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Proposed Process Changes in Product Development Process at Pharmaceutical Company

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ABSTRACT

The cycle of developing new pharmaceutical products, starting from formulation to registration until the product is launched into the market, follows a linear and sequential process but struggles to adapt in delivering innovative, high-quality products while competing in time-to-market arrival and reducing intensive development costs. This study investigates operational inefficiencies in the proposed process changes in product development process at Pharmaceutical Company at Imedco Djaja, a pharmaceutical company facing challenges such as project delays, rising costs, and prolonged time-to-market. The research aimed to identify the root causes of these issues and design a process-related solution to enhance efficiency. Using a qualitative approach, data was collected through semi-structured interviews with key internal stakeholders and analyzed via Directed Content Analysis, Thematic Analysis, and Failure Mode and Effects Analysis (FMEA). The findings pinpointed critical bottlenecks, including cross-functional communication breakdowns, reactive planning, and role ambiguity between new and existing product development teams. In response, the study proposes the integration of select Agile-Scrum elements—such as Sprint Planning, Daily Stand-ups, and defined Product Backlogs—into the current development workflow. The research implies that a tailored, hybrid Agile implementation can significantly improve coordination, accountability, and adaptability, thereby accelerate product launches and reducing development costs without disrupting the stringent regulatory framework of the pharmaceutical industry.

KEYWORDS *Agile integration, backlog management, cross-functional coordination, pharmaceutical R&D, reduce cost, role clarity, sprint planning, time-to-market.*

INTRODUCTION

Recent technological advancement and evolving healthcare demands create new opportunities in numerous healthcare sectors, notably in the pharmaceutical industry (Friedrich & Müller, 2023). As one of the most vital industries in the world—providing life-saving medicines and treatments to millions of people—pharma companies are required to grow and adapt, delivering innovative, high-quality medications while competing in time-to-market arrival and reducing intensive development costs (*Pharma Companies Worldwide by R&D Pipeline Size 2024 | Statista*, 2024; Danzon et al., 2021). The Research and Development (R&D) department serves as the foundation of every pharmaceutical company, with investment typically allocated at least 20% of sales revenue (*Topic: Global Pharmaceutical Industry*, 2024; DiMasi & Grabowski, 2023) for generating science-driven competitive advantages, addressing unmet market needs, and achieving long-term sustainability while navigating stringent regulatory challenges (Thomas, 2025; Wouters & Stevens, 2022). Recent trends show that global R&D spending in the pharmaceutical sector has exceeded $182 billion in 2020, making it one of the highest sectors worldwide, while the Return on Investment (ROI) remains poor compared to others, averaging only 1.8% (Oosterwal, 2023; Mestre-Ferrandiz et al., 2020).

Traditionally and generally, R&D has been viewed as a linear and sequential process, moving from research to engineering and then manufacturing, but currently R&D must also consider the competitiveness of products developed in the market in which the business operates (Oosterwal, 2023; Chahal, 2023). The struggle to overcome ever-changing and dynamic challenges in the drug development process—especially for generic products—is necessary to keep pace in today's competitive environment (Arman & Kahkeshan, 2024; Misbauddin et al., 2024). These challenges were also experienced by a local pharmaceutical company, PT Imedco Djaja, which has positioned its Research and Development (R&D) department as the spearhead of its business strategy and one of its fundamentals for sustaining long-term competitiveness in the pharmaceutical landscape. The urgency to enhance drug development processes drives the company to seek a strategic approach to improve business performance and operational efficiency in its R&D departments (Jaya, 2024; Sharma et al., 2021). The integration of Agile Methodology into the new product development process is recognized as a promising area of exploration, fostering evolution through iterative processes, cross-functional team collaboration, and adaptability to change, all relevant for the dynamic nature of pharmaceutical innovation (Chahal, 2023).

This study will provide in-depth insight into operational challenges and address bottlenecks in the pharmaceutical R&D department, particularly at PT Imedco Djaja (Friedrich & Müller, 2023). By identifying pain points and key bottlenecks, the research investigates the most critical priorities that can significantly improve the generic product development process (DiMasi & Grabowski, 2023; Costa et al., 2021). Through this study, the research also explores how Agile-based approaches can be adopted in designing a revised product development process to accelerate market entry timelines and reduce

development costs in the era of healthcare innovation (Börjesson & Elmquist, 2018; Rahi et al., 2023). The objectives are to identify gaps in product development processes that lead to delays and high development costs, and to investigate key processes to be designed to address business issues at Imedco Djaja, a pharmaceutical company (Brahmachari & Xu, 2020; Mishra & Singh, 2022).

Following the research questions, the objectives of this thesis are: To investigate operational inefficiencies in the product development process and identify the most critical priorities for improvement that significantly reduce development costs; and to design a new product development process that reduces generic product development cycle time. The research focuses on analyzing and exploring potential improvements in the current product development process at Imedco Djaja, a pharmaceutical company developing generic drug products. The study is limited to the research and development areas in addressing business issues such as delays in the new product development stage and rising costs, specifically examining how planning is conducted and how cross-functional coordination is achieved. The primary focus areas include: Evaluating and identifying pain points and operational challenges in the current traditional approach to R&D that cause delays and high costs during the development stage; and the potential and proposed implementation plan for Agile-based Scrum adoption in the product development cycle to improve inefficiencies and reduce delays.

METHOD

This study employed a qualitative research approach with an exploratory and diagnostic design. The primary objective was to gain an in-depth understanding of the operational challenges and pain points within the product development process at the pharmaceutical company Imedco Djaja. The research was guided by the principles of Design Thinking, specifically utilizing the Empathize and Define phases to ensure a human-centered focus on problem identification and framing.

The data population consisted of all internal stakeholders involved in the product development process at Imedco Djaja. A purposive sampling technique was used to select the data sample, which comprised five key informants from cross-functional departments, including Business Development, Quality Assurance, and Research and Development, who possessed direct experience and responsibility in the process under investigation. The primary research instrument was semi-structured interviews, which allowed for the collection of rich, detailed qualitative data on participants' experiences and perceptions. This primary data was triangulated with secondary data sources, including internal company documents such as R&D Management Review Reports and Change Control documents, as well as external BPOM regulations from 2023-2025.

Data analysis was conducted using a combination of three techniques to ensure comprehensive and validated findings. First, Directed Content Analysis (DCA) was applied to interview transcripts, using pre-defined sub-variables to systematically code and quantify recurring issues. Second, Thematic Analysis (TA) was employed to identify underlying patterns and emergent themes, providing a deeper, more nuanced

interpretation of the organizational dynamics. Finally, Failure Mode and Effects Analysis (FMEA) was utilized to prioritize the identified failure modes based on their severity, occurrence, and detection, thereby pinpointing the most critical areas requiring intervention and guiding the development of targeted business solutions.

RESULTS AND DISCUSSION

Analysis

From the primary and secondary data collected, the findings from the research and the analysis conducted are stated as the sub subchapters below.

Directed Content Analysis Result

In this sub-chapter, a comprehensive analysis of operational challenges and pain points in the product development process at Imedco Djaja, using directed content analysis (DCA) with predefined sub-variables from semi-structure interviews transcripts with 5 key stakeholders. The analysis also incorporates design thinking principles, particularly Empathize and Define phases to be more grounded with human-centered perspective. The manual coding of the interview transcripts was presented in the table below, followed by their frequencies across five interviews.

Table 1. Directed Coding Analysis Results

Sub-Variables	Keywords Emerged	Total Frequency
Team Role & Communication Style	Interdepartmental miscommunication, lack of follow ups, Overlapping responsibilities	18
Planning & Structure	Shifting priority and misalignment, Timeline uncertainty	17
Client Involvement	Late stakeholder feedbacks and involvement	14
Documentation	Lack of real-time documentation, last-minutes compilations	13
Speed	Supply delays and discontinuation causing delays, Low adaptability to changes in source, regulation, or material	16
Delivery	Lack of systematic monitoring	10

Figure 1. Final Keyword Frequency in Directed Content Analysis

In addressing the research questions, the emerging keywords further aligned into to two key search areas that would be operational challenges including the pain points and process-related changes with detailed findings as presented below.

Table 2. Alignment Keywords into Two Research Questions Areas

Operational Challenges and Pain Points		Process-Related Changes	
Codes	**Frequency**	**Codes**	**Frequency**
Communication Issues	18	**Improved Communication**	14
Resource Allocation	12	**Enhanced Planning**	11
Regulatory Compliance	10	**Stakeholder Involvement**	13
Supply Chain Management	15	**Documentation Standards**	10
Documentation	9	**Risk Management**	8

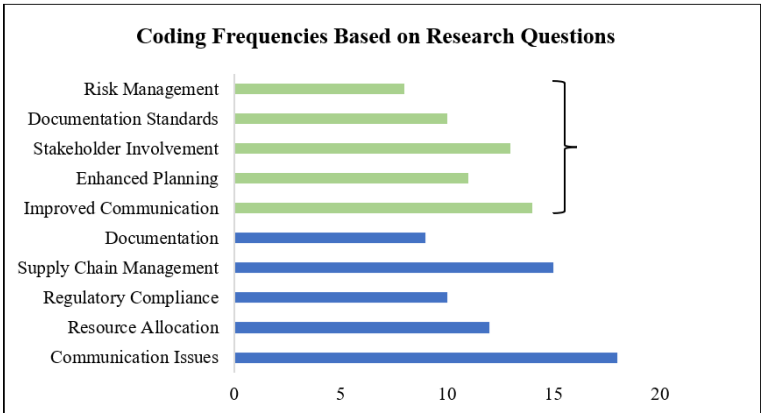

Figure 2. The Coding Frequency Graphic

The findings from Empathize phase in the interview, the author captured collective frustrations and shared barriers in current product development process as the stakeholders frequently mentioned the disappointments experiences when facing late product launching and the loss of opportunity to enter the market earlier. In other hands, the recurrent barriers in information flow such as interdepartmental follow-up were described as “wasting time”, “demotivating” and “exhausting”.

In Define phase, the key problems and insights were framed into pre-specified sub-variables in finding the operational challenges:

1. Team Role and Communication Style (Frequency: 18)

In this sub-variable, the main issues found were the interdepartmental miscommunication, lack of follow-ups in current project status and overlapping responsibilities especially between the existing products and new product development further dilute the focus. From the interviews, the findings where the communication relies heavily on personal chats or assumptions, without structured and transparent communication system that often leading to misalignment in prioritization.

“Kadang komunikasinya hanya lewat chat… status terakhirnya gak semua tahu.”

“Ternyata ada perubahan prioritas, ternyata antara Head dan supervisornya tidak sepaham ternyata”

“..Pengembangan produk baru jadi sedikit molor gitu karena kita harus mengerjakan yang existing juga gitu”

2. Planning & Structure (Frequency: 17)

In this sub-variable, the main issues found were the changing priority in the middle of project execution due to the raw material supply constraints, equipment limitations,

regulatory changes, or sudden urgent reprioritization and the other issue was unclear timeline making the formulators lack of visibility of project roadmaps with no structured backlog planning.

"Di tengah-tengah trial bisa aja prioritasnya berubah… jadi semua tim harus putar balik mendadak."

"Begitu regulasi berubah kita bisa mulai dari nol"

3. Speed (Frequency: 16)

In this sub-variable, the main issues found were the supply disruption in terms of delayed arrival on site, discontinuation, and changes due to unfulfilled minimum order quantity (MOQ), that overall slowdown the product development process and create conflicts where departments blame each other.

"Barangnya nyampe bisa lebih dari sebulan… sering ganti source jadi mundur lagi."

"Kita mau pilot tunggu 3 bulan lagi bahan baku datang itu tuh menyebalkan gitu ya."

"Baru kemudian kita tahu ternyata ada discontinue terhadap barang tersebut atau misalnya lead time jadi lebih panjang karena ada isu perubahan"

4. Client Involvement (Frequency: 14)

In this sub-variable, the main issues found were the late stakeholders' feedback and involvement after the critical decisions are already made, thus this late engagement reates reworks and delays. In example, the regulatory input regarding the additional parameter requirements make a setback in product development process, as well as the procurement involvement in selecting final raw material sources only included near the pilot scale thus any changes due to the supply could create delays and reworks.

"Kalau regulatori dilibatkan dari awal, bisa mengurangi trial ulang dan rework."

"…udah kita dapat sampel dari yang ini-ini aja, dan yang akan di-trial yang ini aja, itunya tentu bisa mengurangi pengerjaan berulang"

5. Documentation (Frequency: 13)

In this sub-variable, the main issues found were the lack of real-time documentation making the clarity of the project status is unclear, and last-minute data compilation close to the deadline, while the data were fragmented in personal notes and takes longer time for submission.

"Sering dicari dokumen saat urgent… kadang dokumennya entah di mana."

"Biasanya kita melengkapi dokumen itu mendekati saat dokumen ini mau diminta untuk registrasi. Untuk proses pembuatannya dokumennya seringnya terburu-buru, jadinya kadang telat juga"

6. Delivery (Frequency: 10)

In this sub-variable, the main issues found were lack of systematic project status monitoring and retrospectives lessons learned from previous projects letting the teams adapt individually with potential repeated failures and missed improvement opportunities.

"Harusnya ada sistem supaya semua pelajaran itu terdokumentasi dan dipakai lagi."

"…akhirnya harus dilakukan investigasi bahkan trial simulasi berkali-kali dengan proses atau mesin sama…. itu pernah terjadi dan ini cukup makan waktu."

The findings on user-centric needs for process-related changes derived from the DCA coding for several recurring requirements emerged from cross-functional stakeholders. These needs became constructive ideas in redesigning the new product development process, which rooted in five codes:

1. Improved communication (Frequency: 14)

One of the user requirements was the improvement in communication process to ensure priority alignment, timeline agreements and collaboration across departments. The communication must answer the proposed suggestion from users such as "intense communication" and "real-time updates" that emphasize timely sharing especially in the dynamic environment, keeping all involved parties stand on the same page, therefore the process changes could quickly be managed and supported. This was a strong signal for a shared communication platform and integrated updates to track real-time progress.

2. Enhanced planning (Frequency: 11)

In managing a project, planning is a foundation and should be well structured to achieve effective process and avoid ambiguity in preventing any delays. The planning in the form of timelines or roadmaps should be mapped to enable team to allocate the resources in fulfilling the deadline. The user requirements in managing the issues were coded as "fixed timeline from the start" and "pull timelines back to anticipate changes", not just relied on informal prioritization clearly underlined the need for early, transparent and adjustable planning mechanisms. To enhance the project planning, adopting a new approach that emphasize practical, manageable but smaller project break down with clear and defined deadlines. This could help in manage a large project to be more flexible and help mitigating risks along the process such as potential bottleneck in material sourcing, regulatory changes, and facility constraints in upscaling.

3. Early stakeholder involvement (Frequency: 13)

Stakeholders' engagements are essential especially in helping redirect the project when changes arrived by accelerates critical decision making and reduce unnecessary trials or reworks. Stakeholders' engagements were desired by the involved departments and noted with "early involvement" and "early and regular feedback" needs that believed could make change implementations more seamless and effective, particularly in vendor selection, dossier preparation, and facility investments, thus reduce duplicated trials and validation, overtimes, or compromised delivery schedules.

4. Documentation Standards (Frequency: 10)

A comprehensive documentation ensures consistency and transparency and essential especially in highly regulated environments. Participants noted that current documentation system especially the change management system already implemented to ensure the involved parties were informed but in pilot scale stage. The current system, though, still lack of structures with centralization, no accessibility and real-time records. The needs of new standardized documentation emphasize elimination of outdated files, last-minutes documentation or scattered notes.

5. Risk Management (Frequency: 8)

Proactive risk management is critical for navigating uncertainties as the participants mentioned the need of "annual evaluation for mitigate immediate changes" and "improved system in absorbing external risks" in building resilient frameworks risks" to address threats like changing regulations and supply chain volatility. The need of proactive system that anticipate risks, especially in delayed lead times and other delivery risks (i.e., MOQ incompatibility, shortages).

Thematic Analysis Result

In complementing the structured, code-base Directed Content Analysis (DCA), Thematic Analysis (TA) was conducted to uncover the deeper patterns, underlying assumptions, latent meaning, and organizational dynamics by looking only what was said, but how and why stakeholders shaped their experiences from the interview scripts. TA enabled bottom-up understanding of the pain points, operational inefficiencies and user expectation intersect across different departments, layers, and managerial levels. From the analysis of 5 semi-structured interviews, the two thematic clusters produced, operational challenges and user-centric needs for process changes voiced by internal key stakeholders.

1. Hierarchical rigidity

The low adaptability against changes, the need for approval from higher management in meeting, late responsiveness against operational disruptions showing that the current product development process more likely operating in a system with rigid approvals, top-down structure where the decision-making is delayed waiting for the management involvement and monthly meeting conclusions. Respondents frequently mentioned that the late-stage reprioritization or shifting priority often prolong the development stage due to forced rework, retests and retrial. This was strengthened by the codes from DCA which revealed the miscommunication, lack of follow-ups, unclear timeline, allowing the teams operate in uncertainty waiting for top-down instructions, while the R&D teams possess the technical capability, their performance were constrained by hierarchical rigidity. Critically, this suggests a cultural reliance on centralized control which could preserve inefficiencies in a dynamic regulatory and market environment.

2. Role ambiguity and overlapping responsibilities

The second major theme observed from the qualitative data was the ambiguity in job roles and overlapping responsibilities, especially in handling new product development (NPD) while pushed to work on ongoing reformulations for existing products. This diluted the teams focus, stretched team capacity, create emotional burden and confusion in balancing the focus and their main role in product development.

3. Planning is reactive, not preventive

The third major theme insight was the planning structure in product development process remains reactive, not preventive which means instead of create an initial planning with known constraints such as long lead times, MOQ limitation and the requirement of additional tests, teams operate in a just-in-case mode and waiting for trigger to act leading

to delayed action, slow responsiveness, prevalent urgent reprioritization and excess overtime to force the deadline fulfillment. This lack of foresight is a hint of risk-based integration failure into the planning structure and shows the vulnerability when exposed to external disruptions (i.e., regulatory changes and raw materials disruption)

4. Disconnect between perceived alignment and operational execution

Another critical theme to be highlighted was the gap between what was discussed and agreed upon the managerial level and what was executed, caused by the absence of structured feedback mechanism, as well as overwhelmed Business Development team, as mentioned in the interview, further create miscommunication, misalignment, trial repetition and delayed deliverables. In addition, the poor coordination was worsened when there was occasional raw material change or delayed arrival, initiated from the procurement but remain uncovered until near final development stage. This slow flow of information significantly impacts the development stage from near final to back to zero stage.

5. Fragmented ownership and accountability culture

The last discovered theme was the lack of ownership of projects and timelines since only few persons really have the end-to-end sense of belonging, delays often passed across the departments and status visibility and cross-functional accountability was lacking, create a confusion to get immediate and real-time project status, potentially lead to development of passive and siloed culture.

In conclusion, these themes reveal systemic inefficiencies in workflow ownership and cross-functional alignment, responsiveness to change, real-time communication and traceability, clear scoping and proactive risk mitigation. These findings demand a transformative redesign of the current process which integrates decentralized decision-making, clear role definitions, robust feedback loops with real-time follow-up system to align the operational execution and strategic goals.

Secondary Data

To ensure the validity of the findings and data analysis on product development process pain points and operational challenges at Imedco Djaja, triangulation was applied by integrating interview data with secondary sources. This approach will provide as a supporting data and provides a more comprehensive view of the issues. The collected secondary data included internal documents of Imedco Djaja which will be R&D Management Review Reports (Q1 – Q4 2024) and Changes Control Documents related to product development. The other secondary data was the BPOM regulations published from 2023 – 2025.

From the R&D Management Review Reports (Q1 – Q4 2024), found that in 2024 the total existing product stability batches compared to the new product development batches was 65 : 35, indicating the focus shifting on existing products. Along with this, the report also noted 25% decline in final formula finding by the end of 2024, directly support that the argument that existing products dilute the focus and reduce new product

development output. This imbalance contributes to role ambiguity, as the team overextended across the competing priorities.

On the other documents, particularly in minutes of monthly development meeting in 2025 highlighted the change of priority products from some ethical to supplements, alongside material changes due to minimum of quantity constraints appeared especially in semisolid products, requiring multiple trials to find the optimum composition, thus further exacerbate delays, reinforcing the theme of reactive planning rather than preventive.

The other findings were the change control documents provided critical evidences of external disruptions:

a. In July 2024, one of the biggest capsule shell suppliers announced to stop their operational in Indonesia, forcing Imedco Djaja to source new suppliers both for existing products and new products.
b. Import restriction of some additives such as sweetener that is critical in formulating syrups directly impact the usage of these excipients required reformulation to identify alternative excipients, further straining the resources and timelines.

Recent Indonesian National Agency of Drug and Food Control (*Badan Pengawas Obat dan Makanan* or BPOM) regulations socialized new requirements that also impact the product development process:

1. Suplemen II Farmakope Indonesia VI (2023) and Suplemen III Farmakope Indonesia VI (2024) mandated enhanced testing protocols
2. BPOM Regulation No. 29/2023 on Safety and Quality Requirements for Natural Ingredients and BPOM Regulation No. 24/2023 on Safety and Quality Requirements for Health Supplement required additional tests

These updated regulations became challenges in product development by requiring extra testing and sometimes limiting the usage of additive compound in the products, aligning with the interview theme of regulatory adaptation struggles. This external pressure, combined with internal reactive planning, significantly prolong and stretch the timelines alongside with cost overruns.

A further quality check was performed to ensure the comprehensiveness and consistency of the collected data. The interview results were cross-reference checked with the secondary data to identify any discrepancy and ensure the validity and reliability of the primary data. From this triangulation confirmation, the validation of interview result was confirmed as the heavy focus on existing products contribute to new product development outputs, the priority shifting, supply disruption, and new updated regulations further exacerbate the delays. These insights highlight the need for process-related improvements to achieve operational excellence and reduce costs at Imedco Djaja.

Business Solutions

Based on the qualitative analysis from the collected data and the prioritization using FMEA method, this research finds a strong signal of applying Scrum Agile-based framework as business solution in addressing the critical operational challenges and

redesigning new product development process at Imedco Djaja. Scrum is selected not as a generic framework but rather as a contextually relevant system that perceived to directly resolve the critical bottlenecks that required immediate resolution such as communication issues, role ambiguity, and reactive yet low adaptive planning structure.

Scrum as the Foundation for Change

Scrum is an Agile-based approach that promotes iterative, time-boxed planning, and role clarity that integrated into an adaptive and flexible approach. It emphasizes collaboration, transparency and adaptability into its framework's pillars, which are the features that needed by the user and align with the failure modes identified recommended action in table 3.

Each failure mode corresponds with a specific Scrum feature as the solutions**:**

Table 3. the failure modes identified

Failure Mode	Potential causes	Scrum-based Solutions
Disconnect between management and operations	Poor feedback mechanisms	Introduce sprint reviews and daily stand-ups, real-time tracking and centralized status
Reactive planning and late urgency	Lack of forward-looking planning structure	Adopt sprint planning
Role ambiguity between NPD and existing products	Unclear roles, overlapping duties	Separate NPD and existing reformulation teams, define job description and boundaries

In addressing the communication disconnection between management and operations in product development process, the company should:

1) Implement a cross-functional daily synchronization routine by proposing daily stand-up meeting 15 minutes interdepartmental per project to enhance transparency and accountability of the related stakeholders, reduce back-and-forth follow-ups, enable rapid adaptation to change while resolving the pain-points of miscommunication, delayed coordination and conflicting project information.
2) Introducing regular sprint review and retrospective after each sprint is delivered to receive feedback mechanism and create a continuous improvement environment.
3) Project card prioritization board (whiteboard) with clear person in charge, targeted timeline, status, and issues that need to be reviewed monthly with upper management in case of re-prioritization when needed. The prioritization categories could be tiered as:

   Tier 1 : High priority/patent-expiry projects/high business value

   Tier 2 : Medium priority projects

   Tier 3 : Low priority or backup projects

   This business solution will help R&D team to allocate time and resources effectively into the right priority and provide clear visibility of project status.
4) Establish real-time tracking and centralized project status in sharing documents that could be accessed by related stakeholders to address the pain points of missed deadlines and lack of project monitoring.

Sprint as Core Execution of Scrum Implementation

To disrupt the reactive planning cycle in product development process, the company must try to breakdown the large project into time-boxed sprint and sprint planning under the Scrum framework that involves in chopping the task lists into 2-4 weeks increment with realistic goals and assigned ownership. As mentioned before, Sprint is the core execution of Scrum applying iterative and looping cycles, where the cross-functional teams commit to deliver a set of defined outcomes with fixed start and end dates (Rubin).

Each sprint must be planned with backlog prioritization and calculated using buffer time consideration and prepare contingency plans for worst case, to make all the risk visible and ready to mitigate. Contingency plans must be prepared by considering and integrating trend data and historical spare-time and constraints, especially related to vendor response times, lagging time of bioequivalence study, or additional submission data to regulatory. Each backlog item should involve related stakeholder to grow cross departmental ownership, be ordered, re-evaluated regularly to keep the planning structure being adaptive in managing dynamic pharmaceutical environment and become agile. Using Sprint also helps teams during planning to keep the plan more realistic and address the risks earlier, also allowing the visibility in project checkpoints with fast feedback to exploit time-sensitive emergent opportunities ahead (Rubin), thus can be very useful in addressing planning structure in product development process at Imedco Djaja.

To address the next failure mode which is role ambiguity between new product development and existing products, the author suggests to proposed new department called “Technical Support” to handle existing product to realign R&D focus in new product development. In handling new product, the product owner with clear job description and responsibility per sprint planning. The sprint backlog visibility should be provided to make all task and work-in-progress transparent to all stakeholders. This approach will increase the team focus and engagement to deliver the project in committed timeline. This also ensures the support for existing products continues without compromising innovation pipelines.

Using these Scrum-based solution will also improve indirectly into two other failure modes, hierarchy-dependent delays and lack of project ownership with mechanisms:

a. Assigning and defining the product owner in each product development process project will inherently reduce the reliance on top-down decision making and empower the sense of belonging and accountability from assigned person-in-charged.
b. Daily stand-up meetings and frequent sprint review also help fostering the environment with growing ownership to the projects.

Key Solution Elements

Based on the business solutions above, the key solution elements in adopting Scrum framework are:

1) Implement daily stand-up meeting involving cross-functional stakeholders and visual project tracking with real-time prioritization. Use these three questions: What did I do yesterday? What do I need to achieve today? What's blocking me?
2) Introduce sprint planning and time-boxed execution +(2-4 weeks) with achievable target
3) Assigning product owner to drive prioritization
4) Sprint reviews and retrospectives after each sprint to encourage iterative improvement

The key solution elements alignment with research goals by improving time-to-market through redesigned, structured, and iterative development framework and reducing the rework, overtime and other operational inefficiencies by stakeholder involvements and stronger team collaborations.

Implementation Plan & Justification

To address directly the top three prioritized issues, namely cross-functional communication breakdown, reactive planning, role ambiguity in resource assignment, and indirectly two less priority issues, namely hierarchy-dependent delays and lack of project ownership from the FMEA, the implementation plan adopts an Agile-based Scrum framework. The Scrum framework is chosen by its iterative development style that emphasize collaboration, adaptability and transparency, which is ideal for evolving requirement in pharmaceutical product development at Imedco Djaja.

The strategy is integration of selection the most relevant Scrum elements aligning with company's business culture and the complex nature of pharmaceutical regulatory requirements into the current product development process at Imedco Djaja, rather than full transformation. This implementation strategy is opted to ensure minimal disruption and seamless transition while introducing practical tools for clarity and accountability such as Scrum ceremonies such as Sprint, Sprint planning, Daily Scrum, Sprint review and Sprint Retrospective in project execution. In the environment with strict compliance, multiple stakeholder gates like pharmaceutical product development, a full Scrum transition may introduce too much procedural shifts and create resistance. Moreover, based on the interview result, the current product development process already works in an iterative cycle from formulation, stability study to registration but experienced poor synchronization, overlapping roles, and reactive planning. A tailored Scrum integration will enhance and optimize the current process without forcing too much change.

The intervention on the top three process inefficiencies, reactive timeline planning, role ambiguity and overlapping responsibilities and communication misalignment perceived will addressing the business issues and research question in improving time-to-market and reducing high development cost.

The implementation timeline spans six months and is structured around incremental change to ensure stakeholder alignment and sustainable adoption over time. The plan is structured into Planning, Training, Pilot Implementation and Scaling and Continuous Improvement to ensure successful adoption and alignment.

Planning

The goal of this phase is to define the desired state from the adoption of tailored Scrum elements. The measurable target is reducing development time by 20% and enhance cross-functional coordination between R&D, Business Development and Regulatory. This phase includes defining Scrum roles: Product Owner, Scrum Master and Development Team in daily operation of product development process. The outcome of this phase is an approved Scrum implementation plan on Table IV.4 with defined teams and processes.

Training

The goal of this phase is to equip teams with Scrum knowledge by deliver a comprehensive training and workshop, especially to familiarize the involved functional team (R&D, Business Development, Procurement, Quality Assurance, Regulatory) with Sprint, Sprint Planning, Sprint Retrospective, Daily Scrum and Scrum artefacts (Sprint backlog, Product backlog, Incremental). The goal of this phase is the fully trained team that ready to implement Scrum.

Pilot Implementation

After the team fully trained and ready to implement, the next phase is to run a test on a selected pilot project using Scrum with clear Sprint planning across committed team to deliver specified value in product development milestone within time-boxed frame. Each Sprint begins with a Sprint planning that stated sprint goals and to-do tasks, Daily stand-up to communicate any obstacles, and should end with Sprint Review and Retrospective. Sprint Review as a channel to gather feedbacks and Retrospective to provide improvement room. At this phase, the Scrum-based framework still on refining phase based on feedbacks, the progress is monitored and regulatory compliance is embedded. The outcome of this phase is the successful pilot completion.

CONCLUSION

This research concludes that the main operational inefficiencies in Imedco Djaja's product development process stem from cross-functional miscommunication, reactive planning, and unclear role definitions, which lead to delayed projects, increased costs, and extended time-to-market for generic pharmaceutical products. Qualitative methods such as Design Thinking, FMEA, and thematic analysis revealed these issues caused cycles of rework and hindered adaptation to industry disruptions. The adoption of tailored Agile-Scrum practices—including sprint planning, daily stand-ups, and structured backlogs—demonstrated a promising framework to boost transparency, accountability, and iterative improvements, thereby accelerating development and lowering expenses while maintaining compliance. For future research, a suggested direction is a quantitative longitudinal assessment of Scrum’s impact on cycle time, cost savings, and product launch rates, alongside comparative studies of Agile integration in other regulated sectors and further exploration of digital communication tools in hybrid Agile-waterfall systems to increase scalability and effectiveness.

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