PARIS, FRANCE

Senior Regulatory Affairs Specialist

Contact: clarisse@elemed.eu

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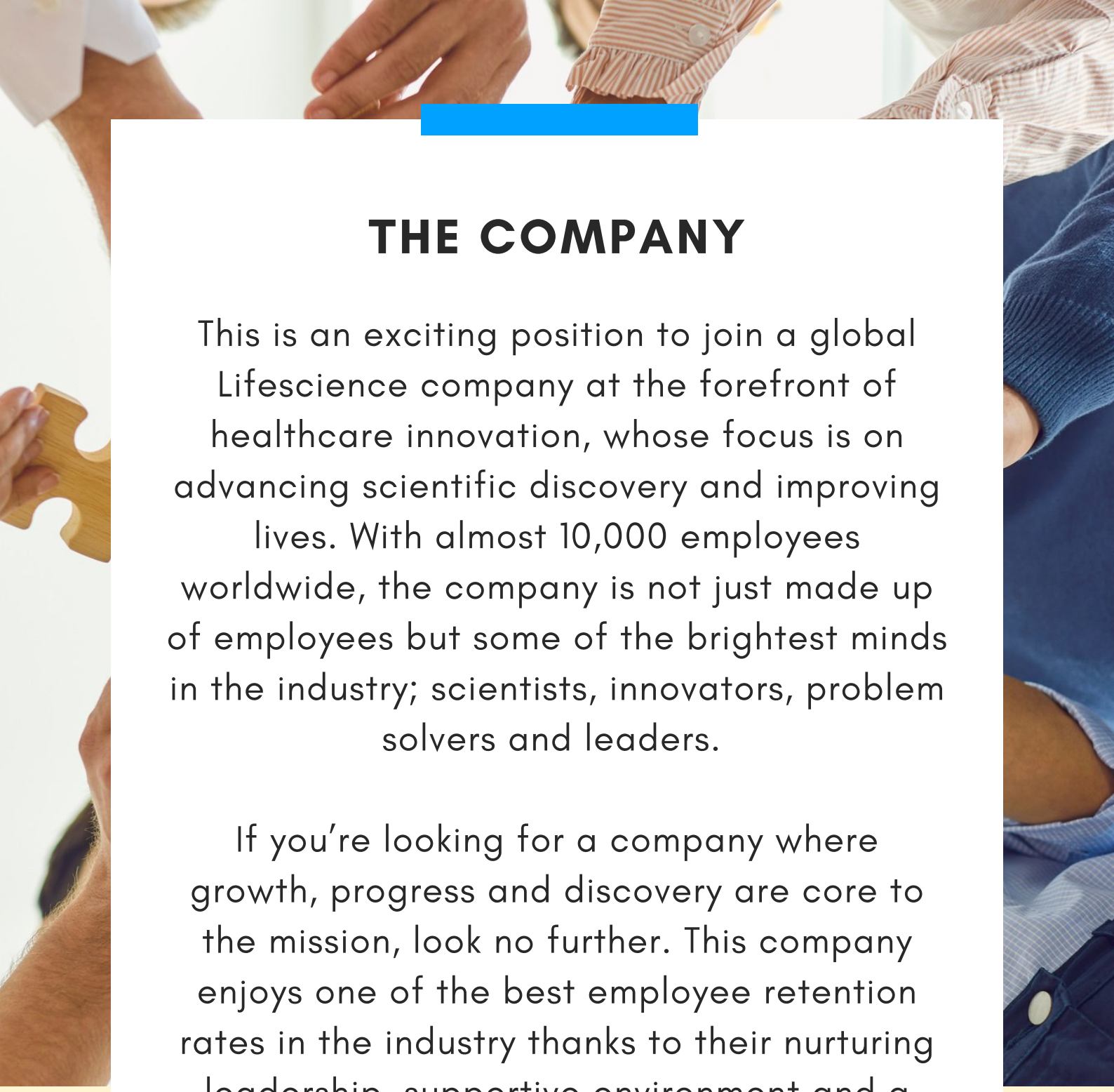

THE COMPANY

This is an exciting position to join a global Lifescience company at the forefront of healthcare innovation, whose focus is on advancing scientific discovery and improving lives. With almost 10,000 employees worldwide, the company is not just made up of employees but some of the brightest minds in the industry; scientists, innovators, problem solvers and leaders.

If you're looking for a company where growth, progress and discovery are core to the mission, look no further. This company enjoys one of the best employee retention rates in the industry thanks to their nurturing leadership, supportive environment and a beautiful site with a great outdoor area to enjoy the sunny days.

THE OPPORTUNITY

If you like to work independently this is the right role for you. Although you will report directly to the Associate Director of Regulatory you will not be micromanaged. Actually the opposite as you will have the chance to cross-functionally manage to ensure the submission of files within the deadline and work independently with a supportive team. This role is centred more in the submissions and PMS side but you will have the opportunity to work in the life cycle on some products.

As Senior Regulatory Affairs Specialist you will be responsible for:

- Developing and creating key technical documentation for product submissions.
- Write a risk management plan and report in compliance with internal procedures and regulatory requirements.
- Prepare and submit annual reports for FDA and other countries with PMS requirements.
- Participate in the update of pre and post-market regulatory requirements according to new regulatory publications.
- Evaluate the regulatory impact of product/process changes and obtain country approval.

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THE REQUIREMENTS

- 3+ years of experience within Regulatory Affairs in the IVD industry or medical devices
- Experience in submitting registration documents with high-risk products
- Previous experience within technical documentation according to ISO 13485
- Any previous experience with the FDA would be a bonus for this role
- Excellent communication skills in English.
- Experience in post-market activities

APPLY NOW!

Interested in further conversation?

PLEASE SEND YOUR APPLICATION DIRECTLY TO CLARISSE@ELEMED.EU

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