

Regulatory Compliance Manager

- **Leading Electronics and Mechanical Manufacturer**
- **China Exposure and FDA Focus**
- **Circa HK\$650,000 p.a.**

Our client is a leading manufacturer specialized in delivering end-to-end manufacturing solutions to various technologies companies. Currently, they are looking for the position to deliver the best services to their clients.

The incumbent will directly report to Head of Compliance.

Responsibilities:

- Develop and implement strategies to facilitate the progress of the company's worldwide medical division and provide input on regional regulatory strategies and implementation
- Work with assigned Medical Division facilities on conformance to company quality and regulatory initiatives
- Serve as liaison with the FDA and recommend regulatory policies to assure adherence to FDA requirements
- Contribute to the modification, development and implementation of company practices and policies for quality and regulatory affairs
- Keep abreast of all pertinent laws, regulations and guidance and provide insight on current regulations and guidance documents relevant to product development projects
- Prepare Standard Operating Procedures and provide review of SOPs as necessary

Requirements:

- Bachelor's degree in a scientific discipline with expert knowledge of FDA regulations
- At least 7 years experience in a Quality/Regulatory and manufacturing environment
- Experience with Device submissions is a plus such as 510K, PMA, IDE
- Strong written and verbal communication skills both in Chinese and English
- Stationed in Eastern China with frequent travelling required

To apply, please send your resume quoting with job reference GSI1005 to lily.lee@gsiconsultants.com.hk or contact **Lily Lee** at +852 3755 5455. All applications will be treated with strict confidentiality. Only shortlisted candidates will be notified.