



Syner-G Brings a New Radiopharmaceutical Facility Toward GMP Operational Readiness

Syner-G is a Strategic Development and Delivery Partner™ to CDMOs helping them overcome capacity, quality, and technology transfer challenges by embedding seasoned experts who bring the right blend of science, strategy, and execution, without the overhead of hiring full-time employees.

Challenge

A radiopharmaceutical manufacturer was preparing to launch a new production facility while navigating concurrent construction, commissioning, qualification, and validation activities along with SOP development. The site needed to meet cGMP requirements, including 21 CFR Part 211 and USP <797>/<825>, while maintaining readiness for regulatory inspection. Mid-project, the facility's scope shifted from commercial manufacturing to Phase I/II clinical production, introducing new operational, regulatory, and staffing requirements.

Solution

Syner-G embedded a cross-functional operational readiness team to provide both program leadership and hands-on execution across engineering, quality, manufacturing, automation, and validation. As the facility's scope transitioned from commercial manufacturing to Phase I/II clinical production, Syner-G rapidly adapted the readiness strategy to align regulatory, operational, and business objectives while maintaining project momentum.

Key deliverables included:

- **Program Governance:** Established an integrated master schedule, KPI dashboards, and clear ownership across workstreams to drive accountability and execution.
- **Leadership Continuity:** Maintained program stability during key leadership transitions, preserving knowledge and minimizing disruption.
- **Facility & Operational Readiness:** Supported facility remediation, commissioning, qualification, and startup activities across equipment, utilities, and automation systems, while coordinating vendors through critical project milestones.
- **Technology Transfer:** Enabled successful product introductions by coordinating and supporting execution of technology transfer activities across R&D, manufacturing, engineering, and quality teams.
- **Supply Chain Readiness:** Led GMP material onboarding and supply chain preparation to ensure qualified materials were available ahead of startup.
- **Quality Systems & Documentation:** Developed and reviewed procedures, protocols, and qualification documentation necessary to support compliant operations from day one.
- **Operational Excellence:** Implemented visual management, tiered governance, and standard work practices to support sustainable performance beyond facility launch.

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Case Study

Operational Readiness by the Numbers

13,000 sq. ft.

13,000 sq. ft. facility prepared for clinical / GMP operations (including R&D, manufacturing, QC, and support functions)

277+

277+ materials onboarded to support GMP manufacturing and analytical testing

720+

720+ quality, validation, engineering, and operational documents generated to support compliant facility activation

Outcome

Syner-G helped the client advance facility startup and GMP operational readiness while managing scope change, leadership transitions, and cross-functional dependencies. The program reduced the risk of compliance gaps, documentation deficiencies, and startup delays, while supporting successful technology transfer and inspection readiness. What began as a single engagement expanded across multiple phases, reflecting the value of a coordinated approach to facility startup, operational readiness, and clinical manufacturing transition.

Facing facility startup, operational readiness, or technology transfer challenges?

Syner-G partners with biopharma manufacturers and CDMOs to provide the embedded expertise, program leadership, and technical execution needed to accelerate readiness, mitigate risk, and support successful regulatory and manufacturing outcomes. Learn how our Strategic Development and Delivery Partner™ model can help bring your next facility online with confidence.

