Dinc Consulting

EXECUTIVE SUMMARY

First Name LAST NAME
Mustafa DINC

Specialty

German, English, Turkish

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EXECUTIVE SUMMARY – Mustafa Dinc, www.dincon.org

Mustafa Dinc, born on 4 December 1973 in Freising (Bavaria), is married and the father of two children. He has a strong engineering background and extensive operational leadership experience. He has successfully managed quality management systems for active and passive medical devices (Class I–III), implants, cardiovascular systems, software (Class IIa), and IVD, supporting global markets including the EU, the US, China, and LATAM.

His expertise covers the entire lifecycle of regulatory compliance in the medical device sector—from technical documentation and risk management (ISO 14971) to supplier quality, validation, the implementation of PMS/PSUR, EU-MDR requirements, QMS systems, cyber security risk assessments, clinical evaluations, vigilance, and UDI, through to audit execution and audit preparation.

He has led Quality and Regulatory Affairs teams in several international companies and has held key leadership roles, including Head of Post Market Surveillance & Operational Quality, Head of Quality Management & Regulatory Affairs, as well as various interim QMS and Regulatory positions. In these roles, he was responsible for resolving extensive NC/CAPA/SCAR backlogs—as well as QMS, technical documentation, PMS, and risk management file backlogs—stabilizing the QMS and supplier landscape and preparing multiple organizations for FDA and ISO audits.

Known for his strong analytical approach, high regulatory integrity, and ability to stabilize and elevate QMS performance in complex environments, Mustafa combines strategic leadership with deep technical insight. His background includes the implementation of MDR-compliant PMS structures, remediation of technical files and DHFs, validation leadership, supplier process optimization, and the digitalization of quality processes.

He holds an MBA in Compliance & Risk Management (with merit), complemented by extensive certifications in MDR, FDA requirements, 510(k), ISO 13485, internal auditing, FMEA moderation, biocompatibility and sterilization.

Mustafa combines strategic vision, regulatory depth, operational excellence, and leadership experience—qualities required to lead Quality and Regulatory Affairs functions at multiple organizational levels, particularly within an innovative and globally operating medical device company.

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