

Accelerating Front-End Planning of Biopharmaceutical Capital Projects Through Project Management and AI Interventions

AMGEN®

BUSINESS PROBLEM

Amgen's volume of capital project proposals has grown rapidly, making front-end planning (FEP) a bottleneck in decision-making. FEP defines early scope, schedule, and cost estimates for a project, but is slowed by rework driven by incomplete scope, misaligned stakeholders, and fragmented information. This leads to repeated meetings, delays, and reduced confidence in capital decisions. The organization needed a way to accelerate the FEP process while maintaining flexibility and accuracy in a highly variable, cross-functional process.

DATA SOURCES

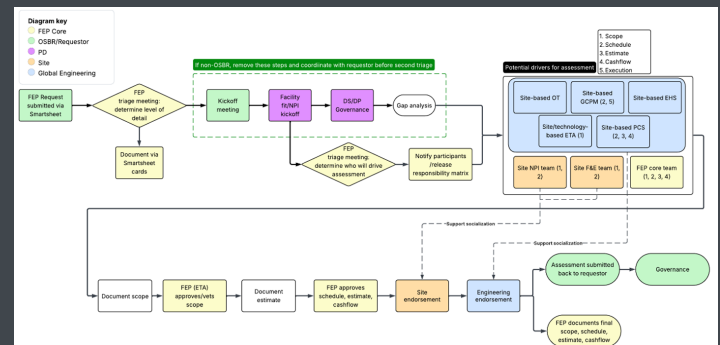
1. Amgen engineering specs and standards
2. Bioreactor agitator turnover packages from EPC/vendor
3. Archive FEP and facility-fit assessments

Data Types and Format

Image, Text, Unstructured

APPROACH

The project combined stakeholder interviews, process mapping, and a Monte Carlo simulation to quantify the impact of rework on FEP timelines. A set of lightweight project management tools (scope template, RACI matrix, triage process, logical framework) was developed to improve alignment and scope completeness. In parallel, a retrieval-augmented AI agent was prototyped to surface relevant standards and past assessments to identify scope gaps. The overall approach paired structured workflows with AI-supported knowledge retrieval.



IMPACT

Simulation results showed rework is a primary driver of delay, with reductions yielding outsized gains. A 20% reduction in rework decreased time-to-decision by 29% and employee-hours by 33%, while a 25% reduction cut time-to-decision by 47% and employee-hours by 42%. Probability of completing assessments on time increased from 25% in the base case to 46–76% with rework reduction.

Project management tools improved scope clarity and stakeholder alignment, reducing late-stage changes and duplicated work. The scope template created a single source of truth, while the triage process improved prioritization and resource allocation.

The AI prototype demonstrated strong potential to surface detailed, relevant information and identify missed scope elements, but was constrained by data fragmentation, latency, and reliability requirements. Overall, the work shows that modest improvements in coordination and scope verification can materially accelerate capital planning and improve decision confidence.

 DRIVERS	Rapid growth doubled to quadrupled FEP demand without added resources, making rework-driven delays a bottleneck. Leadership needed faster, more consistent, and scalable front-end planning to support capital allocation decisions.
 BARRIERS	Fragmented data across systems, unstructured documentation, and limited AI data access. Highly cross-functional process with differing stakeholder incentives. Need for auditability in a GMP environment. Resistance to rigid standardization in a bespoke workflow.
 ENABLERS	Strong support from ETA, FEP, and OSBR stakeholders as well as Amgen mentors. Access to SOPs, standards, and historical assessments. Enterprise AI tools and infrastructure. High stakeholder engagement through interviews and workshops enabled iterative tool development.
 ACTIONS	Conducted stakeholder interviews and process mapping. Built Monte Carlo simulation to quantify rework. Developed project management tools (scope template, responsibility matrix, triage, logical framework). Prototyped RAG-based AI agent. Tested tools with users and iterated based on feedback.
 INNOVATION	Combines lightweight PM structure with AI-assisted scope validation in a regulated environment; introduces “structure with flexibility” and applies RAG to unstructured engineering data to systematically identify scope gaps without over-standardizing the process.
 IMPROVEMENT	Tools reduced late-stage scope changes and improved alignment.
 BEST PRACTICES	Focus on communication and shared sources of truth over rigid structure. Design “minimum viable structure” for adoption. Bring stakeholders in early. Use AI to augment, not replace, expert judgment. Prioritize high-quality, accessible text data.
 OTHER APPLICATIONS	Applicable to capital planning in other high-capex, regulated industries (energy, semiconductors, advanced manufacturing) where early-stage scope definition, cross-functional coordination, and unstructured data limit decision speed.