CV / Charlotte Borgensgaard

Charlotte Borgensgaard

BORGENSGAARD Consulting
quality leadership | quality management | human behavior

Mobile: +45 30 328 327
Mail: charlotte@borgensgaard-consulting.dk
Homepage: https://borgensgaard-consulting.dk

Summary

I have 25 years of global experience heading quality and regulatory affairs in primary plastic packaging for pharmaceuticals and medical devices. During my career I have worked with plants in Europe, US, South America and Asia and have developed and implemented global standards for Quality Leadership, Quality Management and Regulatory Affairs. I have been working with small, medium and large organizations having different complexity and maturity, and know how important it is to understand where they are coming from, to support a good and realistic development process. My approach is business-oriented and holistic with focus on creating value for company, employees, products, customers and end-users. I combine extensive knowledge in quality and regulatory requirements in life science industry with my interest in the science of behavioral psychology. I enjoy working with people and teams helping them with leadership, quality management and improvements. My approach is to ensure that solutions supports the strategy while it is transmitted into practical and workable solutions in compliance with applicable requirements. My personality is open and friendly, and I have a high level of integrity and responsibility and put a lot of passion into my work. I strongly believe in an open and honest communication.

Business Experience

2019 - present BORGENSGAARD Consulting quality leadership | quality management | human behavior	Owner and Senior Management Consultant Consultant services to life science industry with focus on: • Quality Leadership • Quality Management • Human Behavior. For more details: https://borgensgaard-consulting.dk
2018 – 2019 AlfaNordic	Director Medical Device • Responsible for consultant team proving services for quality assurance and regulatory affairs • Strategy, budget and sales • Senior Consultant on Medical Device • Regulatory evaluations and strategies for start-up companies or large organization new to medical device • Process & software validation – evaluation of compliance and proposal for new approach including writing SOPs etc.

	• Counselling on process validation and perform training • Risk Management – Implementation of new approach including writing SOP and perform training • Quality assurance for distributors of medical devices • Evaluation of production facility and quality system and proposal for improvement
2014 – 2018 Gerresheimer Plastic Packaging	Global Senior Director Quality & Regulatory Affairs • Responsible for QA, QC and regulatory affairs covering Denmark, Poland, Spain, India, Brazil & Argentina • Integration of plant in India and quality improvement • New clean room production in Spain & US • Continuous optimization of quality management system and standardization • Focus on zero defect approach, risk management, systematic problem solving & human errors • Implementation of updated regulations/standards • Quality agreements with customers & customer support / visits / quality reviews & partner program with Johnson & Johnson • Quality requirements for distributors • SAP Quality Issue Management implementation & SAP software validation
2012 – 2014 Gerresheimer Plastic Packaging	Director Quality & Regulatory Affairs • Responsible for QA, QC and regulatory affairs covering Denmark, Poland, Spain, Brazil & Argentina – main focus on Europe • Establishment of Regulatory Affairs department • Implementation of updated/new regulations and standards • Implementation of quality vision, strategy, quality culture etc. • Focus on zero defect approach and systematic problem solving • Optimization of supplier quality management • Training programs / webinars globally • Introduction program for new employees
2010-2016 Gerresheimer Group	Chairperson for Gerresheimer Quality Council • Start-up council for Quality Directors from each division • Define and roll-out of quality vision, strategy, quality culture • Define and roll-out reporting of quality KPIs / plants & global key accounts • Optimization of Quality Systems & Cost of Poor Quality (COPQ) • Training program for systematic problem solving • Workshops & presentations internally and on conferences for customers • Software validation of SAP • Global quality management for selected key accounts
2006 – 2012 Gerresheimer Plastic Packaging	Quality Director • Responsible for QA, QC and regulatory affairs with main focus on Europe • Establishing a new division in Gerresheimer with a global quality organization

	• Transfer of production from Germany to Poland • Integration of new plants in Spain, Brazil and Argentina • New plant in Spain and transfer of equipment • Optimization of quality management system & standardization • Quality Agreements with customers & customer support / visits / quality reviews • FDA Drug Master Files, Registration in China, Russia, Ukraine
2002 – 2006 Superfos Pharma A/S	Quality Manager • Responsible for QA, QC, regulatory affairs and environmental management for plants in Denmark and England • Implementation and certification of ISO 15378 • Optimization of quality control and continuous improvement of quality management system • New plants in England and in Denmark • Close down of manufacturing in England • Quality Agreements with customers & customer support / visits • FDA Drug Master Files, Registration in China, Russia • Implementation of a very comprehensive electronic document control system / Library
2001 – 2002 Scribona Distribution A/S	Product Unit Manager • Purchase and marketing of Compaq • Business plan & campaigns • Cooperation and negotiation with Compaq • Increased market share of Compaq in a very challenging market • Support to customer care & sales • Responsible for cross-organizational projects • Implementation of CRM system
2000 – 2001 Scribona Distribution A/S	Business Unit Manager • Responsible for P&L and team for purchase, sales, marketing and support of Compaq and Toshiba • Business plan & campaigns • Account manager on key accounts • Cooperation and negotiation with producers • Increased market share of Compaq in a very challenging market • My position changed after a merge which resulted in re-organization and separate sales department
1997 - 2000 Polystan A/S	Quality Manager • Compliance with ISO 9001, EN 46001, Medical Device Directive, FDA CGMP • Regulatory Affairs • Autonomous groups in production • Driver on mission, vision, strategies • Implementation of process management

	• Quality requirements for partners and subsidiary
1996 – 1997 Philips Medico A/S	PACS Product & Project Manager • Responsible for marketing, sales and project management of Picture Achieving & Communication Systems (PACS) & X-ray management system • New strategic area for company and customers • Project on Slagelse hospital – approval of phase 1 • Training of nurses in X-ray management system • Key driver on customer satisfaction survey study
1995 – 1996 Philips Medico A/S	Marketing, Quality & IT Manager • Key driver on marketing strategy including competitor analysis, mapping of the market, business plan per product segment, communication strategy • Design and Implementation of customer satisfaction surveys • Design and implementation of IT system for mapping of prospects and registration of market shares • Maintenance of Quality Management System • Involved in optimization/implementation of strategies, organization, leadership/management & culture • Position changed in 1996 as marketing position was centralized globally and the Danish organization was reduced with 20% and re-organized
1993 – 1995 Philips Medico A/S	Quality & IT Manager • Responsibility covering Denmark • ISO 9001 + EN 46001 certification • Implementation of Medical Device Directive • Implementation of Total Quality Management • Support to Norway in relation to ISO 9001 + EN 46001 certification • Involved in quality standardization globally in Philips Medical Devices • Key driver on new and first IT strategy • Involved in defining mission and business strategy
1992 – 1993 Philips Medico A/S	Nordic Quality Manager • Responsible for quality management in Denmark, Norway and Sweden and start-up of ISO 9001 project and audits • Involved in quality standardization globally in Philips Medical Devices • Responsible for IT in DK including sourcing of hardware & software • Facilitator in improvement projects in other divisions and cross-divisional teams • My position changed in 1993 as the Nordic organization was dissolved
1986 – 1992 Philips Danmark A/S	IT Developer • Project management, support, training, programming & testing • IT systems for purchase, warehouse, material and production planning • Involved in cross-divisional improvement program for customer satisfaction

Languages

- Danish: Native language
- English: Main language in my professional life both verbally and in writing
- French: Limited but can easily be improved (lived in France for two years as a child and joined French school)
- Swedish: Understand verbally and in writing and can communicate verbally in a mixture of Swedish and Danish.
- Norwegian: Understand verbally and in writing

Education

1991	B.Com, Logistic (HD degree) / Thesis: Quality and Service Management
1986	IT System Developer

Training

List can be handed-out on request
