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Mini Review

Agile Business Management in the Pharmaceutical Industry

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Abstract

This mini-review examines the pharmaceutical industry's shift from rigid, linear operating models toward agile business management. Drivers include personalised medicine, global health crises (e.g., pandemics), and increasing supply-chain complexity. We summarise how agile principles are applied across the value chain, particularly in supply chain, manufacturing, and project management and how enabling technologies (e.g., IoT) support these applications. We also highlight barriers specific to highly regulated environments, including GMP-driven documentation and traceability, cultural inertia, and capability gaps. Finally, we discuss pragmatic adoption strategies, emphasising hybrid models (e.g., Agile–Stage-Gate) and selective implementation of agile practices. Pure agile adoption is often constrained in regulated settings; however, hybridisation and targeted practices can improve responsiveness, resilience, and long-term performance.

Keywords: Agile business management; Supply chain agility; Regulatory compliance; Hybrid governance models; Personalised medicine

1. Introduction

The pharmaceutical industry has traditionally relied on predictable, sequential processes with heavy upfront planning and documentation [1]. This approach is increasingly strained by dynamic demand, shortened innovation cycles, and complex global supply chains. Personalised therapies (e.g., CAR-T) require patient-specific manufacturing, challenging conventional scale-based paradigms [2,7]. The COVID-19 pandemic further underscored the need for rapid adaptation and exposed supply-chain fragility [2].

Under these conditions, waterfall-style planning fixed requirements, late feedback, and costly change becomes a risk rather than a safeguard [5]. Agile business management has therefore gained attention as a framework for faster learning cycles, improved cross-functional alignment, and higher responsiveness under uncertainty [7,19]. This review summarises agile principles, value-chain applications, barriers to adoption in regulated environments, and implementation strategies.

2. Core Agile Principles

Agile management emerged from the Agile Manifesto (2001) [8]. Its core values prioritise (i) people and interactions, (ii) working outputs over exhaustive documentation, (iii) customer collaboration, and (iv) responding to change [8,9].

Operationally, agile relies on iterative delivery (e.g., time-boxed "sprints"), frequent feedback, and cross-functional teams [6,11]. In physical product contexts, iteration outputs are often captured as a protocept, a tangible artifact that can be reviewed and validated (e.g., a design model or prototype) [10,20]. Compared with waterfall methods, agile enables earlier detection of risks and faster correction through repeated planning–execution–review loops [5,11].

3. Agile Applications Across the Pharmaceutical Value Chain

3.1. Supply Chain and Logistics

Pharmaceutical supply chains are highly sensitive to variability and disruption [13]. Agile–lean approaches increasingly use IoT and data analytics to support real-time visibility and adaptive decision-making [14]. Typical applications include smart warehousing, dynamic routing, and continuous cold-chain monitoring for temperature-sensitive products [10,13,14]. These capabilities support market sensitivity, flexibility, networked collaboration, and tighter process integration [13].

3.2. Manufacturing and Operations

Centralised, large-batch manufacturing is efficient for standardised products but poorly suited to personalised or small-batch modalities [2]. Agile manufacturing is increasingly enabled by modular facilities (PODs) and, for autologous therapies, localised/point-of-care manufacturing [2,7,16]. These models aim to reduce lead times, simplify logistics, and scale capacity more dynamically than traditional facilities.

3.3. R&D and Project Management

Evidence from other regulated, safety-critical industries (e.g., automotive/aerospace) indicates that agile project management can improve delivery performance when adapted appropriately [1,10,30]. Reported effective practices include dedicated co-located teams, daily stand-ups, and structured customer feedback cycles [10]. Such practices can increase transparency, shorten feedback loops, and improve stakeholder satisfaction in complex projects [10].

4. Barriers to Agile Adoption in a Regulated Sector

4.1. Regulatory and Compliance Constraints

A central tension exists between agile values and GMP expectations for controlled documentation, validation, and traceability [1,2,8]. Iterative change can complicate inspection readiness and audit trails [1]. In practice, recommendations such as extensive upfront planning may reduce agility and resemble a return to waterfall governance [1]. These tensions are amplified for mobile/modular manufacturing, where regulatory frameworks may not clearly differentiate low-risk relocation from high-risk facility changes [2].

4.2. Organisational and Cultural Resistance

Legacy hierarchies, siloed functions, and risk-averse cultures can impede agile transformation [1]. Resistance may arise from discomfort with transparency, uncertainty, or perceived loss of managerial control [1]. Without sustained executive sponsorship and resource allocation, agile initiatives tend to stall or fragment [10].

4.3. Capability and Adaptation Gaps

Agile requires role clarity and methodological competence. Misapplication (e.g., conflating the product owner and Scrum Master roles) undermines effectiveness [1]. Additionally, translating software-centric concepts into physical-product development is non-trivial; defining iteration-ready protocepts and acceptance criteria is often a key challenge [10].

Table 1: Barriers to agile adoption in pharmaceuticals and recommended implementation strategies

Barrier domain	Typical barrier	Recommended strategies
Regulatory / compliance	GMP-driven documentation, traceability, audit expectations conflict with iterative change	Embed regulatory requirements early; proactive regulator engagement (e.g., FDA/EMA); risk-assessment tools to structure dialogue; hybrid governance (e.g., Agile–Stage-Gate) [1,2,10]
Organisational/cultural	Resistance to change; hierarchical decision-making; fear of control loss	Strong executive sponsorship; formal change management; training/coaching; explicit communication of purpose; reinforcement via recognition and milestone celebration [1,10]
Capability/knowledge	Role confusion; superficial "agile" adoption; lack of experienced practitioners	Use agile coaches/scrum masters; build cross-functional teams for knowledge transfer; start with selective practices rather than full-method adoption [1,10]
Scaling & physical-product fit	Coordination complexity; difficulty defining protocepts and iteration deliverables	Invest in enabling infrastructure; define iteration outputs and acceptance criteria; apply structured risk management across iterations [1,2,10]

Table 1 summarises key barriers to agile transformation in pharmaceutical organisations and maps them to pragmatic mitigation strategies described in the cited literature. Hybrid models (e.g., Agile–Stage-Gate) are emphasised to balance regulatory compliance with iterative learning and faster decision cycles.

5. Conclusion and Outlook

Agile business management is increasingly relevant in pharmaceuticals as product complexity, personalisation, and supply-chain volatility rise [2]. Nevertheless, full "pure" agile adoption is often constrained by regulatory and compliance realities [1,2]. The most actionable path is typically selective adoption of high-impact practices and hybrid governance that preserves traceability while enabling faster feedback and adaptation [10]. Future progress will likely require sustained industry–regulator collaboration to modernise frameworks that can accommodate modular manufacturing and agile operating models without compromising patient safety [2].

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Abbreviations

APM – Agile Project Management

GMP – Good Manufacturing Practice(s)

IoT – Internet of Things

POD – Modular or portable manufacturing unit (pod-based facility)

FDA – U.S. Food and Drug Administration

EMA – European Medicines Agency

CAR-T – Chimeric Antigen Receptor T-cell therapy

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