Dinc Consulting

First Name LAST NAME
Mustafa DINC

Specialty

German, English, Turkish

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Dinc Consulting

OVERVIEW

Professional experience:

- 23 Years: Quality Management
- 8 Years: Regulatory Affairs
- 15 Years: Risk Management
- 5 Years: Validation
- 13 Years: Project Management
- 15 Years: CAPA
- 15 Years: FDA
- 7 Years : EU-MDR
- 8 Years: Active Medical Devices class I-III
- 7 Years: Passive Medical Devices class i-III
- 13 Month: In Vitro Diagnostic

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
- ISO 27001
- LkSG (Supply Chain Act)

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)

EXPERIENCE

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

Freelance Consultant Nonconformities

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 in order 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 according to MDR 2017/745 and Quality Support as Quality Engineer during agile development phases of the Software class IIa:

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

Approach & main achievements

- Clear / concrete definition of NC-Projects (SAP Based)
- Creation and closing of NCs (including NCR, NC, Complaints, CAPAs, SCARs) e.g.: in the clean room area, power failures, bioburden sterility assurance level, particle level, Material failure, production failure etc.
- Development and determination of containment, correction and corrective action as well as material disposition, impact assessment and creation of the related documents.
- Systematic determination of root cause of the non-conformity.
- Creation of Weekly 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 of lubricant

Working in an international environment as a quality validation engineer and project manager. The biggest challenges were to organize different employees from different departments with different education levels for the project as well as large number of articles to analyze and evaluate and to meet the deadlines. Furthermore, the employees had to be trained for the projects. The environment was technical as well as on a business level

Approach & main achievements

- Carrying out of the Validation (IQ, OQ, PQ, Compliance Analysis, Risk Based Validation) for the Manufacturing Machines and Equipment's
- Carrying out of Test Method Validation
- Product Change Management (Technical Files)
- Creation of Project Management Plan
- Creation of Site Validation Master Plan
- Project Leading of Change Management Project Swisscool coolant (lubricant) including change of all concerned technical files.
- Review and creation of the inspection process and inspection sheets
- Creation of the Procedure for the environmental condition of the chemicals and substances and supply chain of the chemicals
- Review and update of the Heat Treatment Procedure for external and internal approach
- Conducting of Periodic Validation Reports
- CAPA

Technical environment & methodologies

- Surgery
- Surgical Instruments
- Test Method Validation in the Production Area
- IQ, OQ, PQ of the CNC Machine in the Production Area
- Statistical Methods in Minitab
- Project plan
- Site Master Validation Plan
- Bio Compatibility Test
- Product packaging

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

Purchasing – Project Leader

Sourcing Quality Engineer and Supplier Quality Engineer

The biggest challenges were integrating the employees with different education. level into the project and implementing the stable purchasing process according to the 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 editing of CAPA, NC and Observation in ETQ as owner,
- Training of employees regarding the introduced purchasing and PP&L procedures.
- 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 about storage conditions under consideration of regulations regarding chemicals and substances including:
    - Investigation of current status (Gap-analysis).
    - Carrying out risk management regarding HiBE (Hilf- und Betriebsmittel)
    - Introduction of workplace design according to 5S
    - Introduction of the procedure from the receipt of goods to the storage of chemicals and substances in the storerooms.
- Achieved Benefit for the site Tuttlingen:
    - Stable HIBE (Hilfs- und Betriebsmittel) process
    - Compliance with storage conditions for the 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 DIN EN ISO 13485:2016 update as well as Medical Device Directive

The biggest challenge for the project was that the preparation for ISO 13485: 2016 certification audit had to be carried out within 8 weeks.

Approach & main achievements

- Gap-Analysis of the Risk Management Procedure as well as Risk Management Files (Especially pFMEA)
- Gap-Analysis of the Process Validation Procedure as well as Process Validation Files (TMV, IQ, OQ, PQ, Packaging, Injection Molding, Sterilization Procedure, 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 biggest challenge in the project was the preparation of the production transfer at a plant in Berlin so that the production of active medical devices in Freiburg could be guaranteed.

Approach & main achievements

- Support Manufacturing Transfer by performing quality activities.
- Creation and Monitoring of engineering and QMS change requests.
- Transferring NC / CAPA to the site receiving the products and lead the completion of the NC / CAPAs
- Support of inspection planning and initial sampling (Main focus)
- Participation in the implementation of the manufacturing process for transferred products.
- Subject matter expert for process risk analysis and FMEA's
- Monitoring of critical process validation (welding, gluing, etc.)
- Support the development and monitoring of processes and equipment 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 biggest challenges in the project were the experience in the Regulation of EU MDR due to new Regulation. The integration into the project was also a challenge because of the new requirements. A lot of persuasion was necessary because of the diversity of the project and processes.

Approach & main achievements

- Introduction of Post Market Surveillance Process according to Medical Device Regulation (2017/745) for class II-III active medical electrical devices (Defibrillators, ECG, Holter ECG, Cardiopulmonary Exercise Testing devices,

AEDs, Monitoring Devices, Spirometry Devices, Blood Pressure Measurement Devices):

• Creation of Post Market Surveillance Plan for class II-III active medical electrical devices (Art. 84)

• Creation of Post Market Surveillance Report (MDR Article 85)

• Creation of Periodic Safety Update Report (MDR Article 86)

• Vigilance Reporting as well as *Medical Device Reporting (MDR Article 87-92)*

- Improvement of Complaint Handling Process
- Improvement of Product CAPA Process
- Improvement of Product Change Management Process
- Risk Assessment as well as Risk Management acc. to ISO 14971:2012
- Creation of Clinical Evaluation Report for active medical electrical devices class II-III acc. to Meddev 2.7.1 Rev4 (7 Reports have been created)
- Preparation of authority inspection (Swissmedic, FDA, MDSAP, TÜV SÜD)
- Reporting to Global Product Management
- Regulatory Affairs (As Regulatory Compliance Manager): Completion of Technical Files for EU (DoC), US (510(k)) as well as Asia Market (China, CFDA)

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 NC and CAPA at the site had to be processed and closed after a defined date in order to meet the FDA requirements.

Approach & main achievements

- Clear / concrete definition of NC-Projects
- Creation and closing of NCs (including NCR, NC, Complaints, CAPAs) e.g.: in the clean room area, power failures, bioburden sterility assurance level, particle level, Material failure, production failure etc.
- Development and determination of containment, correction and corrective action as well as material disposition, impact assessment and creation of the related documents.
- Systematic determination of root cause of the non-conformity.
- Creation of Weekly 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 many CAPA at the site had to be processed and closed after a defined date in order to meet the requirements. In addition, employees received regular training during completion of CAPAs.

Approach & main achievements

- Improvement of CAPA Process
- Creation of a new SOP for CAPA (successful implemented)
- 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
The biggest challenges in the project were to combine many articles (approx. 2000) into article families and to remediate the legacy issues.

Approach & main achievements

- Technical writing-reports and technical justification
- Carry out DHF remediation activities as per approved remediation plan
- Develop protocols and procedures
- Develop understanding in functional / system testing of medical devices
- Analysing of current Risk Management Process Introduction, improvement, Release of Risk Management Files for the implants and instruments (Trauma and Healing Devices)
- Analysing, Introduction, Improvement as well as detection of Use Related Hazards / Human Error Factors according to Surgical Techniques
- Risk Management acc. to DIN EN ISO 14971:2012
- Introducing of Complaint Summary Reports for Implants and Instruments as well as Risk Management Reports

Technical environment & methodologies:

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

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 combine many articles into article families and to remediate the legacy issues.

Approach & main achievements

- Creating of uniform and traceable production risk management analysis for all implants and instruments (with support of further subject matter experts) according to ISO 14971
- Support the manufacturing sites implementing the production risk analysis process.
- Creation 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 to combine a large number of articles into article families and to remediate the legacy issues.

Approach & main achievements

- Compile a traceable process validation documentation for medical devices in respect of cleanliness and biocompatibility.
- Support the manufacturing sites implementing the biocompatibility and cleanliness process.
- Prepare the complete and traceable electronic documentation of the cleanliness validation and biological safety evaluation (part of the Device Master Record (DMR))
- Review and corporation of manufacturing process validation and test data into documentation management systems
- Assess the cleanliness and biocompatibility status of existing manufacturing processes (with support of further subject matter experts)
- Responsible of the conduct of the cleanliness validation in manufacturing
- Coordination of external cleanliness tests in cooperation with a internal unit (e.g. Cytotoxicity, Bioburden, Fourier, Transform Infrared Spectroscopy (FTIR), Total Organic Carbon (TOC)
- Documentation of process monitoring processes regarding cleanliness
- Interface between different functions (manufacturing, process validation, material 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 FMEA during product development process phase and design transfer phase as well as updating of existing FMEAs
- Adherence of the defined methodology and ensuring the formal correctness of the FMEA
- Ensuring consistency between product and process FMEA
- Support of the design experts/development engineers/manufacturing engineers during creation of control plans and reaction plans
- Creation of standardized FMEA modules
- Monitoring the progress of the FMEA projects
- Documentation, approval and archiving of FMEA.

Technical environment & methodologies:

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

Dinc Consulting (Own Company) Bad Neustadt DE **FEB 13 - Now**

Consulting about Quality Management, Regulatory Affairs, Clinical Evaluation, Project Management, Validation regarding Medical Products.

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 challenges in a small and medium-sized company were to analyze all. processes in the company and to increase the quality awareness of employees in the company. This included a lot of persuasion to improve the procedures within the company.

Approach & main achievements

- International product Registration /Regulatory Affairs (Turkey, China, Indonesia, EU(CE), FDA, Russia, Brasil, Korea, Taiwan)

- Maintaining and developing of quality management systems according to DIN EN ISO 13485 and ISO 9001
- Quality planning and quality assurance
- CAPA according to FDA Part 820 and ISO 13485
- Risk management according to ISO 14971 (FMEA, APIS)
- Occupational Health and Safety Management
- Planning and carrying out of internal and external audits.
- Supplier Quality Management / complaint handling
- Clinical evaluation reports of medical electrical devices class IIa, IIb
- Planning and supervising of IEC 60601-1 (3. Edition) validation activities according to IEC 60601-1 (3. Edition), ISO 980, IEC 62304, IEC 62366

Technical environment & methodologies:

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

Austrian Institute of Management (FH Burgerland) **SEP22 – SEP24**

Education

MBA Compliance and Risk Management (Part Time Continuing Education)

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

Education

Education to 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

- 07.08 – 04.09. Six Sigma, Six Sigma Lean, DFSS in house of Volke Consulting
- 08.07 – 06.08 Quality control of vehicle transmission projects during the series
- 01.07 – 07.07 Control of the launch in the vehicle project with temporary employment abroad (England/Goodwood)
- 01.06 – 06.08 Power train development of V8, V12 as change manager
- 07.03 – 12.05 Change and quality manager in hydrogen vehicle project
- 05.02 – 06.03 Process optimization, transparency, cost reduction by changes with the focus whole vehicle project
- 02.01 – 04.02 Project operational strength and materials as test engineer

Technical environment & methodologies:

- Engineering
- Consulting
- Testing
- Automotive