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Novel Formulation Innovation and Advanced Technology Capability in Pulmonary Drug Delivery: The Mediating Role of Delivery Performance and the Moderating Role of Regulatory Support in Commercialisation Implementation Success

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Abstract

Innovation in drug formulation and technology is becoming critical to the successful pulmonary drug delivery and to commercialisation. The study seeks to investigate the role of novel formulation innovation (NFI) and advanced technology capability (ATC) on commercialisation implementation success (CIS) through mediating effect of pulmonary drug delivery performance (PDDP) and moderating effect of regulatory support (RS). A cross-sectional survey was carried out using a quantitative approach to reach 200 pharmaceutical professionals. Descriptive statistics, correlation, regression and bootstrapped mediation and moderation analyses were used to analyse data. All of the eight hypotheses were accepted. The findings demonstrate that NFI and ATC improve PDDP, which contributes significantly to CIS while regulatory support strengthens the PDDP-CIS relationship.

Keywords: Advanced technology capability, Pulmonary drug delivery, Regulatory support, Commercialisation success and Formulation innovation

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1. Introduction

Pulmonary drug delivery has become an emerging alternative method for treating respiratory diseases and delivering therapeutic agents directly to the lungs. Inhalation can deliver drugs directly to the lungs, allowing faster absorption and less exposure to the rest of the body compared with conventional routes. It can also deliver drugs into the bloodstream as the lungs have a large and highly vascularised surface. However, pulmonary delivery is still a challenge due to the effects of lung anatomy, airway clearance, particle properties, patient breathing behaviour and device performance [1] [2]. Thus, novel formulation innovation (NFI) is becoming a more important component in enhancing pulmonary drug-delivery systems. There have been recent advances in engineered particles, nanocarriers, composite particles, controlled-release formulations and improved dry powder formulations, which provide better aerosolisation, stability, lung deposition and drug retention [3]. Concurrently, advanced technology capability (ATC) is revolutionising formulation and device development using particle engineering, computational modelling, artificial intelligence, advanced manufacturing and better inhaler technologies. These properties can enhance formulation-device compatibility, precision and reproducibility of delivery [4].

Technological innovation has progressed to a certain extent though it does not guarantee a successful commercialisation. The formulation stability, manufacturing scale-up, device-formulation integration, analytical testing, clinical translation, regulatory requirements and post-approval changes are all challenges faced by pulmonary products [5] [6]. For drug-device and combination products, there is increasing emphasis by regulatory authorities on the evidence of drug delivery performance [7]. Although existing studies have largely examined formulation innovation, technological development, delivery performance and regulatory issues separately. Limited focus has been placed on developing an integrated framework that describes how the performance of NFI and ATC support the success of commercialisation implementation and the influence of regulatory support on this relationship. Thus, the aim of this study is to investigate the effects of NFI and ATC on the success of implementation of commercialisation with a focus on pulmonary drug-delivery performance (PDDP) as a mediator and regulatory support (RS) as a moderator. The study specifically examines the direct, mediating and moderating relationships represented in the proposed conceptual framework.

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2. Literature Review

2.1 Novel Formulation Innovation and Advanced Technology Capability in Pulmonary Drug Delivery

Novel formulation innovation (NFI) and advanced technology capability (ATC) are increasingly important for improving pulmonary drug-delivery systems. Recent work focuses on the creation of engineered particles, nanocarriers, sophisticated dry-powder formulations and manufacturing processes to enhance aerosolisation, stability, targeting and lung deposition. Simultaneously, computational modelling and artificial intelligence are increasingly being applied to formulation optimisation and prediction of pulmonary delivery outcomes [8] [9]. Although, these trends imply that the novelty of formulations is a requirement for innovation, companies must also be able to develop, integrate and scale advanced technologies. The theory that can be used to explain how organisations build and reconfigure their capabilities to meet technological and market changes is Dynamic Capabilities Theory. Specifically, sensing, seizing and changing potential can be used to foster innovation and build commercialisation capability [10]. Therefore, NFI and ATC should enhance the pulmonary drug-delivery performance.

2.2 Pulmonary Drug Delivery Performance and Commercialisation Implementation Success

PDDP (pulmonary drug delivery performance) reflects the extent to which a formulation and delivery system can provide consistent, efficient and therapeutically appropriate drug deposition in the lungs [11]. Performance is influenced by formulation characteristics, particle properties, device design, manufacturing conditions and patient inhalation behaviour. In recent years, there is evidence indicating that the optimisation of these factors can help increase the aerodynamic particle size, fine-particle fraction, emitted dose and regional lung deposition [12]. Effective delivery performance is important for commercialisation as new pharmaceutical products must work reliably and consistently before they can be successfully introduced to the market. Commercialisation implementation success (CIS) is the ability to take a technically developed product to a scalable, implementable and marketable pharmaceutical solution. Thus, higher PDDP would increase the potential for innovative pulmonary products to be successful in their commercialisation.

2.3 Mediating Role of Pulmonary Drug Delivery Performance

The association between innovation and commercialisation may not be entirely direct. While NFI and ATC could create potential value, this would have to be converted to actual value added in terms of improvement in the performance of drug delivery systems. Formulations could provide for improvements in drug stability, aerosol behavior, targeting and control release, while advanced technologies could result in better

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formulations, consistency of manufacture and precision of delivery [13]. Thus, PDDP may become a medium of translating NFI and ATC into CIS. The ability to consistently provide high-quality, therapeutic and scalable solutions through drug delivery innovation could facilitate the transition from the technological to commercial stage of development [14]. Therefore, PDDP is expected to mediate both the relationship between NFI and CIS and the relationship between ATC and CIS. In other words, better delivery performance can increase the commercial value of new formulations and technologies.

2.4 Moderating Role of Regulatory Support in Commercialisation Implementation Success

Regulatory support can determine whether technically effective pulmonary drug-delivery innovations can successfully progress towards commercial implementation [15]. Clarity regarding safety, manufacturing consistency, product characterisation, clinical evidence and suitable regulatory pathways are potential areas of uncertainty for pulmonary and nanomedicine products. Ambiguous regulatory requirements are emerging as a major hindrance to the translation of advanced nanomedicine technologies to the clinical and commercial setting [16]. Thus, regulatory support, clear requirements, scientific guidance, regulatory communication and adequate evaluation pathways can help to move from successful delivery performance to commercial implementation. Within this proposed framework, regulatory support is not seen as a direct predictor alone, rather it is expected to moderate the PDDP-CIS relationship. Regulatory support may strengthen the positive delivery performance effect on commercialisation, while regulatory uncertainty could have an adverse effect.

2.5 Research Gap

The research developments in terms of understanding of pulmonary formulation technology, manufacturing techniques, formulation optimisation and regulatory issues have been improved though these are studied independently. While there is plentiful evidence from the literature on formulation and technological advances, there has been relatively less work on understanding the combined role of NFI and ATC in helping to achieve CIS through PDDP [8] [12]. Also, the potential influence of regulatory support for enhancing or diminishing the success of delivering commercial outcomes is underdeveloped in a single empirical model. Thus, this study tries to fill this gap by exploring NFI as a predictor, PDDP as a mediator, RS as a moderator and CIS as an outcome, providing an integrated explanation of pulmonary drug-delivery innovation and commercialisation. The following hypotheses were tested,

H1: NFI positively influences PDDP.

H2: ATC positively influences PDDP.

H3: PDDP positively influences CIS.

International Journal of Advanced Multidisciplinary Research and Innovation
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H4: NFI positively influences CIS.

H5: ATC positively influences CIS.

H6: PDDP mediates the relationship between NFI and CIS.

H7: PDDP mediates the relationship between ATC and CIS.

H8: RS moderates the relationship between PDDP and CIS.

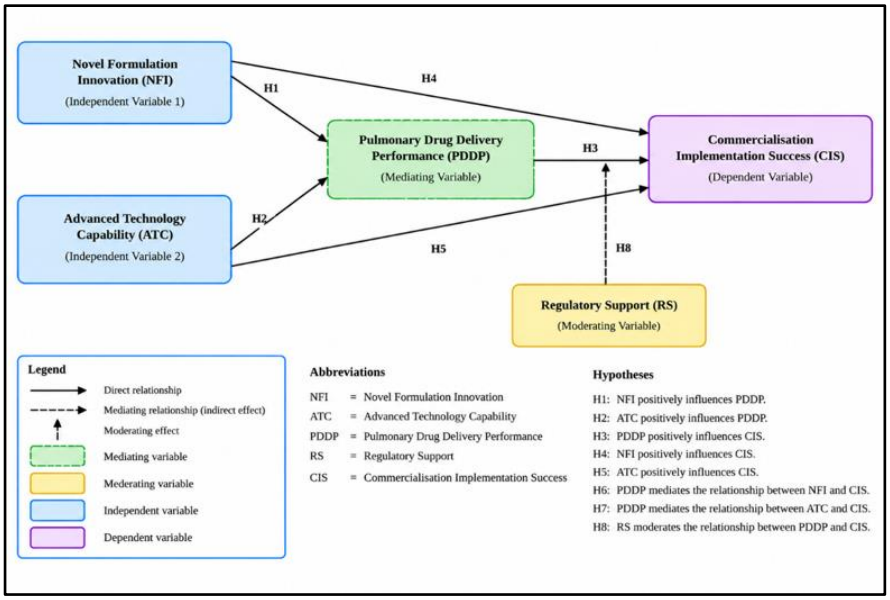

Figure 1: Conceptual Framework

3. Methodology

This study is quantitative based and has a cross-sectional research design that examines the relationship between NFI, ATC, PDDP, RS and CIS. A quantitative design would be suitable for the statistical testing of relationships in the conceptual framework [17]. The target audience would include 250 professionals from the pharmaceutical formulation, Pulmonary drug delivery, pharmaceutical technology, Research and development, Manufacturing, Regulatory affairs or Commercialisation domain with experience in the formulation field. The sample is drawn by simple random sampling from an eligible sampling list (ESL) which consist of 200 respondents [18]. Primary data has been gathered using a structured online questionnaire with a 5-point Likert Scale which comprises the attributes where 1 = strongly disagree, 5 = strongly agree. NFI evaluates formulation novelty, optimisation and stability, ATC evaluates technological integration and capability, PDDP assess the efficiency, consistency and reliability of delivery, RS assess regulatory support, clarity and guidance, CIS evaluates implementation, scalability and market readiness. The data has been analysed in Microsoft Excel. Descriptive statistics have been calculated. The internal consistency items evaluated using Cronbach alpha, values around 0.70 and greater is considered acceptable [19]. Correlations

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calculated using Pearson correlation and regression has been conducted to explore relationships between variables. Regression-based analyses determine whether PDDP affects the relationships between NFI, ATC and CIS. Indirect effects examined via Bootstrapping [20]. Interaction between PDDP and RS examined in predicting CIS to test for moderation. Participation is voluntary, informed consent has obtained and respondent confidentiality with secure data handling maintained.

4. Results

4.1 Data screening and respondent profile

In total, there were 200 completed responses. Based on the data, it was found that the data was appropriate for regression analysis through screening. The moderation model residuals were not significantly different from normal (Shapiro-Wilk p = .154), there was no serious concern of residual autocorrelation (Durbin-Watson statistic = 2.296) and there was no concern for multicollinearity (maximum VIF = 1.044). The sample included various roles in the Pharmacy (Table 1). Pharmaceutical formulation/R&D (22.5%) as well as pharmaceutical manufacturing (18.5%) were the largest professional categories. The experience of most respondents ranged from 6-10 years (32.5%) and 46.5% of them worked in pharmaceutical companies. In terms of education, 25.5% of them possessed doctoral degrees and 42.0% possessed master's degree.

Table 1. Respondent Profile (N = 200)

Characteristic	Category	n	%
Professional role	Pharmaceutical formulation/R&D	45	22.5
	Pharmaceutical manufacturing	37	18.5
	Quality assurance/quality control	29	14.5
	Regulatory affairs	28	14.0
	Pharmaceutical management/commercialisation	27	13.5
	Pulmonary drug-delivery research	26	13.0
	Other	8	4.0
Experience	Less than 2 years	16	8.0
	2-5 years	55	27.5

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	6-10 years	65	32.5
	11-15 years	43	21.5
	More than 15 years	21	10.5
Organisation	Pharmaceutical company	93	46.5
	Contract research/manufacturing organisation	31	15.5
	Research institution/university	30	15.0
	Biotechnology company	24	12.0
	Regulatory organisation	14	7.0
	Other	8	4.0
Education	Bachelor's degree	43	21.5
	Master's degree	84	42.0
	Doctoral degree	51	25.5
	Professional qualification	15	7.5
	Other	7	3.5

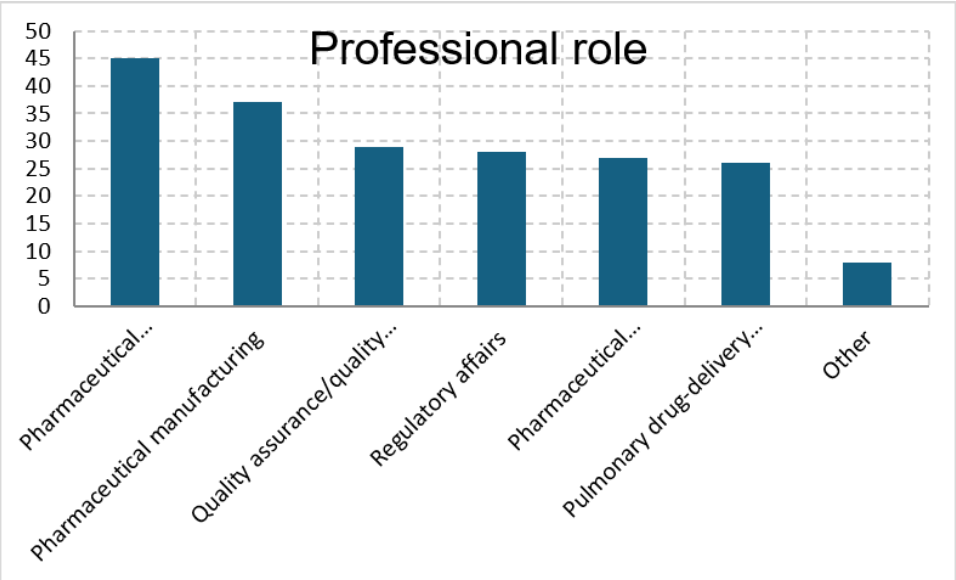

Figure 2: Respondents' distributions based on the professional role

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4.2 Descriptive statistics, reliability and correlations

Mean construct scores are listed in Table 2 and ranged from 2.888 for CIS to 3.031 for ATC. The internal consistencies were high, with Cronbach's α ranging from .917 to .937, which is higher than the standard of .7 [21]. Therefore, the reliability of all five scales was satisfactory.

Table 2. Descriptive Statistics and Reliability

Construct	Items	Mean	SD	Cronbach's α
NFI	8	2.998	0.987	.921
ATC	8	3.031	0.961	.917
PDDP	8	2.994	1.021	.924
RS	8	2.954	1.052	.937
CIS	8	2.888	1.030	.921

The principal hypothesised relationships were found to be positively associated by using Pearson correlations (Table 3). The correlation between PDDP with CIS was the highest (r = .654), and with NFI, ATC was positive (r = .516 and .535, respectively). Additionally, NFI (r = .431) and ATC (r = .496) were also positively correlated with CIS.

Table 3. Pearson Correlations among Constructs

Construct	NFI	ATC	PDDP	RS	CIS
NFI	1.000	.241	.516	.102	.431
ATC	.241	1.000	.535	.125	.496
PDDP	.516	.535	1.000	.022	.654
RS	.102	.125	.022	1.000	.198
CIS	.431	.496	.654	.198	1.000

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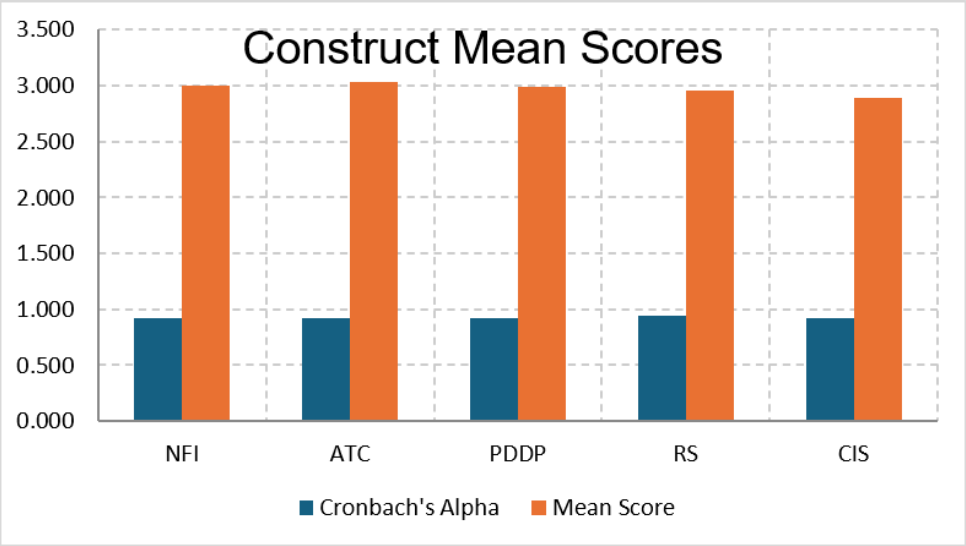

Figure 3: Construct mean scores

4.3 Regression and hypothesis testing

All direct hypotheses (Table 4) were supported by regression analysis. NFI significantly predicted PDDP (H1: *B* = .534, p < .001), while ATC also positively predicted PDDP (H2: *B* = .568, p < .001). The highest direct correlation was with CIS (H3: B = .660, p < .001). NFI (H4: *B* = .450, p < .001) and ATC (H5: *B* = .532, p < .001) also significantly predicted CIS.

Table 4. Direct Regression Results

Hypothesis	Relationship	B	SE	t	p	R^2	Decision
H1	NFI → PDDP	.534	.063	8.479	<.001	.266	Supported
H2	ATC → PDDP	.568	.064	8.903	<.001	.286	Supported
H3	PDDP → CIS	.660	.054	12.155	<.001	.427	Supported
H4	NFI → CIS	.450	.067	6.723	<.001	.186	Supported
H5	ATC → CIS	.532	.066	8.048	<.001	.247	Supported

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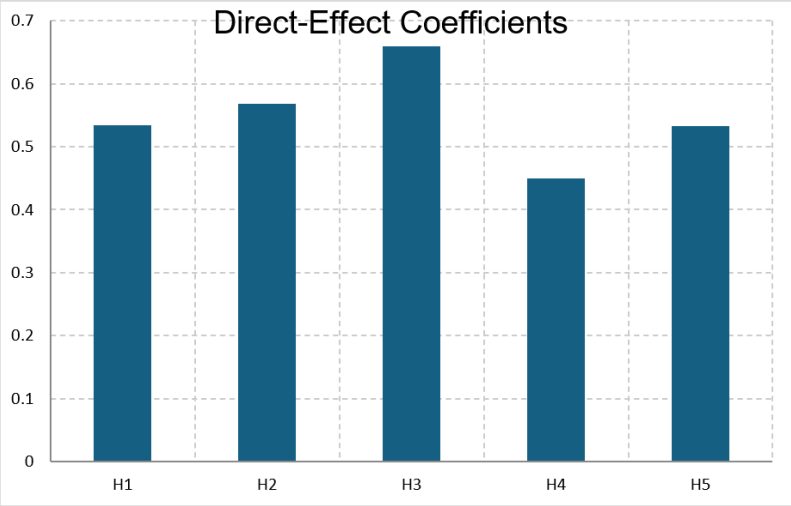

Figure 4: Direct-Effect Coefficients

The results of 5000 bootstrap mediation analysis (Table 5) confirmed that the relationship between NFI and CIS was mediated significantly by PDDP with an indirect effect of .316 (95% CI [.228, .413]), thus supporting for H6. Likewise, the relationship between ATC and CIS was significantly mediated by PDDP with an indirect effect of .312 (95% CI [.219, .423]) that supported H7.

Table 5. Mediation and Moderation Results

H	Effect	Estimate	95% CI / p	Decision
H6	NFI → PDDP → CIS	.316	[.228, .413]	Supported
H7	ATC → PDDP → CIS	.312	[.219, .423]	Supported
H8	PDDP × RS → CIS	.131	p = .012; CI [.029, .232]	Supported

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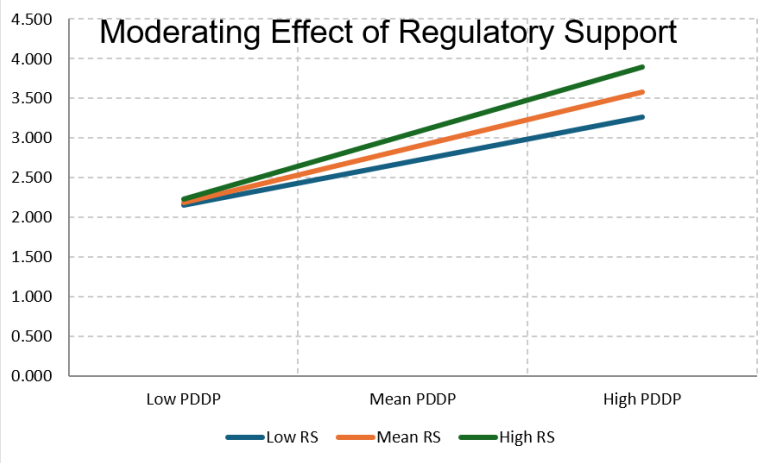

Figure 5: Moderating Effect of Regulatory Support

For H8, the PDDP × RS interaction was positive and significant (B = .131, p = .012, 95% CI [.029, .232]). The moderation model accounted for 47.8% of the variance in the CIS (R^2 = .478). The simple slope on the relationship between PD and CIS rose, from .543 at low RS to .681 at mean RS and .818 at high RS, indicating that the relationship between PD and CIS became more positive with greater regulatory support.

5. Discussion

All eight hypotheses are supported by the results obtained and the proposed model is consistently supported. Most importantly, the marked impact of NFI and ATC on the PDDP results shows both formulation innovation and technological capability can have a positive impact on PD delivery performance. It has been found that drug delivery depends on the active ingredient, the formulation, particle design, aerosol performance and manufacturing process. Focusing on the integration of formulation and technological innovation to enhance deposition, stability and delivery efficiency, the contemporary research in pulmonary delivery highlights this aspect [15] [22]. Support for H3 was provided by PDDP, which shows the strongest direct connection with CIS (B = .660), and points to delivery performance as an important mechanism that makes technology commercial. The results of the mediations also offer some insight into direct relationships of CIS with NFI and ATC. The indirect effects of NFI (.316) and ATC (.312) show that improved PDDP partly explains their positive impact on commercialisation success. This agrees with research showing that successful inhalation products need well-matched formulations, particles and delivery devices [23].

This is further supported by the moderation result, which shows that regulatory support is found to enhance the connection between delivery performance and commercialisation success. The PDDP-CIS slope was

raised from .543 under low regulatory support to .818 under high regulatory support. Thus, regulatory clarity, guidance and communication can help the technical effectiveness of products to go from development to commercialisation. This finding agrees with research showing that regulatory and manufacturing challenges can make it difficult to bring advanced pulmonary technologies to market (Jeong et al., 2025). Overall, the results indicate that in principle there is an integrated commercialisation mechanism. This includes NFI and ATC boost the PDDP, the PDDP then enhances the CIS and supportive regulatory conditions magnify the performance-to-commercialisation link. Thus, the results support treating technical innovation, delivery performance and regulatory support as interconnected rather than independent determinants of pulmonary-product commercialisation.

6. Conclusion

This study shows that new formulation innovation and technology advanced capability are significant factors that affect the performance of pulmonary drug delivery and commercialisation implementations. The results also confirm PDDP as a key link between innovation, technology and commercial value. In addition, regulatory support helps to reinforce the link between delivery performance and commercialisation success. In general, commercialisation is not a solely technological process and relies on delivering the performability of the technology in a regulatory setting. The results have implications for pharmaceutical companies looking to advance the innovation, implementation and commercialisation of pulmonary drug delivery.

References

1. Lam, J.K. and Zhou, Q., 2023. Advances in pulmonary drug delivery systems and inhalation formulations. *Pharmaceutical Research*, *40*(5), pp.1013-1014. https://doi.org/10.1007/s11095-023-03534-9
2. Peng, S., Wang, W., Zhang, R., Wu, C., Pan, X. and Huang, Z., 2024. Nano-formulations for pulmonary delivery: Past, present, and future perspectives. *Pharmaceutics*, *16*(2), p.161. https://doi.org/10.3390/pharmaceutics16020161
3. Islam, N., Suwandecha, T. and Srichana, T., 2024. Dry powder inhaler design and particle technology in enhancing pulmonary drug deposition: challenges and future strategies. *DARU Journal of Pharmaceutical Sciences*, *32*(2), pp.761-779. https://doi.org/10.1007/s40199-024-00520-3
4. Magramane, S., Vlahović, K., Gordon, P., Kállai-Szabó, N., Zelkó, R., Antal, I. and Farkas, D., 2023. Inhalation dosage forms: a focus on dry powder inhalers and their advancements. *Pharmaceuticals*, *16*(12), p.1658. https://doi.org/10.3390/ph16121658
5. Singh, G.J.P. and Peri, S.P., 2025. Scale-Up and Postapproval Changes in Orally Inhaled Drug Products: Scientific and Regulatory Considerations. *Journal of Aerosol Medicine and Pulmonary Drug Delivery*, *38*(2), pp.39-63. https://doi.org/10.1089/jamp.2024.0036
6. Shaibie, N.A., Mohammad Faizal, N.D.F., Buang, F., Srichana, T. and Mohd Amin, M.C.I., 2025. Inhaled biologics for respiratory diseases: clinical potential and emerging technologies. *Drug Delivery and Translational Research*, *15*(11), pp.4098-4114. https://doi.org/10.1007/s13346-025-01909-6
7. FDA, 2024. Essential Drug Delivery Outputs for Devices Intended to Deliver Drugs and Biological Products Guidance for Industry. https://www.fda.gov/media/179545/download
8. Anaya, B.J., Osorio-Vargas, E., Monterrosa-Moreno, S., Tirado, D.F., González-Burgos, E. and Serrano, D.R., 2026. Pulmonary Drug Delivery for Infectious Diseases: Cutting-Edge Formulations and Manufacturing Technologies. *Pharmaceutics*, *18*(2), p.242. https://doi.org/10.3390/pharmaceutics18020242
9. Al-Assaf, H.A., Papadimitriou, S.A., Rahman, A., Badhan, R. and Mohammed, A.R., 2025. Advanced manufacturing methods for high-dose inhalable powders. *Pharmaceutics*, *17*(3), p.359. https://doi.org/10.3390/pharmaceutics17030359
10. Munoz-Penas, J., Clarke, A.H. and Evald, M.R., 2024. Building a commercialization capability: A dynamic capability view. *Industrial Marketing Management*, *117*, pp.344-355. https://doi.org/10.1016/j.indmarman.2024.01.015

11. Cojocaru, E., Petriș, O.R. and Cojocaru, C., 2024. Nanoparticle-based drug delivery systems in inhaled therapy: improving respiratory medicine. *Pharmaceuticals*, *17*(8), p.1059. https://doi.org/10.3390/ph17081059
12. Pawar, H.B., Nayak, P.G., Sreedevi, A., Ravi, R. and Muragundi, P.M., 2026. Artificial Intelligence-Based Optimization of Pulmonary Drug Delivery Performance in Smart Inhaler Drug–Device Combination Systems. *Pharmaceutics*, *18*(8), p.1026. https://doi.org/10.3390/pharmaceutics18081026
13. Alradwan, I.A., Allabban, S.A., Aleissa, A.S., Alqahtani, N.M., Alghamdi, H.A., Al Fayez, N., Alshabibi, M.A., Tawfik, E.A., Almughem, F.A. and Alshehri, A.A., 2026. Pulmonary Drug Delivery in the Era of Nanomedicine: From Biological Barriers to Artificial Intelligence-Driven Optimization. *Pharmaceuticals*, *19*(7), p.1095. https://doi.org/10.3390/ph19071095
14. Ndebele, R.T., Yao, Q., Shi, Y.N., Zhai, Y.Y., Xu, H.L., Lu, C.T. and Zhao, Y.Z., 2022. Progress in the application of nano-and micro-based drug delivery systems in pulmonary drug delivery. *Bio Integration*, *3*(2), p.71. doi: 10.15212/bioi-2021-0028
15. Woodward, I.R. and Fromen, C.A., 2024. Recent developments in aerosol pulmonary drug delivery: new technologies, new cargos, and new targets. *Annual review of biomedical engineering*, *26*. https://doi.org/10.1146/annurev-bioeng-110122-010848
16. Mangla, B., Kumar, P., Javed, S., Pathan, T., Ahsan, W. and Aggarwal, G., 2025. Regulating nanomedicines: challenges, opportunities, and the path forward. *Nanomedicine*, *20*(15), pp.1911-1927. https://doi.org/10.1080/17435889.2025.2533107
17. Kittur, J., 2023. Conducting quantitative research study: A step-by-step process. *Journal of Engineering Education Transformations*, pp.100-112. 10.16920/jeet/2023/v36i4/23120
18. Iftikhar, A., Shi, H., Hussain, S., Abbas, M. and Ullah, K., 2022. Efficient estimators of finite population mean based on extreme values in simple random sampling. *Mathematical Problems in Engineering*, *2022*(1), p.5866085. https://doi.org/10.1155/2022/5866085
19. Hussey, I., Alsalti, T., Bosco, F., Elson, M. and Arslan, R., 2025. An aberrant abundance of Cronbach's alpha values at. 70. *Advances in Methods and Practices in Psychological Science*, *8*(1), p.25152459241287123. https://doi.org/10.1177/25152459241287123
20. Cheung, S.F. and Cheung, S.H., 2024. manymome: An R package for computing the indirect effects, conditional effects, and conditional indirect effects, standardized or unstandardized, and their bootstrap confidence intervals, in many (though not all) models. *Behavior Research Methods*, *56*(5), pp.4862-4882. https://doi.org/10.3758/s13428-023-02224-z

21. Daniel, B., 2026. Use of Statistical Methods in Bachelor and Master Theses: Data Requirements, Sample Sizes, and Practical Guidance with Methods and Examples. https://www.researchgate.net/profile/Binu-Daniel-2/publication/404655153_Use_of_Statistical_Methods_in_Bachelor_and_Master_Theses_Data_Requirements_Sample_Sizes_and_Practical_Guidance_with_Methods_and_Examples/links/6a09605a0fc2cb5022854bf6/Use-of-Statistical-Methods-in-Bachelor-and-Master-Theses-Data-Requirements-Sample-Sizes-and-Practical-Guidance-with-Methods-and-Examples.pdf
22. Jeong, J.H., Choi, J.H., Yoo, J.H., Choi, Y.R., Kang, J.H., Kim, D.W. and Park, C.W., 2025. Recent quality by design approaches for process optimization and quality enhancement of dry powder inhalers. *Journal of Pharmaceutical Investigation*, *55*(3), pp.375-396. https://doi.org/10.1007/s40005-024-00715-5
23. Dhoble, S., Kapse, A., Ghegade, V., Chogale, M., Ghodake, V., Patravale, V. and Vora, L.K., 2024. Design, development, and technical considerations for dry powder inhaler devices. *Drug Discovery Today*, *29*(5), p.103954. https://doi.org/10.1016/j.drudis.2024.103954

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Appendix

Questionnaire

Title: Novel Formulation Innovation and Advanced Technology Capability in Pulmonary Drug Delivery: The Mediating Role of Delivery Performance and the Moderating Role of Regulatory Support in Commercialisation Implementation Success

Participant Information

The purpose of this questionnaire is to analyse the impact of formulation innovation and technology capability on the success of implementing pulmonary drug delivery performance. Furthermore, it will be analysed whether the pulmonary drug delivery performance mediates and whether regulatory support moderates. Your answers will be used only for research purposes and will remain confidential.

Response Scale

For Sections B-F, please select one response for each statement:

1 = Strongly Disagree

2 = Disagree

3 = Neutral

4 = Agree

5 = Strongly Agree

Section A: Demographic Information

A1. What is your professional role?

- Pharmaceutical formulation/R&D
- Pulmonary drug-delivery research
- Pharmaceutical manufacturing
- Regulatory affairs
- Quality assurance/quality control
- Pharmaceutical management/commercialisation
- Other

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Volume 2, Issue 5, September-October 2026

A2. How many years of professional experience do you have in the pharmaceutical/drug-delivery sector?

- Less than 2 years
- 2-5 years
- 6-10 years
- 11-15 years
- More than 15 years

A3. What type of organisation do you work for?

- Pharmaceutical company
- Biotechnology company
- Research institution/university
- Regulatory organisation
- Contract research/manufacturing organisation
- Other

A4. What is your highest level of education?

- Bachelor's degree
- Master's degree
- Doctoral degree
- Professional qualification
- Other

Section B: Novel Formulation Innovation (NFI)

These items assess the organisation's ability to develop and improve innovative formulations for pulmonary drug delivery.

NFI1. Our organisation develops novel formulations for pulmonary drug delivery.

NFI2. Our organisation regularly improves existing pulmonary drug formulations.

NFI3. Our formulations incorporate innovative approaches to improve drug delivery to the lungs.

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Volume 2, Issue 5, September-October 2026

NFI4. Our formulation development activities improve the stability of pulmonary drug products.

NFI5. Our organisation develops formulations that improve drug deposition in the lungs.

NFI6. Our formulation innovations improve the efficiency of pulmonary drug delivery.

NFI7. Our organisation is capable of adapting formulations to meet changing pulmonary drug-delivery requirements.

NFI8. Our formulation innovations provide advantages over conventional pulmonary formulations.

Section C: Advanced Technology Capability (ATC)

These items assess the organisation's technological capability to develop and implement advanced pulmonary drug-delivery solutions.

ATC1. Our organisation has access to advanced technologies for pulmonary drug-delivery development.

ATC2. Our organisation effectively integrates advanced technologies into pulmonary drug-delivery processes.

ATC3. Our organisation has the technical expertise required to use advanced pulmonary drug-delivery technologies.

ATC4. Our organisation uses advanced technologies to improve formulation development.

ATC5. Our organisation uses advanced technologies to improve the precision and consistency of drug delivery.

ATC6. Our technological capabilities support the development of innovative pulmonary drug-delivery products.

ATC7. Our organisation can adapt its technological capabilities to new pulmonary drug-delivery requirements.

ATC8. Our organisation has sufficient technological capabilities to support the scale-up of innovative pulmonary drug-delivery products.

Section D: Pulmonary Drug Delivery Performance (PDDP)

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Volume 2, Issue 5, September-October 2026

These items measure the performance of pulmonary drug-delivery formulations and technologies.

PDDP1. Our pulmonary drug-delivery systems provide consistent drug delivery.

PDDP2. Our pulmonary drug-delivery systems achieve effective drug deposition in the lungs.

PDDP3. Our pulmonary drug-delivery systems provide reliable delivery performance.

PDDP4. Our pulmonary formulations achieve appropriate aerosol or particle characteristics for pulmonary delivery.

PDDP5. Our pulmonary drug-delivery systems provide consistent dosing.

PDDP6. Improvements in formulation and technology have enhanced pulmonary drug-delivery performance.

PDDP7. Our pulmonary drug-delivery systems perform effectively under practical use conditions.

PDDP8. Overall, our organisation achieves high performance from its pulmonary drug-delivery technologies.

Section E: Regulatory Support (RS)

These items measure the extent to which regulatory conditions support the development and commercialisation of pulmonary drug-delivery innovations.

RS1. Regulatory requirements for pulmonary drug-delivery products are sufficiently clear.

RS2. Regulatory authorities provide useful guidance for pulmonary drug-delivery development.

RS3. Our organisation receives adequate regulatory support during product development.

RS4. Regulatory authorities provide appropriate opportunities for communication regarding product requirements.

RS5. Regulatory processes provide sufficient guidance for demonstrating pulmonary drug-delivery performance.

RS6. Regulatory requirements support the development of innovative pulmonary drug-delivery products.

RS7. Regulatory support facilitates the transition of pulmonary drug-delivery innovations towards commercialisation.

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RS8. Regulatory uncertainty does not significantly prevent the commercial implementation of effective pulmonary drug-delivery innovations.

Section F: Commercialisation Implementation Success (CIS)

These items measure the extent to which pulmonary drug-delivery innovations can successfully move towards commercial implementation.

CIS1. Our organisation is successful in implementing innovative pulmonary drug-delivery products.

CIS2. Our pulmonary drug-delivery innovations can be effectively transferred from development to commercial production.

CIS3. Our organisation is capable of scaling innovative pulmonary drug-delivery products for the market.

CIS4. Our pulmonary drug-delivery innovations achieve the level of market readiness required for commercialisation.

CIS5. Our organisation can successfully introduce innovative pulmonary drug-delivery products into the market.

CIS6. Our organisation can effectively manage the transition from technological development to commercial implementation.

CIS7. Our pulmonary drug-delivery innovations have strong potential for successful commercial adoption.

CIS8. Overall, our organisation achieves successful commercial implementation of pulmonary drug-delivery innovations.