Kees den Besten

Summary of Qualifications

Results oriented, pragmatic all-round professional in **quality assurance** and **regulatory affairs** who gained broad hands-on and leadership experience by working in leading multinational companies in medical device industry.

Effectively collaborates with all levels and across functions of an organization; extensive experience in working in international environments and across cultures based on effective interpersonal skills and a solid technical background. Recognized for solid leadership in balancing business interest and compliance through pragmatic solutions. Proven track record on organizational transformation, process and product improvement, quality management and regulatory market access. Fluent in English, German and Dutch.

Relevant Work Experience

D.O.R.C. Dutch Ophthalmic Research Center (International) B.V. (Mar 2020-Aug 2024)

DORC is a global medical device company specialized in the development, manufacturing and servicing of systems and instruments intended for use during ophthalmic surgery with in total about 800 employees and locations in Europe and USA. DORC was acquired by Carl Zeiss Meditec AG in April 2024 after being sold by private equity company Eurazeo.

Chief Compliance Officer (Mar 2020-Aug 2024)
Responsible to establish, maintain and oversee the implementation of strategies in the areas of Quality Assurance, Regulatory Affairs and Clinical Affairs in support of the company business strategy. Responsible for ensuring product and process quality as well as compliance to regulations throughout the lifecycle of the products and maintaining and expanding regulatory approvals in over 60 countries for 33 product families.

Key accomplishments:

- Built cross-functional relationships across the sales organizations as well as internally resulting in a working relationships that were based on mutual respect and collaboration.
- Established effective processes to analyze and monitor internal KPIs and market feedback with the aim to initiate product and process improvements.
- Increased compliance robustness of the company as evidenced by a reducing number of external audit observations over time.
- Increased compliance awareness of the organization through presentations and training.
- Established a Clinical Affairs department
- Implemented a new organization to obtain and maintain regulatory approvals.
- Prepared and lead the vendor due diligence for Quality Assurance and Regulatory Affairs to support the selling process of DORC to potential bidders.
- Conducted buyer due diligence process for several acquisitions of DORC
- Introduced the quality system simplification program
- Prepared DORC for MDR transition

Hoya Surgical Optics (Sep 2014-Mar 2020)

Hoya Surgical Optics is a global medical device company specialized in the development and manufacturing of Intra-Ocular lenses and related accessories with in total about 1000 employees and locations worldwide.

Vice-President Global Quality Assurance and Regulatory Affairs (Jan 2019-Mar 2020)
Responsible to establish, maintain and oversee the implementation of strategies in the areas of Quality Assurance and Regulatory Affairs in support of the company business strategy. Responsible for maintaining and expanding regulatory approvals in over 40 countries for eight product families. In addition, responsible for directing the organization in maintaining product and quality system in compliance with all applicable regulations.

Key accomplishments:

- Lead the due-diligence activities for QA and RA for multiple acquisition targets of HOYA.
- Development and implementation of integration strategy for QA and RA for acquired companies Mid Labs and Ruck companies
- Development and implementation of cross-functional regulatory strategy to meet European Medical Device Regulations requirements
- Completed successfully change of Notified Body and Legal Manufacturer
- Obtained approval for Toric IOL in Japan 6 months ahead of schedule

Vice-President Global Quality Assurance, Regulatory Affairs and Clinical Trial Management (Sep 2014-Dec 2018)
Responsible to establish, maintain and oversee the implementation of strategies in the areas of Quality Assurance, Regulatory Affairs and Clinical Trial Management in support of the company business strategy. Responsible for maintaining and expanding regulatory approvals in over 40 countries for eight product families. In addition, responsible for directing the organization in maintaining product and quality system in compliance with all applicable regulations.

Key accomplishments:

- Establishment and implementation of 5 year strategies for QA, RA and Clinical Trial management
- Transformed the regulatory affairs department from Japan centric to a global organization of 30 HCs
- Implemented global market access management process covering over 40 countries and 8 product families
- Obtained approvals for key products in US, Japan, China, Brazil and Europe
- Successfully executed key clinical trials in support regulatory approvals in Japan and Europe
- No major observations in inspections of FDA, Anvisa, CFDA, KFDA, TUV Sued, and MDC
- Established Global Quality System supported by electronic QMS management platform

Baxter (June 2008 - Aug 2014)

Baxter is a global medical device and pharmaceutical company specialized in dialysis, drug delivery, vaccines and biologics therapies. Baxter has locations worldwide.

Director Quality Assurance Global Gambro Integration (Sep 2013-Aug 2014)
Responsible for the development and execution of the Quality Integration Strategy for the acquisition of Gambro by Baxter. This includes the integration of the both Global Quality Management Systems, supporting plans of other functions as part of maximizing synergies, as well as identifying and delivering on financial and organizational opportunities for the Quality Function.

Key accomplishments:

- The Day 1 of the acquisition went smooth without any quality related question.
- Implemented a method to integrate quality system processes that significantly simplifies the Baxter Quality System.

Director Quality Assurance and Business Excellence EMEA (Apr-Aug 2013)
Responsible for regional implementation and joint development of the Baxter Global Quality System. In addition conducting management oversight activities on audits, CAPA, management review for all Baxter region EMEA plants, as well as supporting the role out of Business Excellence methodologies across the region.

Key accomplishments:
- Achievement of the Corporate Project Team of the Year Award for the CAPA process redesign project, in which I played a key role.

Director Post-Market Surveillance and Quality Systems EMEA (Mar 2009-Mar 2013)
As a member of the EMEA Quality Leadership Team as well as the Global Quality System Leadership Team responsible to align and influence regional, divisional and corporate interests with regards to the development, implementation, and oversight on the global quality system and product quality. From an operational perspective responsible for regional Quality System implementation and compliance, FCA coordination for EMEA, as well as product artwork development, and global ISO Quality System Certification management.

Key accomplishments:
- Successfully reorganized the Quality System, FCA and Complaint Handling groups resulting in a more effective and efficient organization
- Successful track record in representing and defending regional interests at Corporate level
- Established effective methods for regional management oversight over the 14 operating entities in EMEA
- Established and executed strategy for Global Quality System Certification management
- Negotiated a Global Service Level Agreement with TUV for certification and Notified Body services
- Being acknowledged and respected as a knowledgeable contributor and influencer at global level
- Build close relationship with management of Notified Body TUV Sued as key account liaison
- Achieved significant success in people development.

Country Quality Assurance Director EMEA (June 2008-Mar 2009)
Provided leadership to a team of more than 80 persons located in more than 20 countries in EMEA. This team was responsible for adherence to Good Distribution Practices and local pharma regulations, field service, as well as the implementation of Field Corrective Actions and local Complaint Handling for all Baxter products.

Key Accomplishments:
- Developed and engaged team in deployment of strategy aimed at moving from an operational only approach to operational and business focused approach.
- Resolved several resource issues in the organization.
- Build effective relationships with business leaders across Europe.

Cordis Corporation, a Johnson & Johnson Company (Sep 2004-May 2008)

Cordis was a global medical device company, which was at that time part of Johnson & Johnson. Cordis was specialized in treatment and diagnosis of cardio-, endo- and neurovascular diseases and had locations in Florida, New Jersey, California, Puerto Rico, Mexico, and the Netherlands.

Program Director Quality Assurance (June 2007-May 2008)
As Program Director based in Miami responsible for achieving one of the key objectives of the Corporate Quality VP, being the redesign of the global change management process.

Key Accomplishments:
- Achieved alignment between all critical stakeholders on the strategy for change assessment
- Completed on-time the successful implementation of a new Change Control Process

Plant Quality Assurance Director (Sep 2004-May 2007)
At the Cordis plant in the Netherlands provided leadership to the Quality Assurance organization, who supported the manufacturing of stents and catheters for cardio- and endovascular applications, as well as the warehousing and OUS distribution of all Cordis products. The plant had over 1000 employees. Main responsibilities were to improve product quality in an environment where manufacturing costs had to decrease significantly, and to change quality culture within the company.

Key Accomplishments:
- Changed quality culture from quality-police mindset to close collaboration between manufacturing and quality assurance
- Achieved significant product quality improvements, simultaneously with cost reductions by applying six-sigma and lean principles
- Managed various regulatory inspections without obtaining major observations (e.g. FDA)
- Led QA and plant organization through several significant layoffs
- Achieved significant successes in people development
- Supported the due diligence activities of J&J in the attempt to acquire Guidant.

Vitatron, a Medtronic Company (Sep 1999-Aug 2004)

Vitatron was a subsidiary of Medtronic, and at that time acted as an independently operating, global pacemaker company based in the Netherlands.

Director Quality and Regulatory Affairs (Sep 1999-Aug 2004)
Provided leadership to a team responsible for maintaining compliance of products and quality system with European, US and Japanese regulations. In addition responsible for obtaining and maintaining regulatory approval for products in the markets where the company performed its business (e.g. EU, Japan, US).

Key Accomplishments:
- Transformed the focus from the Quality Assurance organization and the quality system from documents to process management
- Transformed the attitude of quality personnel towards Medtronic from defensive to collaborative.
- Led successfully a major recall involving extensive press coverage and regulatory authority interactions
- Obtained EU RA approval for the first digital pacemaker platform in industry
- Obtained FDA approval for the established Vitatron pacemakers in collaboration with Medtronic RA
- Restructured as interim Clinical Director clinical department after organizational breakdown

KEMA Registered Quality (1995-1999)

KEMA was an international test and certification house for products, services and quality systems, located in the Netherlands, currently operating under the name DEKRA Certification.

Several positions with increasing responsibility in KEMA Notified Body (Apr 1995-Aug 1999)
As auditor, account manager and later on as certification manager worked in a small team to turn KEMA into one of the leading Notified Bodies in the starting years of the Medical Device Directive. Responsible for providing guidance to manufacturers, developing methods to verify compliance with the directives, conducting technical and design file reviews, as well as performing audits.

Key accomplishments:
- Established an efficient certification documentation structure and supporting quality system that turned out to be a competitive advantage
- Was account manager for 50+ accounts in mainly US, Israel and the Netherlands without losing a single customer
- Achieved alignment between the US and European branch of KEMA on the methods of auditing and operations.
- Developed as first among Notified Bodies a method for auditing development processes in the context of the Medical Device Directive

Education and Training

Formal Education

Executive MBA, University of Bradford (2002-2004)
- Management project focused on risk and crisis management especially in medical device industry.

PhD in Electrical Engineering, University of Twente (1989-1993)
- Project on the development and realization of a measurement system for intra-ocular pressure applying a new micro-mechanical sensor design

Master in Electrical Engineering, University of Twente (1983-1989)
- Master project on the realization of a silicon based microphone for hearing aids