

EXTERNAL ASSOCIATE



UNITES STATES OF AMERICA



**NAME AND
SURNAME:**

Daira Komić

AFFILIATION:

Senior Quality Engineering Manager at MIMEDX
Group

**AREA OF
EXPERTISE:**

Program Management, Project management,
Human tissue product

SHORT BIOGRAPHY

Daira Komic is an accomplished senior-level Quality Engineering Manager with over 26 years of experience in human tissue, biopharmaceutical, and medical device manufacturing. She possesses expertise in various regulatory standards, including FDA CFR Part 211, FDA CFR Part 820, FDA CFR Part 1271, ISO 9001, ISO 13485, ISO 14971, ISO17025, ISO 11137, ISO11138. Daira has a strong track record of leading diverse quality engineering teams, excelling in regulatory compliance audits, risk analysis procedures, process validation, sterilization validations, technical file creation, CAPA management, and equipment qualification. She is skilled in program management, project management, and process development, with experience in Class I and II medical devices, human tissue products, and biologics. Daira is a dedicated team leader and trainer, proficient in risk analysis management, design reviews, and RACI methodology.

In her current role at MiMedx Group, Daira manages a team of experienced quality engineers responsible for various aspects of quality control, process validations, equipment qualifications, sterilization programs, and product stability studies for a range of medical and surgical products, including human tissue, medical devices, and biologics. She has a history of leading quality system audits within diverse material and service suppliers.

Over her career, Daira has progressed through various roles, including Senior Quality Engineering Manager, Quality Engineering Manager, and Senior Quality Engineer. She is adept at project management, utilizing tools like SWOT Analysis and RACI to assess and improve business operations. Daira has experience in troubleshooting, problem-solving, decision-making, and delivering detailed reports on validation results. She has also managed supplier qualifications and audits, ensuring quality control and compliance.

Daira's career journey has taken her through notable organizations in the medical and healthcare industry, including MiMedx Group, Spine Medica (a MiMedx subsidiary), Cardinal Health, Snowden Pencer, Genzyme Biosurgery, and Alphamed Inc. Her educational background includes a Master of Science in Quality Assurance from Southern Polytechnic State University and a Bachelor of Science in Biochemistry and Food Technology from the University of Banja Luka, Bosnia, and Herzegovina.

She has further enhanced her professional development with certifications, including Certified Quality Auditor (CQA) from the American Society for Quality (ASQ), and a Certified Tissue Bank Auditor from The Colyn Group, among others. Daira Komic is a dedicated quality professional with a wealth of experience and expertise in ensuring the highest standards of quality and compliance in the healthcare and medical manufacturing industry.

