ARE YOU READY?

LEADING PHARMACEUTICAL MANUFACTURER, USA

GMP MANUFACTURING CYCLE TIME REDUCTION

CASE STUDY: OPERATIONAL EXCELLENCE

GMP Manufacturing Cycle Time Reduction

CLIENT HISTORY

CAI has maintained a long-term relationship with this global pharmaceutical manufacturer, providing commissioning, qualification, validation, and operational excellence (OE) services across multiple facilities.

This engagement represented an expansion of CAI's support into data-driven process improvement for manufacturing performance.

PROJECT COST:
$255,906

PROJECT DURATION:
12 months

WHY CAI?

The client's site was experiencing extended and inconsistent manufacturing cycle times between batches. CAI's on-site team recognized the opportunity to improve performance through a structured OE approach and partnered with site leadership to define and implement practical, measurable solutions.

PROJECT OVERVIEW

CAI was engaged to observe and analyze inter-batch manual operations, identify efficiency opportunities, and support improvement implementation.

The project evolved from an initial assessment into a year-long engagement focused on reducing time variability and strengthening process consistency.

CAI's team gathered and analyzed detailed process data to establish performance baselines and pinpoint high-impact improvement areas.

KEY ACCOMPLISHMENTS

- Established a reliable process for conducting TBB in under 6.5 hours
- Facilitated removal of redundant robot line clearances, saving approximately 1 hour
- Eliminated redundant reconciliation clearance steps, saving an additional 30 minutes
- Supported change control development to divide the room into operational zones
- Created and maintained a detailed TBB tracking tool with averages and standard deviations
- Developed instructional and visual management tools, including a Line Clearance (LC) training video and operator status boards
- Revised controlled documentation and job aids to reflect process updates
- Strengthened communication and alignment across Operations, QA, Mfg Support and Supervision

CLIENT CHALLENGES

The site lacked a formal method to track TBB performance or variability, resulting in inefficiencies, inconsistent execution, and limited visibility into process constraints.

Frequent operator turnover and varying levels of experience compounded the issue, leading to inconsistent execution of key steps such as line clearance and reconciliation.

Standard Operating Procedures (SOPs) provided insufficient guidance, and high variability in TBB was recognized as a costly issue affecting throughput and productivity.

CAI SOLUTIONS

CAI applied its proven Operational Excellence framework to analyze performance data, identify constraints, and implement practical process improvements.

MACHINE 1

- Analyzed and visualized Functional Challenge Test (FT) steps to identify major downtime sources
- Coached operators on pre-test cleaning procedures and increased replacement frequency of FT kits to improve pass rates
- Developed swim-lane diagrams to visualize process flow and align on improved methods

MACHINE 2

- Removed redundant robot line clearances and repositioned steps to streamline workflow
- Divided the inspection room into two zones to enable parallel clearance activities
- Introduced standardized Line Clearance coaching materials and visual aids to reduce variation between shifts

Together, these actions reduced TBB duration by **36%** and variability by **49%**, achieving consistent cycle times and measurable productivity improvements

PROJECT SUCCESS

The project validated CAI's data-driven approach to Operational Excellence and demonstrated the impact of structured process improvement on cycle-time performance. Using the DMAIC problem-solving framework, a small and relatively junior CAI team—supported by senior consultants—delivered record cycle-time results for the client. The success of this project positioned CAI as a trusted partner for continuous improvement and reinforced the value of applying OE methodologies to large-scale pharmaceutical manufacturing environments.

> "For the cost of one operator the production line has achieved record performance."
>
> **- Client Area Lead**

ARE YOU READY?

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