

MEDICAL ENGINEERING CONSULTANTS ● ● ●



OVERVIEW

PROJECT TYPE: INTEGRATION ACQUISITION

CHALLENGE: Integrate Quality Management System (QMS) while preserving compliance with drug led combination regulatory requirements. Acquisition consisted of combination drug/device Target by a Medical Device exclusive company.

SCOPE: Integration of QMS, Distribution, Economic Operators, Regulatory and Quality IT systems.

MEC Technical Program Manager partnered with Target process owners to span the gap and help translate the needs received from the Acquiring Company.

Target QMS was reviewed for compliance with applicable regulations and alignment to Acquiring Company practices. All gaps noted were prioritized on a risk basis and resourced / executed accordingly. Intermittent assessments were conducted to ensure compliance with regulations and to confirm implementation of Acquiring Company practices.

MEC assigned team members to execute in each workstream but critically the Target process owners owned their workstreams.

MEC provided expertise and review of drug-led combination requirements to influence impacted policies at the Acquiring Company to reduce audit risk.

QMS integration and document updates were completed with sensitivity to preserve drug-led combination requirements.



APPROACH



RESULTS



Major CAPAs



Observations



Minor Nonconformances



Quality/Regulatory/
Clinical IT Systems



Remediation
Initiatives

500+ QMS documents reviewed and integrated



CONCLUSION

MEC effectively bridged the gap between these two companies with expertise in large and small company QMS transformations. The newly integrated QMS remained compliant with 21 CFR 4/11/803/806/820/210/211, ISO13485, ISO14971, MDR and MDD. This project's early completion was essential in meeting leadership and FDA expectations.

Strong engagement of Target process owners allowed them to have a hand in QMS integration and a full understanding of Acquiring Company requirements. Through the support of MEC resources these Target process owners were able to engage and direct the vision for their processes while still running day to day operations.