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**CHIEF REGULATORY OFFICER**

*All-round executive with 20+ years of broad experience in diagnostic & medical device industry, regulations, compliance, clinical, operations, and reimbursement.*

Accomplished, analytical thinker, and passionate problem solver with the ability to read and interpret complex regulations and make accurate operational decisions. Skilled in developing and implementing policies, procedures, and programs, ensuring compliance with existing regulations and best practices. Proven expertise in evaluating compliance issues within startups and global multi-national organizations and formulating action plans to improve operational performance.

**Highlights of Expertise**

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| * Regulatory Compliance * Operations Management * Marketing Strategies * Quality Assurance * Team Leadership & Mentoring | * Market Landscape * Risk Mitigation * Revenue Generation * Distribution Development * Continuous Process Improvement |

**Career Experience**

**Philips Consumer Life Style, Eindhoven Area, Netherlands** (March 2018 to Present)

*Philips has a 125+ year heritage of innovation. Turning great ideas into meaningful innovations is at the core of company.* *Future ambitions of Philips include Adaptive Intelligence Implementation, Connectivity & IoT, Test & Verification, Circular*

*Economy, Industry 4.0 and NBX Expert Pool.*

**DIRECTOR REGULATORY AFFAIRS, COMPLIANCE AND SAFETY**

Deliver robust guidance on global regulatory strategy, CE Marking, product registrations, and clinical evaluations. Supervise a team of 23 regulatory affairs specialists to create and implement global regulatory strategy and roadmap through competitive market landscape, regulatory / legislative initiatives, and product marketing strategy. Coordinate with product marketing teams to perform formal compliance reviews and risk assessments of new and enhanced products and service offerings. Translate complex regulatory requirements for new consumer regulated products and services to address practical implications of business.

* Setup Regulatory Team executing Medical Transition Program of Direct to Consumer Medical Device businesses.
* Identified compliance risks and provide oversight to corrective actions when necessary.
* Partnered with regulatory compliance team-leads on management of regulatory compliance activities, providing direction for registration and driving timely delivery of new products and modifications to existing ones.

**MDxHealth, Nijmegen Area, Netherlands** (July 2016 to Present)

*MDxHealth is a multinational healthcare company that provides actionable epigenetic information to personalize the*

*diagnosis and treatment of prostate and bladder cancer.*

**SENIOR VICE PRESIDENT CLINICAL DIAGNOSTIC AFFAIRS**

Provided expert guidance to a global cross functional team, managing overall aspects of product development, from conception to market launch. Drove and promoted the Leading Regulatory and Quality Assurance activities for ISO13485 accredited laboratory and CE-marked IVD’s in the EMEA market. Cultivated strong relations between EU and US operations, and aligned project prioritization to turn opinion leaders of major markets into marketing allies.

* Developed In Vitro Diagnostic business model parallel to the company’s CLIA and ISO central laboratory service business for products such as SelectMDx, ConfirmMDx and AssureMDx.
* Selected IVD platform(s) for kit development, development and optimization of product design control program, project management, reimbursement, and budgeting.
* Transformed a Central Laboratory Test into a Point of Care IVD solution, comprising of a Urine Collection Device, Laboratory Reagent Kit, and a Software Application, by developing and launching a medical CE-marked IVD Prostate Cancer Kit.
* Remodeled a Prostate Cancer Research Laboratory into an ISO13485 accredited Diagnostic Laboratory to serve European Patients.

Agendia (Nov 2003 to August 2016)

*Founded in 2003 as a spin-off from the Netherlands Cancer Institute / Antoni van Leeuwenhoek Hospital in Amsterdam, for commercializing molecular diagnostics using DNA microarray technology for cancer diagnosis and drug development.*

**VICE PRESIDENT REGULATORY AFFAIRS AND MARKET ACCESS EMEA** (May 2014 to August 2016)

Spearheaded global regulatory affairs, compliance and quality assurance activities of Agendia. Supervised the commercial activities related to distribution development and reimbursement for improving access to the European market, comprising of 750M people in 55 countries, including Middle East and Asia. Co-Authored with the U.S. FDA of the published Special Control Guidance Document on the development of Breast Cancer Mult-Gene Assays in U.S.

* Executed European commercial strategy, increased business to 15% market penetration and a 90% market share with 90% insurance coverage in home country, equivalent to €3.6M revenue.
* Converted a "70-gene research patent" into the MammaPrint Breast Cancer Test serving Breast Cancer Patients Worldwide, starting with 5 people and €1M loan, to 220 people staff with a €385M valuation.
* Attained the first U.S. FDA clearance for a multi-gene Breast Cancer Assay in the World.
* Procured seven additional U.S. FDA medical Devices Clearances, and European Medical CE marks for the MammaPrint diagnostic assay.
* Acquired ISO13485 certifications, U.S. CAP, and U.S. CLIA Laboratory Certifications for both E.U. and U.S. laboratories.

**VICE PRESIDENT REGULATORY AFFAIRS AND COMPLIANCE** (January 2013 to August 2016)

Handled additional responsibilities of Compliance Officer along with VP Regulatory Affairs. Duties included: overseeing and regulating implementation and operation of Global Compliance Program in compliance with codes of European Advamed and Office of Inspector General of U.S. Health and Human Services (OIG of HHS).

* Implemented full Corporate Compliance Program for both U.S. and European Laboratories as outlined by Office of Inspector General (OIG), the AdvaMed code, California Health and Safety regulations, as well as the EDMA Code.

**VICE PRESIDENT REGULATORY AFFAIRS AND QUALITY ASSURANCE** (May 2011 to January 2013)

Promoted by management with the responsibility to establish importance of Regulatory Affairs at strategic executive level. Incorporated long-term Regulatory Affairs strategies in liaison with marketing and sales departments. Provided assistance to Compliance Officer by developing and implementing fraud and abuse compliance plans.

* Supported Quality Assurance programs roll out to whole company.

**SENIOR DIRECTOR OF REGULATORY AFFAIRS, QUALITY ASSURANCE & REIMBURSEMENT** (May 2007 to May 2011)

Developed E.U. and U.S. reimbursement strategies including health economic studies, coding, pricing, and coverage strategies. Represented the company in public industry and governmental meetings.

* Recognized by management for building U.S. diagnostic laboratory and promoted to lead U.S. Regulatory activities such as, acquiring product FDA clearances and federal and state inspections.

Additional Experience

**DIRECTOR OF REGULATORY AFFAIRS & QUALITY ASSURANCE** (2005 to 2007) ▪ Agendia

**QUALITY MANAGER** (2003 to 2005) ▪ Agendia

**ENTREPRENEUR MARKETING STRATEGIES** (2002 to 2003) ▪ Netherlands Cancer Institute / AVL Hospital

**QUALITY MANAGER PATHOLOGY** (1999 to 2003) ▪ Netherlands Cancer Institute / AVL Hospital

**Education & Credentials**

MBA, Marketing & Sales

*Dutch Institute for Marketing (NIMA), Amsterdam*

BSc. Clinical Chemistry, Pathology, Histology, Cytology, Molecular Pathology, Hematology

*University of Applied Sciences, Leiden*

*Languages:* **Dutch:** *Native*|**English***: Fluent* |**German**: *Basic*

Professional Development

* + - Leadership development program 2013 - The Center for Creative Leadership (CCL®), Brussels

Affiliations

* + - **EPEMED** – Board of Directors
    - **ADVAMED** – Company’s representative at Board of Directors