

ISO 13485 GAP ANALYSIS IDENTIFIES INVESTMENT OPPORTUNITIES

ABOUT 411 INDUSTRIES L.L.C. 411 Industries is a locally-owned Greeneville, Tennessee-based company providing testing and inspection, small bench work, assembly & fabricating, sorting, special projects, contract assembly services, packaging services, quality inspection, and rework services for other OEM and tier suppliers.

THE CHALLENGE. While already ISO 9001 certified, the company was interested in expanding to the medical device industry and requested that TMEP, part of the MEP National Network™, facilitate an ISO 13485 gap analysis incorporating both of their manufacturing locations. The gap analysis is important to identify discrepancies between the existing ISO 9001 quality management system and the requirements outlined in ISO 13485:2016.

MEP CENTER'S ROLE. A TMEP certified ISO 13485 Lead Auditor spent sixteen hours across both locations reviewing and documenting 411's production processes. The consultant worked with 411 employees to review existing documentation, procedures, and policies, observed processes, and noted discrepancies between the existing QMS and ISO 13485 requirements. Recommendations were provided to close the gaps and a detailed action plan was developed for the 411 team to implement.

"The TMEP team were very helpful and quick to respond to needs. They came to my facilities on multiple occasions and assisted with multiple needs. Very professional. Glad they are partners with 411 Industries!"

-Brian, VP of Operations

RESULTS



\$250,000 in new or retained sales



\$130,000 in new investment



\$10,000 in workforce investment

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