



Dinc Consulting

Project Overview

First Name LAST NAME

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Specialty

German, English, Turkish

MUSTAFA DINC

Medical Technology Project Overview | Selected Consulting Engagements — Quality Management · Regulatory Affairs · Supplier Quality · Validation · CAPA

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CONSULTING PROFILE

This overview supplements the curriculum vitae and documents selected consulting engagements in regulated medical device and IVD environments. It focuses on the scope of responsibility, regulatory environment, methodological approach, and demonstrable contributions; confidential product or company information is not disclosed. The engagements range from short-term remediation and audit readiness assignments to multi-year programs involving CAPA, post-market surveillance, preparation and updating of clinical evaluations, supplier quality, validation, technical documentation, and the global registration of medical devices across different risk classes and product categories.

Areas of Focus

- QMS development, process optimization, and audit readiness in accordance with ISO 13485, FDA requirements, and the EU MDR.
- CAPA, NC, SCAR, complaint handling, FSCA, root cause analysis, and effectiveness verification.
- Supplier quality management, outsourced processes, supplier qualification, and supplier audits.
- Technical documentation, MDR remediation, GSPR, MDD-to-MDR transition, PMS/PMCF/PSUR, and UDI.
- Validation and qualification of equipment, processes, and test methods, as well as change management.
- Interim management, cross-functional project leadership, training, and management reporting.

Working style confirmed by references: rapid familiarization with complex subject matter, systematic structuring of extensive documentation, clear and proactive communication, flexible prioritization under tight deadlines, and the practical translation of regulatory requirements into concrete recommendations for action.

Professional Experience in Years

- More than 24 years: Quality Management (automotive and medical technology)
- More than 10 years: Regulatory Affairs
- More than 17 years: Risk Management
- More than 6 years: Validation
- More than 16 years: Project Management
- More than 16 years: CAPA Management
- 16+ years: FDA-regulated environments
- 9 years: EU MDR
- 8 years: Active medical devices, Classes I to III
- 7 years: Non-active medical devices, Classes I to III
- 13 months: In vitro diagnostics
- More than 24 years: Leadership experience
- More than 16 years: Audit experience

Specialized Expertise

- Quality Management
- ISO 13485, ISO 14971, and ISO 10993
- Validation and GMP
- Post-Market Surveillance
- Regulatory Affairs
- Risk Management
- EU MDR and MDD
- FDA Requirements
- MDSAP
- Supplier Quality Management
- Project Management
- Leadership and Team Management
- Clinical Evaluation Reports
- IEC 60601, IEC 62366, ISO 15223, IEC 62304, ISO 11135, ISO 11137, and ISO 11607
- ISO 31000
- ISO 37301
- ISO 37001
- ISO 37002
- ISO 27001
- German Supply Chain Due Diligence Act (LkSG)
- Internal and External Audits

Industry Expertise

- Medical technology: active, non-active, and software-based medical devices
- Automotive
- In vitro diagnostics, including experience at Roche

IT Skills

- Microsoft Office
- Microsoft Visio
- Microsoft Project
- CAD
- SAP
- Minitab
- Tableau

Key Strengths

- Quality management in accordance with FDA requirements, DIN EN ISO 13485:2016, and DIN EN ISO 9001:2015
- Validation
- Regulatory Affairs
- Leadership Skills
- Project Management
- Technical Expertise
- Interpersonal Skills
- Risk Management
- Clinical Evaluation
- Post-Market Surveillance
- Vigilance
- Process Optimization

Language Skills

- **German:** fluent, near-native proficiency
- **Turkish:** fluent, near-native proficiency
- **English:** fluent

Specialist Training

- Medical Device Regulation, TÜV SÜD
- DIN EN ISO 13485:2016, Pates GmbH
- Quality Management Representative, DEKRA
- Internal Auditor, DEKRA
- Quality Management Requirements for Medical Devices in the US Market, TÜV SÜD
- Preparation of a 510(k) Premarket Notification, TÜV SÜD
- SAP applications at DePuy Synthes, Zimmer Biomet, Stryker GmbH, Roche, and Maquet
- Agile Way – Software Processes for FDA-Regulated Environments, Inbus Academy
- MasterControl, document management system
- Agile, document management system
- Supplier Quality Collaboration System, GE Healthcare
- Biocompatibility, DePuy Synthes
- Medical Device Packaging, Teleflex

- EU MDR Post-Market Surveillance and Post-Market Clinical Follow-up, TT Group, Brussels
- APIS FMEA Facilitation, APIS GmbH

SELECTED ENGAGEMENTS

01 | International Pharmaceutical and Medical Device Company (confidential engagement)

07/2026 - Present

Senior Consultant, Quality Management & Regulatory Affairs · Germany / Spain

Product / Industry Context: AI-enabled, active, non-invasive Class IIa wearable medical device incorporating sensors, a smartphone app and a cloud component

Regulatory Environment: EU MDR 2017/745, MDCG 2021-27 Rev. 1, MDCG 2021-26, ISO 13485, MPDG, MPBetreibV, MPAV, SGB V, vigilance/FSCA, data protection

Initial Situation and Objective: *Regulatory and quality assessment of a cross-border, multi-tier distribution and patient-supply chain. The key question was whether the German distribution company required a standalone QMS or could operate under a tiered corporate/local QMS model.*

- Document-based review of distribution, quality, vigilance, service and training agreements; transparent classification of findings as documented, inferred, unclear or requiring evidence.
- Assessment of MDR economic-operator roles and non-delegable obligations across the supply chain - manufacturer, Distributor A, Distributor B and patient/user - including potential importer and Article 16 scenarios.
- Development and comparison of QMS scenarios: a standalone German QMS, integration into the Corporate QMS, and a proportionate partial-QMS with central processes and mandatory local SOPs, work instructions, registers and evidence.
- Analysis of German interfaces under the MPDG, MPBetreibV, MPAV and SGB V, including the roles of Patient Support, logistics, fitting/customisation and other service providers; preparation of a prioritised action and evidence plan.

Contributions and Results

- Evidence-based recommendation for a three-tier partial-QMS model: corporate governance and central processes, interface controls by the European distributor, and locally implemented, auditable processes for the German distribution company.
- Prepared a role-and-responsibility matrix for the actors, a process-based RACI matrix, and a risk-based gap analysis with prioritised action areas and scenario-based pre-launch recommendations.

Methods / Systems: Evidence-based assessment, gap analysis, RACI, scenario analysis, EU MDR Articles 13-16 and 25, MDCG 2021-27/2021-26, ISO 13485, MPDG, MPBetreibV, MPAV, SGB V, vigilance/FSCA, service-provider governance

Reference: Confidential engagement; project documentation is available

02 | International Manufacturer of Dental Implants (confidential engagement)

06/2026 – present

Senior Consultant Quality & Regulatory Affairs · Switzerland

Product / Industry Context: Dental implants and sterile/reusable accessories, Classes IIb / Is / Ir

Regulatory Environment: EU MDR 2017/745, ISO 13485, ISO 14971, sterilization, supplier quality, technical documentation

Initial Situation and Objective: Structured remediation of Notified Body findings and improvement of technical documentation and supplier controls under tight deadlines.

- Assessment and remediation of technical documentation, GSPR structures, and evidence required under Annexes II and III.
- Remediation of supplier documentation for critical and outsourced processes, including sterilization, packaging, and raw materials.
- Preparation and review of supplier classifications, qualification evidence, audit rationales, and action plans.
- Coordination of open items with Quality, Regulatory, Purchasing, and external process partners.

Contributions and Results

- Rapid structuring of an extensive backlog and transparent prioritization of regulatory-critical topics.
- Improved traceability of the technical documentation; engagement extended due to the quality, speed, and systematic approach of the work delivered.

Methods / Systems: EU MDR Annexes I–III, ISO 13485, ISO 14971, ISO 22441, ISO 11607, supplier qualification, documentation reviews

Reference: Written reference available

03 | BEC Robotics / BEC Medical

02/2026 – 04/2026

External Consultant QMS & Regulatory · Pfullingen / Magdeburg, Germany

Product / Industry Context: Active medical device, Class IIb (MDR) / Class II (FDA)

Regulatory Environment: ISO 13485, FDA clearance requirements, IEC 60601-1, IEC 60601-1-2, usability engineering (IEC 62366), IEC 62304, MDR 2017/745

Initial Situation and Objective: Preparation of regulatory documentation for FDA activities and external product testing, along with the structured further development of the QMS.

- Planning and preparation of external product testing in accordance with IEC 60601-1 and IEC 60601-1-2.

- Support for FDA readiness, regulatory strategy, and QMS structuring.
- Delivery of regulatory and quality-related workshops with cross-functional teams.

Contributions and Results

- Rapid identification and structuring of missing or unclear documentation content and preparation for testing and regulatory submission activities.
- The client confirmed a high level of technical expertise, a structured working approach, and rapid familiarization with the subject matter.

Methods / Systems: ISO 13485, FDA, 510(k) readiness, IEC 60601-1/-1-2, usability engineering, technical documentation

Reference: Written reference available

04 | Bosch + Sohn GmbH & Co. KG (boso)

05/2025 – 12/2025

Consultant Quality, Regulatory Affairs and Supplier Quality · Jungingen, Germany

Product / Industry Context: Blood pressure monitors and accessories, Classes I (Im, Ir) to IIa

Regulatory Environment: EU MDR 2017/745, ISO 13485, ISO 14971, UDI, biocompatibility, PMS

Initial Situation and Objective: *Follow-up of audit findings, reduction of open quality records, and MDR-related further development of the QMS for a broad product portfolio.*

- Processing and reduction of NC/QAB, CAPA, and complaint backlogs, as well as support for audit-related actions.
- Optimization of supplier management, incoming inspection, change management, and QMS documentation.
- MDR support for legacy devices, technical documentation, UDI, and selected PMS topics; practical workshops and training sessions.

Contributions and Results

- According to the client reference, significant improvements in process efficiency and QMS structure were achieved.
- Clear communication, results-oriented implementation, and sustainable added value for quality and regulatory processes.

Methods / Systems: ISO 13485, EU MDR, ISO 14971, CAPA/QAB, UDI GS1/HIBC, supplier quality, change management

Reference: Written reference available

Senior Consultant Nonconformities, CAPA, Supplier Quality & FSCA, Test Methods (100%, Hybrid) · Aachen, Germany

Product / Industry Context: Cardiac support system / heart pump, Class III

Regulatory Environment: FDA, EU MDR requirements, ISO 13485, CAPA, NC, FSCA, risk assessment, sterilization, biocompatibility, supply chain

Initial Situation and Objective: Support for the quality organization in the systematic handling of complex nonconformities and CAPA cases within a global, highly regulated environment.

- Processing and management of NC and CAPA cases in accordance with internal SOPs and FDA, ISO, and EU requirements.
- Trend, root cause, and risk assessments, as well as preparation of audit-ready decision-making and supporting documentation.
- Collaboration with global Engineering, Manufacturing, and Quality teams; support for supplier quality and FSCA activities, as well as the optimization and improvement of test methods.
- Team leadership for four external consultants.
- Delivery of regulatory and quality-related workshops with cross-functional teams.

Contributions and Results

- Reliable completion of complex cases with high documentation quality and clear stakeholder communication; reduction of nonconformities, improved audit readiness for FDA and EU MDR 2017/745 requirements, and successful closure of audit actions.
- Contract extensions and positive performance feedback throughout the 22-month long-term engagement.

Methods / Systems: CAPA, NC, FSCA, root cause analysis, risk assessment (ISO 14971), trend analysis, global quality processes, complaint handling, change management, SAP S/4HANA, cleanroom environment, EU GMP, audits

Interim Quality Consultant & CAPA Manager (100%, Hybrid) · Rheinfelden, Germany

Product / Industry Context: Active implantable medical devices, Class III; accessories, Classes I and II

Regulatory Environment: FDA, ISO 13485, EU MDR, paper-based CAPA system

Initial Situation and Objective: Assumption and stabilization of the CAPA system, which had a substantial backlog of NC, SCAR, and CAPA records ahead of regulatory deadlines.

- Overall management of the CAPA system, status and trend reporting, and escalation of overdue actions.

- Facilitation of root cause analyses; definition of corrections, corrective actions, and effectiveness checks.
- Development of CAPA-related actions in the areas of validation, process validation, material flow, biocompatibility, and deviations in cleanrooms and controlled environments.

Contributions and Results

- Structured prioritization and reduction of a substantial case backlog.
- Improved transparency, clear responsibilities, and higher methodological quality in CAPA processing.

Methods / Systems: CAPA, SCAR, NC, root cause analysis, effectiveness checks, change management, risk management, management reporting, audit readiness, sterilization, EU GMP, biocompatibility, cleanroom environment, test methods, production flow, process validation, 5S, storage

Reference: Available by telephone

07 | Carl Zeiss Meditec AG

10/2020 – 12/2022

Quality Engineering & PMS Consultant (50–100%) · Munich, Germany

Product / Industry Context: Ophthalmic software, Class IIa

Regulatory Environment: EU MDR, ISO 13485, PMS/PSUR under the EU MDR, complaint handling, cybersecurity risk management, agile development, IEC 62366, and IEC 62304

Initial Situation and Objective: MDR-compliant implementation and further development of post-market surveillance and quality processes for medical software.

- Preparation and maintenance of PMS plans, PMS reports, and PSURs.
- Risk-based complaint handling, trending, CAPA, and cybersecurity risk management.
- Quality support within agile development cycles; coordination with Software, Regulatory, and Product teams.
- Delivery of regulatory and quality-related workshops with cross-functional teams.

Contributions and Results

- Establishment of MDR-compliant PMS structures and improved traceability of post-market surveillance activities.
- Integration of complaint, risk, CAPA, and development information to support robust management decisions.
- Contract extensions and positive performance feedback throughout the 27-month long-term engagement.

Methods / Systems: EU MDR Articles 83–86, PMS plan, PMS report, PSUR, ISO 13485, cybersecurity risk management, agile software development (IEC 62304, IEC 62366, Jira, Azure, backlog management, software testing)

Reference: A verbal or written reference can be provided by the client upon request.

08 | Maquet Cardiopulmonary GmbH / Gefinge

01/2022 – 06/2022

Senior Quality Engineer (50–100%, Hybrid) · Rastatt, Germany

Product / Industry Context: Perfusion technology and oxygenators, Class III

Regulatory Environment: FDA, ISO 13485, EU MDR, sterility, bioburden, particulates, production deviations, cleanroom environment, supply chain

Initial Situation and Objective: *Deadline-driven processing of an extensive NC/CAPA backlog in a sterile manufacturing environment.*

- Processing of NC, NCR, CAPA, SCAR, and complaints in SAP.
- Assessment of cleanroom, sterility, bioburden, particulate, material, and production deviations.
- Definition of containment, correction, corrective action, material disposition, and effectiveness checks; weekly progress and risk reporting to senior management.

Contributions and Results

- Structured reduction of critical quality records and improved transparency regarding processing status.
- Traceable root cause and impact assessments for regulatory-sensitive deviations.
- This was the second engagement since 2017.

Methods / Systems: SAP QM, NC/CAPA/SCAR, root cause analysis, sterility assurance, bioburden, cleanrooms, management reporting, SAP, material disposition, material flow, risk management

09 | DePuy Synthes / Johnson & Johnson

11/2019 – 05/2020

Quality Validation Project Lead (100%, On-site and Hybrid) · Tuttlingen, Germany

Product / Industry Context: Implants and surgical instruments, Classes I–III

Regulatory Environment: ISO 13485, ISO 14971, IQ/OQ/PQ, TMV, change management, biocompatibility, supply chain, purchasing, and controlled environments

Initial Situation and Objective: *Leadership of a complex validation and change program covering manufacturing equipment, test methods, and product-related technical documentation.*

- Planning and execution of risk-based IQ, OQ, and PQ activities for equipment and processes.
- Test method validation, Site Validation Master Plan, and project-specific validation planning.
- Change management, including the updating of affected technical files and test processes; coordination of functional departments and training of project participants.

Contributions and Results

- Traceable, audit-ready validation structure for equipment, processes, and test methods.
- Improved coordination between Engineering, Quality, Production, and Technical Documentation.

Methods / Systems: IQ/OQ/PQ, TMV, Minitab, Validation Master Plan, change control, technical documentation

Reference: A verbal or written reference can be provided by the client upon request.

10 | DePuy Synthes / Johnson & Johnson

11/2018 – 11/2019

Supplier Quality Engineer & Purchasing Process Lead (100% On-site) · Tuttlingen, Germany

Product / Industry Context: Implants and surgical instruments

Regulatory Environment: ISO 13485, supplier quality, purchasing controls, CAPA/NC, chemical substances, and storage conditions

Initial Situation and Objective: Stabilization and redesign of purchasing, supplier, and master data processes, together with the remediation of audit-relevant CAPA topics.

- Analysis, improvement, and implementation of purchasing, ordering, material master, and auxiliary/operating materials processes.
- Optimization of the Approved Supplier List and management of supplier changes.
- Processing of CAPA, NC, and observations as Process Owner in ETQ; risk-based improvement of storage, transport, and chemical handling, including leadership of the technical project and training.

Contributions and Results

- Stable purchasing, ordering, master data, and ASL processes, together with improved compliance in chemical storage.
- According to the project documentation, no corresponding findings were identified in subsequent audits.

Methods / Systems: ETQ, Agile PLM, SAP, Approved Supplier List, 5S, CAPA/NC, purchasing controls, supplier audits

Reference: A verbal or written reference can be provided by the client upon request.

11 | Medical Service GmbH

08/2018 – 10/2018

Quality Management Project: Audit Preparation (100%, On-site) · Bad Liebenzell, Germany

Product / Industry Context: Urological catheters and packaging systems

Regulatory Environment: ISO 13485:2016, MDD, ISO 14971, ISO 11607, process validation, sterilization, CSV

Initial Situation and Objective: Preparation of the company for transition to and certification under ISO 13485:2016 within a tight timeframe.

- Gap analysis of risk management procedures and risk management files.
- Review of process validation procedures and validation files, including TMV, IQ/OQ/PQ, packaging, injection molding, sterilization, and CSV.
- Preparation of a prioritized quality improvement plan with concrete recommendations.

Contributions and Results

- Transparent presentation of critical gaps and a clear action plan for audit preparation.
- Risk-based focus on the evidence essential for certification and product safety.

Methods / Systems: ISO 13485:2016, ISO 14971, ISO 11607, IQ/OQ/PQ, TMV, CSV, audit readiness

Reference: Written reference available

12 | Stryker Leibinger GmbH & Co. KG

03/2018 – 07/2018

Quality Engineering Consultant – Manufacturing Transfer (100%, On-site) · Freiburg, Germany

Product / Industry Context: Active medical devices for image-guided therapies, Class IIb

Regulatory Environment: ISO 13485, manufacturing transfer, change control, FMEA, process validation

Initial Situation and Objective: Quality assurance for a manufacturing transfer from Berlin to Freiburg without interruption of compliant production.

- Preparation and monitoring of Engineering and QMS change requests.
- Transfer and closure of open NC/CAPA activities at the receiving site.
- Inspection planning, first-article assessment, FMEA/process risk support, and monitoring of critical validations, including welding and bonding.

Contributions and Results

- Structured quality assurance of the transfer and transparent tracking of critical changes.
- Improved integration of transfer planning, process validation, inspection planning, and CAPA management.
- Analysis and definition of appropriate in-process controls.

Methods / Systems: change control, NC/CAPA, FMEA, process validation, risk management in accordance with ISO 14971, inspection planning, inspection protocols, manufacturing transfer, supply chain, controlled environments, biocompatibility, sterilization

13 | Maquet Cardiopulmonary GmbH

10/2016 – 05/2017

Senior Quality Consultant (100%, On-site) · Hechingen, Germany

Product / Industry Context: Perfusion technology and oxygenators, Class III

Regulatory Environment: FDA, ISO 13485, NC/CAPA, cleanrooms, sterility, bioburden, particulates

Initial Situation and Objective: Processing and timely closure of numerous NC and CAPA records to meet regulatory requirements.

- Definition and processing of NC projects, including complaints and CAPA.
- Assessment of deviations involving cleanrooms, utilities, bioburden, sterility, particulates, materials, and production.
- Definition of containment, correction, corrective action, material disposition, and impact assessments; systematic root cause analysis and progress reporting.

Contributions and Results

- Improved transparency and structured closure of regulatory-relevant quality records.
- Robust documentation of root cause, risk, and action decisions.

Methods / Systems: NC/CAPA, root cause analysis, impact assessment, sterility assurance, bioburden, cleanrooms, EU GMP, supplier management, material flow, material disposition, risk management, change management

14 | Roche PVT GmbH / Roche Diagnostics

09/2015 – 09/2016

CAPA Lead / CAPA Coordinator (100%, On-site) · Waiblingen / Mannheim, Germany

Product / Industry Context: Laboratory automation systems for in vitro diagnostics

Regulatory Environment: IVD, CAPA, SAP, SOP development, complaint/case investigation

Initial Situation and Objective: Stabilization and improvement of the CAPA process and processing of an extensive case portfolio under regulatory time pressure.

- Updating and maintenance of CAPA cases in SAP and review of the associated documentation.
- Revision of the CAPA process and development of a new CAPA SOP.
- Coordination of 136 CAPA cases, facilitation of root cause analyses, and training of participants; alignment with Quality, Regulatory, Engineering, and Case Investigation.

Contributions and Results

- Approximately 80% of the assigned CAPA cases were closed during the engagement.
- The CAPA process was stabilized and improved; Roche colleagues confirmed the contribution to better structure and a high level of personal commitment and reliability.

Methods / Systems: SAP, CAPA, SOP development, root cause analysis, training, trend and status reporting

Reference: Written reference available

15 | Zimmer Biomet GmbH

01/2015 – 08/2015

DHF Remediation Engineering Consultant · Tuttlingen, Germany

Product / Industry Context: Implants and surgical instruments, Classes I–III

Regulatory Environment: DHF remediation, ISO 14971, usability/human factors, technical rationales

Initial Situation and Objective: Structuring approximately 2,000 items into product families and regulatory remediation of historical design and risk documentation.

- Technical writing and preparation of regulatory-robust rationales.
- Remediation of Design History Files in accordance with the approved project plan.
- Analysis and improvement of the risk management process, approval of risk management files, and identification of use-related hazards based on surgical techniques.

Contributions and Results

- Consistent, traceable structure for product families and the associated DHF and risk documentation.
- Improved consistency between product knowledge, surgical application, risk management, and technical rationale.

Methods / Systems: DHF, ISO 14971, usability hazard analysis, technical rationales, product family grouping

Reference: Written reference available

16 | DePuy Synthes GmbH

10/2014 – 12/2014

Senior Quality Engineering Consultant – Production Risk Analysis · Högendorf, Switzerland

Product / Industry Context: Implants and surgical instruments, Classes I–III

Regulatory Environment: ISO 14971, production risk analysis, FMEA, cross-site harmonization

Initial Situation and Objective: Development of consistent and traceable production risk analyses for a large number of implants and instruments.

- Preparation of standardized production risk analyses in cooperation with subject-matter experts.
- Support for manufacturing sites in implementing the risk management process.
- Development of reusable FMEA modules and templates.

Contributions and Results

- Harmonized approach and improved comparability of production risks across product families.
- More efficient preparation and maintenance of FMEA and risk documentation.

Methods / Systems: ISO 14971, pFMEA, production risk analysis, standard modules, product families

Reference: Written reference available

17 | DePuy Synthes GmbH

11/2013 – 06/2014

Manufacturing Engineering / Validation Consultant · Zuchwil, Switzerland

Product / Industry Context: Implants and surgical instruments, Classes I–III

Regulatory Environment: process validation, cleanliness, biocompatibility, DMR, external laboratory testing

Initial Situation and Objective: Complete and traceable validation documentation for cleanliness and biocompatibility aspects of manufacturing processes.

- Compilation and review of process validation and test data relating to cleanliness and biological safety.
- Preparation of electronic DMR documentation and assessment of the status of existing manufacturing processes.
- Coordination of external testing (cytotoxicity, bioburden, FTIR, TOC); interface between Manufacturing, Validation, Materials Testing, and Risk Management.

Contributions and Results

- Improved completeness and traceability of validation evidence.
- Clearer assessment of cleanliness and biocompatibility risks in existing manufacturing processes.

Methods / Systems: process validation, DMR, biocompatibility, cleanliness, cytotoxicity, bioburden, FTIR, TOC

Reference: Written reference available

ADDITIONAL LEADERSHIP EXPERIENCE OUTSIDE THE CONSULTING ENGAGEMENTS

In addition to the engagements listed above, direct line-management and leadership responsibilities include Head of Quality and Regulatory Management at Ganshorn Medizin Electronic, Head of Post-Market Surveillance & Operational Quality at SCHILLER AG in Switzerland, and Team Leader Quality & Change Management at Volke Consulting Engineers (details are provided in the curriculum vitae).

CONFIDENTIALITY NOTICE

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