Job Description

Job title: **QUALITY & REGULATORY OFFICER**

Reporting to: BACK OFFICE MANAGER MENARINI DIAGNOSTICS
Hours: Full Time
Location: BENELUX –The Netherlands
Applicable from: January 2015

Position summary

The purpose of the quality and regulatory officer is to implement and maintain the quality management system following the requirements described in the ISO9001 & ISO 13485 standards, the requirements defined by Menarini Benelux N.V., division Diagnostics and following the BeNeLux legal requirements.
In his/her turn the quality officer reports directly to the Back Office Manager.

Responsibilities & duties

Responsibility 1 – The quality manager is responsible to assure that the company guidelines or company official documents are up to date, available and distributed to all Menarini Benelux N.V., Division Diagnostics employees. It is his/her job train and assist all employees on the quality management system, company processes and QMS procedures and to promote the awareness of customer requirements throughout the organization.

Responsibility 2 – To manage the follow up, correct handling and validation of all customer complaints, credit notes and back shipments. It is his/her responsibility to coordinate and communicate all product complaints to the suppliers. (Including the reporting of product "A" complaints as part of PPR)

Responsibility 3 – To report to management on the performance of the quality management system, advice management on quality related improvements/changes. Reports of KPI's, analysis of complaint statistics, credit note statistics, returned product statistics etc… with the goal to define the need for improvement/ improve the internal company processes.

Responsibility 4 – To perform internal department audits and follow up corrective and preventive actions (as result of internal audits, but also as result of complaint/credit notes…analysis) including verification of CAPA implementation and effectiveness. It is his/her responsibility to initiate actions to prevent the occurrence of any non-conformity related product and service, coordinating, recommending or providing solutions on

quality improvement through designated channels. In addition it is his/her responsibility to assure all quality records are archived and available.

Responsibility 5 – To update and maintain the risk management file: establishing risk acceptability criteria, risk analysis, risk evaluation, risk control and monitoring.

Responsibility 6 – To assure follow up of supplier shortcomings and field safety activities (withhold, field safety notice, recall…), report vigilance activities and if applicable contact competent authorities.

Responsibility 7 – To destroy stock (Expired, damaged, quarantine, instruments, biohazard waste…) in cooperation with F&A department according local legislation.

Responsibility 8 – Supervising delivery or installation of non-conforming products. Supervising the quarantine area. Supervising customer returned products (Visa/approval of outgoing products) and manage return of non-conforming products to suppliers.

Responsibility 9 – Follow up of regulatory requirements BE, NL and LU. (Implementing local or European regulations or directives if applicable) Assure availability of valid standards or directives applicable for Menarini Benelux N.V. (Assure legal requirements related Bebat, Stibat, Recupel, NVMP, Ecobatterien, packbase NL and Packbase BE.)

Responsibility 10 – Update job descriptions and related training program by function in cooperation with STAFF management. Training records available and follow up of employee trainings.

Responsibility 11 – Update legal and technical file per product line.

Responsibility 12 – Suppliers evaluation and qualification realized: supplier's management and update all suppliers' files, procedures, agreements etc... in cooperation with logistics/purchase.

Responsibility 13 – Planning and follow up of the test equipment technical service.

Work experience – skills – academic qualifications

Business Skills: Able to establish, implement and maintain a quality management system according the ISO 9001 & ISO 13485 standards. (Process approach management systems). Able to understand and if applicable implement local regulatory requirements related medical devices and/or IVD medical devices.

Specific Job Skills: You have a bachelor degree in engineering, chemistry, pharmacy or equivalent. Preferably you have experience in healthcare industry or experience in Quality Assurance or this knowledge is gained by experience. You have an advanced knowledge, orally and in writing of Dutch, French and English. You understand the principles of complaint handling, handling of non-conforming products etc.

Computer skills: Must be adept in use of MS Office, particularly Excel, Word, Adobe Acrobat, Visio, internet and email and in-house specific computer software.

Management Ability: You must have the competence to motivate, explain and train staff members and internal people of the importance of the quality and legal requirements. You must be able to work with targets and establish plans in order to reach the defined targets.

Personal qualities & behavioral traits

Personality: Self-driven with a clear focus on high quality and business profit.
You are credible and you are reliable. Tolerant but also determined.
Flexible and willing to travel between the office in Belgium and the office in the Netherlands. You are willing to learn, willing to invest in knowledge which is necessary to do the job. You are punctual and accurate.

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* Please write name and first name the text “for receipt” and your signature.