Greta Gozzi

+39 3451843553 greta.gozzi.gg@gmail.com

Profile

I am a sociable and dynamic individual with very pronounced soft skills that have allowed me to successfully work in teams of all sizes. Being a resourceful and naturally problem-solving oriented person, I am able to coordinate complex projects, remaining attentive to the budget and available resources.

Professional experiences

(April 2022 – Present)
Senior Regulatory Affairs Consultant (Jsb-Solutions)

As a senior Consultant I work for many customers in order to assist, organise and implement their Quality and Regulatory system. My role involves simplifying the client's activities, coordinating projects that require transversal knowledge such as the regulatory, quality and research and development part.

- Management of technical documentation of medical devices
- for MDR (2017/745), management of the company's CE marking
- Management, updating and creation of risk analysis (product/process)
- Management of the certification of new products
- Management of relations with notified bodies and supervisory institutions / competent authorities
- Management of non-EU registrations and preparation of supporting technical / regulatory documentation
- Management of Quality System Documentation, including updating and creating procedures, operating instructions and all other records according to ISO 13485 and ISO 9001 standards
- Customer support for implementing the Quality and Regulatory system

(November 2020 – April 2022)
Head of Quality and Regulatory (Newmed SRL)

- Management of technical documentation of medical devices for MDR (2017/745), management of the company's CE marking
- Management, updating and creation of risk analysis (product / process)
- Management of the certification of new products
- Management of relations with notified bodies and supervisory institutions / competent authorities

- Management of relations with the Ministry of Health: obtaining free sale certificates, registration of medical devices, contact person during inspections, management of forms for reporting accidents and near misses
- Management of non-EU registrations and preparation of supporting technical / regulatory documentation
- Management of requests regarding certifications / markings made by foreign distributors, sales agents, technicians and supervisory authorities
- Management of Quality System Documentation, including updating and creating procedures, operating instructions and all other records according to ISO 13485 and ISO 9001 standards
- Coordination and support for inspection visits by notified bodies
- Planning, management and evaluation of corrective actions to be taken due third-party audit reports
- Active participation in the Management Review and in the drafting of quality objectives
- Covering the role of management representative and responsible person for MDR
- Support for requests from the technical office and management of new projects / project changes
- Support for requests from the purchasing department and collaboration in the evaluation / re-evaluation of suppliers
- Conducting and organising audits at suppliers
- Management of internal company audits and management of corrective / preventive actions to be taken
- Registration of non-conformities / complaints from suppliers and / or end customers, analysis of the causes and management of corrective actions to be taken
- Analysis of macro data relating to post-sales surveillance
- Monitoring of the quality of business processes and analysis of macro data with consequent creation of trends
- Identification of the training / training needs of all staff on the issues of quality and teaching in training
- Management of the Technical File for pressure equipment and maintenance of the PED certification together with the managers of the technical office
- Management of documentation and activities related to the topic of Safety in collaboration with the RSPP
- Monitoring of machine maintenance activities and calibration / calibration activities and control of related records.
- Coordination of an asset and organisation of activities

(June 2020 – October 2020)
Complaint management and CAPA coordinator (Haemotronic)

- Complaints management including organisation of the evaluation team, supervision of the compliance with the closing times of the individual process steps, closing the complaint and preparing the report to be sent to the customer.
- CAPA management and organisation, including the organisation of the team identified for the implementation of the same.

- Interaction and collaboration with the various company services for the management of the various Complaints processes, CAPA and PMS.
- Monitoring of KPIs through interaction with the other services involved.
- Preparation of documentation to support Management meetings, Management Review, customer audits, notified body audit, etc ...
- Collaboration with RA in the drafting of the PMS.

(September 2019 – June 2020)
Quality Assurance Specialist (Cantel Medical)

ESSENTIAL DUTIES AND RESPONSIBILITIES

- Management of Quality documents in compliance with the regulations of different countries:

EUROPE	- 93/42/CEE Medical Device Directive (and subsequent amendments and addenda) - ISO 13485:2016
ITALY	- D.L. 46 02/27/1997 Implementation of Directive 93/42/EEC relating to medical devices (and subsequent amendments and addenda),
USA	- 21 CFR 820.40 (a)(b), 820.20(e) Quality System Regulation (GMP Current Edition)
CANADA	- MDR SOR/98-282 Medical Device Regulation
JAPAN	- MHLW MO169
AUSTRALIA	- Therapeutic Goods (Medical Devices) Regulations 2002
INTERNATIONAL	- UNI EN ISO 13485 Medical devices - Quality Management Systems - Requirements for regulatory purposes - MDSAP companion document

- People management (coordination of a team and organisation of weekly activities).
- Manage NC's process for Chemistry products and Disposable machines (including support to management of raw materials/components issues raised in Incoming and Production areas).
- Support CAPA's process and follow-up on corrective actions to ensure that they are implemented on time and are effective.

- Ensure product complaints are promptly investigated and, where needed, adequate corrective/preventive actions are accordingly raised and implemented.
- Participation in preparation of PFMEAs.
- Evaluate opportunities for improvements to the operation of the QA department.
- Support periodic review of department internal control procedures.
- Where necessary, gather and trend quality data for periodic review and Quality Management Reviews.
- Support the QA Supervisor for internal and external audits activities.
- Assist the QA Supervisor in developing the corrective action plans for any findings resulting from internal and external audits.
- Ensure that personal training records are maintained in conjunction with the HR department.

(May 2019 - September 2019)
Regulatory Affairs - Pharma Dept (Diaco Biofarmaceutici)

In addition to coordinating Quality Assurance, I was recently given responsibility for Regulatory Affairs. I am responsible for the Regulatory Affairs Department (Pharma, Medical Device and Cosmetics) where I lead the following activities:

- keeping the sector legislation up to date
- information to the company management and to all the involved functions of the legislative innovations concerning the products and the production workshop
- guarantee of maintenance of product and production site authorizations
- marketing support for the development of new products
- internal Pharmacovigilance referent and trainer
- periodic update of Site Master File (STM)

I coordinate a resource that takes care of the Regulatory Affairs related to medical devices (Technical File, registration process in extra EU countries, printing material),

(July 2018 - September 2019)
Quality Assurance Specialist (Diaco Biofarmaceutici)

I am responsible for Quality Assurance for the part related to the production of medical devices and cosmetics, my main responsibilities are:

- writing procedures that deal with operations, quality control (QC) and quality assurance (QA) according to ISO 13485, ISO 22716 and GMP;
- managing of deviations and non-compliances, root cause analysis;
- self inspection activities of production units;
- supplier audits and redaction of audit report;
- batch record release;
- continuous improvement activities.

The main objective is the construction of a quality system, considering the recent entry on the market of medical devices and cosmetics. I also work to streamline process flows and training of all staff. The company is GMP certified, all the quality systems are managed in

compliance with good manufacturing practices. I coordinate a resource that deals with the operational part related to process quality of Medical Device and Cosmetics.

(July 2017 - July 2018)
Quality Assurance Engineer (Stevanato Group - Nuova Ompi)

I work in the Quality Assurance business unit, my main responsibilities were:

- writing procedures that deal with operations, quality control (QC) and quality assurance (QA) according to ISO 9001, ISO 15378, ISO 13485, ISO 14001 and GMP;
- managing of deviations and non-compliances;
- self inspection activities of production units;
- supporting customer audits and redaction of audit report;
- batch record activities and orders fulfilment.

My job is horizontal to all company departments. This helps me to deepen my knowledge of every company process and in the meantime I can improve my social and teamwork skills.

(October 2016 - April 2017)
Intern at Biomaterial laboratory (University of Trieste).

(February 2016 - September 2016)
Intern in the Orthopaedics department at Rotterdam Medical Centre (Netherlands)

(September2015 - February 2016)
Intern at Biomaterial laboratory (University of Trieste) and Ospedale Maggiore (Trieste)

(March 2015 - September 2016)
Intern at Burlo Garofalo Pediatric Hospital in Trieste

(March 2014 - July 2014)
Intern at LNCIB in Trieste

(June 2008 - September 2008)
Intern at Progeo in Reggio Emilia

Studies

(November 2019)
Internal auditor certificate ISO 19001 at IMQ

(July 2019)
Highly specialised course in Regulatory Affairs (Pharma, Medical Device, Cosmetics and Food) at Alma Laboris Business School.

(October 2014 - July2017)
Master Degree in "*Nanobiotechnology*" at University of Trieste.

(October 2010 - July 2014)
Bachelor Degree in "*Biotechnology*" at University of Parma.

(July 2009)
High school Diploma at *Antonio Zanelli* Agrarian Institute

Language skills

- ***Italian*** : fluent
- ***English*** : fluent

IT skills

- Very good knowledge of Microsoft Office (Word, Excel, Power Point);
- Familiar with the statistical software R;
- Experienced in the use of GraphPad.

Interests

I like running, crossfit and traveling to see different cultures.