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Innovative Formulation and Advanced Technological Capabilities in Pulmonary Drug Delivery: The Mediating Influence of Delivery Performance and the Moderating Effect of Regulatory Support on the Success of Commercialisation Implementation

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Abstract

Modern pulmonary drug delivery relies more and more on the combination of innovation capabilities in formulations, technological advancements, good performance in delivery and regulatory backing. This research investigates the impact of formulation innovation capabilities and advanced technological capabilities on the success of commercialisation implementation, using delivery performance as a mediator and regulatory backing as a moderator. Quantitative and cross-sectional design were applied, based on 175 valid responses from pharmaceutical development, manufacturing, regulation and commercialisation specialists. The data were processed in Microsoft Excel applying reliability tests, Pearson correlation, multiple regression analysis, bootstrapped mediation and interaction-based moderation. The findings suggest that both the capabilities increase pulmonary drug delivery performance and that performance becomes the major determinant of commercialisation success. Moreover, it acts as a partial mediator for both capability-commercialisation relationships. Regulatory backing increases the impact of performance on commercialisation implying that the success in technical aspect is more likely to lead to implementation success when backed by favorable regulations.

Keywords*:* Pulmonary drug delivery; formulation innovation; technological capability; delivery performance; regulatory support; commercialisation implementation

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1. Introduction

Pulmonary drug delivery has evolved from conventional inhaled medicines into systems integrating engineered particles, innovative formulations, inhaler devices, manufacturing processes and computational technologies. The pulmonary route allows for direct access to the respiratory tract and facilitates the successful targeting of the lungs, the rapid efficacy of the therapeutic action and for selected drugs or substances, systemic uptake with reduced systemic exposure [1, 2]. However, this does not automatically mean that a new technology is going to be a success in the market. Pulmonary products need to produce a specified dose, be effective when delivering to the right target area, not be susceptible to degradation from either physical or chemical weathering, be safe, behave as needed after delivery, be manufacturable, and meet regulatory standards [4, 8, 9].

Formulation design is thus very important from the perspective of delivery performance, inasmuch as the properties of the particles, loading of the drug, dissolution and release and aerosolization depend on formulation design [1, 2, 10, 11]. The recent literature provides evidence that: (i) solubility, stability and pulmonary transport problems can be solved by using cocrystals, nanocrystals and systems based on biopolymer (bps) components [1], [2], [10]. A Carrier Free Inhalable Cocrystal can be prepared having an aerodynamic size suitable for deep lung deposition by employing a Quality-by-Design approach, as shown by Wong et al. [1]. Those kinds of findings make formulation a commercially meaningful function when it results in results which can be measured and reproduced.

Advanced technological capability further contributes through inhaler engineering, particle processing, scale-up and complex therapeutic delivery. Advanced manufacturing, porous formulation and reproducibility, coupled with device geometry and airflow and resistance, have a negative impact on aerosolization and deposition [4], [8], [12]. Stewart et al. [4] demonstrated that the aerosol properties of the spray-dried powders could be preserved upon optimisation and pilot-scale manufacture, while Sarode et al. [6] were able to convert mRNA lipid nanoparticles into an inhalable dry powder.

The current study thus proposes a conceptual framework that considers the success of implementation of commercialisation as an ability-performance-control journey. It explores whether they contribute towards enhancing pulmonary drug-delivery performance, whether they enhance the performance of pulmonary drug Delivery or whether delivery performance that enhances the success of commercialisation implementation, and whether they enhance the performance of drugs delivered or whether commercialisation implementation is enhanced through delivery performance supported by regulatory support. This holistic view covers a gap in the literature where technical, performance and regulatory concerns are analysed separately.

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2. Literature Review

Innovative formulation capability and delivery performance

Innovative formulation capability represents the ability to transform pharmaceutical and process knowledge into inhalable products capable of meeting targeted performance requirements. Aerosol behaviour, and lung deposition of particles is affected by particle size, morphology, surface characteristics, powder flow characteristics, drug loading and dissolution characteristics [1; 2; 10]. Yue et al. [2] highlight that nanocrystals could improve the dissolution and bioavailability of drugs that are poorly soluble in water, and Maloney Norcross et al [10] have noted the potential of biopolymeric systems for controlled release and overcoming the barriers in the pulmonary system.

Formulation innovation is important because of measurable performance outcomes. Wong et al. [1] reported developing a carrier-free favipiravir - theophylline cocrystal by means of Quality by Design, which gave a fine particle fraction of 79.3% and mass median aerodynamic diameter of 2.93 μm. This highlights the value of systematic optimisation of the formulation attributes and their relationship with deep lung delivery performance. Al-Assaf et al. [11] also outline particle engineering technologies and advanced manufacturing methods to enhance the cohesion, flow/dispersion of high dose inhalable powders. But as formulators innovate, there can be translation obstacles. Huang et al [3] list some major issues associated with peptide-containing metered-dose inhalers as incompatibility between drug and propellant, and low drug loading. Formulation capability must therefore combine novelty with stability, dose capacity, compatibility and manufacturability.

Advanced technological capability and delivery performance

Advanced technological capability includes device engineering, processing particle technologies, scale-up technologies, computer-based models, and technologies for complex therapeutics. There is a strong dependency of pulmonary delivery on the formulation-device interaction. Dhoble et al. [8] state that flow geometry, airflow and engineering design all influence the efficiency of DPI and computational fluid dynamics (CFD) are used to optimise device design. Sikora et al. [12] also show that both resistance of device and capsules and the orientation of the capsules, characteristics of the piercings, and inspiratory flow affect FPFD and APSD.

Technology capability is also important for transferring laboratory formulations into reproducible production. Stewart et al. [4] demonstrated single step spray-dry optimization and scaling of the CPZEN-45 powders without compromising the suitability of the aerodynamic properties and ability to manufacture to cGMP standards. Recent research by Sarode et al. [6] has shown the potential for advanced processing of the pulmonary delivery route for the development of inhalable mRNA lipid nanoparticles, highlighting the

growing technological envelope for pulmonary delivery. The results suggest that these systems need to be optimized as a composite or multi-component system and not optimized individually.

Delivery performance, commercialisation and regulatory support

High value added can only be realized through delivery performance, which sits between the technical capability and implementation of commercialisation. An aerosol product needs to be aerosolised, deposited on the desired location, delivered at the correct dose, remain stable and be safe for use in a clinical setting and during commercialisation. Chan et al. [5] recognize the "bench to bedside" gap associated with inhalable nanoscale particle-based dry powders and note the need for an improved characterisation of the connection between powder- and aerosol-generated properties and response in terms of biological outcomes. The same, Wang et al., [7] highlight the need for designing as a cohesive process of formulations, carriers and devices towards clinical translation.

The industrial scalability and replicability needed for commercialisation are also essential. Maloney Norcross et al. [10] suggest that biopolymeric dry powders provide some advantageous opportunities for formulation, but also have some pulmonary and manufacturing challenges. Hence, while delivery is required, it is not enough to be sufficient for commercialisation, manufacturing robustness, scalability and supporting evidence are still important.

The success of converting delivery performance to market implementation could depend on regulatory support. The complexity of regulatory considerations to drugs delivered orally include devices, performance, locally acting drug assessment, and drug-device relationship. Singh [9] suggests that there are variations between approaches to CE and safety of OIPs in the US and EU and this can result in uncertainty during registration. Therefore, clarity of guidance, certainty of assessment and supportive regulatory pathways would be a key enabler of translating high-level technical performances to commercial outcomes. The presented literature is consistent with a model, in which innovative formulation capability and advanced technological capability intervene in the delivery performance; the delivery performance moderates the implementation success in commercialisation; and regulatory support, is a moderator in the final relationship. This study addresses the gap by examining these pathways simultaneously.

3. Methodology

This study used a quantitative, cross-sectional and explanatory research design to examine the relationships between innovative formulation capability (NFI), advanced technological capability (ATC), pulmonary drug-delivery performance (PDDP), regulatory support (RS) and commercialisation implementation success (CIS). The deductive approach was used, because there were eight hypotheses with the relationships specified before

the statistical testing. A quantitative approach was suitable as the study aimed to measure the direct links and the process by which technological and formulation capabilities convert to commercialisation results.

The term NFI and ATC highlights recent advances in the field of pulmonary drug delivery where the optimisation of the formulation, particle engineering, device-formulation integration and computational technologies can increasingly influence aerosol performance and lung deposition [13, 14, 16]. Advanced modelling, device development and technology-supported optimization are also key aspects of inhaled product development that are highlighted in contemporary research into pulmonary delivery [17, 19, 20].

The intended audience included professionals with appropriate experience within the pharmaceutical R&D, formulation development, pulmonary/inhalation drug delivery, manufacturing, quality assurance, regulatory affairs, clinical/product development, technology management, pharmaceutical commercialisation, etc. Purposive sampling was used since the respondents needed some professional expertise to judge the study constructs. 175 valid responses were received.

A structured questionnaire was used for data collection. There were 25 items in the principal measurement section, five items for each of the following measurements: NFI, ATC, PDDP, RS and CIS. They were answered on a 5-point Likert scale ranging from 1 - strongly disagree to 5 - strongly agree. The items related to PDDP were related to dose consistency, aerosol/inhalation performance, deposition, and overall delivery performance, which correspond to literature items which have been identified as important/key factors for inhaled therapies as related to their aerodynamic behaviour, deposition and reproducible product performance [16 - 18]. The need for regulatory support was identified and included in the following areas: clarity, guidance, regulatory interaction, accommodating innovation and moving towards commercialisation, which are recognised regulatory issues with complex inhalation products [15, 19].

Microsoft Excel was used for the complete quantitative analysis. Initial screening involved testing for missing observations, out of range responses, duplicate IDs and influential observations. Construct scores were summarized (Mean) by the five corresponding items for each construct. To check the internal consistency of the items, Cronbach's alpha was calculated, and a value of 0.70 was deemed acceptable.

Multiple regression followed descriptive statistics and Pearson correlations were used. To test H1 - H2, Model 1 regressed PDDP on NFI and ATC, and to test H3 - H5, Model 2 regressed CIS on NFI, ATC and PDDP. Mediation hypotheses H6-H7 were examined using indirect effects and 5,000 bootstrap samples and 95% confidence intervals. The mean-centering of PDDP and RS, and the inclusion of the interaction term PDDP × RS in the CIS regression model, was used as a test for H8. Model diagnostics included VIF, Breusch-Pagan testing, Durbin-Watson statistics, residual normality and Cook's distance. P value < 0.05 was considered statistically significant.

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4. Results

4.1 Data Screening and Respondent Characteristics

The 175 questionnaires were all usable with no missing data, duplicates, or incorrect responses among the 25 core Likert questions. There was a diversified pool of professionals who participated in the study. Out of the total number, 50.3% were males while 46.3% were females. The major age range was that of people aged between 25 and 34 years (40.6%) followed by those aged between 35 and 44 years (24.0%). Most of them had a Master's degree (37.1%) while 19.4% had a doctoral qualification. As for experience, 36.6% had 6 to 10 years while 32.0% had 2 to 5 years of experience.

Table 4.1: Selected Respondent Characteristics

Characteristic	Largest/Relevant Categories	n	%
Gender	Male	88	50.3
	Female	81	46.3
Age	25–34 years	71	40.6
	35–44 years	42	24.0
Education	Master's	65	37.1
	Doctoral/PhD	34	19.4
Experience	6–10 years	64	36.6
	2–5 years	56	32.0
Organisation	Pharmaceutical company	70	40.0
Involvement	Substantial	50	28.6
	Direct/primary responsibility	40	22.9

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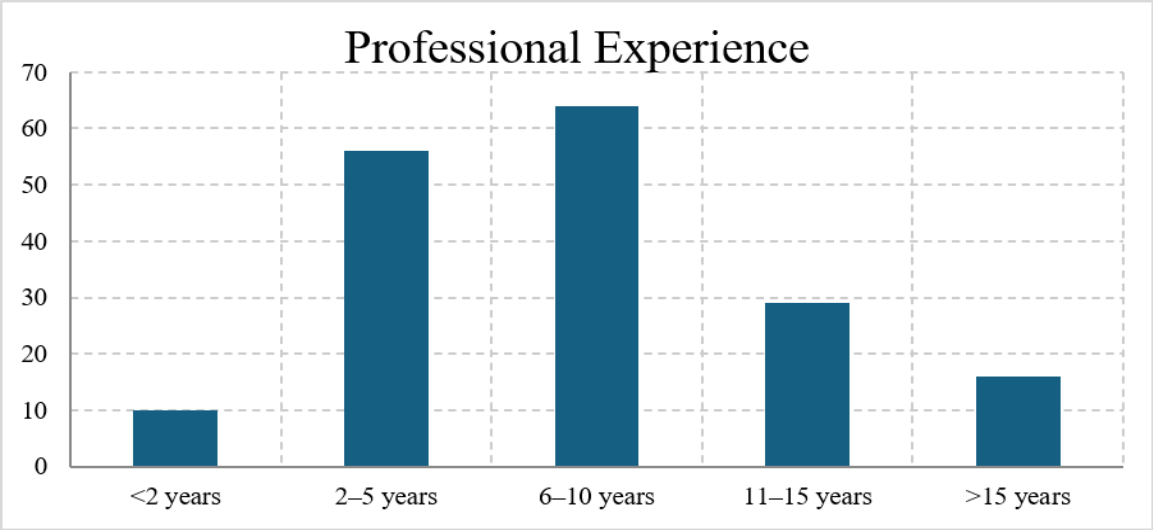

Figure 4.1: Professional Experience

4.2 Reliability, Descriptive Statistics and Correlations

All constructs were highly reliable, with Cronbach's alpha between 0.891 and 0.907. The mean values were close to the mid-point of 3.00, which implied that there were no extremely high or low evaluations.

Table 4.2.1: Reliability and Descriptive Statistics

Construct	Mean	SD	Cronbach's α
NFI	2.995	1.009	0.891
ATC	3.009	1.047	0.907
PDDP	3.001	1.023	0.895
RS	3.007	1.033	0.896
CIS	3.017	1.001	0.893

From the correlation analysis, it was found that there was a strong correlation between PDDP and CIS ($r = 0.715$, $p < 0.001$). On the other hand, NFI correlated positively with PDDP ($r = 0.555$) and CIS ($r = 0.516$), and ATC correlated with PDDP ($r = 0.528$) and CIS ($r = 0.468$), with $p < 0.001$ for both. There is no zero-order correlation between RS and CIS.

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Table 4.2.2: Pearson Correlations

Variable	NFI	ATC	PDDP	RS	CIS
NFI	1.000				
ATC	0.305	1.000			
PDDP	0.555	0.528	1.000		
RS	−0.077	−0.009	−0.036	1.000	
CIS	0.516	0.468	0.715	−0.015	1.000

4.3 Hypothesis Testing

Model 1 is statistically significant, $F(2,172) = 70.441$, $p < 0.001$, with 45.0% of PDDP variation being explained ($R^2 = 0.450$). NFI significantly influences PDDP ($\beta = 0.434$, $p < 0.001$), thus proving H1. Additionally, ATC is shown to have a positive impact on PDDP ($\beta = 0.396$, $p < 0.001$), which also proves H2. In Model 2, 54.3% of CIS variation is explained ($R^2 = 0.543$; $F(3,171) = 67.691$, $p < 0.001$). PDDP has the highest impact on CIS ($\beta = 0.556$, $p < 0.001$), thus proving H3. At the same time, both NFI ($\beta = 0.170$, $p = 0.007$) and ATC ($\beta = 0.122$, $p = 0.046$) retain their significance, thus proving H4 and H5.

Table 4.3 : Hypothesis Testing Results

H	Relationship	Effect	Statistical Result	Decision
H1	NFI → PDDP	β = 0.434	p < 0.001	Supported
H2	ATC → PDDP	β = 0.396	p < 0.001	Supported
H3	PDDP → CIS	β = 0.556	p < 0.001	Supported
H4	NFI → CIS	β = 0.170	p = 0.007	Supported
H5	ATC → CIS	β = 0.122	p = 0.046	Supported
H6	NFI → PDDP → CIS	Indirect = 0.240	95% CI [0.152, 0.339]	Supported
H7	ATC → PDDP → CIS	Indirect = 0.211	95% CI [0.136, 0.292]	Supported
H8	PDDP × RS → CIS	β = 0.176	p < 0.001	Supported

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Both CIs for mediation did not include zero, and the direct influence of NFI and ATC stayed significant, hence, partial mediation through PDDP was observed. The interaction term raised R^2 from 0.543 to 0.572 ($\Delta R^2 = 0.029$, $p < 0.001$). The slope of PDDP rose from 0.332 at low RS to 0.655 at high RS, thus, confirming H8. The diagnostics are good – maximum VIF = 1.91, DW = 2.142, Breusch-Pagan p = 0.724, maximum Cook's D = 0.044.

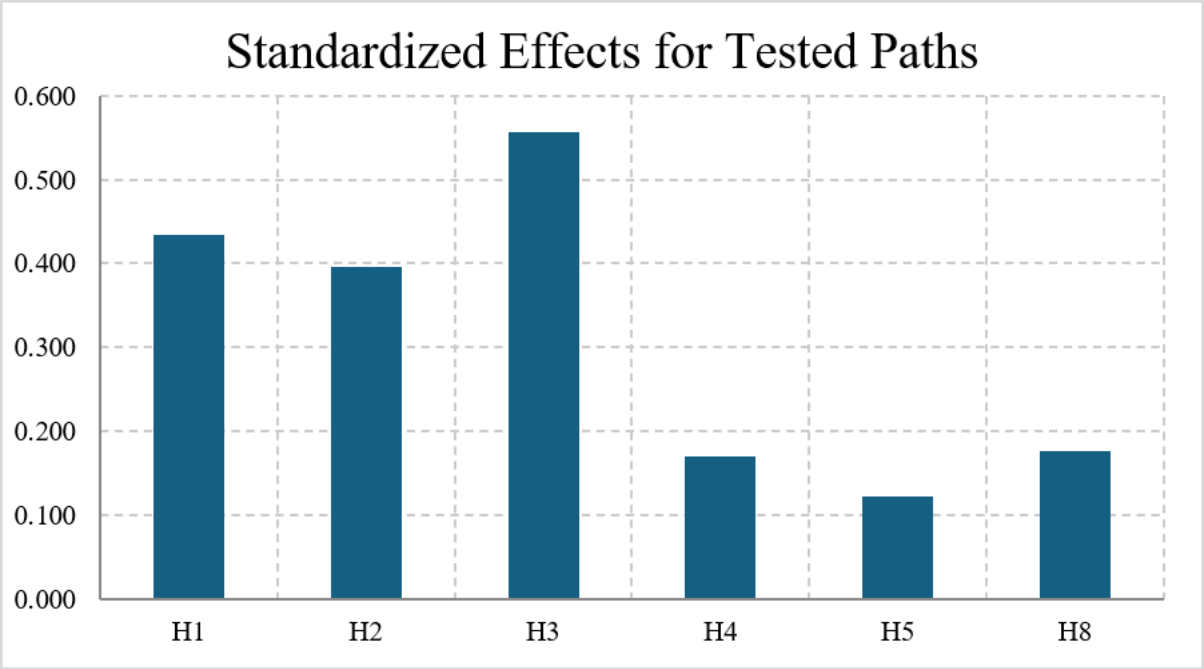

Figure 4.3.1: Standardized Effects for Tested Paths

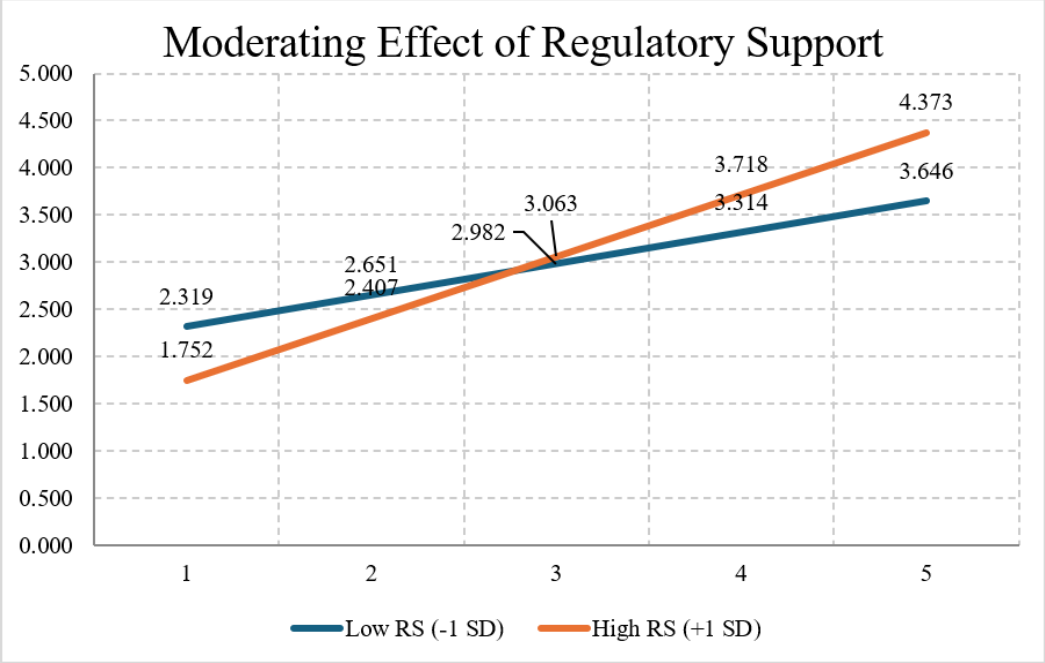

Figure 4.3.2: Moderating Effect of Regulatory Support

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5. Discussions

From the above results, it is clear that both innovative formulation capability and technological capability have an impact on the performance of drug delivery to the lungs. The H1 hypothesis had a relatively strong effect (NFI → PDDP; β = 0.434). It shows that formulation optimization capability correlates with superior performance of drugs delivered to the lungs. This finding is in agreement with the fact that particle size, morphology, carrier, and the process of formulating the product play a key role in aerosolisation, deposition, and stability [16]. Besides, nano-formulation can increase the deposition and bioavailability in the lungs [18]. The positive and significant influence of technological capability on the delivery of drugs to the lungs (ATC → PDDP; β = 0.396) confirms the role of advanced technologies in drug delivery to the lungs. In current literature, computation fluid dynamics, modelling, advanced device engineering, and digital technologies play an important role in the improvement of inhaler performance [19]. Besides, current literature suggests that molecular modelling can be used in formulating the product, predicting drug–excipient interactions, and optimisation of regional deposition [20]. Therefore, the technological capability seems to supplement the formulation capability.

The most important finding is that PDDP was the strongest predictor of CIS (β = 0.556). It means that sophisticated technologies or innovative formulations alone are not sufficient. Nowadays, inhalation product development focuses on reproducible dose delivery, compatibility of formulation and delivery device, and reliable lung deposition as necessary features of the products [13], [14], [17].

The mediation analysis confirms the interpretation. PDDP partially mediates the indirect effects of NFI and ATC on CIS (NFI → PDDP → CIS; indirect effect = 0.240, ATC → PDDP → CIS, indirect effect = 0.211). The fact that the indirect path remains significant means that formulation capability and technological capability also generate commercial value independently from delivery performance.

Finally, the regulatory support positively and significantly moderated the relationship between PDDP and CIS (β = 0.176; $\Delta R^2 = 0.029$). Unlike PDDP, RS does not correlate with CIS directly. Nevertheless, this finding is meaningful because regulation seems to act as an enabler in the process of implementation but not as an independent factor. The regulation literature on inhaled products stresses the importance of validation of evidence, development expectations, and alignment with testing requirements [15], [19], [21].

6. Conclusions

The study shows that innovative formulation capabilities and advanced technology capabilities have positive effects on pulmonary drug-delivery performance and commercialization implementation success. PDDP was

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found to be the main driver in connecting the organizational capabilities and commercialization successes, partially mediating both the relationships. Regulatory backing played an additional role in increasing the success of converting delivery performance into commercial success. Hence, organizations engaged in the development of pulmonary drugs need to consider formulation innovation, advanced technology capabilities, and performance improvement, along with regulatory involvement, rather than separating each function out. While the limitations of the study make any causality claim difficult, the findings do offer a clear empirical model that can be verified through future studies.

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Appendix A. Survey Questionnaire

Study Title

Innovative Formulation and Advanced Technological Capabilities in Pulmonary Drug Delivery: The Mediating Influence of Delivery Performance and the Moderating Effect of Regulatory Support on the Success of Commercialisation Implementation

Participant Information

The purpose of the questionnaire is to investigate how innovative formulation capacity and technological capacity affect the performance and implementation success of pulmonary drug delivery. The questionnaire will also consider the effect of pulmonary drug delivery performance as a mediator and that of regulatory support as a moderator.

The intended audience of the questionnaire comprises individuals who have either knowledge or experience in pharmaceutical research & development, formulation development, pulmonary/inhalation drug delivery, pharmaceutical manufacturing, quality assurance, regulatory affairs, clinical/product development, technology management, or pharmaceutical commercialisation. Your participation in this research is entirely optional and any personal information obtained will remain strictly confidential and be used for research purposes only.

Section A. Eligibility Screening

A1. Do you currently work, or have you previously worked, in the pharmaceutical, biotechnology, drug-delivery, healthcare technology, or related life-sciences sector?

☐Yes

☐ No

A2. Does your professional experience include at least one of the following areas: pharmaceutical research and development, formulation development, pulmonary/inhalation drug delivery, drug-device development, pharmaceutical manufacturing, quality assurance or quality control, regulatory affairs, clinical/product development, technology or innovation management, or pharmaceutical commercialisation/business development?

☐Yes

☐ No

Respondents who answered "No" to both screening questions were not eligible to continue the survey.

Section B. Respondent Profile

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B1. Gender

☐ Male

☐ Female

☐ Prefer to self-describe

☐ Prefer not to say

B2. Age Group

☐ Below 25 years

☐ 25–34 years

☐ 35–44 years

☐ 45–54 years

☐ 55 years and above

B3. Highest Educational Qualification

☐ Bachelor's degree

☐ Master's degree

☐ Doctoral degree/PhD

☐ Professional pharmaceutical/medical qualification

☐ Other

B4. Primary Professional Area

☐ Research and development

☐ Formulation development

☐ Pulmonary/inhalation drug delivery

☐ Pharmaceutical manufacturing

☐ Quality assurance/quality control

☐ Regulatory affairs

☐ Clinical/product development

☐ Technology/innovation management

☐ Commercialisation/business development

☐ Other pharmaceutical/life-sciences role

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B5. Total Professional Experience

☐ Less than 2 years

☐ 2–5 years

☐ 6–10 years

☐ 11–15 years

☐ More than 15 years

B6. Type of Organisation

☐ Pharmaceutical company

☐ Biotechnology company

☐ Contract research organisation

☐ Contract development/manufacturing organisation

☐ Academic/research institution

☐ Regulatory/government organisation

☐ Healthcare technology/device company

☐ Other

B7. Level of Involvement in Pharmaceutical Product Development or Commercialisation

☐ Limited involvement

☐ Occasional involvement

☐ Moderate involvement

☐ Substantial involvement

☐ Direct/primary responsibility

Section C. Main Study Variables

Please indicate the extent to which you agree with each statement based on your professional experience and knowledge.

Response Scale

Score	Response
1	Strongly Disagree

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2	Disagree
3	Neutral
4	Agree
5	Strongly Agree

C1. Innovative Formulation Capability (NFI)

Code	Statement
NFI1	Our organisation is capable of developing innovative formulations specifically suited to pulmonary drug delivery.
NFI2	We effectively optimise formulation characteristics to improve the delivery of active pharmaceutical ingredients to the lungs.
NFI3	Our formulation development capabilities support improvements in drug stability and performance during pulmonary administration.
NFI4	We can adapt formulation approaches effectively when pulmonary drug-delivery requirements change.
NFI5	Our organisation successfully integrates novel formulation approaches into the development of pulmonary drug-delivery products.

C2. Advanced Technological Capability (ATC)

Code	Statement
ATC1	Our organisation has access to advanced technologies required for pulmonary drug-delivery development.
ATC2	Advanced analytical and characterisation technologies are effectively used during pulmonary product development.
ATC3	Our organisation effectively uses advanced manufacturing technologies to improve pulmonary drug-delivery products.
ATC4	Digital, modelling, or computational technologies support the optimisation of pulmonary drug-delivery development.
ATC5	Our organisation has sufficient technical expertise to integrate emerging technologies into pulmonary drug-delivery systems.

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C3. Pulmonary Drug-Delivery Performance (PDDP)

Code	Statement
PDDP1	Our pulmonary drug-delivery systems achieve consistent and reliable dose delivery.
PDDP2	The developed systems demonstrate satisfactory aerosol or inhalation performance.
PDDP3	Our pulmonary drug-delivery approaches support effective deposition of the drug at the intended respiratory site.
PDDP4	The performance of our pulmonary delivery systems remains sufficiently stable and reproducible during development.
PDDP5	Overall, our pulmonary drug-delivery systems achieve the expected technical and therapeutic delivery performance.

C4. Regulatory Support (RS)

Code	Statement
RS1	Regulatory requirements relevant to pulmonary drug-delivery development are sufficiently clear.
RS2	Regulatory guidance provides useful direction for the development of innovative pulmonary drug-delivery products.
RS3	Regulatory interactions help our organisation address important development and approval issues.
RS4	Existing regulatory processes adequately accommodate technological and formulation innovations in pulmonary drug delivery.
RS5	Regulatory support facilitates the progression of promising pulmonary drug-delivery products toward commercial implementation.

C5. Commercialisation Implementation Success (CIS)

Code	Statement
CIS1	Our organisation effectively translates promising pulmonary drug-delivery developments into commercially implementable products.
CIS2	Pulmonary drug-delivery innovations are successfully progressed from development toward market implementation.

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CIS3	Our organisation is effective in scaling pulmonary drug-delivery innovations for commercial application.
CIS4	Commercialisation activities for pulmonary drug-delivery products are implemented within acceptable organisational and market requirements.
CIS5	Overall, pulmonary drug-delivery innovations achieve satisfactory commercialisation implementation outcomes.

Section D. Additional Contextual Questions

D1. In your opinion, which factor presents the greatest challenge to the successful commercialisation of pulmonary drug-delivery innovations?

☐ Formulation limitations

☐ Technological limitations

☐ Manufacturing and scale-up challenges

☐ Regulatory requirements

☐ Financial/commercial constraints

☐ Market adoption

☐ Other

D2. How would you rate the overall level of innovation in pulmonary drug-delivery development within your organisation?

☐ Very Low

☐ Low

☐ Moderate

☐ High

☐ Very High

End of Questionnaire

Thank you for participating in this study.