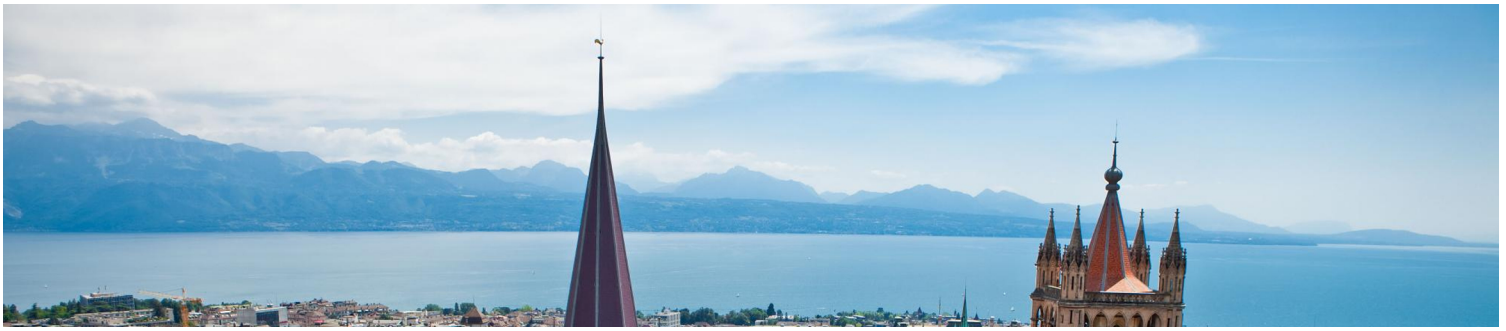

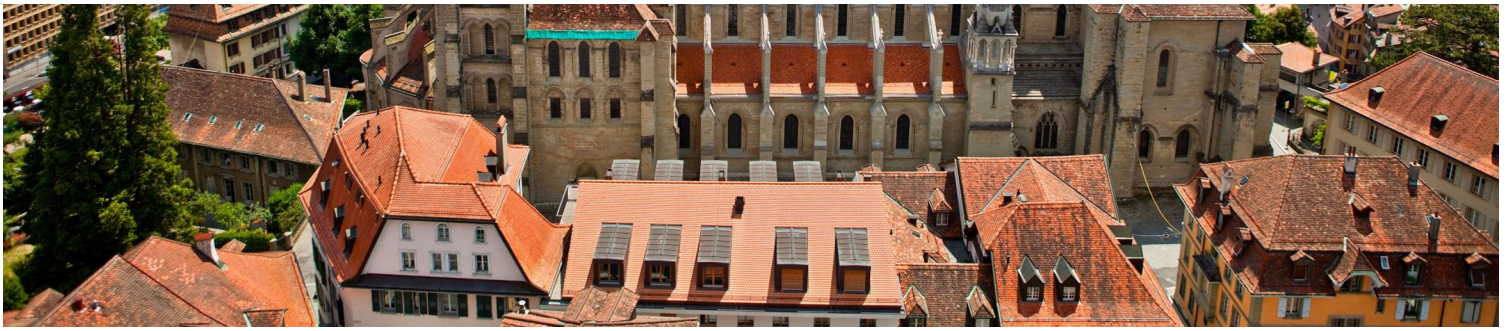

SENIOR REGULATORY SPECIALIST

COMBINATION PRODUCTS

Geneva - Lausanne, Switzerland

1 year fixed term contract

Come and join one of the world's biggest healthcare companies whose new ideas are transforming the future!

THE OPPORTUNITY

With 65 thousand employees across the globe they are committed to improving safety, efficiency and better diagnosis of diseases. Dedication and passion are the driving forces to face the challenges of developing innovative solutions for global issues and you could be a part of it!

This is an opportunity to bring a brand new combination product to market in one of the biggest healthcare players in the world. You will work closely with pharmaceutical professionals to create and defend the technical files for the submission of their combination product; a great way to gain insight of the pharma side.

RESPONSIBILITIES

As Senior Regulatory Affairs Specialist you will:

- Perform a gap assessment between the MDD requirements and the CTD file to determine what supplementary information is needed
- Author the technical file for the combination product to be compliant with MDD/MDR
- Submit to dossier to the target markets for the portfolio
- Collaborate with cross functional teams to retrieve, assess and assemble technical data
- Maintain and ensure existing licenses are compliant with local regulations
- Support local registrations of the combination products to meet the regulatory requirements

EXPECTATIONS

We are looking for strong regulatory professionals who are experienced in writing technical files and professionals with medical device experience, who are experienced with and have good attention to detail. We would love to hear from you if you have:

- Minimum degree level scientific background
- 4+ years experience in regulatory affairs in the medical device industry
- 3+ years experience writing technical files
- English language skills

hello@elemed.eu