CHINA REGULATORY AFFAIRS REMEDIATION MANAGER 中国法规事务项目管理领导人

Remote within Germany
德国境内远程办公

FRANKIE@ELEMED.EU

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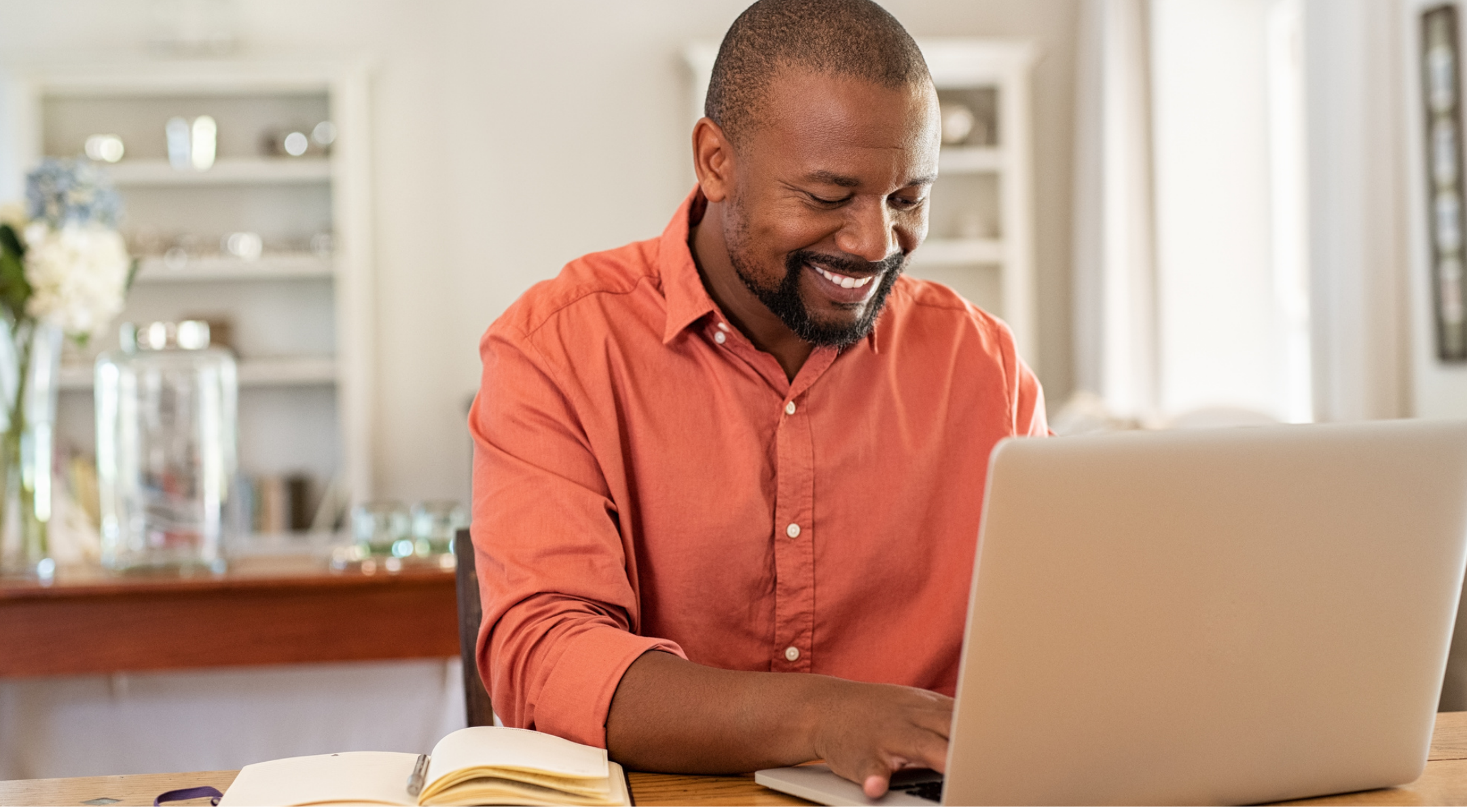


THE COMPANY

Are you someone who speaks German, Mandarin Chinese, and English? Do you have Medical Device Registration experiences in China? Are you looking for the next step in your career in the medical devices industry where your work is visible by multiple departments at the Headquarters? Do you see yourself joining an established, international company where there is constant innovation?

If yes, Here is a rare and great opportunity to join an international leader in surgical technology and be part of this company's new regulatory affairs processes. As the China Regulatory Affairs Remediation Manager, you will be reporting directly to their global headquarters in Germany and work in a German, English and Chinese Speaking environment.

THE OPPORTUNITY

This is a company-critical role and your past experiences in Medical Device clinical affairs will be key to help this manager to implement new internal processes that will ultimately improve patient safety and user-satisfaction.

This exciting position will give you the opportunity to work in an international environment and work closely with German, Chinese and European teams - including: Regulatory Affairs, Product Development, Quality Management, Clinical and Upper Management teams.

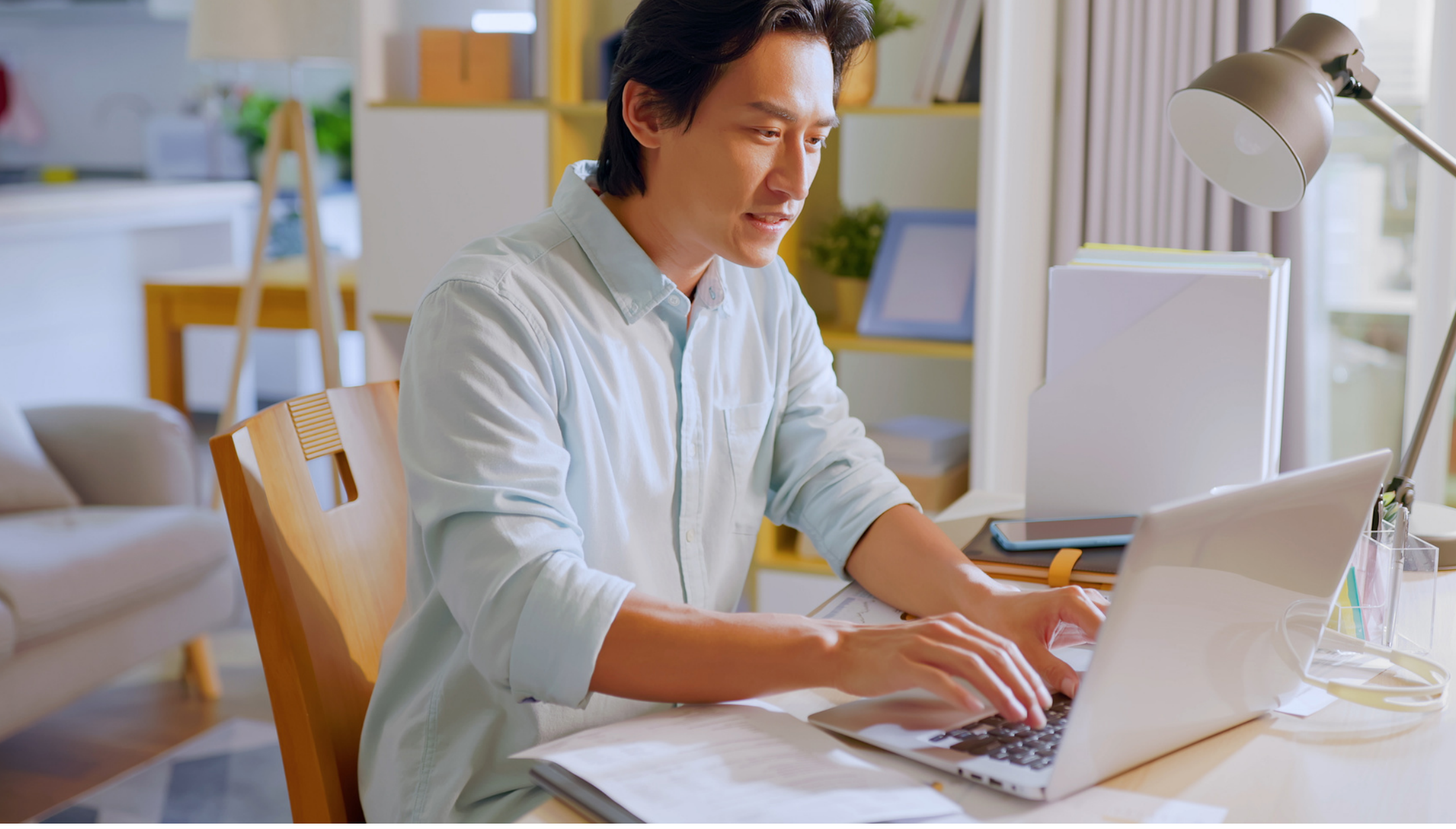
You will be responsible for the renewals and re-registration for these surgical instruments with Chinese authorities. Furthermore, you will be responsible for influencing internal teams across different functions to help them understand what the Chinese authorities expect, what are the new regulations, introduce new processes, and assist the HQ with more efficient Chinese Regulatory Affairs processes. .

In this role you will report directly to the Senior Director for Technical Documentations and Executive Director of International Regulatory Affairs.

THE RESPONSIBILITIES

As the China Regulatory Affairs Remediation Manager you will:

- Lead & Manage the Registrations and the Remediation Project with the Chinese authorities and teams in China
- Identify, review, and advise internal teams of the latest Chinese and wider APAC regulatory changes
- Help to shape the international and APAC Regulatory Affairs strategy for the company
- Key point-of-contact for the company's subsidiaries, partners, agents, and authorities in China
- Leading clinical data collection for submission and PMCF
- Assess & Improve Patient Safety Risks by escalating cases and creating new processes and new measures
- Show leadership through translating Chinese Regulatory requirements and Cultural Differences for European teams for effective regulatory affairs processes in Germany
- Influence internal and external stakeholders to make them prioritize Chinese regulatory affairs



YOUR QUALIFICATIONS:

- At least 2 years' experience with Chinese Regulatory Affairs with a Medical Devices Manufacturer
- Experience within either the medical device or Pharma industry is required
- Fluent written & spoken in German, Mandarin Chinese, and English
- Eligible to live and work in Germany

INTERESTED TO EXPLORE THIS FURTHER?

If you are interested in this exciting role, please send your application directly to

FRANKIE@ELEMED.EU

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