

Light Business Case Modeling Tool Development for Manufacturing Innovations in the Biopharmaceutical Industry

sanofi

BUSINESS PROBLEM

The biopharmaceutical industry faces rising cost and sustainability pressures, requiring continuous manufacturing innovation to remain competitive. At Sanofi, subject matter experts (SMEs) who identify potential process improvements rely on the Bioprocess Modeling team to perform any first-pass COGS and sustainability analysis - a process creating a bottleneck that limits the velocity of innovation proposals reaching the innovation review board, a cross-functional strategic leadership forum. No standardized, accessible tool existed (potentially across the industry) to enable SMEs to perform this analysis autonomously, motivating this project.

DATA SOURCES

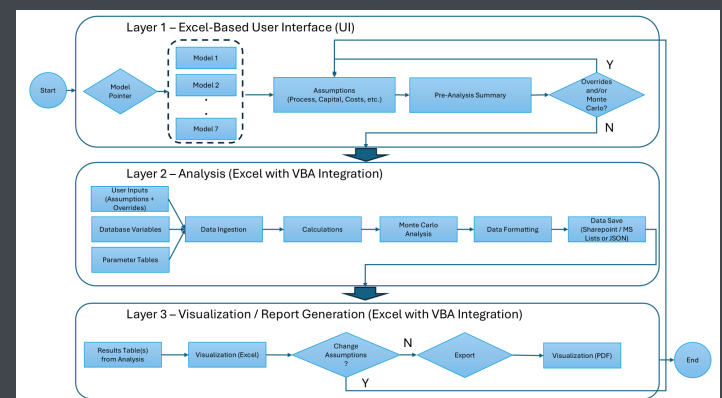
1. Existing COGS Models - Excel-based models for biologics manufacturing processes from the Sanofi Bioprocess Modeling team.
2. Manufacturing Parameters - Titer, demand, dose, labor rates, CapEx, material consumption rates from internal data - redacted from publications.
3. Industry Literature & NIIMBL Guidelines - Published COGS benchmarks, Monte Carlo methodology, and ontology schemas.

Data Types and Format

Boolean, Categorical (nominal), Count (integer), Graph Structure, Numeric, Ordered (ordinal), Static, Structured

APPROACH

A Light Business Case Modeling Tool was developed in Microsoft Excel with VBA, aggregating 8 existing COGS models into a unified, guided interface requiring no specialized software or programming knowledge. SMEs select a baseline process, describe the proposed innovation, and enter inputs via guided user forms. A Monte Carlo engine (triangular distribution, 5,000 iterations) handles uncertainty in titer, dose, and demand. Outputs include COGS, NPV, Profitability Index, and PMI (sustainability). GxP data integrity is enforced through locked cells, version control, and traceable result storage.



IMPACT

- Elimination of multiple rounds of email exchange per analysis request: SMEs can now conduct first-pass COGS and sustainability analysis fully autonomously, with zero involvement of the Bioprocess Modeling team.
- Unlimited scenario analyses: Previously constrained by expert team capacity; SMEs can now rerun what-if scenarios indefinitely, improving the quality and specificity of innovation review board proposals.
- Freed expert capacity: The Bioprocess Modeling team is freed from first-pass requests to focus on deeper, pre-approved 360-degree business case analyses.
- Potential cost avoidance of licensing cost for software: Scaled for tens of SMEs across MSAT and CMC, this can amount to tens of thousands of dollars in case the company is stuck with extending the previous method to the SMEs.



DRIVERS

Rising COGS and sustainability pressures in biopharma industry; potential organizational bottleneck in the innovation proposal pipeline; Sanofi's strategic commitment to COGS and sustainability discipline (Take The Lead framework); FDA and NIIMBL mandates for digital-ready, ontology-mapped manufacturing infrastructure are the key drivers.



BARRIERS

Organizational readiness for advanced platforms (Snowflake/Dataiku and Data Mesh not ready for this use case during internship); Excel/VBA performance limits forcing conscious design simplifications in the proof-of-concept (limiting Monte Carlo iterations to 5,000 with only four Monte Carlo variables, etc.).



ENABLERS

An excellent, supportive, and highly qualified Bioprocess Modeling team as primary stakeholders; pre-existing, excellently detailed Excel COGS models developed by the Bioprocess Modeling team; strong LGO advisors (Prof. Sean Willems, Dr. J. Christopher Love); past LGO theses; NIIMBL ontology guidelines.



ACTIONS

Conducted stakeholder interviews to define functional, usability, and technical requirements. Performed best-value option analysis across 6 candidate platforms. Designed tool architecture, aggregating 8 bioprocess models into a unified VBA-based interface. Built Monte Carlo engine (triangular distribution, 5,000 iterations). Optimized runtime by 96% via batch I/O. Validated with a test case. Documented and handed over with full GxP compliance.



INNOVATION

Based on limited literature review, this is the first simplified tool to unify COGS and sustainability (PMI) modeling for ongoing lifecycle manufacturing innovations at the SME level - bridging a gap between exhaustive simulation tools and early-stage techno-economic analysis calculators. The architecture for data storage has laid the foundation for future schema mapping toward Industry 4.0 ontology as per Sanofi's digital strategy.



IMPROVEMENT

Elimination of multiple rounds of email exchange per analysis request. Unlimited scenario analyses for SMEs at zero incremental expert cost. Bioprocess Modeling team capacity freed for 360° deep-dives. Potential cost avoidance of licensing costs for paid software at scale for SME usage. Tool aligned with GxP data integrity standards.



BEST PRACTICES

Define minimum viable requirements before platform selection; use weighted best-value option analysis to avoid over-engineering. Structured, guided UX reduces user error. GxP-aligned data integrity must be built in from day zero. Detailed model documentation is essential for maintainability and handover in regulated environments.



OTHER APPLICATIONS

Other large biopharma companies with similar CMC/MSAT organizational structures; small -molecule manufacturing at Sanofi or other companies in this industry; CDMOs evaluating platform technology investments; any manufacturing organization requiring lightweight first-pass techno-economic analysis before committing to full simulation modeling.