulatory
REPORTING LOCATION:	Rheinfelden (Switzerland)
WORKING LOCATION:	Rheinfelden (Switzerland) or Niefern-Öschelbronn (Germany)

1. ROLE SPECIFICATION

1.1 Job Objective

Provide guidance, expertise and support to the Eurofins Agrosience Services Regulatory team regarding preparation of the toxicological sections of registration dossiers for active ingredients and formulated products regulated under the Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market.

These tasks will be undertaken in order to achieve the business's agreed strategic, financial and quality objectives

1.2 Key tasks

- (a)** Evaluate client data under the focus of regulatory requirements for toxicological data (Data Gap Analyses, Risk Assessments, Exposure Estimates, Product Classification)
- (b)** Develop of strategies to assist clients in experimental programs according to European, international and national data requirements
- (c)** Organise of experimental work comprising requesting, quoting, monitoring and time scheduling in and outside the Eurofins Agrosience Service Group
- (d)** Summarise experimental data for authorisation including judgement of experimental work with regard to satisfying the quality and focus to fulfil the regulatory requirements
- (e)** Prepare of risk assessments for human safety
- (f)** In conjunction with the regulatory team (project manager, residue experts, etc.) reflect on the overall human safety of the agrochemical products in their intended use

1.3 Key Result Areas

(a) Revenue generation

Support Project manager to prepare quotations and contracts within the Eurofins Agrosience Services Regulatory team, in accordance with pre-agreed quotation guidance documents

(b) Production management

Assume responsibility for the generation, preparation and presentation of formal product registration and safety review submissions. Ensure that close liaison with study management staff is maintained in order that studies which form part of submissions made by the team are reported with appropriate accuracy / timeliness.

(c) External consultancy

Liaise with third party consultants / CRO's where in-house capabilities are insufficient to complete certain aspects of a dossier. Assume responsibility for checking quotations, contracts, NDA's etc submitted by such CRO's

(d) Internal consultancy

Provide, as appropriate, internal consultancy on regulatory affairs related to plant protection products, including advising technical staff on regulatory issues

(e) Project Management

Where appropriate and with the agreement of the Head of the Business Unit Regulatory, act as Project Manager for certain programmes that are designed to generate data specifically for inclusion in a submission to be compiled by the Eurofins Agrosience Services Regulatory team

(f) Sales & Marketing

May be asked to liaise with client on toxicological issues including the delivery of presentations to prospective and existing customers during visits arranged by the Sales & Marketing Group. Attend external training and technical conferences focused on regulatory affairs related to plant protection products

1.4 Responsibilities

(a) Supervision

This is a non-supervisory role

The jobholder is required to provide regular performance reviews in the designated responsibilities to the designated supervisor

(b) Training and development

The job holder will be required to make recommendations for, and provide / assist in, training and developing staff in activities / procedures in which the job holder has achieved the necessary level of competency

(c) Monitoring / measurement of performance

The jobholder's performance will be monitored periodically by the designated supervisor. However, day-to-day supervision is minimal, and the jobholder is expected to use personal judgement and make decisions in his / her defined area of responsibility

(d) Client / external relations

The role involves regular liaison with clients and regulatory authorities. The jobholder may also be required periodically to assist other members of staff by representing the business at presentations / meetings / conferences

(f) Overseas travel

The role is likely to require occasional overseas travel (30 nights per year), chiefly to participate in meetings with clients and / or regulators

(g) Confidentiality / use of IT

The jobholder has access to commercially-sensitive information affecting most areas of the business. Confidentiality and discretion is central to the role. Information / issues discussed at Senior Management level must not be released to other members of staff without the prior

agreement of Senior Management

The job holder is required to observe the business's 'agreed usage' rules in connection with IT systems

(h) Health and safety

The job holder must observe strictly the company's Health and Safety policy and procedures, and ensure that appropriate corrective action is taken to address any faults/potential hazards in equipment / machinery, test systems or facilities. The job holder should also take reasonable steps to ensure that designated subordinates are aware of, and observe, appropriate health and safety precautions

2. PERSON SPECIFICATION

2.1 Qualifications and Attributes

(a) Education / qualifications

- Master, Ph. D in biology or Pharm. D with specialization in human toxicity
- Ideally European Registered Toxicologist (ERT)
- 5 to 10 years of professional experience as regulatory toxicologist

(b) Additional technical / vocational recognition

- Ideally possessing additional technical / professional qualification, (e.g. QSAR modelling, proceeding in AOP models)
- Membership of relevant professional / trade association

(c) Personal attributes

- Able to work outside normal office hours, according to business / team workloads
- Able to travel overseas

2.2 Skills and Aptitudes

(a) Technical skills, knowledge and expertise

- Regulatory affairs with primary focus on plant protection products. Additional knowledge on industrial chemicals and biocides would be a plus
- Regulatory quality systems
- Study management
- Knowing the business
- Utilising relevant IT and modeling tools

(b) Personal aptitudes

- Customer service orientation, under consideration of business focus
- Initiative, information seeking, autonomous, creative
- Problem solver
- Analytical and conceptual proceeding
- Excellent communication skills
- Good team spirit, enthusiastic,