Life Sciences Case Study

PROJECT OVERVIEW

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Building a Business-Led Digital and AI Roadmap for Clinical and Commercial Manufacturing

INDUSTRY:

Biotechnology

PRODUCTS AND SERVICES:

Biologics and Advanced Therapies

BUSINESS TRANSFORMATION STORY & BUSINESS CHALLENGE

The client, a biotechnology company, needed its in-house manufacturing site to maintain clinical supply while preparing for commercial operations and supporting growth in programs, batch volumes, and headcount. Although core enterprise resource planning (ERP), manufacturing execution (MES), quality, and laboratory systems were in place, critical workflows relied on manual handoffs and duplicate data entry. Product and process data ownership was unclear, and the technology support model wasn't built to scale.

With an FDA pre-license inspection (PLI) and multiple technology transfers approaching, the site had little tolerance for disruption. The client engaged Clarkston Consulting to develop a site-specific Digital & AI Roadmap that aligned investments with its five-year vision and sequenced the work around regulatory milestones.

PRIMARY OBJECTIVES

- Define the digital, data, and AI capabilities required to support growing clinical volumes and scalable commercial manufacturing
- Assess current-state processes and capabilities across seven site-enabling value streams to identify capability gaps and integration needs
- Prioritize and sequence initiatives that establish the operational foundation for growth while protecting PLI readiness
- Define a future-state capability and integration model that replaces manual system handoffs with controlled, end-to-end information flows
- Equip leadership with a budget-ready, three-horizon roadmap for funding, resourcing, and launching the first year of work



SOLUTION

- Facilitated a workshop with business and IT leaders to align the roadmap with the five-year site vision and define three planning horizons: build the foundation in the near term, scale with the portfolio in the mid term, and sustain commercial operations in the long term
- Interviewed more than 25 stakeholders across seven site-enabling value streams to assess current-state processes and capabilities
- Grouped 160 pain-point mentions into six demand categories and quantified manual effort
- Documented process changes repeated across 10–15 documents and systems, along with approximately 300 supply chain hours per technology transfer
- Mapped business needs to enabling technology and data capabilities to define the future-state capability model
- Designed a shared integration layer to replace point-to-point links and a separate analytics layer for manufacturing and quality data
- Evaluated six initiatives against business requirements, clinical/commercial campaign readiness, solution dependencies, regulatory milestones, and execution readiness
- Advanced three priorities for the 2027 budget – MES expansion, quality management system (QMS) transformation, and governed AI adoption – and sequenced work around PLI readiness
- Prepared implementation plans and governance by right-sizing the remaining initiatives (*site scale readiness, digital technology transfer, and master data governance*) and drafting project charters to define scope, timing, outcomes, teams, budgets, dependencies, and risks

KEY BENEFITS

- Established a single, sequenced roadmap connecting the five-year site vision to the capabilities, systems, and investments required for execution
- Concentrated the 2027 plan on three foundational initiatives and folded the other three into targeted budget lines, contract support, and work embedded in the priority initiatives
- Kept production batch records unchanged through PLI and scheduled the ERP–MES integration go-live and QMS cutover after the inspection, with the MES upgrade in a planned shutdown window

KEY BENEFITS

- Defined a governed integration model designed to replace point-to-point workarounds and duplicate data entry with reusable data flows across ERP, MES, quality, and laboratory systems
- Moved AI from ad-hoc use of enterprise tools to one or two function-owned proofs of concept that must show measurable value before scaling, under a site AI working team
- Gave site and IT leaders the sequencing, resource needs, and draft project charters needed to take the three priorities into 2027 budgeting

KPIs

- 25+ stakeholders interviewed
- 7 site-enabling value streams assessed
- 160 pain points synthesized into 6 themes
- 6 initiatives narrowed to 3 for the 2027 budget
- Roadmap delivered in 6 weeks



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