PERSONAL INFORMATION

Mag. Thomas van den Oever

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vandenoever.at

Sex: Male | Date of birth: 22/04/1970 | Nationality: Austria

JOB APPLIED FOR POSITION

CAPA Expert, First-/Second-Party Quality Auditor, implementing and improving QM Systems, preparing for FDA Audits, implementing and improving lean Production Systems for Medical Devices, supporting Production transfers and change processes in regulated Environment (DIN EN ISO 9001, DIN EN ISO 13485, QSR 21 CFR 820)

WORK EXPERIENCE

Aug. 2013 – on going

Management Consultant

Mag. Thomas van den Oever e.U.

- Quality Management, Lean Production, Interim Leadership

References:

Supplier for IVD Subassemblies / Graz: Implantation of QM System according to ISO 13485 (in progress)

Supplier for IVD Subassemblies / Graz: Qualification of whole Production Equipment

Medical Device Manufacturer / Germany: Preparing for FDA Audit, Implementation of CAPA Process, adapting Audit and Training process. Remark: CAPA Process was mentioned at FDA Audit Summary as excellent.

Business or sector Medical Device Industry, Plant Engineering

Sep. 2011 – on going

University Lecturer

Hamburger Fern- Hochschule

- Quality Management

Business or sector University of Technology

Jan. 2007 – Jul. 2013*

* cancellation because of Site transfer to Switzerland

Head of Product Supply Group Instruments

Roche Diagnostics Graz GmbH

- Responsible for the Production Process starting with Incoming Inspection and ending with the supply of Blood Analysers to the Customers with a Revenue of ~ € 30 Mio. / year, ~ 100 Employees including Engineering Group
- Internal and External Quality Auditor
- Leading outsourcing and relocation Projects related with Instrument manufacturing

Business or sector Medical Device Industry

Feb. 2005 – Jan. 2007

Head of Quality Assurance and Quality Control

Roche Diagnostics Graz GmbH

- Responsibility for the Quality of all Products (Blood Analysers, Reagents, Biochemical Sensors and Spare parts), heading three QC Departments and the Quality Assurance Department. Accountable for Supplier development (Part of a worldwide operating Supplier development Team)

Business or sector Medical Device Industry

Dez. 2003 – Feb. 2005

Director Quality Assurance

Roche Diagnostics Graz GmbH

- Implementing and improving Quality System in compliance with DIN EN ISO 9001, DIN EN ISO 13485, QSR 21 CFR 820
- Supplier development (Quality Audits)

Business or sector Medical Device Industry

Aug. 2002 – Dez. 2003

Projektmanager Simultaneous Engineering

Roche Diagnostics Graz GmbH

- Reducing development cost and reducing time to Market for new Products

Business or sector Medical Device Industry

Jan. 2002 – Aug. 2002

Projektmanager

Roche Diagnostics Graz GmbH

- Technical Documentation for IVD registry
- Commissioner for TÜV-, CSA-, UL-, ÖVE- marks and Audits

Business or sector Medical Device Industry

1990 – 1993

Electrical Engineer

Mayer & Schöftner GmbH

- Plant Engineering in different Projects for Siemens, Volkswagen, BMW, Vöst Alpine
- Technical Draughtsman at Telecom Austria

Business or sector Plant Engineering

EDUCATION AND TRAINING

Education

2007 - 2008	▪ Six Sigma Green Belt; Six Sigma Austria
2005 - 2010	▪ Roche extended Leadership Program; Wildenmann Consulting
2003 - 2004	▪ Certified Quality Manager; Danube-University Krems
1995 - 2001	▪ Master of Business Administration, Karl Franzens University Graz Master Thesis: “Implementing ISO 9001 standard in Red Cross organisation Graz”
1994 - 1995	▪ Qualification training for Master Study, Karl Franzens University Graz
1986 - 1989	▪ Technical College Electronics; HTBL Kapfenberg

Training

2012	▪ MS Project; BIT
2010	▪ Negotiation according to Harvard Concept II; Europe-MPO International Consulting
2010	▪ Lean Production Basic education; Six Sigma Austria
2010	▪ Test planning in Medical Device Industry; Quality Austria
2009	▪ Negotiation according to Harvard Concept I; Europe-MPO International Consulting
2006	▪ Six Sigma Champion; Six Sigma Austria
2006	▪ European Excellence Assessor; Quality Austria

PERSONAL SKILLS

Mother tongue: German

Other language

	UNDERSTANDING		SPEAKING		WRITING
	Listening	Reading	Spoken interaction	Spoken production	
English	C1	C1	B2	B2	C1

Levels according Common European Framework of Reference for Languages

Communication skills

- Good communication skills gained through my experience as international external Auditor and leader in international Projects as wells as over 10 Years Leadership experience

Organisational / managerial skills

- Leadership - more than 10 Years of relevant experience, disciplinary responsibility up to 100 people
- Project management – Leading several national and international Projects
- Crisis management - Company Closing and Transfer during 2 Years' time period
- Change management - Implemented Six Sigma and Lean thinking in the Organisation, applied new Production Layout, scale up of new Consumable Production line according to the Toyota Principle

Job-related skills

- Expert in Quality Management Systems according to FDA CFR 21-820, ISO 13485 ISO 9001, GMP
- Professional First-/Second-Party Quality Auditor FDA CFR 21-820, ISO 13485 ISO 9001, GMP
- Expert in change and transfer projects
- CAPA Expert:
  Implementing CAPA process
  Run the CAPA Process in terms of implementation of corrections, initial Risk Analysis, Root Cause Analysis, final Risk Assessment, corrective Action, preventative Action, final Assessment, verification or validation of Measures if necessary, by using appropriate tools for every step.
- Execute Risk Analyses (FMEA) for Qualification, Process Validation, for CAPA Cases especially in Case of critical Complaints
- Preparing Organization for FDA Audits
- Conducting Quality and Lean Management Trainings

Computer skills

- Good command of Microsoft Office™ tools
- Good command of Microsoft Project ™
- Basic knowledge in SAP