



## Production Process Integration and OPV Bulk Manufacturing Efficiency at PT Bio Farma (Persero): An ABC, CBA, and FMEA-Informed Evaluation

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**Abstract**

**Background:** Sustained global demand for oral poliovirus vaccine requires manufacturers to shorten production cycles without weakening pharmaceutical quality controls. At PT Bio Farma (Persero), the Polio Single Harvest (PSH) stage includes an approximately 60-day holding period before clarification and sterile filtration, extending baseline bulk-production lead time to 274 days and increasing storage and utility requirements.

**Objective:** This study evaluates whether integrating the PSH-to-Polio Monovalent Bulk (POL) process improves production efficiency while preserving regulatory compliance, and examines the operational benefits, risks, and requirements for industrial adoption. Its contribution lies in evaluating stage integration within a vaccine-manufacturing quality system.

**Methods:** A mixed-method, evaluative single-case study combined direct process observation, focus group discussion, and production records from 2021-2025. Quantitative assessment used Activity-Based Costing (ABC) and a preliminary Cost-Benefit Analysis (CBA), while an FMEA-informed qualitative risk review identified critical failure modes and required controls for the proposed integrated flow.

**Results:** The proposed integration reduced simulated production lead time from 274 to 213 days (22%). Quantified material and utility savings reached at least Rp345.3 million per batch, excluding labor-cost effects, while direct labor requirements decreased by 6.83%. Key risks concerned aseptic integrity, product comparability, validation, quality hold points, and regulatory change control.

**Conclusion:** Production process integration can improve OPV bulk-manufacturing efficiency if implementation is governed through process validation, comparability studies, aseptic process simulation, quality-risk management, and regulatory approval. The study extends lean-process improvement into a tightly regulated biological manufacturing context.

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## INTRODUCTION

Poliomyelitis remains a global public-health concern because infection can cause irreversible paralysis, particularly in children. Since the Global Polio Eradication Initiative began in 1988, global cases have fallen by more than 99%; however, endemic transmission and outbreak response continue to sustain demand for oral poliovirus vaccine. WHO and UNICEF projections indicate that bivalent OPV supply will remain necessary through 2027 for routine immunization and outbreak response (Initiative, 2024; Organization, 2025b; UNICEF, 2024). Consequently,

2436 | Journal of Business, Social and Technology

manufacturing performance is strategically important: vaccine availability depends not only on immunization coverage but also on the ability of producers to deliver sufficient volumes on time while maintaining validated quality controls.

At the manufacturing-system level, increasing global vaccine demand presents its own challenges for the pharmaceutical manufacturing industry, particularly in vaccine production processes that have complex characteristics, require sterile environments, and must meet Current Good Manufacturing Practices (cGMP) and WHO regulatory standards. One factor affecting low production efficiency is the presence of non-value-added activities, such as waiting time, intermediate storage, freezing, thawing, and repeated material transfers. From a lean manufacturing perspective, these activities are categorized as waste that can increase production lead time, raise operational costs, and reduce company productivity (Mukund Pharande & Ashok Nimbalkar, 2026; Shingo & Dillon, 1989; Womack & Jones, 2003). Prior studies address related inefficiencies from different angles. Sucipta and Kusumastuti (2025) identify laboratory testing and product release as major sources of pharmaceutical waiting time, while Anjalee et al. (2021) demonstrate the value of FMEA for proactive risk identification and Abdolazimi et al. (2021) and Srinivasa Rao et al. (2022) show how activity-based classification can improve resource decisions. These streams, however, are rarely integrated to evaluate a regulated vaccine-process sequence.

These constraints are evident in OPV bulk manufacturing at PT Bio Farma (Persero). Under the current sequential flow, the intermediate product in the form of Polio Single Harvest (PSH) must undergo a series of quality tests before it can be further processed into Polio Monovalent Bulk (POL). This stage requires the product to be stored in frozen conditions for approximately 60 days before entering the clarification and sterile filtration processes. This waiting time impacts increased total production lead time reaching 274 days, increased storage costs, electricity consumption, liquid nitrogen usage, water requirements for the thawing process, and increased use of labor and supporting materials. In addition to increasing the company's operational costs, this condition also reduces the company's flexibility in meeting urgent vaccine demand, particularly during polio outbreaks in various countries. Thus, the lengthy waiting time in the production process not only impacts the company's internal efficiency but also has the potential to affect the timeliness of vaccine distribution as part of the global health system (Organization, 2023; Persero, 2014, 2025).

Based on these conditions, this study treats production process integration as the operational intervention and production efficiency as the outcome, measured through lead time, material cost, direct labor requirements, and storage and utility use. Activity-Based Costing (ABC) traces the resource costs attached to activities removed or modified by integration, Cost-Benefit Analysis (CBA) evaluates measurable economic benefits against implementation requirements, and an FMEA-informed risk assessment examines quality and operational risks associated with the revised sequence. The research gap is that earlier work commonly examines lean waste reduction, economic analysis, or quality risk as separate problems, whereas evidence remains limited on their combined use to evaluate PSH-to-POL stage integration under vaccine-specific quality constraints. The study therefore contributes an integrated evaluation of parallelized production flow while retaining cGMP and WHO quality gates. Its objective is to determine the efficiency effects of the proposed integration, quantify measurable benefits, identify critical implementation risks, and specify the controls required for industrial adoption; practically, the findings provide a decision basis for regulated vaccine manufacturers considering process redesign.

## METHOD

This study employed an embedded mixed-method, evaluative single-case design at PT Bio Farma (Persero). The quantitative component compared production lead time, material cost, direct labor requirements, and storage/utility use between the existing and proposed integrated flows. The qualitative component examined operational feasibility, quality risks, and implementation requirements through direct observation and focus group discussion (FGD). The single-case design was appropriate because the proposed change was evaluated within a specific regulated manufacturing system rather than as a population-level causal experiment.

The research was conducted at PT Bio Farma (Persero) located at Jalan Pasteur No. 28 Bandung, West Java, Indonesia. This company was chosen because it is the only major Oral

Poliovirus Vaccine (OPV) producer in Indonesia and one of the world's polio vaccine suppliers that has obtained prequalification from the World Health Organization (WHO). The research was conducted on the Polio Single Harvest (PSH) and Polio Monovalent Bulk (POL) production processes, which are the main focus of the process integration development. Data collection was carried out during the research activities utilizing historical production data from 2021–2025 as well as observations of ongoing production processes so that the analyzed conditions represent the company's actual operational processes ([Persero, 2025](#)).

This research focuses on identifying the causes of low OPV production process efficiency due to long waiting times between the Polio Single Harvest (PSH) stage and Polio Monovalent Bulk (POL). The research focus is directed at several main aspects: production process time, material usage, direct labor requirements, storage utility utilization, and readiness for implementing production process integration. Additionally, the research also considers compliance with cGMP, Indonesian Good Manufacturing Practice (CPOB) requirements, and WHO regulations so that the proposed process design still meets pharmaceutical product quality standards ([Harmonisation, 2023](#); [Organization, 2023](#)).

The unit of analysis comprised OPV bulk-production activities at the Polio Single Harvest (PSH) and Polio Monovalent Bulk (POL) stages. Purposive sampling selected informants representing OPV Production, Quality Assurance, Quality Control, Regulatory Affairs, and Planning and Logistics because these functions directly govern process execution, product-quality decisions, regulatory compliance, and supply planning. Their input was used to evaluate operational feasibility and implementation risk.

The study used primary and secondary evidence. Primary data came from direct process observation and FGD. Observation mapped process sequence, waiting points, material transfers, resource use, and relevant control steps, while the FGD followed a structured guide covering expected benefits, potential failure modes, organizational readiness, and regulatory requirements for the proposed integration.

Secondary evidence comprised Batch Production Records (BPR), Standard Operating Procedures (SOP), production reports, material-use records, utility data, product-rejection data, and historical production records from 2021–2025. These records were used to verify baseline lead-time and resource-use estimates and to compare the existing and integrated process scenarios. Analytical validity was strengthened through source and method triangulation: observations, controlled production documents, and FGD judgments were compared for convergence, and discrepancies were rechecked against traceable BPR/SOP evidence before being retained in the analysis.

The researcher coordinated data collection and interpretation using a structured observation guide, an FGD guide, and a document-extraction sheet aligned with the study indicators: lead time, material cost, labor, utilities, operational risk, and implementation requirements.

Analysis proceeded in three linked stages. First, the existing and proposed process maps were compared to quantify changes in lead time and resource consumption. ABC assigned material, labor, storage, and utility use to activities eliminated or modified by integration. CBA then compared quantifiable recurring operating benefits with identifiable implementation requirements. Because validation and regulatory implementation costs were not monetized in the available records, the study reports measurable benefits and feasibility constraints rather than a final benefit-cost ratio.

Second, an FMEA-informed risk assessment identified potential failure modes introduced by the revised sequence and examined their consequences, likelihood, detectability, and required controls through expert discussion. Numerical Risk Priority Numbers were not calculated because validated severity-occurrence-detection scoring data were unavailable; risks were therefore prioritized qualitatively. Third, triangulation compared quantitative records, observation, and FGD evidence, with interpretation restricted to findings supported by convergent evidence or traceable controlled documentation ([Harmonisation, 2023](#); [Organization, 2015](#); [Taylor et al., 2021](#)).

## RESULTS AND DISCUSSION

### Results

#### *Operational Context of OPV Bulk Production*

This research was conducted at PT Bio Farma (Persero), a state-owned pharmaceutical company and the largest vaccine producer in Indonesia. The company has a strategic role in meeting national and international vaccine needs through the production of various types of vaccines, including Oral Poliovirus Vaccine (OPV). As one of the vaccine producers that has obtained prequalification from the World Health Organization (WHO), PT Bio Farma (Persero) is required to maintain product quality while simultaneously improving production process efficiency to meet the continuously increasing global market demand. Production activities are carried out based on cGMP and Indonesian Good Manufacturing Practice (CPOB) standards so that every process change must maintain vaccine product safety, quality, and effectiveness.

The production of Oral Poliovirus Vaccine (OPV) at PT Bio Farma (Persero) is carried out through several main interrelated stages, starting from media and equipment preparation, cell culture, virus culture, to final product formation. In this study, the observation focus is on the Polio Single Harvest (PSH) and Polio Monovalent Bulk (POL) production stages because these two stages contribute the most to the lengthy production time. Based on field observations and production document reviews, it is known that the PSH storage process before clarification and sterile filtration is the main cause of increased production time and increased company resource usage. This condition became the basis for developing the process integration concept expected to eliminate non-value-added activities without reducing the quality of the resulting products (Organization, 2023; Persero, 2014).

#### *Research Variable Description*

This study examines the relationship between production process integration as the independent variable and production efficiency as the dependent variable. Production process integration is realized through the combination of clarification and sterile filtration activities directly after the virus harvesting process without waiting for all quality tests at the Polio Single Harvest (PSH) stage to be completed. Through this approach, quality testing processes are still conducted but proceed in parallel with subsequent production processes, thus accelerating process flow. This approach aligns with lean manufacturing principles that seek to eliminate waste activities such as waiting time, excess storage, and material transfers that do not add value to the product (Organization, 2023; Womack & Jones, 2003).

Production efficiency in this study was evaluated using four main indicators: production lead time, material costs, direct labor requirements (direct man-hours), and storage and utility costs. These four indicators were chosen because they represent resource usage during the OPV production process. In addition, the study also considered implementation readiness through risk analysis so that the proposed process changes still meet pharmaceutical product quality standards and national and international regulations. Thus, production efficiency is measured not only based on cost reduction but also on the company's ability to maintain product quality after the integration process is implemented (Boardman et al., 2018; Horngren et al., 2012; Mrayyan et al., 2023; Schmidt, 2022).

#### *Production Lead Time Efficiency*

Baseline production records show that the sequential flow requires approximately 60 days of PSH holding while quality-test results are completed, contributing to a total production lead time of 274 days. Under the proposed integration, clarification and sterile filtration begin after virus harvesting while VCF testing continues in parallel, thereby removing temporary freezing, thawing, and associated internal transfers. Table 1 summarizes the resulting process-time change.

The integrated scenario reduces simulated total lead time to 213 days, or approximately 22% relative to the existing process, while retaining the required quality-control activities. The improvement therefore comes from changing process sequencing rather than shortening biological culture or quality-testing requirements.

**Table 1***Production Lead Time Comparison*

| Stage                 | Existing Process | Integrated Process | Reduction      |
|-----------------------|------------------|--------------------|----------------|
| Production lead time  | 274 days         | 213 days           | 60 days (22%)  |
| PSH storage           | 60 days          | 0 days             | 100%           |
| Production completion | March 26, 2026   | January 24, 2026   | 60 days faster |

*Source: Processed from PT Bio Farma (Persero) production data, 2026.*

These findings show that lead time reduction not only accelerates production completion but also increases the company's flexibility in responding to urgent vaccine demand. In the pharmaceutical industry, especially in vaccine production, the ability to produce products in a shorter time is an important factor in maintaining the sustainability of the global supply chain. The shorter the lead time a company has, the higher its ability to meet routine immunization needs and outbreak response. Therefore, production process integration not only provides benefits from an operational perspective but also provides strategic value in increasing the company's competitiveness as an internationally recognized vaccine producer ([Organization, 2025a](#); [UNICEF, 2024](#)).

Overall, the results on the first indicator show that process integration successfully eliminates non-value-added activities without reducing product quality testing stages. By maintaining all quality control procedures according to WHO and CPOB standards, the company can achieve production efficiency improvements through reduced waiting time and optimized production process flow. These findings provide a basis that the process integration strategy is worthy of consideration as an alternative for productivity improvement in the vaccine manufacturing industry. Direct labor requirements also decreased by 6.83% because packaging, freezing, storage, thawing, and repeated internal-transfer activities were removed or reduced, indicating that the efficiency effect extends beyond lead time to workforce utilization.

**Production Cost Reduction**

The research results also show potential cost savings from production processes that are no longer carried out due to process integration, namely: PSH Distribution & Packaging, Quick Freezing, Cold Storage, and Thawing. Using Activity-Based Costing (ABC) analysis, eliminating these processes means that temporary packaging materials such as 3L PE bottles, seals, heat seals, and rubber bottle caps normally used to package Polio Single Harvest (PSH) or Virus Culture Fluid (VCF) intermediates are no longer used. Furthermore, utilities such as liquid nitrogen and freezer capacity normally used for storage are also reduced. Through this ABC analysis, process integration can save up to Rp333 million per batch (2.73%) in raw materials and Rp12.3 million per batch (41.28%) in electricity utilities for freezers and liquid nitrogen.

**Table 2***Production Cost Comparison*

| Stage                                   | Existing Process       | Integrated Process     | Reduction                     |
|-----------------------------------------|------------------------|------------------------|-------------------------------|
| <i>Material Cost</i>                    | Rp 12.19 billion/batch | Rp 11.86 billion/batch | Rp 333 million/batch (2.73%)  |
| <i>Freezer Electricity Utility Cost</i> | Rp 15.5 million/batch  | Rp 11.8 million/batch  | Rp 3.7 million/batch (23.87%) |
| <i>Liquid Nitrogen Utility Cost</i>     | Rp 14.3 million/batch  | Rp 5.7 million/batch   | Rp 8.6 million/batch (60.12%) |

*Source: Processed from PT Bio Farma (Persero) production data, 2026.*

Beyond the cost components shown in Table 2, direct labor requirements decreased by 6.83%. The preliminary CBA identifies at least Rp 345.3 million per batch in recurring material and utility benefits (Rp 333.0 million in materials, Rp 3.7 million in freezer electricity, and Rp 8.6 million in liquid nitrogen), excluding labor-cost savings. A final benefit-cost ratio is not reported because validation, comparability, and regulatory implementation costs were not available for monetization. The FMEA-informed risk review identified four principal implementation concerns: aseptic integrity during the revised flow, downstream progression before critical quality

acceptance is confirmed, post-change product comparability, and incomplete change-control/regulatory documentation. Required controls include aseptic process simulation, process validation, predefined quality hold points, comparability studies, and regulatory approval before routine implementation.

## Discussion

### ***Analysis of Production Process Integration on Oral Poliovirus Vaccine (OPV) Production Efficiency***

The observed lead-time reduction indicates that the dominant inefficiency is sequence-dependent waiting rather than the biological production stages themselves. Integrating clarification and sterile filtration converts a serial workflow into a partially parallel workflow, removing storage, freezing, thawing, and repeated transfers without eliminating quality-control requirements. The key implication is therefore not merely a faster process, but the release of manufacturing capacity through workflow redesign while regulated quality gates are preserved. This extends lean manufacturing from generic waste elimination to a quality-constrained biomanufacturing context.

These findings support Lean Manufacturing's treatment of waiting and inventory as non-value-added waste (de Carvalho et al., 2025; Shingo & Dillon, 1989; Womack & Jones, 2003). Unlike Sucipta and Kusumastuti (2025), whose emphasis is on laboratory and release-stage inefficiency, the present study intervenes in physical stage sequencing and connects time savings to activity cost and quality-risk controls. Methodologically, ABC makes the source of recurring savings traceable, while the FMEA-informed review prevents efficiency from being interpreted independently of failure risk (Abdolazimi et al., 2021; Anjalee et al., 2021; Ghahremani-Nahr et al., 2025). Together, these elements provide a more integrated operational explanation than a simple before-and-after time comparison.

In addition to improving operational efficiency, process integration also shows increased effectiveness in utilizing company resources. In the previous production process, operators had to perform several additional activities such as intermediate product distribution, freezing, storage, thawing, and material transfer to the filtration process. These activities required labor, utilities, and relatively long production time. After process integration was implemented, most of these activities could be eliminated so that human resources could be focused on production activities that truly provide added value. This shows that production efficiency is not only about cost reduction but also about optimizing the use of all company resources to produce higher output with lower input (Efendi et al., 2025; Horngren et al., 2012, 2022; Khan, 2025).

### ***Analysis of Production Lead Time Reduction***

The approximately 22% reduction from 274 to 213 days indicates that much of the avoidable delay resides in inter-stage waiting rather than in cell-culture or virus-culture duration. Parallelizing eligible downstream activities therefore improves flow without claiming that required biological or quality-control steps themselves have been shortened.

The lead-time result is consistent with Sucipta and Kusumastuti (2025), who identify testing and release-related waiting as a major source of pharmaceutical inefficiency. The present study differs by redesigning the physical sequence rather than primarily digitalizing laboratory administration: clarification and sterile filtration proceed while testing continues in parallel. The novelty therefore lies in decoupling non-value-added holding from required quality evaluation, not in reducing the rigor or duration of the quality tests themselves.

From an operations management perspective, lead time reduction has much broader impacts than just accelerating the completion of one production batch. A shorter lead time will increase the company's ability to respond to changes in market demand, accelerate inventory turnover, and increase production scheduling flexibility. In the vaccine industry, response speed is a very important factor considering that vaccine demand often increases suddenly during outbreaks or disease epidemics. Thus, a 60-day lead time reduction not only improves the company's internal efficiency but also strengthens PT Bio Farma (Persero)'s capability to support national immunization programs and global vaccine needs coordinated by WHO and UNICEF (Organization, 2025a; UNICEF, 2024).

When viewed from a Supply Chain Management perspective, lead time reduction also

contributes to increased supply chain resilience. Vaccine products have special characteristics because they require cold chain storage during the distribution process. The longer a product is in the storage stage, the greater the logistics costs and the risk of disruption to product stability. Therefore, production process integration not only reduces production time within the company but also has the potential to accelerate vaccine distribution to end users. In other words, the benefits of process integration do not stop at the manufacturing level but provide impacts on the entire vaccine supply chain from production processes to public health services. These findings reinforce the importance of developing adaptive production systems as part of a strategy to increase the competitiveness of the Indonesian pharmaceutical industry at the global level.

### ***Analysis of Production Cost Reduction***

The research findings show that production process integration has a significant impact on production cost efficiency. The elimination of the PSH Distribution & Packaging, Quick Freezing, Cold Storage, and Thawing stages simplifies the process flow and eliminates activities that do not add value to the final product.

Based on the Activity-Based Costing (ABC) approach, the elimination of these processes results in cost savings in two main components: raw material costs and utility costs. In the raw material component, the elimination of 3L PE bottles, seals, heat seals, and rubber bottle caps as temporary packaging for Polio Single Harvest (PSH) or Virus Culture Fluid (VCF) intermediates results in savings of Rp333 million per batch or approximately 2.73% of total raw material costs. Although the percentage appears relatively small, the absolute value of these savings is quite large given the high material costs in the vaccine industry. When multiplied by the number of production batches in one year, the potential cost efficiency becomes even more significant.

On the utility side, process integration reduces the need for liquid nitrogen and freezer capacity previously used during the 60-day testing period in cold storage. ABC analysis shows savings of Rp12.3 million per batch or approximately 41.28% of total utility costs associated with these two activities. The high percentage of savings indicates that the frozen storage process is one of the activities with high energy consumption, so the elimination of this process provides greater efficiency impact compared to material savings. From a Pharmaceutical Quality System (PQS) perspective, however, these savings are conditional on controlled change management. ICH Q9(R1) requires quality-risk decisions to be evidence-based and commensurate with uncertainty and potential harm, while ICH Q10 places manufacturing changes within a lifecycle pharmaceutical quality system. Accordingly, industrial implementation should proceed only after aseptic process simulation, process validation, comparability assessment, predefined quality hold points, regulatory approval, and post-change monitoring confirm that efficiency gains do not shift risk to product quality ([Harmonisation, 2008; 2023; Organization, 2015, 2023](#)).

### **CONCLUSION**

This study demonstrates that integrating the PSH-to-POL flow can improve OPV bulk-manufacturing efficiency at PT Bio Farma (Persero) by eliminating non-value-added holding and handling while retaining required quality-control steps. The proposed flow shortens simulated lead time from 274 to 213 days (about 22%), reduces material and utility expenditure, and lowers direct labor requirements by 6.83%. The principal contribution is a combined operational-economic-risk evaluation showing that lean workflow redesign in vaccine manufacturing is viable only when efficiency gains are coupled with pharmaceutical quality and regulatory controls.

The findings are limited to a single OPV manufacturing case and a proposed integration scenario; in addition, the available records did not permit monetization of all implementation costs or calculation of validated FMEA Risk Priority Numbers. Industrial adoption therefore requires production-scale validation, comparability studies, aseptic process simulation, formal change control, and regulatory approval. Future research should test the design at pilot and industrial scale, quantify long-term economic and quality outcomes, and examine digital manufacturing and Industry 4.0 tools for real-time process monitoring, data integration, and risk-based control across other biological products.

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### AUTHOR CONTRIBUTION STATEMENT

Nanda Yulanda contributed to the conceptualization, research design, data collection, process analysis, application of Activity-Based Costing (ABC), Cost-Benefit Analysis (CBA), and Failure Mode and Effect Analysis (FMEA)-informed evaluation, manuscript preparation, and revision. Dermawan Wibisono contributed to methodology development, supervision, validation of analysis, interpretation of findings, and critical revision of the manuscript. Both authors reviewed and approved the final version of the manuscript for submission.

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