H&T PRESSPART

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 (UK), Marsberg (GER), Tarragona (ESP) or Nidau (CH)

Your Key Responsibilities:

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

- Supporting the existing team to ensure administration of all aspects of Regulatory Affairs.
- Auditing of ISO 13485 and ISO 15378 within the organization and associated supply chain partners where appropriate.
- 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 and 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

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 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

Thomas Mitchell
Director, Global Quality Assurance and Regulatory Affairs
E- Mail: thomas.mitchell@presspart.com