H&T PRESSPART
Blackburn

Challenge The Future With Us - Join Our Global Team

H&T Presspart is part of the Heitkamp and Thumann Group. The family owned group comprises more than 20 small and medium-sized enterprises located in 9 different countries and employing 2000 people. H&T Presspart is a global leader in the manufacture and supply of respiratory drug delivery components including metered-dose inhaler cans and actuators for the pharmaceutical market. Find out more about working at H&T Presspart at www.presspart.com

For H&T PRESSPART we are searching for a

Regulatory Affairs Specialist

located at Blackburn, Marsberg (GER) or Tarragona (ESP)

Your Key Responsibilities:

Reporting to the Director Global QA&RA, to help build and sustain QA&RA systems and processes, by:

- Ownership and administration of all aspects of Regulatory Affairs.
- Management of ISO 13485 Compliance, Development, Implementation and Training of all related and supporting processes.
- Auditing all aspects of ISO 13485 and ISO 15378 within the organization and associated supply chain partners where appropriate.
- Ownership of External Regulatory Affairs Audit Program.
- Maintenance of Drug Master Files (DMF), Annual reports and updates as appropriate in addition to all Product Approvals and CE Declarations.
- To maintain an independent perspective on Product Approval Manufacturing Production Processes and Product Performance
- To ensure the monitoring and reporting of Product Performance and Post Sales Management
- Regulatory management of customer complaints and Corrective and Preventive Action Management
- Forward looking for (external) changes to regulatory landscape and participation in relevant working groups

Key capabilities:

- Knowledge of EU/2017/745, 90/385/EEC, 93/42/EEC, 89/79/EC and related ISO 13485 and ISO 15378.
- Knowledge of UK Legislation and UKCA Marking Requirements.
- Knowledge of Business management, Change Management and Improvement Methodologies.
- Ability to work flexibly in a fast-paced and challenging environment is essential to add value to the organisation
- Ability to work Independently and maintain independent view point.
- Exhibits Coaching, Teamwork and Tenacity
- Ability to travel regularly to Sites and Suppliers
- Proficiency in Microsoft Office (Word, Excel and PowerPoint)

We are offering:

- Independent and challenging tasks with a high degree of self-responsibility
- The opportunity to participate in the success of a leading global manufacturer of precision components with a dedicated and experienced team

You are interested?

Please forward your application to

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