

Job Type **Safety Leader, Full Time**
Work Location Basel, Switzerland

Anaveon is an immune-cytokine company entering clinical trials with our no-alpha IL-2 agonist ANV419. In our steadily expanding and dynamic organization, we are looking for a Safety Leader who will help deliver new therapeutic breakthroughs for patients.

You will be responsible for Safety Management at Anaveon, reviewing all safety data from various sources throughout the clinical development process. In addition, your responsibilities include various operational safety/PV activities including reporting and as well as tasks associated with new drug applications / regulatory filings, benefit risk assessment and safety risk assessment.

Key responsibilities include:

- Develops and is responsible for (sections of) key internal (IB, DSUR, RMP) Anaveon safety documents and vendor related ones (e.g. Safety Management Plan) through complete drug life cycle.
- (Parts of) the integration, analysis, and clinical interpretation of safety information from all sources, including preclinical through future post-marketing, as well as internal and external data.
- Ensures that these and all other project- related safety documents are consistent with one another. Responsible for overall signal detection, monitoring, evaluation, interpretation and appropriate management of safety information.
- Provides expert medical safety input to the clinical development program and clinical trials and projects
- Provides integrated safety input into all regulatory documents required during active development.

What you bring to the role:

- Medical Director, sound knowledge in safety data bases and adverse event collection process and case processing
- Extensive experience w/ MedDRA terminology and coding
- Experience with medical writing and delivering high quality documents such as RMPs, DSURs Strong experience with (safety or others) issue management
- Strong knowledge of global regulatory requirements for safety reporting and labelling
- Expertise in preparing clinical safety assessments and regulatory reports/ submissions involving safety information

Anaveon embraces diversity and equal opportunity. We are proud to offer competitive compensation packages and an inclusive workplace that cultivates innovation through collaboration and empowerment. Please send your application to **jobs@anaveon.com**.