



EXTERNAL BRIEF

Quality Operations Director Healthcare

Job & Candidate profile



Birn+Partners
2022

The Company

Orifarm was founded in Denmark in 1994 by Birgitte and Hans Bøgh-Sørensen.

They started out with an entrepreneurial mission which was later re-named the 'explorer spirit'. This concept describes a company culture in which we are always looking for new ways to develop and improve, with respect for both quality and the individuals in our company.

The results speak for themselves: Today, Orifarm Group is the largest supplier of parallel imported pharmaceuticals in Europe and we have a strong presence on the Nordic generic markets. They have become an international company and we operate in Denmark, Czech Republic, Germany, Sweden, Norway, Finland, the Netherlands, Austria, the UK, Poland, Belgium, the Baltic States, and the USA. The entire group now employs close to 2,200 people and we continue to add new employees to support us in our growth.

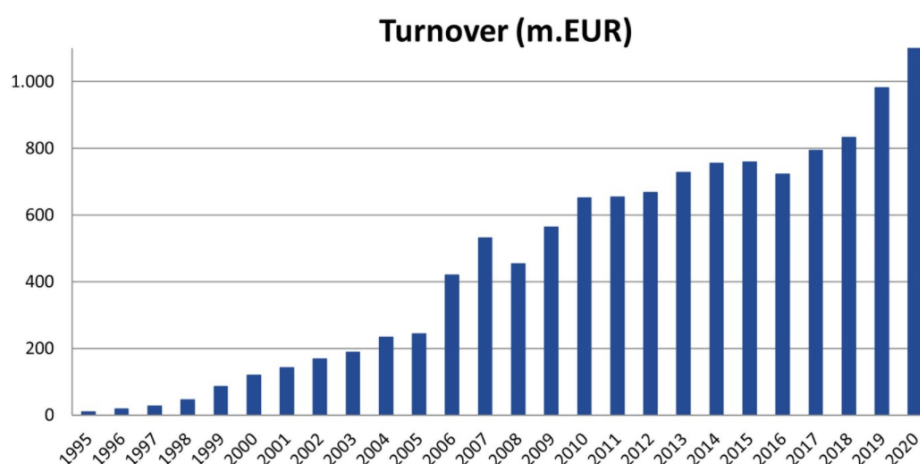
Vision&Mission

Orifarm is built on solid values and a clear vision and mission. Their values as well as their vision and mission constitute the foundation of the company. In order to understand who Orifarm is and where they are going, one must understand this foundation. It was developed by owners and employees and guides us in everything they do.

ORIFARM'S MISSION: We challenge the market and make affordable healthcare available

ORIFARM'S VISION: We want to be no. 1 in making healthcare a better deal

They challenge everything they face to the benefit of the end user. Every end user within the healthcare market deserves affordable pharmaceuticals. Through all their efforts they aim at creating competition and provide large savings for end users (the patients) and societies.



Quality organisationen

Quality and Compliance organisation has been re-designed in Orifarm as a part of our Play to Win strategy (2020-2025) to enable Orifarm to deliver on Trade, Healthcare and New Biz ambitions. They want to be number 1 in making Healthcare a better deal and grow their business to 2 Billion Euro in net turnover by 2025.

They will support the corporate strategy by ensuring patient safety, compliance, high quality standards and reliable supply to patients. They are going to establish an integrated scalable model and take a proactive approach to govern and manage quality across Orifarm's Business areas.

THE POSITION

As the new Quality Operations Director you will be leading the development of the newly defined Quality Operations team within the Healthcare Business Unit. You play a critical role in the business by ensuring products meet quality standards and Orifarm Healthcare/Generics meets all obligations as MA holder. You will be working cross functionally and cooperate with Regulatory, Business development, own plants and contract manufacturers within the Healthcare business unit as well as corporate functions, Finance, IT, Legal, HR and Corporate Compliance.

You will build, develop and lead a skilled team of app. 35 employees.

Main responsibilities:

- ⊕ Interactions with 3rd Party Customers, CMO's and Own sites in support of quality plans, issue escalation and notification, corrective and preventive actions to specific issues and quality governance.
- ⊕ Assure consistent quality of production by developing and enforcing good manufacturing practice systems and documentation to ensure contract manufacturers (CMO) and Own plants comply with Orifarm requirements.
- ⊕ Responsible for all tasks and actions in relation to batch release for QP certified products.
- ⊕ Initiate Change controls are required by Orifarm procedures.
- ⊕ Coordination with Corporate Compliance teams to support regulatory inspections.
- ⊕ Make sure all necessary licenses are obtained according to the markets legislations
- ⊕ Collaborate with internal teams and functions and other internal stakeholders (e.g; Legal, finance) with respect to resolution of claims or quality related issues
- ⊕ Liaise with the RA (regulatory affairs department) to ensure Regulatory Control Files (RCF) are approved by all suppliers for QP certification by the supplier.
- ⊕ Preparation of Quality Quarterly reports
- ⊕ Ensure that all activities are in compliance with the requirements of GMP and Orifarms obligations as MA Holder.
- ⊕ Various other additional tasks that may be required in accordance with the overall goal of the company

THE CANDIDATE PROFILE

Professional background:

- ⊕ Pharmaceutical, or other Chemical, Biological scientific degree
- ⊕ Experience in corresponding position in the pharmaceutical industry. A wide range of product knowledge, including solid dose, liquids, Steriles and Medical Devices would be an advantage.
- ⊕ Experienced leader with minimum 8 years team leadership or management roles with demonstrated results.
- ⊕ High level of analytical and strategic thinking around a product, initiative, drive, and commitment
- ⊕ Team mindset as well as demonstrated ability to lead quality integrity and compliance

Personal background

- ⊕ You are analytical, fact-driven, and pro-active
- ⊕ You are strong in building and maintaining relationships and collaboration
- ⊕ Strong communications skills - Ability to communicate cross functional and international - and gain respect internally as well as and externally
- ⊕ Highly adaptable and adjusts quickly to change
- ⊕ You are innovative, creative, and service minded

SUCCESS CRITERIAS

- ⊕ Redesigning critical processes according international pharma standards, foster a culture of continuous improvement using the Orifarm PAC community.
- ⊕ Develop and nurture Orifarm culture throughout the team.
- ⊕ Recruitment, Coaching and Mentoring for the Teams (select talents and succession planning)
- ⊕ Improve and maintain QKPI's in area of responsibility and to ensure integrity of Orifarms Quality system.

CHALLENGES

- ⊕ Redesign quality release processes
- ⊕ Resourcing the team, training and development.
- ⊕ Establish agile mindset
- ⊕ Culture change become a more transparent team fully engaged in Orifarms business model and aspirations.
- ⊕ Be a mentor and/or coach

NOTE: position will report directly to Acting COO for first 6 months then VP Product Supply.

WORKPLACE

Odense – possibility to work from home when suitable, however we envisage “full time” need for the initial 6 months.

LANGUAGE COMPETENCES

- ⊕ Danish – fluent in oral and writing
- ⊕ English – fluent in oral and writing

IT COMPETENCES

- ⊕ Microsoft Office 365
- ⊕ QMS Veeva would be an advantage
- ⊕ SAP/ Microsoft dynamics also as advantage

CONTACT INFORMATION

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