

Perspective Summary: Reframing Pharmaceutical Localization for Resilient Health Systems

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Executive Summary Global efforts to localize biopharmaceutical manufacturing are accelerating, but many capital-intensive initiatives stall due to a focus on industrial policy over health-system implementation. This leads to a "capability trap" characterized when governments or sovereign wealth funds authorize massive, over-specified infrastructure projects that mirror state-of-the-art facilities in the Global North - where physical infrastructure construction outpaces workforce capability, regulatory maturity, and quality readiness, risking the creation of expensive stranded assets.

In this paper, Jacob Hallengreen proposes a fundamental paradigm shift: a disciplined, stage-gate delivery architecture governed by a neutral "Integrator" operating as a boundary organization. The paper introduces the Minimum Viable Solution for Localization (MVS-L), underpinned by Real Options Analysis (ROA). By explicitly tying modular capacity expansion to verified, pooled public demand, the MVS-L framework de-risks initial capital expenditure and preserves strategic flexibility. Ultimately, reframing localization through this integrated systems-engineering lens provides an actionable blueprint to transform political ambitions into sustained, resilient access to essential therapeutics.



The Challenge: The Capability Trap and Stranded Assets

- Global efforts to localize biopharmaceutical manufacturing are frequently driven by industrial policy rather than health-system implementation.
- These programs routinely fall into a "capability trap" known as isomorphic mimicry, where the rapid construction of physical infrastructure heavily outpaces workforce capability, regulatory maturity, and quality readiness.
- Consequently, emerging markets risk creating expensive stranded assets rather than functional, life-saving manufacturing capacity.
- Traditional Engineering, Procurement, and Construction (EPC) delivery models are structurally misaligned with these complex projects because they incentivize rapid physical completion rather than the essential maturation of Quality Management Systems (QMS).
- Without guaranteed long-term anchor demand, localized facilities are highly susceptible to intense pricing pressures from established global incumbents operating at massive scale.

The Governance Solution: The Integrator Model

- To resolve the structural misalignment between physical construction, capability transfer, and regional demand, localization should be governed by a neutral "Integrator".
- Operating as a boundary organization, the Integrator orchestrates the highly complex interface between capital delivery, scientific technology transfer, and rigorous regulatory compliance.
- The Integrator acts as a vital buffer between the divergent interests of sovereign governments, commercial contractors, and global technology donors.
- By utilizing strict "Readiness Gates," the Integrator can halt the progression of capital deployment until scientific criteria and workforce competencies are empirically validated.
- To maintain neutrality and protect the technical integrity of the transfer, the Integrator function must leverage blended finance mechanisms and be completely insulated from sovereign political pressure.

MVS-L and Real Options Analysis

- The Minimum Viable Solution for Localization (MVS-L) is a disciplined health-systems design threshold that explicitly ties modular capacity expansion to verified, pooled public demand.
- This framework enforces rigorous specification control to prevent scope creep, ensuring the facility is engineered to meet immediate viable volumes and stringent Good Manufacturing Practice (GMP) parameters, and nothing more.
- To financially justify this agile approach, health economists and investors must shift from deterministic valuation models to Real Options Analysis (ROA).
- ROA explicitly values the strategic flexibility inherent in a phased project, treating the initial capital investment as a real option to expand, defer, or stage based on newly acquired information.
- Under MVS-L, initial modular deployments severely limit downside risk and sunk costs while preserving the option to rapidly scale capacity if regional demand is proven.

The 5-Stage Execution Architecture

A disciplined stage-gate framework ensures capital is only released when multidisciplinary deliverables are independently validated by the Integrator.

- Stage 1: Demand Architecture & Feasibility: Validates the health rationale, assesses local capability gaps, and secures anchor demand through executed procurement MoUs.
- Stage 2: Conceptual Design & Governance: Establishes the binding governance charter, selects modular platforms, and strips away speculative engineering scope.
- Stage 3: Basic Design & Tech Transfer Commitment: Synchronizes the engineering design with scientific process requirements and locks the Master Schedule.
- Stage 4: Execution & Quality Readiness: Validates tacit experiential knowledge, certifies workforce competence, and implements Readiness Gates.
- Stage 5: Health-System Integration: Executes Process Performance Qualification (PPQ) batches, secures regulatory alignment, and ensures accelerated patient access without compromising quality standards.

Outlook for Policy and Implementation

- Localizing pharmaceutical manufacturing presents a historic opportunity to rectify deeply entrenched inequities in global health access and fortify systems against future pandemics, geopolitical crises, and climate disruptions.
- Realizing this ambition requires a radical departure from traditional, linear infrastructure models that have consistently produced stranded assets.
- Localization must be fundamentally recognized as a highly complex, socio-technical capability transfer, rather than a mere industrial construction project.
- By governing execution via a neutral Integrator within a disciplined stage-gate framework, the global health community can bridge the extreme gap between policy intent and operational reality.
- Anchoring capital investments in quantifiable public health demand through the Minimum Viable Solution for Localization (MVS-L) and Real Options Analysis provides the necessary systemic rigor.
- Ultimately, this integrated approach ensures that future facilities avoid the capability trap, transforming political ambitions for sovereignty into reliable, life-saving capacity and tangible health equity.

