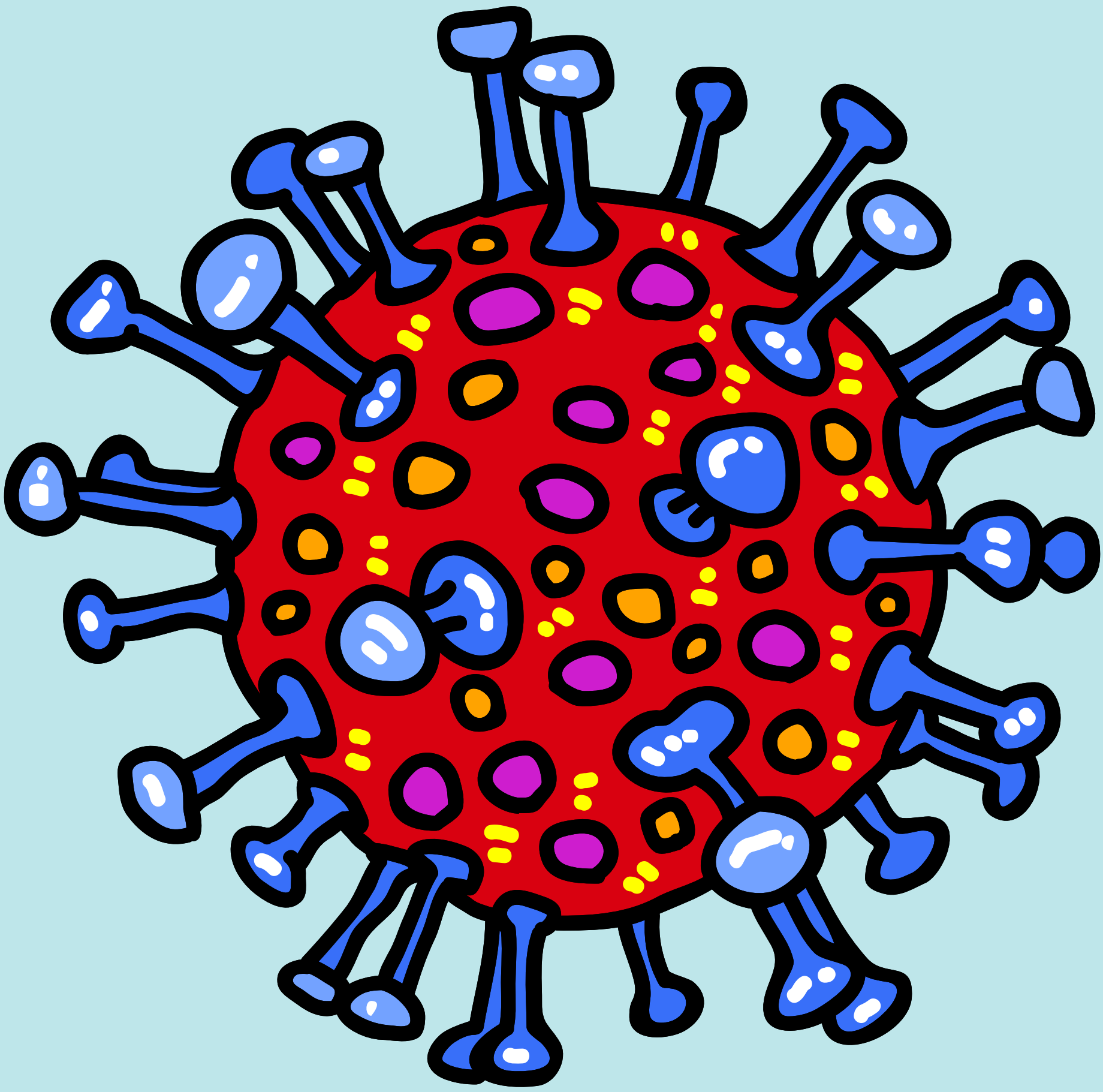
DIRECTOR REGULATORY AFFAIRS & QUALITY

LYON, FRANCE

RELOCATION POSSIBLE



French speaking not necessary for this role

IN VITRO DIAGNOSTICS

THE COMPANY

Ready for something extremely dynamic and different to the norm?
We are recruiting for a super high growth molecular biology IVD startup that has not doubled, not tripled, not quadrupled, but that has enjoyed a 10x growth in the last 2 years! With its team of molecular and mechatronic experts, it designs, produces and markets high added value reagents and automation systems for medical biology laboratories in France and abroad.

This is a company that is different from the norm. Do you love collaborative working environments?

This startup was founded by one of the best molecular biology minds in the business, and has enjoyed exponential and explosive growth in the last few years, due to the COVID pandemic. This small startup company dominates a large percentage of the French market through high ticket strategic partnerships and exclusive distribution agreements.

As they reach the next stage of their company growth, the goal is to reinvest the profits back into the business with a new, ambitious plan: to transform their current business model from one of distributor to one of legal manufacturer.

Calling a Director of Quality and Regulatory Affairs!
Your mission: to enable this ambition to be realised.

THE ROLE

In this role as Director Regulatory and Quality you'll have the chance to lead the company across both areas, acting as the bridge between the business, the leadership team and technical QA/RA requirements.

REGULATORY AFFAIRS

- Regulatory monitoring and ensuring compliance with regulatory requirements specific to In Vitro Diagnostics including preparation of IVDR transition
- CE marking: drafting and updating of technical files
- Defining the regulatory strategy for new product introductions into new markets
- Overseeing international registrations through connections with local partners
- Compliance of commercial documentation with regulatory requirements
- Regulatory watch of marketing countries
- Coordination of technical and clinical evaluation of products by testing laboratories
- Coordination of product risk analysis; writing user manuals
- Post-market monitoring of products

QUALITY ASSURANCE

- Management and continuous improvement of the Quality Management System
- Management of operational quality activities
- Ensuring compliance with the standards applicable to IVD systems such as ISO 13485
- Third-party audit follow-up, process risk analysis, management of change control
- Driving the quality agenda and building an internal culture of quality
- Spearheading continuous improvement projects

THE REQUIREMENTS

- 5+ years of experience in a regulatory affairs role with In Vitro Diagnostics from the perspective of a legal manufacturer
- Working experience with ISO 13485 and a strong understanding of the IVDR ; in vitro diagnostics regulation 2017/746
- Fluent written English (French not required - the team is very international)

INTERESTED TO EXPLORE THIS FURTHER?

Please send your CV to Elena at elena@elemed.eu to arrange a confidential career discussion.