Dinc Consulting

EXECUTIVE CURRICULUM VITAE

First Name LAST NAME
Mustafa DINC

Specialty

German, English, Turkish

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PROFILE -EXECUTIVE SUMMARY-

International quality and regulatory leader with 24+ years of experience in Quality Management, 8 years in Regulatory Affairs,, 16+ years in Leadership, deep technical understanding (mechanical engineering background), and extensive expertise in FDA, EU-MDR, ISO 13485, MDSAP, ISO 14971, validation, CAPA management, Clinical Evaluation and Post-Market Surveillance.

Proven track record in strategic development, transformation, and leadership of QMS and RA organizations, including technical documentation, risk management, supplier quality, global registrations (EU, FDA, China, Asia, LATAM), PMS/PSUR, vigilance, and audit management.

Strong leadership, high analytical capability, and excellent communication across all organizational levels. Experienced with active and passive medical devices Class I–III, implants, software, IVD, and cardiovascular devices.

CORE COMPETENCIES (MEDICAL DEVICE SECTOR):

Quality & Regulatory:
FDA 21 CFR 820 • EU-MDR • MDSAP • ISO 13485 • ISO 9001
Technical Documentation • PMS/PSUR • UDI (GS1/HIBC), Clinical Evaluation, Risk Management, Gap-Analysis, High-level analytical competence, Leadership

Validation:
IQ/OQ/PQ • Test Method Validation • Manufacturing Process Validation

Quality Systems & Processes:
CAPA Excellence • SCAR • Supplier Quality • Audit Management (FDA, MDSAP, EU)

Product Experience:
Active Devices (Class 1-III) • Passive Devices (I-III) • IVD • Software (Class IIa) • Cardiovascular Devices

INDUSTRY EXPERIENCE:

- Medical Devices (Class I–III, active & passive, software)
- In-vitro Diagnostics
- Automotive

KEY STRENGTHS:

- Independent root cause analysis and implementation of solutions for non-conformities, CAPA processes, audit preparation, and support
- Translating regulatory requirements into technical solutions
- Development and implementation of best practices
- International project work with cross-functional teams

- Risk Management (FMEA, PFMEA, Risk Management according to DIN EN ISO 14971, ISO 31000, ISO 27001)
- Supply Chain Due Diligence Act Germany (LkSG)
- Verification and Validation
- Creation of Clinical Evaluation Reports
- MEDDEV 2.7.1 and 2.12.1
- IEC 606061, IEC, 62604, ISO 10993, DIN EN ISO 11607, IEC 62366, ISO 15223
- DIN EN ISO 13485, ISO 9001, ISO 37301, ISO 27001

LANGUAGES:

German (native), Turkish (native), English (Upper Intermediate – Fluent)

IT SKILLS:

SAP, MS Project, Minitab, Tableau, Agile, Master Control, CAD, Windchill, MS-Visio, Mind map, MS Office, ETQ, ABAS, KUMAVISION

PROFESSIONAL TRAINING (SELECTION)

- TÜV SÜD: EU MDR, US Medical Device Requirements, 510(k)
- DEKRA: Quality Management Representative, Internal Auditor
- APIS: FMEA Moderation
- PATES GMBH: DIN EN ISO 13485:2016
- DIN AKADEMIE: Clinical Evaluation
- J&J: Biocompatibility (ISO 10993), Sterilisation, Packaging (ISO 11607)
- Agile FDA-compliant software processes
- WBS AG: Project Management

ACADEMIC BACKGROUND:

Master of Business Administration (in Compliance & Risk Management)

Hochschule Burgenland, Austria | 2022 – 2025
Master`s thesis on the German Supply Chain Due Diligence Act (LkSG)
Grade: Passed with Merit (2025)

EDUCATION:

State-Certified Mechanical Engineering Technician

Technical College in Munich | 1999 – 2003
Grade Point Average (GPA): 2.88 - satisfactory achievement
EU Classification: Bachelor Professional (DQR /EQF Level 6)

APPRENTICESHIP:

Apprenticeship in Machining Technology (CNC Milling)

Krauss Maffei AG, Munih | 1990 – 1994

CONSULTING SERVICES

Consultant – Quality Management, Regulatory Affairs, Risk Management, Clinical Evaluation and Project Management

Dinc Consulting (Founder), Waldshut-Tiengen | Since 2013

- Medical Devices – Active, Passive, Software; International Clients
- www.dincon.org

PROFESSIONAL EXPERIENCE:

Freelance Consultant – Quality & Regulatory Affairs

Bosch + Sohn GmbH & Co. KG (boso), Jungingen | 05/2025 – 12/2025
Active Medical Devices Class I–IIa (Blood Pressure Diagnostics)

- MDR compliance support for legacy devices; technical documentation updates
- QMS optimization (ISO 13485), gap assessments, internal training
- Comprehensive NC/CAPA management and supplier quality activities
- Risk management (ISO 14971), validation, ISO 10993 biocompatibility
- UDI (GS1/HIBC) and PMS related documentation activities

Freelance Consultant – Nonconformities / CAPA, Supplier Quality, FSCA

Abiomed / Johnson & Johnson MedTech, Aachen | 06/2023 – 03/2025
Class III Heart Pump

- NC and CAPA processing according to SOP, ISO, FDA and EU requirements
- Deep involvement in trend analysis, root cause analysis, audit preparation
- Collaboration with global engineering and quality teams

Freelance CAPA Manager (Interim)

OSYPKA AG, Rheinfelden | 03/2023 – 06/2023
Implants & Active Medical Devices Class I–III

- Ownership of the entire CAPA system (paper-based)
- Clearance of significant NC/SCAR/CAPA backlog under FDA, ISO 13485, MDR
- CAPA method development, staff training, escalations, reporting to management
- Representation of the CAPA system during internal and external audits

Freelance Quality Engineering & PMS Consultant

Carl Zeiss Meditec AG, Munich | 10/2020 – 12/2022
Software Class IIa – Ophthalmology

- MDR-compliant PMS implementation (PMS Plan, PMS Report, PSUR)
- Complaint handling, CAPA management, cyber security risk management
- Support of agile development cycles with QMS and validation activities

Freelance Senior Quality Engineer

Maquet Cardiopulmonary GmbH (Getinge), Rastatt | 01/2022 – 06/2022
Perfusion, Oxygenators (Active Medical Device, Class III)

- Resolution of NC/CAPA backlog involving sterility, bioburden, particle & process failures
- Definition of containment, correction, corrective action & effectiveness checks
- Weekly progress reporting to leadership

Freelance Quality / Validation Project Leader

DePuy Synthes (J&J), Tuttlingen | 11/2019 – 05/2020
Implants (Passive Medical Devices, Class I-III)

- Validation leadership (IQ/OQ/PQ, TMV) for equipment & processes
- Change management for technical files and site validation master planning
- Definition of inspection processes and environmental controls

Freelance Supplier Quality Engineer & Purchasing Process Lead

DePuy Synthes, Tuttlingen | 11/2018 – 11/2019
Implants (Passive Medical Devices, Class I-III)

- Stabilization and redesign of supplier quality and purchasing workflows
- Approved Supplier List optimization; inventory & chemical storage compliance
- SCAR/CAPA/NC/Observation management in ETQ
- Audit Preparation; Execution of supplier audits

Freelance Quality Management – Project Leader

Medical Service GmbH, Bad Liebenzell | 08/2018 – 10/2018
Urology, Catheter, Product Packaging DIN EN ISO 11607

- Audit Preparation for DIN EN ISO 13485:2016 update as well as Medical Device Directive

Freelance Quality Management Consultant for Manufacturing Transfer

Stryker Leibinger GmbH & Co. KG, Freiburg DE | 03/2018 – 07/2018

Image guided therapies (Active Medical Devices, Class IIb)

- Supported manufacturing transfer from Berlin to Freiburg through comprehensive quality engineering activities; Managed and monitored engineering and QMS

change requests
- Led inspection planning and initial sample evaluations
- Supported implementation of manufacturing processes for transferred products
- Process risk analysis and FMEAs; Oversaw critical process validations (e.g., welding, gluing)
- Supported development and qualification of equipment and production processes

Head of Post Market Surveillance & Operational Quality

SCHILLER AG, Baar (Switzerland) | 2017–2018
Active Medical Electrical Devices (Defibrillators, ECG, Spirometry, Monitoring, Class II-IIb)

- Full ownership of PMS processes and Operational Quality
- Implementation of MDR-compliant PMS (Art. 84–86)
- Vigilance & global reporting, complaint handling & CAPA improvements
- Creation of Clinical Evaluation Reports (MedDev 2.7.1 Rev.4)
- Preparation for FDA, Swissmedic, MDSAP, TÜV SÜD audits
- Leadership of cross-functional quality teams

Freelance Senior Quality Consultant

Maquet Cardiopulmonary GmbH, Hechingen | 10/2016 – 05/2017

- Handling NC, NCR, complaints, CAPA, root cause analysis
- Ensuring regulatory and FDA compliance in active medical device manufacturing

Freelance CAPA Lead – Quality Management

Roche PVT GmbH / Roche Mannheim, Waiblingen / Mannheim | 09/2015 – 09/2016
In Vitro Diagnostics

- Management of 136 CAPA cases (80% successfully closed)
- Development and implementation of a new CAPA SOP
- Training of employees across multiple departments

Freelance DHF Remediation Engineering Consultant

Zimmer Biomet GmbH, Tuttlingen | 01/2015 – 08/2015

- Comprehensive DHF remediation for ~2,000 implant & instrument families
- Risk management, usability hazard analysis, technical justification

Senior Quality Engineering Consultant – Production Risk Analysis

DePuy Synthes GmbH, Hägendorf (CH) | 10/2014 – 12/2014
Passive Medical Devices Class I–III – Surgical Instruments & Implants

Key Responsibilities & Achievements:
- Developed uniform, traceable production risk analyses for implants and instruments (ISO 14971)
- Supported manufacturing sites in implementing production risk analysis processes
- Created standardized FMEA modules and templates

Freelance Manufacturing Engineering & Validation Consultant

DePuy Synthes GmbH, Zuchwil (CH) | 11/2013 – 06/2014
Passive Medical Devices Class I–III – Surgical Instruments & Implants

Key Responsibilities & Achievements:
- Compiled complete, traceable process validation documentation for cleanliness and biocompatibility
- Supported implementation of cleanliness and biocompatibility processes across sites
- Prepared electronic DMR documentation (cleanliness validation & biological safety evaluation)
- Reviewed and integrated validation and test data into documentation systems
- Assessed cleanliness and biocompatibility status of manufacturing processes
- Conducted cleanliness validations and coordinated external testing (cytotoxicity, bioburden, FTIR, TOC)
- Documented process monitoring activities and served as interface between manufacturing, validation, testing, and risk management

Quality Engineer / FMEA Moderator

PREH GmbH, Bad Neustadt | 05/2013 – 11/2013
Automotive – Multimedia Device Manufacturing, Injection Molding

- FMEA Moderation

Head of Quality Management & Regulatory Affairs

Ganshorn Medical Electronic GmbH, Bad Neustadt | 09/2009 – 05/2013
Active Medical Devices – Lung Function Diagnostics (Class IIa)

- International registrations: CE, FDA, China, Russia, Brazil, Korea, Turkey
- QMS establishment & maintenance (ISO 13485, ISO 9001)
- CAPA, supplier quality, internal/external audits
- Clinical Evaluation Reports
- IEC 60601, IEC 62304, IEC 62366 validation oversight

Education in Project and Quality Management

WBS Trainings AG, Munich, Germany | 04/2009 – 08/2009
Education in European Quality and Project Management
Passed with Merit

Contents:
- Fundamentals of management, business administration, and communication
- Quality Management (DEKRA)
- Internal Auditor Certification (DEKRA)
- Project Management I and II
- Methodological and analytical skills for project management

Quality and Process Management in Automotive Sector

Volke Consulting Engineers GmbH & Co. KG, Munich | 02/2001 – 04/2009
Team Leader Quality and Change Management

Key Responsibilities & Achievements:
- 07/2008 – 04/2009: Six Sigma, Six Sigma Lean, and DFSS (Design for Six Sigma) implemented in-house at Volke Consulting
- 08/2007 – 06/2008: Quality control for vehicle transmission projects during series production
- 01/2007 – 07/2007: Oversight of vehicle project launch, including temporary assignment abroad (England/Goodwood)
- 01/2006 – 06/2008: Powertrain development for V8 and V12 engines as Change Manager
- 07/2003 – 12/2005: Change and Quality Manager for hydrogen vehicle development project
- 05/2002 – 06/2003: Process optimization, transparency enhancement, and cost reduction initiatives across complete vehicle projects
- 02/2001 – 04/2002: Test Engineer for project operational strength and materials testing

INDUSTRIAL WORK EXPERIENCE

Maurer & Söhne und Co. KG, Munich | 03/1998 – 01/2001
Machinist (CNC milling and turning) for bridge bearing structural components

Texas Instruments Deutschland GmbH, Freising | 03/1994 – 08/1994 and 06/1995 – 05/1997
Production Specialist (Semiconductor Industry)

Krauss Maffei AG, Munich | 08/1995 – 05/1997
Milling and Turning Professional (Manufacturing of Injection Molding Machines)

Texas Instruments Deutschland GmbH, Freising | 03/1994 – 08/1995
Production Specialist (Semiconductor Industry)