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Stéphanie LHUILLIER

Quality, Regulatory and Medical Affairs Director

Employment Experience

2021 - 2024 **Deputy Director of Quality, Regulatory and Medical Affairs**

FH ORTHO (subsidiary of the Olympus group, design, manufacturing and distribution in France and export, orthopedic implants and metal instrumentation, Mulhouse (68), (110 employees, 2*8), ISO 13485, ISO 9001.

- Strengthening a high-quality culture
- Management of the Quality System and its improvements (ISO 13485, Directive 93/42/EEC and Regulation 2017/745, 21CFR)
- Post-market monitoring of products
- Participate in post-market surveillance according to applicable standards
- Participate in the control of distributors
- Manage Customer Complaints, Materiovigilance and Product Recalls
- Manage medical affairs and regulatory affairs: develop the clinical strategy for all of our references on the market and manage distributor regulations

2019- 2020 **Quality Manager** (Management Committee)

TISZATEXTIL Packaging, production of primary packaging-minibags for pharmaceutical industry / plant of 70 employees), ISO 15378, 9001, 14001

- Development of efficient communication with Customers
- Animation of problems solving groups
- Managing of Customers audits
- Guarantee and improvement of quality performance
- Customer requests management (claims, audit, questionnaires, 8D, specifications, change control)
- Quality control management with team
- Organization of training in Good Manufacturing Practices
- Manage GMP SOPs and ensure their compliance with applicable GMP/GDP regulations
- Ensure high quality of all product related activities and documents in accordance with SOPs and GMP requirements

2018-2019 **Quality Manager** (CODIR)

CONSTANTIA Jeanne d'Arc, austrian company (manufacturing of flexible packagings for the food industry /plant of 60 employees), ISO 9001, BRC standard

- Management of customer complaints, quality action plan and KPI indicators + Optimization of the non-conformance
- Quality control management with team (checking, release, sampling in laboratory)

2009-2018 **Quality Environment Safety and Health Manager** (CODIR)
AESCULAP, german company (metal knee orthopedics implants / plant of 120 employees)

- Animation of quality relations with customers and internal teams managing customers' claims
- Improvement of quality performance - analyzing main performance gaps
- Piloting actions plan at local level included in a group actions plan (scraps analysis, quality costs efficiency)
- Mastering metrology
- Pilot standards improvement and support quality teams on key practices application (FMEA, 8D, CAPA)
- Defining and managing of the QEHS organization of the plant in accordance with the group
- Sharing technical expertise with german group and french plants on improvements in manufacturing steps
- Management of 13 employees team quality (Production Control, Validation, Metrology, System Quality)
- Management of ISO 13485 quality certification audits
- Implementation of US FDA requirements: 21CFR part 820
- Organization of audits (internal - external) and auditor
- Development of production quality and indicators
- Maintain and improve Quality Management System in accordance with company policies, applicable international regulations
- Coordinates, plans and conducts contractor audits and internal audits
- Initiate, evaluate, and approve change controls and deviations

Education

2006 **Magister Hygiéniste du Travail et de l'Environnement,**
Postgraduate degree following my Postgraduate degree as Hygienist of Work and Environment, IHIE-CNAM, Amiens

2004 **DESS- Master Ingénierie Ecologique**
Postgraduate degree following my master's in Ecological Engineering University of Corsica, Corté

2003 **MST Eaux, Sols, Pollutions,**
Master's Degree in Water, Soils, Pollution, University of Strasbourg,

2001 **DUT Génie Biologique option environnement,**
Higher National Diploma in Biological Engineering with environment

Skills

Software : Excel Computing, Word, Power Point, Access
Skills : Quality tools (PDCA, 5M, 8D, AMDEC), QRQC analysis, 5S method,
Training : Validation of computerized systems, Quality Manager, MDR Regulation, 21CFR PART 820, Team Manager, Internal and External Auditor ISO 9001, ISO 13485, ISO 15378, ISO 14155, ISO 14971

Languages

French	First language.
English	Spoken and written. TOEIC : 825: higher operational

Hobbies

Tennis(30/1), running, guitar and cycling