

CONFIDENTIAL, MASSACHUSETTS, USA

CASE STUDY

Project Management & Strategic Planning Services

Program & Project Management



WHEN YOU NEED TO MEET A HIGHER STANDARD® +1 317-271-6082 • cagents.com

Project Management & Strategic Planning Services

Project Overview

CAI has had the pleasure of partnering with a progressive drug design and development organization to support their in-house, real time release, continuous processing oral solid dosage (OSD) manufacturing initiative in Massachusetts, USA.

Services Provided

- Revised and maintained global milestone schedule
- Restructured project teams to achieve maximum performance and streamline communications
- Facilitated two program teams focused on establishing operating philosophy to guide planning and work in the manufacturing facility
- Liaised between management, design, and construction teams
- Upon completion of construction, formed Site Leadership Team and started several initiatives within that team:
 - Site Continuous Improvement Program
 - Revised all departments' metrics and KPIs
 - Created master scheduling/enterprise management tool
- Maintained schedule and tracked milestones for pre-approval inspection readiness
- Provided consultants for process and cleaning validation strategy, planning, and execution

Value Delivered

The site facility construction and commissioning were completed. Facilities support personnel were hired, trained, and put in place to support the site. The continuous processing rig was delivered and installed. Support personnel were also hired, trained, and relocated to the site through an effective transition of ongoing team activities. CAI's team helped establish site leadership as well. Process and cleaning validation were completed successfully, and the facility pre-approval inspection was completed with no major observations. In the end, the new drug was approved for manufacturing.



CLIENT: CONFIDENTIAL

LOCATION: MASSACHUSETTS, USA

TIME FRAME: 2 YEARS

CONTRACT SIZE: UNKNOWN

Program & Project Management

