Dinc Consulting

CURRICULUM VITAE

Detailing of Professional Experience and Projects

First Name LAST NAME
Mustafa DINC

Specialty

German, English, Turkish

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Dinc Consulting, www.dincon.org . Ust-ID: DE298370260

OVERVIEW

Professional experience:

- 24+ Years: Quality Management
- 8 Years: Regulatory Affairs
- 17 Years: Risk Management
- 5 Years: Validation
- 16+ Years: Project Management
- 16 Years: CAPA
- 15 Years: FDA
- 8 Years : EU-MDR
- 8 Years: Active Medical Devices class I-III
- 7 Years: Passive Medical Devices class i-III
- 13 Month: In Vitro Diagnostic
- 16+ Years: Leadership Experience
- 16+ Years: Audit

Specific area of expertise:

- Quality Management
- ISO13485, ISO 14971, ISO 10993
- Validation
- Post Market Surveillance
- Regulatory Affairs
- Risk Management
- EU-MDR and MDD
- FDA
- MDSAP
- Supplier Quality
- Project Management
- Leadership
- Clinical Evaluation Report
- IEC 60601, IEC 62366, ISO 15223, IEC 62304, ISO 11135, ISO 11137, ISO 11607
- ISO 31000
- ISO 37301
- ISO 37001
- ISO 37002

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- ISO 27001
- LkSG (Supply Chain Act)
- Audit

Sectors of activity:

- Medical Device (Active, Passive, Software)
- Automotive
- In Vitro Diagnostic (Roche)

IT Skills:

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

Main Strengths:

- Quality Management (FDA, DIN EN 13485:2016, DIN EN ISO 9001:2015)
- Validation
- Regulatory Affairs
- Leadership
- Project Management
- Technical Know How
- Social Skills
- Risk Management
- Clinical Evaluation
- Post Market Surveillance
- Vigilance
- Process Improvements

Languages:

German: Fluent (Native Tongue)

Turkish: Fluent (Native Tongue)

English: Upper Intermediate - Fluent

Specific training:

- Medical Device Regulation (TÜV SÜD)
- DIN EN ISO 134585: 2016 (Pates GmbH)
- Quality Management Representative (DEKRA)
- Internal Auditor (DEKRA)
- Quality Management Requirements for medical devices in the US-Market (TÜV SÜD)
- Creation of 510(k) premarket notification (TÜV SÜD)
- SAP (DePuy Synthes, ZimmerBiomet, Stryker GmbH, Roche, Maquet)
- Agile Way – Software Process for FDA (Inbus Academy)
- Master Control (Document Management System)
- Agile (Document Management System)
- Supplier Quality Collaboration System (GE Healthcare)
- Bio Compatibility (DePuy Synthes)
- Packaging (Teleflex)
- EU MDR Post Market Surveillance and Post Market Clinical Follow Up (TT Group in Brussel)
- Apis FMEA Moderation (APIS GmbH)

Education:

MBA in Compliance and Risk Management, passed with merit.
Thesis: *The German Supply Chain Due Diligence Act (Lieferkettensorgfaltspflichtengesetz) and Its Impact on Companies with More Than 1,000 Employees, Including Recommendations to Facilitate Implementation.*

EXPERIENCE

Bosch & Sohn GmbH & Co. KG – Jungingen **May. 25 – Dec. 25**

Consultant for Regulatory and Quality Affairs in Medical Devices, in the Field of Blood Pressure Diagnostics:

Medical device Risk Class I-IIa
Consulting services in the areas of;

- technical documentation,
- biocompatibility in accordance with ISO 10993,
- CAPA, quality deviations,
- risk management in line with ISO 14971,
- MDR/MDD gap analyses,
- validation, process validation, and UDI consulting.
- Guidance on transitional provisions from MDD to MDR (EU 93/42/EEC / EU MDR 2017/745) for legacy products,
- change management, and quality management according to ISO 13485,
- Gap analyses with respect to MDR and usability.

Challenges:

Managing a large portfolio of blood pressure monitoring devices and accessories, coordinating with numerous suppliers, delivering comprehensive employee training, and increasing overall quality and regulatory awareness within the organization.

Abiomed Europe GmbH / J&J MedTech – Aachen **Jun. 23 – Mar. 25**

Freelance Consultant Nonconformities (NC, CAPA, FSCA, Leadership, Risk Assessment, Root Cause Analysis)

Medical Device Risk Class:

- III

Technical environment & methodologies:

non-surgical heart pump

Osypka AG – Rheinfelden **Mar. 23- Jun. 23**

CAPA Manager (Interim Solution):

The biggest challenge was that many NC, SCAR and CAPA at the site had to be processed (paper based) and closed after a defined date to meet the FDA, EN ISO 13485:2016, MDR 2017-745 requirements.

Working in an international environment as a quality consultant:

- Document non-conformities and CAPAs and register them in database.
- Maintain CAPA database and provide regular status and trend reporting to management.

- Monitor due dates, regularly remind responsible staff members, and escalate to management if due dates are exceeded.
- Schedule and conduct regular CAPA meetings with staff members.
- Define and plan implementation of CAPA's and subsequent ECs (effectiveness checks) together with staff members.
- Take part in, lead and independently conduct root cause analysis.
- Create and update SOPs related to the CAPA process.
- Provide training on CAPA system and application of quality tools for root cause analysis to staff members.
- Represent and explain the company's CAPA system during internal and external audits.

Medical Device Risk Class:

- I-III

Technical environment & methodologies:

- Electrophysiology
- Interventional Cardiology
- Pacing
- OEM Services

Carl Zeiss Meditec AG – Munich **Oct. 20- Dec. 22**

Consulting and support during PMS activities in accordance with MDR 2017/745, as well as quality support as a Quality Engineer during agile development phases of Class IIa software.:

Working in an international environment as a quality engineering consultant:

- Cyber Security Risk Management,
- Risk Based Complaint Handling acc. to DIN EN ISO 13485 as well as acc. to MDR 2017/745
- CAPA
- Risk Management
- PMS Implementation (PMS Plan, PMS Report, PSUR) acc. to MDR 2017/745
- Creation of PMS and Complaint Trending Reports

Technical environment & methodologies:

- Ophthalmology

Maquet Cardiopulmunary GmbH – Raststatt DE **Jan. 22 -Jun. 22**

Quality Management

Senior Quality Engineer:

The main challenge was that many NCs, SCARs, and CAPAs at the site had to be processed (in SAP) and closed by a defined deadline to comply with FDA, EN ISO 13485:2016, and MDR 2017/745 requirements.

Approach & main achievements

- Clear and well-defined specification of NC projects (SAP-based)
- Creation and closure of NCs (including NCRs, NCs, complaints, CAPAs, SCARs), e.g., cleanroom deviations, power failures, bioburden/sterility assurance level issues, particle contamination, material failures, production defects, etc.
- Development and determination of containment, correction, and corrective actions, as well as material disposition, impact assessments, and preparation of the associated documentation.
- Systematic identification and analysis of the root cause of nonconformities.
- Preparation of weekly progress reports

Technical environment & methodologies:

- Perfusion technology
- Oxygenator

DePuy Synthes - Tuttlingen **OCT.19 – MAY.20**

QUALITY Management – Project Leader

Quality validation engineering and project change management for lubricants

Working in an international environment as a Quality Validation Engineer and Project Manager. The primary challenges included organizing employees from various departments and with different educational backgrounds, managing and evaluating many articles, and meeting strict deadlines. In addition, staff needed to be trained for the respective projects. The work environment was both technically complex and business-oriented

Approach & main achievements

- Execution of validations (IQ, OQ, PQ, compliance analysis, risk-based validation) for manufacturing machines and equipment
- Test Method Validation
- Product change management, including updates to technical file
- Development of the project management plan
- Creation of the site validation master plan
- Project leadership for the lubricant change management project, including updates to all affected technical files.
- Review and creation of inspection processes and inspection sheets

- Development of a procedure for environmental conditions related to chemicals and substances, including their supply chain
- Review and update of the heat-treatment procedure for both external and internal applications
- Preparation of periodic validation reports
- CAPA

Technical environment & methodologies

- Surgery
- Surgical Instruments
- Test Method Validation in the production environment
- IQ, OQ, PQ of CNC machines in the production area
- Statistical methods using Minitab
- Project plan
- Site Master Validation Plan
- Bio Compatibility Test
- Product packaging

DePuy Synthes – Tuttlingen **NOV. 18 – OCT.19**

Purchasing – Project Leader

Sourcing Quality Engineer and Supplier Quality Engineer

The biggest challenges were integrating employees with different educational backgrounds into the project and implementing a stable purchasing process within the defined deadlines.

Approach & main achievements

- Analysis, improvement and introduction of purchasing process,
- Analysis, improvement and implementation of purchase ordering process,
- Analysis, improvement and introduction of article master data process,
- Analysis, improvement and implementation of HiBE (Hilfs- und Betriebsstoffe) process,
- Document processing of DCR and DCO in Agile,
- Creation and revision of CAPAs, NCs, and Observations in ETQ (as process owner),
- Training employees on the newly introduced purchasing and PP&L procedure.
- Analysis, improvement of the Approved Supplier List in Tuttlingen
- Analysis, improvement of the transport packaging and transport handling procedure

- Project management in the context of CAPA regarding storage conditions for chemicals and substances, including:
    - Investigation of the current status (gap-analysis).
    - Execution of risk management activities related to HiBE (auxiliary and operating materials)
    - Introduction of workplace design in accordance with 5S principles
    - Implementation of procedures governing the receipt, handling, and storage of chemicals and substances in designated storage areas.
- Achieved Benefit for the Tuttlingen site:
    - A stable HiBE (auxiliary and operating materials) process
    - Compliance with storage requirements for chemicals
    - Stable ordering process
    - Stable suppliers change process.
    - Stable article master data process
    - Stable order processing process
    - No observation/findings after audits
    - Stable ASL (Approved Supplier List) Procedure

Technical environment & methodologies

- Surgery
- Surgical Instrument class I-II

Medical Service GmbH Bad Liebenzell **Aug. 18-Oct. 18**

Quality Management – Project Leader

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

The biggest challenge for the project was the preparation for ISO 13485: 2016 certification audit had to be completed within eight weeks.

Approach & main achievements

- Gap-Analysis of the Risk Management Procedure as well as Risk Management Files (particularly pFMEA)
- Gap analysis of the Process Validation Procedure and the corresponding validation files (TMV, IQ, OQ, PQ, packaging, injection molding, sterilization procedures, CSV)
- Creation a Quality Improvement Plan
- Recommendations

Technical environment & methodologies

- Urology

- Catheter
- Product Packaging DIN EN ISO 11607

Stryker Leibinger GmbH & Co. KG – Freiburg DE **Mar 18 -Jul 18**

Quality Management

Quality Engineering Consultant for Manufacturing Transfer (Active Medical Device)

The primary challenge of the project was to prepare the production transfer from the Berlin facility in a way that ensured uninterrupted and compliant manufacturing of active medical devices at the Freiburg site.

Approach & main achievements

- Supported the manufacturing transfer by performing a wide range of quality-related activities
- Created and monitored engineering and QMS change requests
- Transferred NCs/CAPAs to the receiving site and led the completion of all NC/CAPA activities
- Supported inspection planning and initial sample evaluations (main focus)
- Contributed to the implementation of manufacturing processes for transferred products
- Served as a subject matter expert for process risk analyses and FMEAs
- Monitored critical process validations (e.g., welding, gluing)
- Supported the development and monitoring of equipment and process validations/qualifications.

Technical environment & methodologies

- Image guided Therapies

Schiller AG – Baar CH **April 17 -Feb 18**

Quality Management - Leadership

Head of Post Market Surveillance & Operational Quality

The main challenges in this role were related to gaining practical experience with the newly introduced EU MDR requirements and integrating these regulatory changes into existing processes. The complexity and diversity of the project landscape required significant stakeholder engagement and persuasion to ensure cross-functional alignment and regulatory compliance.

Approach & main achievements

- Introduction of the Post-Market Surveillance (PMS) process in accordance with the Medical Device Regulation (MDR 2017/745)
- Development of PMS documentation, including:
  – Post-Market Surveillance Plan (MDR Article 84)
  – Post-Market Surveillance Report (MDR Article 85)
  – Periodic Safety Update Report (PSUR) (MDR Article 86)

- Execution of vigilance activities and Medical Device Reporting in accordance with MDR Articles 87–92
- Enhancement of quality system processes, including:
  – Complaint handling
  – Product CAPA processes
  – Product change management processes
- Risk assessment and risk management in accordance with ISO 14971:2012
- Creation of Clinical Evaluation Reports (CERs) for Class II–III active medical electrical devices in accordance with MEDDEV 2.7/1 Rev. 4 (seven CERs completed)
- Preparation for regulatory inspections (Swissmedic, FDA, MDSAP, TÜV SÜD)
- Reporting to Global Product Management
- Regulatory Affairs responsibilities (as Regulatory Compliance Manager):
  – Completion of Technical Documentation for the EU (DoC)
  – Preparation of submissions for the US (510(k))
  – Support for registrations in the Asian market (China, CFDA/NMPA

Technical environment & methodologies:

- Active Medical Devices
- Blood Pressure Analysis
- Electrocardiography
- Lung Function Testing
- HL7 Applications
- Spirometry
- Ergo Spirometry (Cardiopulmonary Exercise Testing)
- Bodyplethismogrphy

Maquet Cardiopulmunary GmbH – Hechingen DE **OCT 16 -MAY 17**

Quality Management

Senior Quality Engineer:

The biggest challenge was that a large number of NCs and CAPAs at the site had to be processed and closed by a defined deadline in order to meet FDA requirements.

Approach & main achievements

- Clear / concrete definition of NC-Projects
- Creation and closure of NCs (including NCR, NC, Complaints, CAPAs) in area such as clean room, power failures, bioburden sterility assurance level, particle level, Material failure, production failure etc.

- Development and determination of containment, correction and corrective action corrective action, including material disposition, impact assessments, and creation of all related documentation.
- Systematic determination of root causes for non-conformities.
- Preparation of weekly status and progress reports

Technical environment & methodologies:

- Perfusion technology
- Oxygenator

Roche PVT GmbH Waiblingen DE **SEP 15 -SEP 16**

Quality Management – Leadership:

CAPA Process and CAPA Coordination

The biggest challenge was that numerous CAPAs at the site had to be processed and closed by a defined deadline in order to meet regulatory requirements. Additionally, employees received regular training during the completion of the CAPAs

Approach & main achievements

- Improvement of CAPA Process
- Development and successful implementation of a new CAPA SOP
- CAPA Coordination (Amount of CAPA: 136, 80% were completed)

Technical environment & methodologies:

- In Vitro Diagnostic
- Laboratory Systems for In Vitro Diagnostic

ZimmerBiomet GmbH - Tuttlingen DE **JAN 15 -AUG 15**

Quality Management – Leadership:

DHF Remediation Engineering Consultant

Organizing ~2,000 articles into families and remediating legacy issues.

Approach & main achievements

- Technical writing and technical justifications
- DHF remediation according to approved plan
- Development of protocols and procedures
- Understanding system/functional testing of medical devices
- Analysis and improvement of Risk Management Process; release of RM files for implants and instruments
- Identification of use-related hazards/human factors based on surgical techniques

- Risk management according to ISO 14971
- Introduction of complaint summary reports and risk management reports

Technical environment & methodologies:

- Passive Medical Devices Class I-III
- Surgery
- Surgical Technics
- Surgical Instruments and Implants

DePuy Synthes GmbH - Hägendorf CH **OCT 14 - DEC 14**

Quality Management

Senior Quality Engineering Consultant/Production Risk Analysis Consultant

The biggest challenges in the project were to consolidate many articles into article families and to remediate the associated legacy issues.

Approach & main achievements

- Creation of uniform and traceable production risk management analyses for all implants and instruments (in collaboration with subject matter experts) in accordance with ISO 14971
- Support for manufacturing sites in implementing the production risk analysis process
- Development of standardized FMEA modules and templates

Technical environment & methodologies:

- Passive Medical Devices Class I-III
- Surgery
- Surgical Instruments and Implants for the specific therapies

DePuy Synthes GmbH - Zuchwill CH **NOV 13 -JUN 14**

Manufacturing Engineering / Validation

GRQP Manufacturing Engineering Consultant/Validation Consultant

The biggest challenges in the project were consolidating a large number of articles into article families and remediating the associated legacy issues.

Approach & main achievements

- Compiled traceable process validation documentation for medical devices with respect to cleanliness and biocompatibility.
- Supported manufacturing sites in implementing biocompatibility and cleanliness processes.
- Prepared complete and traceable electronic documentation of cleanliness validation and biological safety evaluation (as part of the Device Master Record, DMR).

- Reviewed and integrated manufacturing process validation and test data into documentation management systems.
- Assessed the cleanliness and biocompatibility status of existing manufacturing processes (in collaboration with subject matter experts).
- Responsible for conducting cleanliness validation activities within manufacturing.
- Coordinated external cleanliness testing in collaboration with internal units (e.g., cytotoxicity, bioburden, Fourier Transform Infrared Spectroscopy (FTIR), Total Organic Carbon (TOC)).
- Documented process monitoring activities related to cleanliness
- Acted as an interface between various functions (manufacturing, process validation, materials testing, risk management)

Technical environment & methodologies:

- Passive Medical Devices class I-III
- Surgery
- Surgical Instruments and Implants for the specific therapies

PREH GmbH – Bad Neustadt DE **MAY 13 -NOV 13**

Quality Management

Quality Engineer / FMEA Moderator

Approach & main achievements

- Moderation of FMEAs during the product development and design transfer phases, as well as updating existing FMEAs
- Ensuring adherence to the defined methodology and compliance with all formal FMEA requirements
- Maintaining consistency between Design FMEA (dFMEA) and Process FMEA (pFMEA)
- Supporting design experts, development engineers, and manufacturing engineers in the creation of control plans and reaction plans
- Developing standardized FMEA modules
- Monitoring the progress and timely completion of FMEA projects
- Documenting, reviewing, approving, and archiving FMEA records

Technical environment & methodologies:

- Automotive
- Manufacturing of the Multimedia Device for the cars
- Injection Molding of Plastic

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

Ganshorn Medizin Electronic GmbH Bad Neustadt DE **SEP 09 -April 13**

Quality Management and Regulatory - Leadership

Head of Quality Management and Regulatory Affairs:

The biggest challenge in this environment was to analyse all company processes and to strengthen the quality awareness of employees across the organization. This required substantial persuasion and change-management efforts to improve procedures and align the organization with regulatory and quality expectations.

Approach & main achievements

- International product registration / Regulatory Affairs (Turkey, China, Indonesia, EU (CE), FDA, Russia, Brazil, Korea, Taiwan)
- Maintenance and further development of the Quality Management Systems according to DIN EN ISO 13485 and ISO 9001
- Quality planning and quality assurance across the entire product lifecycle
- CAPA management according to FDA 21 CFR 820 and ISO 13485
- Risk management in accordance with ISO 14971 (including FMEA and APIS methodologies)
- Occupational Health and Safety Management
- Planning and execution of internal and external audits
- Supplier Quality Management and complaint handling
- Preparation of Clinical Evaluation Reports for active medical electrical devices Class IIa and IIb
- Planning and oversight of IEC 60601-1 (3rd edition) validation activities, including IEC 60601-1, ISO 980, IEC 62304, and IEC 62366 compliance

Technical environment & methodologies:

- Active Medical Devices
- Lung Function Testing
- Body plethysmography
- Cardiopulmonary Testing
- Spirometry
- Software for the Lung Function Testing Devices

Hochschule Burgerland **SEP 22 – MAR 25**

Education

MBA Compliance and Risk Management (Part Time Continuing Education)

Grade: Passed with Merit

WBS Trainings AG - Munich DE **APR 09 -AUG 09**

Education

Education in European Quality and Project Management:

- Management basics, business administration, communication
- Quality Management (DEKRA)
- Internal Auditor (DEKRA)
- Project Management I and II
- Methodological skills for project management

Volke Consulting Engineers GmbH & Co. KG – Munich **FEB 01 – APR 09**

Quality and Process Management

Team leader Quality and Change Management:

Approach & main 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

Technical environment & methodologies:

- Consulting
- Testing
- Automotive
- Engineering