# Dinc Consulting
# CURRICULUM VITAE

First Name LAST NAME
**Mustafa DINC**

**Languages**

German, English, Turkish

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# MUSTAFA DINC

## Consulting in Quality Management ·Regulatory Affairs ·Supplier Quality ·Validation

Bloisstr. 42A, 79761 Waldshut-Tiengen, Germany | +49 178 459 40 12 | mustafa.dinc@dincon.org | linkedin.com/in/mustafa-dinc-97007846
Born on 4 December 1973 in Freising

## PROFESSIONAL PROFILE

Quality and Regulatory Affairs executive with more than 24 years of professional experience in regulated industries, including 17 years in the medical device industry and more than one year in IVD. Proven responsibility for QMS structures in accordance with ISO 13485 and ISO 9001, Regulatory Affairs (EU MDR, FDA), CAPA, audits, Supplier Quality, risk management, validation and qualification (IQ/OQ/PQ, TMV), sterilization, technical documentation and Post-Market Surveillance. Strong technical background in mechanical engineering and manufacturing, complemented by an MBA in Compliance & Risk Management. Combines strategic leadership with pragmatic execution and sustainably stabilizes complex quality organizations, including GMP-related environments and projects with tight regulatory deadlines.

## CORE COMPETENCIES

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| **Quality Management** | ISO 13485, ISO 9001, ISO 19011, QMS strategy and development, Management Review, KPIs, process management, audit readiness, GMP-related processes, change management, conduct of internal and external audits |
| **Regulatory Affairs** | EU MDR 2017/745 (medical device risk classes I–III), MDD-to-MDR transition, FDA requirements, 510(k) preparation, global registrations, UDI, vigilance, Clinical Evaluation, PRRC, Post-Market Surveillance, EU AI Act, Swiss MDR / MedDO, IEC 62366 (implementation), IEC 60601 (test preparation), IEC 62304, ISO 15223, ISO 10993, risk management in accordance with ISO 14971, REACH Regulation, RoHS, Clinical Evaluation Reports: ten reports prepared to date. |

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| **Operational Quality** | CAPA, NCs/deviations, Complaint Handling, Root Cause Analysis, 8D, SCAR, change management, trend analyses, process risk analyses |
| **Supplier Quality** | Supplier selection, qualification and classification, audits, monitoring, outsourced processes, Purchasing Controls |
| **Product & Engineering** | Technical documentation, ISO 14971, IQ/OQ/PQ, test method validation, sterilization, biocompatibility, packaging (ISO 11607) |
| **Leadership & Transformation** | Line and interim management, program and project leadership, training and coaching, organizational development, digital QMS/CAQ processes |

## PROFESSIONAL EXPERIENCE

**Founder and Senior Consultant**
**Quality Management & Regulatory Affairs** **09/2013 – Present**

*Dinc Consulting (DINCON), Waldshut-Tiengen — medical devices, IVD and regulated technical industries*

- Strategic and operational consulting for manufacturers (Classes I–III, IVD) in Quality Management, Regulatory Affairs, Supplier Quality, risk management and Clinical Evaluation.
- Development, optimization and remediation of QMS structures; ISO 13485, MDR and FDA readiness, including audit preparation and support.
- MDD-to-MDR transition; preparation and review of technical documentation, GSPR, PMS/PMCF/PSUR, UDI and support for international registrations.
- Management of CAPA, NC, SCAR and complaint programs, including Root Cause Analysis, effectiveness checks and management reporting; stabilization of extensive backlogs for clients including Johnson & Johnson, Roche, Getinge and Zeiss.
- Validation and qualification of equipment, processes and test methods (IQ/OQ/PQ, TMV), as well as sterilization, cleanroom and packaging topics in sterile manufacturing environments.
- Interim management, cross-functional project leadership and implementation of digital quality and SAP/ERP-supported workflows; employee training and coaching.

*A detailed overview of selected engagements (including Johnson & Johnson MedTech, Roche Diagnostics, Carl Zeiss Meditec, Getinge, Stryker, Zimmer Biomet,*

*Bosch und Sohn GmbH & Co. KG and BEC Robotics GmbH) is provided in the separate project portfolio.*

**Head of Post-Market Surveillance & Operational Quality** **04/2017 – 02/2018**

*SCHILLER AG, Baar, Switzerland — internationally active manufacturer of active medical electrical devices*

- Leadership responsibility for Post-Market Surveillance, Operational Quality, vigilance, Complaint Handling and CAPA; management of cross-functional quality teams.
- Implementation of MDR-compliant PMS structures; preparation of PMS plans, PMS reports, PSURs and Clinical Evaluation Reports.
- Regulatory responsibility for technical documentation, UDI/labeling, changes and international approval activities.
- Preparation for and support during Swissmedic, FDA, MDSAP and other external audits.

**FMEA-Moderator Automotive** **04/2013 – 10/2013**

*Preh-GmbH, Bad Neustadt an der Saale — Automotive*

- *FMEA facilitation using APIS software, including the facilitation of Design FMEAs, Process FMEAs, and Control Plans.*

**Head of Quality and Regulatory Affairs /**
**Management Representative** **09/2009 – 05/2013**

*Ganshorn Medizin Electronic GmbH, Bad Neustadt a. d. Saale — pulmonary function diagnostics, active medical devices and software*

- Overall responsibility for the implementation, maintenance and continuous improvement of the QMS in accordance with ISO 13485 and ISO 9001; direct reporting to executive management.
- Planning and conduct of internal and external audits; primary contact for customers, OEM partners, suppliers and testing bodies.
- International product approvals and technical documentation for the EU, USA, China, Russia, Brazil, Korea, Taiwan, Indonesia and Turkey.
- Management of CAPA, risk management, verification/validation, product and process releases, Management Reviews and Supplier Quality.
- Oversight of the implementation of IEC 60601, IEC 62304 and IEC 62366.

**Professional Development –**
**European Quality and Project Management** **04/2009 – 08/2009**

*WBS Training AG, Munich*

- Qualification as Quality Management Representative and Internal Auditor; Project Management I/II, management fundamentals and communication.
- Overall score: 89%; graduated with distinction.

**Team Lead, Quality & Change Management** **02/2001 – 04/2009**

*Volke Consulting Engineers GmbH & Co. KG, Munich — automotive, technical development and manufacturing processes*

- Leadership and coordination of quality, change and process management activities in complex vehicle development projects.
- Implementation of transparent change processes; interface management across engineering, quality, project management, structural durability and testing.
- Process optimization, cost and schedule control, test planning, and evaluation of strength and materials tests; introduction of Six Sigma, Lean Six Sigma and DFSS approaches.

## MANUFACTURING INDUSTRY EXPERIENCE

**CNC Machinist** **03/1998 – 01/2001**

*Maurer & Söhne GmbH & Co. KG, Munich — mechanical and steel engineering; production of complex components for bridge bearings (CNC milling and turning)*

**Career Break to Care for My Grandparents in Turkey** **06/1997 – 02/1998**

**Production Specialist in Semiconductor Manufacturing** **06/1995 – 05/1997**

*Texas Instruments Deutschland GmbH, Freising — semiconductor manufacturing in a cleanroom environment as a Production Specialist*

**Machinist, Milling and Turning** **08/1994 – 05/1995**

*KraussMaffei AG, Munich — manufacture of injection molding machines*

**Production Specialist in Semiconductor Manufacturing** **03/1994 – 08/1994**

*Texas Instruments Deutschland GmbH, Freising — semiconductor manufacturing in a cleanroom environment as a Production Specialist*

## EDUCATION AND ACADEMIC QUALIFICATIONS

**Master of Business Administration (MBA), Compliance & Risk Management**

**2022 – 2025**

*University of Applied Sciences Burgenland, Austria — Degree classification: Passed with Merit*

*Thesis topic: The German Supply Chain Due Diligence Act and recommendations for implementation by obligated companies with more than 1,000 employees in Germany*

**Professional Development –**
**European Quality and Project Management** **04/2009 – 08/2009**
*WBS Training AG (full-time), Munich*

- Qualification as Quality Management Representative and Internal Auditor; Project Management I/II, management fundamentals and communication.
- Overall score: 89%; graduated with distinction.

**State-Certified Mechanical Engineering Technician** **1999 – 2003**
*Technical College, Munich — DQR/EQF Level 6 (Bachelor Professional)*

**Vocational Training as a Precision Machinist** **1990 – 1994**
*KraussMaffei AG, Munich*

## RELEVANT TRAINING AND EXPERTISE

EU MDR and Medical Device Requirements (TÜV SÜD) · 510(k) Premarket Notification · ISO 13485:2016 · Quality Management Representative and Internal Auditor (DEKRA) · Clinical Evaluation · APIS FMEA Facilitation · Biocompatibility, Sterilization and Packaging · FDA-compliant Agile Software Processes · Project Management · UDI · ISO 14971 · EU AI Act · German Supply Chain Due Diligence Act · International Approvals / Product Registrations · REACH Regulation · RoHS · Validation · EU GMP · Compliance Management · Semiconductor Manufacturing (Wafers) · Technical Documentation in accordance with EU MDR 2017/745 · AI in Medical Devices

## LANGUAGES AND IT SYSTEMS

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| **Languages** | German: near-native · Turkish: near-native · English: fluent in international project work |
| **IT / Systems** | MS Office, MS Project, MS Visio, SAP, QM, Minitab, Tableau, MasterControl, Windchill, ETQ, Agile PLM, ABAS, KUMAVISION, CAD, AI, Adobe |

## REFERENCES

Employment certificates and references from the medical device, IVD and automotive industries, as well as from leadership positions in Switzerland, are available. Contact persons will be provided upon request, subject to existing confidentiality agreements.