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Pharmaceutical Innovation in Dry Powder Inhaler: Advances, Challenges, and Future Prospects

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Abstract

Dry Powder Inhalers (DPIs) have become fundamental elements in pulmonary drug delivery, providing a propellant-free and easy-to-use solution for the treatment of respiratory diseases including asthma, chronic obstructive pulmonary disease (COPD), cystic fibrosis. Recent innovations in formulation science, particle engineering and device design have greatly enhanced the aerosolization performance, lung delivery deposition patterns as well as therapeutic effects of dry powder (DP) respiratory drugs. Through nanotechnology based formulation for improved drug bioavailability and targeted pulmonary delivery followed by the development of smart inhaler devices combined with Artificial Intelligence (AI) or Internet of Things (IoT)-enabled networks that provide real-time monitoring subsequently adherence tracking. However, the challenges of manufacturing scale-up, formulation stability and regulation still exist. Pollution control programs with green materials and low–carbon inhaler system designs additionally affect the continuing invention of DPI systems over time. Future directions of research are likely to focus on AI-informed formulation development, biologic and peptide delivery approaches alongside next generation sensor enabled inhalers. This review discusses recent advances, present challenges and abiotic cues that are paving the way to DPI-based respiratory therapeutics.

Keywords: Dry powder inhalers; Artificial intelligence; Internet of things; Smart inhalers; Mobile health applications; Nanoparticles; Nebulizers; Chronic obstructive pulmonary disease

Introduction

The administration of therapeutic drugs to the lungs is an effective approach in treating respiratory diseases with rapid onset and maximized bioavailability while minimizing side effects from systemic absorption, which pulmonary drug delivery systems are helping revolutionize. Out of these methods, dry powder inhalers (DPIs) have become a useful development in the area of respiratory drug delivery. DPIs are an attractive non-invasive, convenient and effective method of drug delivery making them a viable option for the treatment of chronic respiratory diseases including asthma, COPD or cystic fibrosis. These indications typically necessitate extended medication courses, so reliance on DPIs presents an attractive means of drug delivery compared with standard nebulizers and pressurized metered-dose inhalers (pMDIs) that require coordination between actuation and inhalation or contain propellants [1,2].

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A major benefit of DPIs is their dry powder medication delivery without the use of propellants, which are needed in pMDIs. This not only makes DPIs green but also a stable formulation which has an increased shelf life. In addition, DPIs depend on the patient's inhalation effort for dispersion of drug particles that increases lung target delivery. Such common indications for use include asthma and COPD, where the presence of airway obstruction is exacerbated by inflammatory processes that cause poor airflow. DPIs achieve more beneficial drug effects by targeting the lungs directly, which allows for lower doses to be used while minimizing systemic side effects compared with oral or intravenous delivery of medications [3,4].

Millions of people all over the globe suffers from asthma, a chronic inflammatory disease of airways characterized by airway hyperresponsiveness and obstruction. Inhaled corticosteroids and bronchodilators are mainstays of asthma treatment that can be effectively delivered via DPIs. DPIs are associated with ease-of-use, portability and rapid release of drugs. Likewise, chronic obstructive pulmonary disease (COPD), its airflow limitation and inflammation persist in an irreversible way will also largely benefited from the long-acting bronchodilators DPI formulations especially with combination therapies. As COPD is frequently diagnosed in older adults, many of whom may experience difficulty with the coordination required for pMDIs, DPIs provide a realistic alternative that streamline medication administration [5,6].

DPI-based drug delivery is also advantageous for cystic fibrosis, a hereditary disorder in which the lungs produce thick mucus. Cystic fibrosis patients are start taking mucolytics, antibiotics and bronchodilators periodically to alleviate symptoms. DPIs enable efficient delivery of these agents to the lung, enhancing efficacy while reducing systemic exposure. It will also benefit from innovations in DPI technology like engineered particles and novel carriers systems to improve drug dispersion, bioavailability as well delivering biologics and macromolecules for targeted therapy [7,8].

However, DPIs do present unique challenges to the drug delivery process; in particular they require adequate inspiratory effort for dispersion of constituent aerosol particles. Patients with severe respiratory impairment may be unable to generate the flow required for optimal drug delivery. Yet, advances in device design to breath-actuation and drug powder formulation have worked on overcoming these challenges with the aim of expanding their applicability across a wider spectrum of patients. DPIs (dry powder inhalers) are a high-efficiency, convenient option for the treatment of pulmonary medicinal diseases. The capacity to improve patient compliance, mitigate side effects and optimize therapeutic effectiveness highlights their importance in contemporary respiratory medicine [9,10].

Evolution of DPIs and the Need for Innovation

Table 1 highlights the key phases of DPI evolution while emphasizing the continuous need for innovation to enhance efficiency, patient usability, and therapeutic outcomes.

Table 1: Evolution of dry powder inhalers (DPIs) and the need for innovation.

Era	Key Developments	Need for Innovation
1960s - 1970s	Introduction of early DPIs (Spinhaler, Rotahaler)	Limited drug dispersion, dependence on patient inhalation effort [11].
1980s - 1990s	Development of multi-dose DPIs (Turbuhaler, Diskhaler)	Need for improved drug delivery efficiency and consistent dosing [12].
2000s	Incorporation of carrier-based formulations (Lactose-based powders)	Challenges in particle engineering and flow properties [13].
2010s	Advances in particle engineering, novel excipients, and high-performance inhalers (Breezhaler, Ellipta)	Need for optimized aerosolization and reduced dependence on patient effort [14].
2020s - Present	Smart inhalers, breath-actuated DPIs, and nano/microparticle-based formulations	Enhancing drug deposition, improving adherence, and enabling biologic delivery [15].

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Technological Advancements in DPIS:

Formulation Innovations

DPIs have evolved over the past few decades as a result of advancements in formulation science with both carrier-based and free formulations. Carrier based formulations, usually using Lactose as a carrier, assist in the improvement of powder flow and dispersibility; it also helps to accomplish more uniform drug distribution. Such formulations have been utilized in several commercially available DPIs to ensure dose reliability. In spite of such progress, there is still a need to develop formulations that enhance aerosolization and allow deeper penetration into the lungs, which has led to the development of carrier-free systems often consisting engineered particles designed with favourable size shape and surface properties affecting their deposition in airways [16]. In excipient-free powders, the active pharmaceutical ingredient (API) is not mixed with different substances; therefore, it does not require additional material to be designed as an inhalation dosage form. To enhance the aerodynamic performance of DPI formulations, many interesting strategies such as integration of nanoparticles and spray-dried microparticles into one particle platform have also been investigated for effective drug delivery at much lower inspiratory flow rates. These innovations improve bioavailability, therapeutic efficacy and patient compliance [17,18].

Device Design Improvements

Innovations in DPI devices design have been vital to enhanced dosage accuracy, ease of use, and improved adherence for therapy. Digital sensors and Bluetooth-enabled smart inhalers now enable real-time monitoring of different patterns in which the patient inhales, their medication adherence, how they use the device etc. Breath-actuated DPIs do not rely upon synchronisation of actuation and inhalation which makes them more advantageous for golden-age patients or those with misallocated lung function. Inclusion of dose counters, notifying patients about the remaining medication helps prevent missed or overdosed treatment. Contemporary DPI designs prioritize ergonomics and user-friendly interfaces to make inhalers more intuitive, minimizing errors in the technique of drug delivery via respiratory tract. With the integration of these technology advancements, DPIs are becoming more efficient and patient centric driving better treatment outcomes in chronic respiratory diseases [19,20].

Aerosolization Techniques

DPIs exhibit moderate-dependent effectiveness, as aerosolization technology is crucial in drug dispersion and lung deposition. By utilizing methods to induce turbulence in the airflow and novel inhaler geometries, dispersion technology has dramatically improved drug delivery efficiency. Newer designs use mechanical and sometimes electrostatic methods to enhance dispersion, making these DPIs more reliable for patients with low inspiratory effort compared with traditional devices that depend on the patient's respiratory power alone in order to generate airflow sufficient enough disperse powder into an aerosol [21,22].

The deposition efficiency of inhaled drugs depends primarily on the particle engineering, which determines the particles size distribution range (1–5 μm) such that most medication reaches deep lung regions rather than being deposited in oropharynx [10]. Engineered porous particles and spray-dried formulations can improve aerodynamic performance, decrease dose variability and increase bioavailability. These innovations in aerosolization technology further enhance the performance of DPIs, guaranteeing aimed and precise delivery of drugs to patients with respiratory ailments [23,24].

Nanotechnology and DPI Development:

Role of Nanoparticles in Enhancing Drug Bioavailability and Lung Deposition

Nanotechnology has recently and an effective approach for DPI development, enhancing drug bioavailability with improved pulmonary deposition. In contrast, nanoparticles have a small size (usually <500 nm), with increased surface area and dissolution rates which allows them to increase their contact time with lung epithelial cells for better absorption of drugs.

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Nanoparticles allow for a more uniform dispersion than conventional micronized drug particles that have typically displayed poor flow properties and inconsistent lung deposition, thus decreasing dose variability [25,26].

In addition, they can escape mucociliary clearance and rapid uptake into alveolar macrophages to give a prolonged residence time in lungs, which is responsible for their sustained therapeutic effects. Furthermore, nanoparticles can be tailored to improve solubility and permeability, rendering them especially advantageous for the delivery of poorly water-soluble drugs. These benefits render nanotechnology a promising approach for developing DPI formulations aimed especially at chronic respiratory diseases such as asthma, COPD and lung infections [27,28].

Illustration 1 is depicting the role of nanoparticles in enhancing drug bioavailability and lung deposition through Dry Powder Inhalers (DPIs). Nanoparticles improve dispersion, evade lung defenses, and enable prolonged drug retention, making them effective for treating chronic respiratory diseases like asthma, COPD, and lung infections.

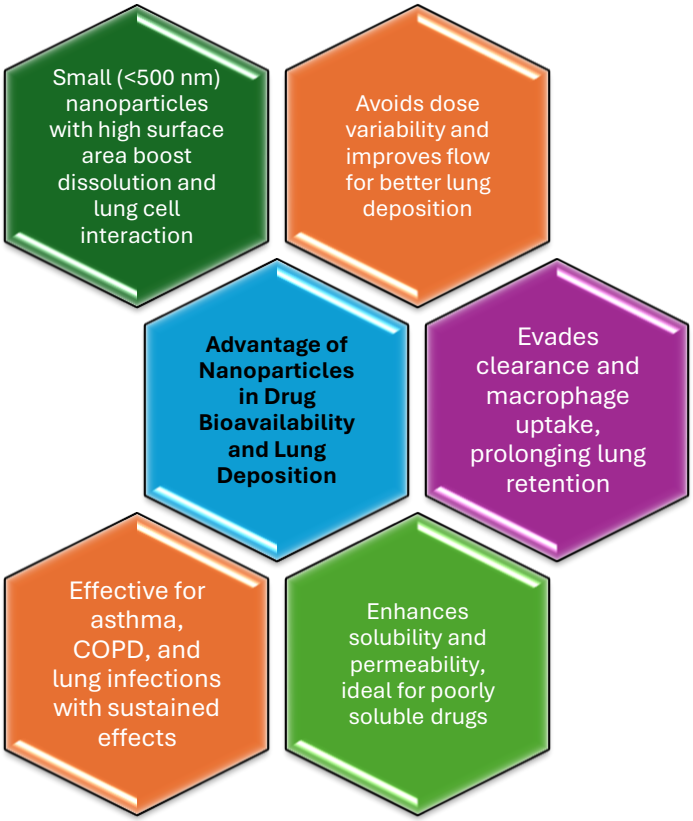

Figure 1: Advantage of Nanoparticles in Drug Bioavailability and Lung Deposition.

Lipid-based and Polymeric Nanoparticle Formulations for DPIs

Thus far, pharmaceutical scientists have developed major two types of nanocarriers for DPI formulations: nanoparticle lipid-based and polymeric nanoparticles. Lipid-based nanoparticles (solid lipid nanoparticles [SLNs], nanostructured lipid carriers [NLCs]) have advantages of biocompatibility, controlled drug release and improved stability. The formulations are mainly carriers of hydrophilic and lipophilic drugs in order to improve solubility properties as well as pulmonary absorption. Lipid nanoparticles are highly mucopenetrating, therefore increasing lung penetration and retention time of drug [29,30].

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Polymeric nanoparticles that are created with polymers such as poly (lactic-co-glycolic acid) (PLGA), chitosan, and polyethylene glycol (PEG) have additional advantages for sustained drug release and targeted delivery. Nanoparticles are also amenable to functionalization with ligands that promote site-specific deposition within the lungs, improving therapies for pulmonary infections as well as lung cancer and cystic fibrosis [31].

The recent prospect of using polymeric nanoparticles to protect drugs from enzymatic degradation has increased their potential for use in DPI systems. The design of these DPI formulations based on nanoparticles, however, relies heavily upon particle size and surface charge as well as the aerodynamic properties that need to be optimized for inhalation and deep lung deposition [32].

Challenges in Nanoparticle Stability and Manufacturing Scalability

Nanoparticle-based DPI formulations are clinically powerful, but face barriers such as low stability and challenges in producing large-scale manufacturing. Nanoparticles tend to agglomerate because of high surface energy, resulting in poor flowability and variable dosing. To avoid this, custom drying approaches (spray-dried and freeze-dried) are used to produce inhalable dry powders of nanoparticles by stabilizing them during the process. Nonetheless, these processes demand controlled formulation parameters to avoid flocculation and a compromise of functionality [33].

Another issue is scalable manufacturing of the product. Current methods for producing nanoparticle-based DPIs are complex and expensive, making them challenging to scale up into commercial manufacturing. Scale-up process is additionally complicated through ensuring batch to batching consistency, excessive drug filling efficiency and regulatory compliance. The additional complexity being the extensive need for sophisticated methods to characterize and monitor nanoparticles properties/protein-coating, as well as efficiency of lung deposition. Overcoming these obstacles via novel formulation strategies and scalable production technologies will be the key to successfully commercializing nanoparticle-DPI products [34,35].

However, despite the multiple benefits offered by nanoparticle-based DPI formulations, a number of limitations may prevent their clinical translation. Moreover, this is especially important since inhaled nanoparticles have the potential to cause oxidative stress and inflammation that in turn can induce cellular necrosis or be retained within pulmonary tissues with long exposure times. In addition, the formulation of nanoparticle-based systems is fundamentally complex because particle size, morphology and surface properties can influence aerosol aerodynamic behaviour and reproducibility of lung deposition [36].

The manufacturing and scaling up processes face hurdles like equipment, high production costs with consistency from batch to batch in terms of quality. Despite the success of several nanoparticle formulations in preclinical studies, relatively few have been translated to clinical use due to regulatory limitations and inadequate long-term safety data or laboratory-scale successes that cannot easily be developed into commercial products. Thus, more study will need to be performed in order overcome these challenges and enable the clinically safe with wide application of nanotechnology-based DPI systems [37,38].

AI and Digital Health Integration:

Role of Artificial Intelligence (AI) and IoT in Personalized Inhaler Use

Digital technologies are being utilized in DPIs, augmenting the management of respiratory diseases through improved monitoring and patient assistance. Existing smart inhaler systems mainly integrate sensors, Bluetooth communication technology and cloud platform and/or a smartphone application to record the use of inhalers, monitor adherence with set criteria followed by alerts or feedback on technique.

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These IoT-enabled systems enable healthcare professionals to remotely analyze patient data, which may reveal patterns typical of poor disease control. Although AI algorithms are being assessed for the analysis of data from inhalers and prediction of exacerbations, most AI-driven personalized dosing devices (automated treatment optimization; predictive adaptive inhaler) remain investigational or experimental rather than routine in clinical practice [39,40].

These intelligent solutions assist in prognosis before exacerbation of diseases such as asthma and COPD, preventing acute hospital admissions. DPIs can also be helped by using AI-driven algorithms to provide adaptive feedback for patients, enhancing the efficacy of each use through optimized inhalation techniques. This personalized approach improves disease management by enabling precision care to the patient with specifically defined respiratory needs [41].

Smart Inhalers with Real-Time Monitoring, Adherence Tracking, and Mobile Health Applications

Smart inhalers use innovative DPI technology with built-in digital sensors, Bluetooth connections and cloud storage to support tracking adherence in real-time. These can record frequency of inhalation, technique and peak inspiratory flow so that patients and physicians understand the efficacy of treatment. Smart inhaler–related mobile health (mHealth) applications provide personalized reminders, usage tips, and coaching on proper technique for inhalation of medications to improve patient adherence [42].

These apps are able to connect with EHRs and share real-time data, permitting continuous patient monitoring so doctors can intervene or adjust therapy as needed via remote consultation. Certain intelligent DPIs have voice or visual feedback systems to assist users with proper inhalation technique, thereby minimizing misuse and maximizing the quantity of drug correctly deposited into the lungs. Together, these features improve disease control, reduce gaps in treatment and give patients better tools for self-management [43].

Data Analytics for Optimizing Drug Delivery Efficiency

This approach analyses large datasets derived from smart inhalers, and data analytics is really vital to optimising DPI based drug delivery. With predictive analytics powered by AI, one can detect patterns in medication adherence or identify signs of a disease worsening and recommend personalized treatment adjustments. Machine learning models trained on injectable inhalation data are able to predict patient responses towards medications, contributing to tailored doses and enhanced therapeutic results [44].

AI-driven analytics can evaluate environmental data like air quality and humidity in relation to signs reported by a patient, advising on preventive decisions. Anonymized inhaler usage data can be used by pharmaceutical companies and healthcare providers to optimize the design of DPIs, enhance user satisfaction with different designs, and develop individualized treatment protocols. With the emergence of AI and data analytics, DPI technology will be developed into more effective, patient-oriented outcomes-driven respiratory care solutions [45].

Regulatory and Manufacturing Challenges:

Regulatory Requirements for New DPI Formulations and Devices

New DPIs, are carefully developed and subjected to numerous regulatory requirements on safety, efficacy, and quality prior to commercialization. Numerous international and regional regulatory agencies, including the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) as well many global health authorities require stringent practices for approval of DPI formulations/devices prior to market entrance. When it comes to new formulations of drugs, they need to pass through preclinical studies and clinical trials that test the drug activity in a variety of aspects such as efficacy against infection, lung deposition efficiency (the precision which the substance reaches its target lungs), patient usability etc [46].

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Currently, comparability studies are needed on DPI designs when switching a product from traditional formulations to new innovative breath responsive devices due to changes in particle engineering and excipients or inhaler mechanics that may alter the delivery of therapeutically relevant doses. Also, DPIs fall under the regulation of combination products since it contains both a drug and device component, and requires compliance with pharmaceutical as well as medical device regulations. Lastly, the inclusion of AI-powered smart inhalers adds even more complexity in terms of regulation requiring not just software validation but also cybersecurity measures and data privacy protocols designed to validate compliance with continuous monitoring in patients [47,48].

Challenges in DPI Manufacturing, Including Consistency in Powder Flow and Stability

Manufacturing DPIs is not easy, and yield powder flow consistency as well as dose delivery uniformity are difficult to achieve points along with having long term stability. DPIs are breath-actuated, so their effectiveness depends on very specific aerodynamic properties of the powder formulations such as particle size and shape, and surface characteristics. Good powder flowability is essential to prevent dose variability, as poorly flowing powders can cause non-uniform drug dispersion and decreased therapeutic effect [49].

DPI manufacturing is also a very sensitive technology, especially in terms of stability. Some critical factors that affect the dispersibility and lung deposition efficiency of bioactive dry powders are moisture absorption, electrostatic interactions, and aggregation. Carrier-based formulations (e.g. lactose) or engineered particles can circumvent these challenges, but scaling up nanoparticle based and excipient-free DPI formulations remains difficult to overcome. Advanced spray drying, freeze drying and particle coating approaches that improve stability need well controlled multi-process techniques for batch-to-batch consistency. Additionally, automation and real time process monitoring are being favored to preserve the efficiency of production as well as lower variability in large-scale DPI manufacturing [50,51].

Quality Control and Standardization of Inhalation Devices

To ensure patient safety and consistence drug delivery DPI device must be standardized. In vitro performance testing, including aerodynamic particle size distribution (APSD), delivered dose uniformity (DDU) and resistance to inhalation flow variability are mandated by regulatory agencies. Device robustness assessments are an important requirement for DPIs, along with testing their mechanical durability and reliability under relevant environmental conditions, as well the usability of devices across a range of patient populations [52].

The main challenges in DPI standardisation is due to the variability between inhaler resistance and patient inspiratory effort which can affect drug delivery efficiency. With the aim to minimize patient-dependency on technique, efforts are being made to harmonize DPI designs in general but a universal standard design for DPIs is still not realistically achievable as diverse formulation and disease-specific needs of patients remain counteractive. Also, the availability of smart inhalers will also bring new quality regimens that need to be developed to determine detection and reliability in data transfer as well as successful integration with mobile health platforms [53].

Clinical and Pharmacokinetic Considerations:

Drug Absorption, Bioavailability, and Systemic vs. Localized Effects

DPI's pharmacokinetics is of utmost importance for the success of therapy, as it determines drug absorption to target tissue in relation to bioavailability both locally and systemically. DPIs enable drug absorption through the alveolar epithelium, where its thin barrier and significant surface area allow for rapid uptake into the pulmonary circulation. But the particle size, solubility and formulation properties also governed deposition and absorption profile [54].

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Bioavailability in DPI therapy is dependent on depoition site within respiratory tract. Optimization of particle engineering for effective bronchial and alveolar delivery along with minimizing oropharyngeal deposition and systemic exposure. DPIs, unlike oral or intravenous drug delivery promote local rather than systemic effects in the lungs thereby minimizing side effects and improving safety of therapy. Other drugs such as inhaled corticosteroids or some antibiotics may undergo systemic absorption with the potential for adverse events including adrenal suppression and dysbiosis. Therefore, formulation strategies to dose optimization and selection of excipients are key approaches in order to maximally maintain the local-to-systemic drug ratio for improved efficacy and safety [55,56].

Patient Variability and the Impact of Inhalation Techniques

Age, lung function, inspiratory flow rate and comorbidities are variables which directly influence drug deposition and absorption in the clinical setting of DPI therapy. In contrast, while pMDIs supply the drug in suspension within a propellant aerosol, DPIs require that airflow be generated by patient inspiratory effort to achieve powder dispersion. This renders inhalation technique one of the key determinants in drug delivery efficiency [57].

Common inhalation errors include low inspiratory flow, poor breath coordination and exhalation before-inhaled, resulting in blood on adequate lung deposition for effective desired therapeutic response. Many older adults, children, and patients with severe COPD or neuromuscular disorders cannot generate sufficient inspiratory flow to obtain an effective aerosol from a DPI; therefore low-resistance DPI devices/alternative delivery systems should be used [58].

Teaching how to use DPIs and educating patients are vital for successful DPI utilization, and increasing role of smart-inhalers/digital health solutions assist in monitoring those error issues. AI-assisted inhalers provide real-time feedback through an app, track adherence to treatment plans, and offer personalized guidance for proper technique in puffs. Device selection must be guided by the patient specific lung function and inspiratory capacity to enable effective drug deposition as well as optimal clinical benefit. Optimizing the inhalation technique, patient variability and addressing pharmacokinetic considerations can yield greater consistency in DPI therapies as well increase adherence to these medicines along with enhancing respiratory disease management [59].

Comparison of DPIs with Other Pulmonary Delivery Systems

Table 2 outlines the key differences and advantages of Dry Powder Inhalers (DPIs) compared to Metered-Dose Inhalers (MDIs) and nebulizers, helping to illustrate their suitability for different patient needs and clinical scenarios.

Table 2: Key differences and advantages of Dry Powder Inhalers (DPIs) as compared to Metered-Dose Inhalers (MDIs) and nebulizers.

Characteristic	Dry Powder Inhalers (DPIs)	Metered-Dose Inhalers (MDIs)	Nebulizers
Mechanism of Action	Breath-actuated; powder dispersion relies on inspiratory effort [60].	Requires actuation to release drug in aerosolized form [61].	Converts liquid medication into mist via compressed air or ultrasonic waves [62].
Drug Delivery	Delivers dry powder to the lungs	Delivers aerosolized medication through a propellant	Delivers fine mist for inhalation
Ease of Use	Requires patient to generate adequate inspiratory flow [63].	Requires coordinated timing of inhalation and actuation [64].	Easier to use for patients with limited lung function or young children [65].

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Device Size and Portability	Compact, portable, and lightweight	Portable but often heavier and less convenient	Larger, less portable, requires power source
Onset of Action	Rapid, with immediate lung deposition [66].	Fast onset, with aerosol reaching the lungs quickly [67].	Slower onset, as mist is generated and inhaled over a longer period [68].
Required Inhalation Technique	Proper inspiratory flow necessary for optimal dose delivery	Requires correct coordination of inhalation and device activation	No specific inhalation technique required
Environmental Impact	Propellant-free, more eco-friendly [69].	Uses propellants (HFCs) that have environmental concerns [70].	Generally, more energy-intensive but no propellant used [71].
Maintenance	Low maintenance, easy to carry and clean	Requires regular cleaning and checking for propellant availability	Requires frequent cleaning, and parts may need to be replaced
Suitability for Specific Populations	Suitable for patients with good inspiratory effort	Suitable for adults and children (with proper technique)	Suitable for young children, elderly, or patients with poor lung function
Cost	Relatively cost-effective [72].	Inhalers can be cost-effective but higher in long-term cost due to propellant usage [73].	Generally higher upfront cost and more maintenance involved [74].

Sustainability and Environmental Impact:

Transition from Propellant-Based Inhalers to Eco-Friendly DPI Solutions

Moving from pMDIs to DPIs is a major step towards improving the environmental performance of inhalation therapies. Conventional pMDIs utilize hydrofluorocarbons (HFCs) as a propellant, leading to climate change damage through greenhouse gas emissions. On the other hand, DPIs are more sustainable since they do not use propellant. Regulatory bodies, including the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA), are encouraging pharmaceutical companies to transition to low-carbon inhaler technologies in response to global climate commitments, such as the Montreal Protocol and the Paris Agreement. Many healthcare organizations are also promoting greener prescribing practices, prioritizing DPIs over pMDIs when clinically appropriate. DPIs offer possibly the most environmentally sustainable solution toward respiratory treatment due to their widespread adoption, which is poised for significant reduction in carbon footprint associated with increased pharmaceutical innovation [75,76].

Recyclability and Biodegradability of DPI Components

The materials used in inhaler devices contribute to their environmental impact, necessitating efforts to enhance recyclability and biodegradability. Conventional DPI inhalers are primarily composed of plastics and metal components, which are often non-recyclable due to drug residue contamination. However, manufacturers are now developing eco-friendly DPI designs using biodegradable polymers, recyclable plastics, and paper-based packaging to minimize waste. Initiatives such as inhaler recycling programs, where used devices are collected and processed for material recovery, are being implemented in several countries. Research into biodegradable DPI materials focuses on reducing long-term plastic waste while maintaining device integrity and performance. These innovations contribute to a more circular economy in inhaler production, ensuring that sustainability goals align with patient care needs [77,78].

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Reducing Carbon Footprint in Inhaler Manufacturing and Disposal

DPIs not only have an environmental footprint when in use, but during manufacturing, throughout the supply chain logistics process and even at end of life. Inhalers use energy intensive processes and thus must be powered by renewable sources of energy, green manufacturing practices or sustainable supply chains to reduce emissions. Corporations are adopting carbon-neutral production practices (utilizing bio-based materials, reducing plastic emissions and improving transportation logistics to lessen emission levels) [79].

Disposal at the end of their useful life is another critical issue, Most DPIs, along with many different types of inhalers ultimately are incinerated or landfilled which contributes to the environmental burden. By encouraging disposal, take-back programs and components that lead to biodegradation of waste. The sustainability initiative can be further augmented by patient education campaigns focused on Responsible inhaler disposal and recycling options.

By prioritizing eco-friendly DPI solutions, recyclable materials, and low-carbon manufacturing processes, the pharmaceutical industry can significantly reduce the environmental footprint of inhalation therapies, contributing to a more sustainable and climate-conscious healthcare system [80].

Regulatory Challenges for Digital Inhalers and Nanoparticle-Based DPI Formulations

The rise of digital inhalers and nanoparticle based DPI formulations have further complicated the regulatory path as compared to more traditional inhalation products. Digital inhalers are a type of combination product that pull in elements from drug, medical device and software sometimes through cloud-based health platforms. Regulatory authorities are asking for evidence not simply of pharmaceutical quality and clinical efficacy, but additionally software reliability, cybersecurity, interoperability with different methods to ensure data integrity and affected person privacy safety. In the event, continuous software updates, AI-based decision support systems and remote monitoring functions require lifecycle management approaches to maintain continued compliance with changing digital health rules. Extending this to seek validation of real-world adherence data, particularly integrating with electronic health records is a key step in regulatory review [81,82].

Nanoparticle DPI formulations confer different regulatory challenges owing to their intricate morphology and distinct biopharmaceutical profiles. Data on particle size distribution, morphology, surface charge and drug loading efficiency/release kinetics/long-term stability are needed for regulatory agencies. Other key issues include pulmonary toxicity, immunogenicity (passive or active), biodistribution and nanoparticle clearance routes with the potential for prolonged retention in lung tissues. In vitro–in vivo correlations of nanoparticle formulations are difficult to establish and frequently rely on more extensive preclinical and clinical studies than those required for traditional DPI products. These challenges are exacerbated when scaling up because small changes in production parameters can have major effects on nanoparticle properties and clinical performance. As a result, regulatory agencies progressively highlight Quality-by-Design (QbD) concept as well as advanced analytical methods for characterization of inhaled nanomedicine and asserting batch-to-batch consistency to aid in the approval and commercialization process [83-84].

Knowledge Gaps and Future Research Priorities:

While significant advancements have been made in DPI technologies, many scientific, clinical, regulatory and manufacturing challenges remain currently unsolved. Overcoming these areas of knowledge deficiency will be critical for enabling innovative technologies, so they can progress from discovery to usable clinically actionable and commercially viable products.

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We have demonstrated the superiority of asymmetric nano sponges in DPI formulations containing a protein, disclosing exceptional activity within preclinical models; however long-term pulmonary safety data on these technologies are scarce. Additional studies are necessary to assess chronic exposure, pulmotropic disposition, immunogenicity together with inflammatory responses and systemic effects following repeated delivery [85].

The limited predictivity of existing in vitro aerosol performance testing for in vivo lung deposition and therapeutic outcome is a key challenge area in DPI development. In order to create reliable, recommended in vitro–in vivo correlations and enhance the formulation screening throughput, models mimicking lung physiology more closely or employing computational simulations and imaging-based deposition studies need to be developed. DPI performance can still be affected by how patients breathe. Inhalers should preferably be designed for broader range of inspiratory flow rates, age groups and severity of the diseases for future research. This approach compares human-factor studies and clinical usability assessments to determine where device designs can be refined and errors can be avoided in order to increase the inhalation [86].

Although smart inhalers provide a substantial improvement to adherence monitoring and personalised disease management, there are no defined methodologies of evaluation for sensor accuracy, data quality analysis including cutoffs for acceptable thresholds (specifically focusing on non-adherence), interoperability, cybersecurity and clinical effect. Harmonised regulations and performance criteria are required to enable adoption of digital inhalers. The manufacturing complexity and cost of the nanoscale, carrier-free, biologic-loaded DPI systems usually hinders commercial translation. Research priorities for the future should focus on scalable particle-engineering technologies, continuous manufacturing approaches and QbD strategies to secure reproducible product quality with consistent batch-to-batch consistency [87].

The prospect of targeting directly the pulmonary route with inhaled proteins, peptides, monoclonal antibodies, mRNA and gene-based therapies is nevertheless promising but significant research efforts will be needed to address issues such as formulation stability, pulmonary absorption (in some cases) intracellular delivery and their regulatory approval pathways. Its security, efficacy and enduring remedial advantages should be affirmed in broad based clinical trials. Inhalation therapy has used as any other field does with the consideration of environmental sustainability. Future studies should assess the total life-cycle effects of DPI devices, including material sourcing, manufacturing, packaging, shipping, recycling and final disposal. Developing biodegradable materials & circular-economy approaches must stay on the agenda [88,89].

In summary, interdisciplinary collaboration among pharmaceutical scientists, engineers, clinicians, regulatory agencies, and digital health experts will advance the future promises of DPI. By addressing these knowledge gaps, we can expedite the advancement of next-generation inhalation systems that are safer and more efficacious for patients while also being more sustainable from an environmental perspective. Efforts should continue to avoid biodegradables, and circular-economy approaches [90].

Conclusion

Several major advances, innovations in dry powder inhalers (DPIs) design include formulation science, nanotechnology, digital health integration and environmentally sustainable device development. Introduction of engineered particles, nanoparticle-based delivery systems, smart inhalers and AI-assisted monitoring platforms is greatly improving drug deliver efficiency, patient adherence and therapeutic outcomes. This potential for DPIs extends beyond appropriate agents that are traditional respiratory medications, as they can be used delivery mechanisms of biologics and peptide-based therapeutics. Though advances have been made, many vital research priorities remain.

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Studies in the future need to develop AI-based predictive models with specific emphasis towards optimization of formulation and personalized inhalation therapy. More focus needs to be on the stability, aerosolization and pulmonary bioavailability of biologics, peptides and nucleic acid-based therapeutics. It is important that research also tackles scalable and cost-effective manufacturing technologies for DPI formulations based on nano administration with batch-to-batch consistency and compliant with regulatory standards. Well-designed largescale clinical studies need to be conducted to determine the sustained efficacy, compliance and cost-effectiveness of real-time clinically integrated smart inhalers. Regulatory frameworks for AI-enabled inhalation devices and digital health platforms should be harmonised. Research and development of biodegradable materials, recyclable device components and low-carbon manufacturing processes are needed for increased environmental sustainability of inhalation therapies. Interdisciplinary collaboration targeting these gaps in knowledge will expedite the development of next-generation drug delivery systems and bring us closer to precision respiratory medicine.

AI Declaration

AI tools were used solely for grammar and language correction. All ideas, analysis, interpretations, conclusions, and content presented in this article are the original work of the author.

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