



EBOOK

MAPPING THE RELIABILITY JOURNEY

THE PROVEN VALUE OF RELIABILITY
ASSESSMENTS AND BENCHMARKING



Project Overview

A global medical device manufacturer sought to improve Safety, Equipment Reliability, Overall Equipment Effectiveness (OEE), and cGMP regulatory compliance by performing a plant-wide reliability and best-practice benchmarking assessment.

The goal: perform a thorough reliability assessment and benchmarking against industry standards, OSHA, and cGMP requirements to establish a reliability roadmap for moving the organization into regulatory compliance and industry best practice performance.

With the collaborative support of the Plant Manager, Plant Leadership Team, Total Productive Maintenance (TPM) Steering Committee and Six Sigma LEAN Team, CAI's Asset Management & Reliability (AMR) Technical Consultants assessed and benchmarked the facility against regulatory requirements and industry best practices.

From Reactive to Proactive

A large multi-national producer of medical devices was experiencing poor safety results and equipment reliability due to reactive and immature programs and systems. The client had no industry point of reference to use as a basis for evaluating OSHA and cGMP regulatory compliance and the effectiveness of their maintenance program.

WORKING TO FIND A SOLUTION

The company chose CAI to assist them with this initiative based on their integrated reliability assessment methodology and extensive experience working with other clients in the medical device industry.



CAI also maintains a proven track record of assessing clients to achieve regulatory compliance in manufacturing plants.

The CAI team of AMR engineers worked closely with the client's leadership team and front-line employees to define and evaluate relevant assessment metrics and establish the future state vision for transitioning the organization to achieve regulatory compliance and best practice performance.

Ensuring cGMP Regulatory Compliance

The facility was evaluated with regards to the International Standards Organization (ISO) 55000 Asset Management Standards, the International Society for Pharmaceutical Engineering (ISPE) Maintenance Good Practice Guide (GPG) and the ICH Q9 Quality Risk Management Approach. The ISPE Maintenance GPG is used as a resource for achieving compliance towards cGMP Regulatory requirements of the FDA 21 CFR Part 820 – Current Good Manufacturing Practice for Medical Devices.

The sixteen categories identified represent the foundational elements for a cGMP compliant maintenance program.

- Self-Audit or Assessments
- Maintenance Interfaces
- Maintenance Classifications
- Training Programs
- Inventory Management
- Risk Assessment
- Contract Management & Outsourcing
- Performance Management
- Maintenance Systems and Execution
- Change Control
- Maintenance Plans & Work Orders
- Training Plans
- Spare Part Applications
- Roles and Responsibilities
- Discrepancies
- Deferred Maintenance



Assessment Recommendations

Recommendations generated from the four phases of CAI's AMR Assessment include:

PHASE 1: QUANTITATIVE ASSESSMENT

- **Safety findings** – OSHA Recordable Rate, safety program deficiencies and overall safety attitude
- Opportunity to reduce product quality rejection rate and scrap
- Planning and Scheduling opportunity to address reactive environment

PHASE 2: QUALITATIVE ASSESSMENT

- Organizational structure supports reactive mentality
- Lack of reliability engineering and strategic focus
- • Lack of understanding reliability concepts to build Maintenance strategy
- Lack of OSHA & cGMP regulatory compliance programs & procedures

PHASE 3: cGMP REGULATORY COMPLIANCE ASSESSMENT

- Lack of documented maintenance and reliability processes and SOP's aligned with the reality of the plant
- Lack of documented processes integrating the Business Process Flow and Roles and Responsibilities into each SOP
- Opportunity to leverage active continuous improvement processes
- Prioritized cGMP and OSHA specific strategic and tactical plans for compliance

PHASE 4: THREE-TO-FIVE YEAR STRATEGIC PLAN, BUSINESS CASE & ROADMAP

- Documented Gap analysis against OEE opportunities identifying \$1.6 MM in savings annually
- Prepared a three to five year strategic roadmap and business case

Project Success

Subsequent to the delivery of CAI's recommendations the following changes and results were achieved:

- Hired a safety manager and established OSHA compliant safety policies and procedures
- Established annual performance KPI for entire leadership team of proactive:reactive ratio
- Decentralized the maintenance organization and hired two new positions for reliability engineers
- Assigned a champion of the plan to the position of maintenance manager
- Integrated AMR best practices into the engineering specification & URS template for new capital projects
- Maintenance leading the charge to integrate Design for Reliability (DfR) into capital planning
- Trained essential engineering and maintenance personnel in reliability concepts
- Capturing highest failure modes in current equipment to design them out in the next generation equipment
- Established a AMR field guide for project engineers to apply AMR best practices

In less than one year, the client observed a significant improvement in the plant wide OSHA recordable rate from 2.2 to 0.75. Additionally, the plant team drove a 10% reduction in scrap and a 10% improvement in efficiency resulting in a cost of goods savings of over \$100,000/year from the assets that these improvements had been implemented on. It's expected the Life Cycle Costs and reliability of new capital equipment will continue to improve.

CONTACT COMMISSIONING AGENTS, INC. TO IMPLEMENT SIMILAR SOLUTIONS ON YOUR SITE.

Commissioning Agents, Inc. (CAI) provides technical and consulting services to improve the delivery, reliability, and efficiency of your equipment, facilities, and production operations. For manufacturing start-up, smart operations, asset maintenance and reliability programs, energy use optimization, and regulatory and process consulting – CAI adds value to your bottom line.



RICHARD TREE is a 22-year veteran of submarine naval nuclear power operations who upon retirement entered into manufacturing operations. He is a recognized operations excellence leader and has held leadership roles as VP of Operations and Chief Operating Officer where he was responsible for multi-site manufacturing plants and their supply chains. He is a lean operations expert – certified lean six sigma. Some of his most impactful work was in the area of Enterprise Asset Management involving asset & system design, sourcing, life cycle management, and reliability. Richard's approach to asset life cycle management is one that

develops a framework for continuous improvement based on the business' objectives for their value added needs. His efforts led to dramatic gains in operating equipment effectiveness (OEE) from as low as 40% to as high as 90% as a result of improved reliability. Through simplified spare parts strategies one company alone saved more than \$2 million per year and cut maintenance costs per unit produced by 30%. Richard holds an MBA from Southern Methodist University and is currently working on his PhD dissertation in the field of Operations Management from the University of Texas Arlington.