ELA BYSTRZYCKA

Mobile: (0) 508 512 517
Email: ela.bystrzycka@gmail.com

Ul. Macedonska 5/9
51-113Wrocław

PERSONALE PROFILE

Confident, self-motivated and presentable professional with over 10 years of significant Quality Management experience acquired in the Medical Device industry. Adaptable and competent at working in diverse environments. An ambitious, diligent individual with positive attitude is seeking a challenging career opportunity.

BUSINESS EXPERIENCE

Speciality Fibres and Materials Limited, Coventry **04.2014-15.07.2016**
Roles and Responsibilities - Senior Quality Assurance Officer (WOUND CARE)

- Management of the Quality Management Systems within the business, ensuring compliance to ISO 9001, ISO 13485, MDD, FDA 21 CFR and CMDCAS standards and regulations;
- Involved in leading FDA as well as numerous announced and unannounced BSI inspections;
- Responsible for management of the Internal Audit programme and Lead Auditor for internal audits, along with management and implementation of corrective actions;
- Successfully implemented a new procedure for management of Supply Chain;
- Involved in audits of key suppliers as part of the supplier evaluation and approval process;
- Acting as the focal point of contact and providing consultation and support with guidance on quality and compliance for the Document Control, CAPA, Customer Complaints and Change Control Management;
- Completed, distributed, involved and evaluated Management Review data and meetings as well as monthly and quarterly trending reports;
- Involved in deployment and management of the electronic Quality Management software support application (Q-Pulse), with recent introduction of new module for Calibration Program;
- Active member of the New Product Development launch team;
- Developed and implemented quality project for the Validation Processes within the business;
- Designing and providing training on all QMS areas;
- Deputy for the Quality Assurance Manager.

Advena Medical Limited, Warwick **09.2012 - 04.2014**
Roles and Responsibilities - Quality Manager (MEDICAL DEVICE CONSULTANCY)

- Management and implementation of the Quality Management System to EN ISO 13485 or 9001 and MDD.
- Proactively interpreted quality and regulatory requirements and devised and implemented solutions to build, support the maintenance and enhancement of company's Quality Management System;
- Provided consultancy to Medical Device Manufacturers to enable them to achieve Notified Body Certification and CE Mark;
- Supported creation of the Technical Product Documentation for Medical Device Technical Files including
  - Risk Management,
  - Clinical Safety and Efficacy Classification,
  - Essential Requirements,
  - Declaration of Conformity,

- Technical Document Index ;

- Engaged with colleagues on all levels and contracted clients when promoting continuous improvement, sharing best practices and promoting compliance culture;
- Managed the ACTIV QMS electronic software system.

Smith and Nephew Orthopaedics, Leamington Spa **05.2008 - 05.2012**
Roles and Responsibilities - Quality Associate (IMPLANTABLE ADVANCE BEARING SYSTEMS)

- Management of Customer Complaints and Post Market Clinical Evaluations;
- Managed the drafting, approval, reviewing and implementation of SOPs;
- Facilitated continuous improvement programs, including Kaizen blitz and lean;
- Involved in company's road show demonstrations and "Show Site" visits as a Tour Guide to provide potential customers with opportunity to see products in use and its' clinical value.

Smith and Nephew Orthopaedics, Leamington Spa / Warwick **09.2006 - 05.2008**
Roles and Responsibilities - Quality Inspector

- Management of Goods Inwards Raw Material and Surgical Instruments Inspection in accordance with the specifications for the required products and coordination of final product release;
- Managed non-conformities for vendors' issues and Supplier Chain Management System;
- Evaluation and report on Quality System Data progress and results to senior management.

COURSES / TRAININGS

11. 2015 - Train the Trainer, KL Consultancy
07. 2015 - Process Validation, MaetricsLtd
09. 2014 - FDA QS Regulation 21CFR Part 820, Medicom
10. 2013 - IEC/EN 62304 Medical Device Software, Intertek
02. 2013 - Medical Device Directive 93/42/EEC, SGS Academy
03. 2011 - Management of Customer Complaints and Recalls for pharma and medical, NSF DBA
10. 2010 - Product Complaint Investigations, training brought by "ComplianceOnline"
11. 2009 - Risk Management and ISO 14971:2007, Pink Associates Limited, ACP by BSI
10. 2009 – CAPA Management, Chartered Quality Institute (CQI)
10. 2009 - Auditor of ISO 13485, Pink Associates Limited, ACP by BSI

EDUCATION

10. 2009 - 06.2012 - CQI, Diploma in Quality Level 5, Birmingham City University
10. 2001 - 06.2006 - MA in Journalism, University of Zielona Gora, Poland
09. 1996 - 06.2001 - Food Technologist, Technical School, Nowa Sol, Poland

SKILLS

- Conceptual and analytical way of thinking, efficient and results orientated.
- Communicative and good at relationship building internally and externally.
- Well-developed multitasking and project management capabilities with efficient time management skills.
- Experience of managing multi-functional teams.
- Competent with Microsoft Office, Word, Power Point, Excel and Visio.
- Expert in Quality tools and techniques

LANGUAGES

Polish and English – fluent, German - basic