浙江华海药业股份有限公司
ZHEJIANG HUAHAI PHARMACEUTICAL CO.,LTD.

中国首家制剂通过美国、欧盟cGMP认证的制药企业
中国首家在美国、欧盟获得制剂批准文号的制药企业
中国首家实现制剂规模化出口美国、欧盟市场的制药企业

First Chinese pharmaceutical company approved by both US and EU authorities for cGMP manufacturing of formulation.

First Chinese pharmaceutical company approved by both US and EU authorities for ANDA licenses.

First Chinese pharmaceutical company to commercially launch formulation in US and EU.

Head of Global Regulatory Affairs (China)

Main Responsibilities :
1.Be responsible for the management and implementation of all product registration around the world
2.Instruct the global RA team to write and revise related registration documents
3.Communicate with relevant officials authorities in different countries to update registration information

Head of Global Clinical Trials (China)

Main Responsibilities :
1.Take in charge of protocol design and clinical research planning for all products globally including generic and new patented medicines
2.Ensure the projects completed according to the expected time and budget quality
3.Manage clinical data and cooperate with registration departments for clinical declaration

Head of Global Business Development (Zhejiang/Shanghai)

Main Responsibilities :
1.Set up international and regional business development plan according to the company strategy
2.Continuously search and develop new businesses opportunities in global subsidiary companies
3.Be responsible for overseas business analysis, project negotiation and specific implementation

Head of New Drug Research & Development (Shanghai)

Main Responsibilities :
1.Screen and identify new drug development direction, and set up proposals and formulate feasible plans for new drug research
2.Work out development tasks and guide, coordinate and manage the research teams
3.Organize technical research in accordance with the requirements of international drugs registrations

Head of Formulation Quality Management (Zhejiang)

Main Responsibilities :
1.Fully responsible for the quality management and supervision of formulation branches and pharmaceutical factories
2.Review and improve quality management policies, procedures, systems and operation standards
3.Ensure all the quality system of the group meeting the requirements of registration and certification at domestic and abroad

Formulation Development Director (Zhejiang)

Main Responsibilities :
1.Provide technical guidance for the design and implementation of QbD in product development and develop robust formulation process
2.Develop Topical and other new dosage form products for US market
3.Be responsible for product development reports per FDA guidance

Head of Comprehensive Health management (Zhejiang)

Main Responsibilities :
1.Analyze the comprehensive health industry, find and negotiate potential targets
2.Be responsible for new project analysis due diligence etc.
3.Pay close attention to comprehensive health segments and understand the patterns trends and opportunities of these industries

Formulation QC Director (Zhejiang)

Main Responsibilities :
1.Be responsible for oversight and direction of Quality Control operations at several manufacturing facilities
2.Lead the team in product quality analysis, formulation analysis and validation of all analytical methods
3.Monitor the team to solve various technical problems and summarize the results in time

Senior Staff of Analytical Research (Zhejiang)

Main Responsibilities :
1.Lead research and development activities for finished drug product, new analytical method development, establishment of specification and support sample tests
2.Be responsible for analytical method validation protocol and reports, method development reports, technology transfer reports etc.
3.Guide instrument maintenance calibration and compliance

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