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Dry Powder Inhalers in the Age of Digital Health: Current Status, Regulatory Considerations and Future Perspectives

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Abstract

Dry powder inhalers (DPIs) are established drug–device combination products in which therapeutic performance is governed by the interaction between formulation properties, device engineering, and patient-specific inhalation behavior. Although advances in particle engineering and inhaler design have improved dose delivery and aerosol performance, real-world effectiveness remains limited by variability in inspiratory flow, inhalation technique, and disease state. These challenges underscore the need for a systems-based approach that recognizes DPIs as integrated delivery platforms rather than conventional dosage forms. The emergence of digital health technologies, including embedded sensors, connectivity, data analytics, and software-driven feedback, has enabled the development of digitally enabled or "smart" DPIs. Such products have the potential to function as connected combination products, supporting inhalation monitoring, adherence assessment, and personalized therapy. From a regulatory perspective, the integration of digital components introduces considerations related to software as a medical device (SaMD), data integrity, cybersecurity, interoperability, and lifecycle management, as outlined in evolving FDA and EMA digital health and combination product frameworks. This review summarizes the current status of DPI technology in the context of digital health integration, with emphasis on formulation–device–patient interactions, clinically relevant digital functionalities, and performance evaluation. Key regulatory expectations for development, validation, and post-market oversight of digital DPIs are discussed, including alignment with quality by design and risk-based regulatory approaches. Finally, future perspectives are presented to identify scientific and regulatory gaps that must be addressed to enable next-generation digital DPIs capable of delivering reliable, patient-centric, and outcome-driven inhalation therapy.

Keywords: Dry powder inhalers; Digital health technologies; Software as a medical device; Regulatory consideration; Quality by design

INTRODUCTION

Inhalation therapy remains a cornerstone in the management of respiratory diseases and an increasingly attractive route for systemic drug delivery. Over the past decade, a substantial rise in scientific publications and market analyses has reflected sustained growth in interest toward inhaled medicines, particularly dry powder inhalers [1, 2]. This trend is driven by the rising global burden of chronic respiratory disorders, such as asthma and chronic obstructive pulmonary disease, alongside the demand for more effective maintenance and combination therapies. The inherent advantages of pulmonary delivery including rapid onset of action, high local drug concentrations, and reduced systemic exposure have further reinforced the role of DPIs as a key platform in modern drug delivery strategies [3, 4].

DPIs are now widely recognized as drug–device combination products rather than simple dosage forms, as their clinical performance depends on a complex and highly interdependent relationship between formulation attributes, inhaler design, and patient-specific inhalation behavior. Despite notable advances in particle engineering, carrier-based formulations, and device mechanics, variability in inspiratory flow rates, inhalation technique, age, and disease severity continue to compromise real world effectiveness. These limitations highlight the need for a systems-based understanding of DPIs, consistent with contemporary regulatory expectations for combination products, quality by design, and risk-based development [5, 6].

In parallel, digital health technologies have rapidly expanded across healthcare and medical devices, reshaping expectations for therapy monitoring, adherence, and personalization. Within the inhalation space, the integration of sensors, microprocessors, connectivity, and software-driven analytics has led to the emergence of digitally enabled or "smart" inhalers. These systems offer the capability to detect inhalation parameters, identify critical use errors, support adherence tracking, and generate real-world evidence[7, 8].

When integrated with software components, such products increasingly fall within regulatory frameworks governing software as a medical device (SaMD), cybersecurity, data integrity, and interoperability, as defined by evolving FDA and EMA guidance. While alternative inhalation platforms, such as soft mist inhalers, have introduced patient-centric innovations, DPIs remain the most widely used breath-actuated systems and are uniquely positioned to benefit from digital augmentation. Nevertheless, technological, clinical, and regulatory challenges continue to limit widespread adoption of next-generation digital DPIs [(8)].

This review examines the current status of DPIs in the age of digital health, focusing on formulation–device–patient interactions, emerging digital functionalities, and performance evaluation strategies. Regulatory considerations specific to digitally enabled DPI combination products are discussed, and future perspectives are outlined to identify key scientific and regulatory gaps that must be addressed to enable reliable, patient-centric, and outcome-driven inhalation therapy.

CURRENT STATUS AND LIMITATIONS OF CURRENTLY AVAILABLE DPIS

Modern DPI development is advancing beyond traditional device mechanics toward systems that incorporate sensors, connectivity, and data analytics to monitor inspiratory flow, usage patterns, and adherence in real time. These digital enhancements aim to overcome long-standing challenges of DPIs such as variability in patient inhalation technique and adherence by providing actionable feedback to patients and clinicians, enabling personalized therapy adjustments and more accurate assessment of treatment response. Regulatory bodies are actively responding to this trend, recognizing software as a key component of device performance and patient safety, which leads to added requirements for software validation, data security, and lifecycle management. Clinically, early evidence suggests that digital DPIs can improve adherence and technique through reminders and user coaching, although widespread adoption is still emerging and contingent on demonstrating clear benefits in health outcomes, interoperability with electronic health records, and cost-effectiveness. As real-world data accumulate, the convergence of digital monitoring with DPI therapy is positioned to enhance disease management, support precision medicine approaches, and inform future regulatory frameworks for combination products and software-enabled therapies [8]. Despite their widespread clinical use, currently marketed DPIs exhibit considerable variability in aerosolization efficiency and lung deposition, with reported pulmonary delivery spanning a broad range. Such inconsistency in performance is primarily driven by two interrelated factors. First, strong inter-particulate cohesive forces within dry powder formulations, coupled with suboptimal inhaler design, can limit efficient powder deagglomeration and aerosol generation. Second, the reliance of DPIs on patient-generated inspiratory effort introduces a significant source of variability, as not all users are able to consistently achieve the airflow required for effective dose dispersion [8].

While notable progress has been made in formulation engineering and inhaler mechanics, the influence of patient-related factors particularly inhalation pattern, correct device handling, and long-term adherence remains insufficiently addressed. Key Challenges in inhalation therapy and digital enabled solutions in Inhalation, covering DPIs are presented in **Table 1.** Most commercially available DPIs are breath-actuated systems that require a rapid, deep inhalation to overcome device resistance and disperse the powder into respirable particles. Higher inspiratory flow rates are generally associated with improved aerosol performance; however, optimal drug delivery also depends on appropriate matching between device aerodynamic resistance and the patient's inspiratory capacity. Failure to achieve this balance may result in incomplete dose emission or increased oropharyngeal deposition [8, 9].

This limitation is especially relevant for vulnerable patient populations, including paediatric and elderly individuals, as well as patients with compromised pulmonary function, such as those with asthma, chronic obstructive pulmonary disease, or cystic fibrosis. In these groups, reduced inspiratory capacity often leads to suboptimal therapeutic outcomes. Moreover, substantial inter- and intra-individual variability in inhalation technique further undermines the reproducibility of drug delivery. In addition to physiological constraints, poor adherence and incorrect inhaler technique remain pervasive challenges. A significant proportion of patients across respiratory indications demonstrate inadequate adherence to inhaled therapies, and clinically relevant handling errors are frequently observed. Common mistakes include improper device positioning, failure to prepare the dose correctly, inadequate exhalation prior to inhalation, insufficient inspiratory effort, and omission of post-inhalation breath holding. These errors are influenced by patient-specific factors such as age, education level, comorbidities, and the quality of training provided by healthcare professionals. Collectively, these limitations underscore the need for next-generation DPI technologies capable of reducing user dependency and improving the reliability of pulmonary drug delivery [10, 11].

Table 1: Key Challenges in inhalation therapy and digital-enabled solutions in DPIs

Key challenge / digital objective	Digital and design-enabled solutions	Digital Examples
Reduction of patient handling and use errors	Development of simple and intuitive DPI designs with a minimal number of handling steps; adoption of standardized inhaler platforms across multiple therapies; implementation of digital guidance to support correct device use	Integrated digital DPIs such as Digihaler® with inhalation flow sensing; sensor-enabled DPIs providing app-based technique guidance
Improving compliance with inhalation instructions	User-friendly inhaler designs requiring limited patient training; provision of real-time or post-inhalation feedback on inhalation performance; use of visual, acoustic, or mobile application-based alerts	Digihaler® mobile application providing inhalation feedback; smart DPI prototypes equipped with pressure or flow sensors
Enhancing patient adherence to prescribed therapy	Reduction in the number of inhalations required per dose; compact and portable DPI designs; integration of digital reminders and adherence analytics	Add-on DPI sensors compatible with platforms such as Hailie®; connected DPI systems with clinician-facing adherence dashboards
Improving safety of inhaled therapies	Optimization of formulations to minimize unnecessary excipients; use of disposable or single-patient inhalers for specific indications; digital monitoring to reduce misuse and contamination risk	Single-use digital inhaler concepts; traceable DPI systems for vaccines or inhaled antibiotics
Enhancing therapeutic efficacy	Advanced inhaler designs balancing inter-particulate cohesion, dispersion energy, and lung deposition; digital verification of effective inhalation parameters	Integrated digital DPIs with inspiratory flow validation; research-stage DPIs incorporating inhalation analytics
Specialized or personalized inhalation therapy	Patient- or population-specific DPI designs tailored to inspiratory capacity and disease state; digital adaptation to individual inhalation profiles	Digital DPIs stratifying users based on inspiratory performance; smart DPI algorithms enabling patient-specific feedback
Reducing overall cost of inhaled therapy	Implementation of simple, cost-effective DPI architectures; streamlined formulation approaches; use of digital adherence tools to reduce treatment failure and healthcare utilization	Smartphone-connected DPIs improving real-world effectiveness; scalable sensor add-on technologies for existing DPI platforms

DIGITALIZATION IN INHALATION DRUG DELIVERY

Digitalization has emerged as a transformative and rapidly evolving strategy with the potential to reshape inhalation drug delivery by enabling more patient-centered, data-driven, and outcome-oriented care. Marketed, approved, under development, early research digitalized inhalation devices details are presented in Table 2. The convergence of inhalation technology with digital health tools offers realistic solutions not only for patients but also for healthcare providers, regulators, and pharmaceutical manufacturers. Digitally enabled inhalation systems can enhance clinical outcomes by improving medication adherence and reducing critical use errors. Connectivity with mobile applications allows delivery of reminders, real-time feedback, and step-by-step guidance on correct inhaler technique, thereby addressing common causes of therapeutic failure Figure 1. From a clinical standpoint, access to objective, real-time data on inhaler use and inhalation patterns enables healthcare professionals to distinguish between truly refractory disease and poor disease control arising from non-adherence or incorrect device use an especially relevant challenge in chronic respiratory conditions such as asthma, COPD, and cystic fibrosis. At a broader level, digitally captured real-world data may support health technology assessment, pharmacovigilance, and regulatory decision-making by providing insight into product performance under routine clinical use [12].

Figure 1: Schematic representation of the available current digital health functions flow of the digitalized DPIs

Digitalization also offers substantial advantages in the context of clinical development of inhaled drug device combination products. Patient-related handling errors, inconsistent inhalation techniques, and poor adherence can confound efficacy and safety outcomes in clinical trials. The integration of digital tools such as inhaler sensors, audio-based adherence monitors, connected wearables, and companion mobile applications can improve data quality by objectively capturing dosing events, inhalation parameters, physical activity, and patient-reported outcomes. This enhanced granularity supports a more accurate assessment of the true therapeutic performance of inhaled products, independent of user-related variability [13, 14].

“Smart” inhalers represent a key outcome of this digital transformation and can be broadly classified into add-on devices that externally attach to existing inhalers and fully integrated systems in which electronic modules are embedded within the device. Early developments focused primarily on recording inhaler actuation events and timestamps, enabling basic adherence monitoring. Subsequent generations introduced more sophisticated functionalities, including detection of inhalation flow, assessment of inhalation technique, audio-visual feedback to guide correct use, and cloud-based data transmission. Parallel advances were observed in intelligent nebulizer systems capable of synchronizing aerosol generation with the patient’s inspiratory cycle, thereby reducing drug wastage and improving delivery efficiency.

More recent innovations have expanded the scope of digital inhalers beyond adherence tracking. The incorporation of geolocation, environmental data, and predictive analytics has enabled identification of environmental triggers and high-risk situations for disease exacerbation. Additionally, integrated breath-actuated systems capable of registering dose delivery only upon correct inhalation have been developed to minimize technique-related errors and improve dose accountability. Collectively, these advancements illustrate the progressive evolution of inhalation devices from passive drug delivery tools to connected therapeutic systems [8,15].

Digitally enabled DPIs typically incorporate sensors such as pressure, flow, or acoustic sensors within the inhaler to capture inhalation parameters including peak inspiratory flow, inhalation duration, and timing of dose actuation. These data are transmitted via wireless connectivity (Bluetooth) to companion mobile applications, where they can be translated into actionable feedback for patients and clinicians **Figure 2.**

The most prominent commercial example is the Digihaler® platform (Teva Pharmaceuticals), an integrated digital DPI that records inhalation flow characteristics and dosing events, supports adherence monitoring, and provides feedback through a smartphone interface. Such systems exemplify the transition of DPIs into connected therapeutic platforms aligned with digital health ecosystems [14, 15]. Beyond fully integrated devices, digitalization in DPIs also includes add-on sensor technologies compatible with existing inhalers. These external modules track usage patterns and dosing frequency, offering a pragmatic approach to improving adherence without redesigning the inhaler itself. Although add-on solutions do not directly influence aerosolization performance, they generate real-world evidence that can inform clinical decision making and population level disease management.

Figure 2: Schematic representation of Digital inhaler platform with connection between patient, inhaler sensors, and healthcare provider. A). Patient self- assessment, record adherence & Inhaler use reminders; B). Personalization of care

From a development and regulatory perspective, digital DPIs increasingly fall within frameworks governing combination products and software as a medical device (SaMD). Their evaluation extends beyond traditional in vitro aerosol performance testing to include software validation, cybersecurity, data integrity, and lifecycle management. Importantly, digital DPI data can help differentiate poor disease control due to inadequate inhalation technique or non-adherence from true pharmacological non-response, a distinction that is critical in both clinical practice and clinical trials [16].

Table 2: List of marketed, approved, under development, early research digitalized inhalation devices

Device/Brand Name	Device Type	Digital Feature	Integrated or Add-On	Developer / Company	Status and Key notes
I-neb® Adaptive Aerosol Delivery (AAD®)	Nebulizer	Breath-pattern sensing, adaptive aerosol release	Integrated	Koninklijke Philips NV	Marketed; adjusts aerosol delivery to inhalation phase
Nebulizer Chronolog	Nebulizer	Actuation timestamping	Add-On	Forefront Engineering	Early smart nebulizer (first FDA-cleared)
AeroEclipse®	Jet nebulizer	Breath-actuated delivery	Integrated	Monaghan / Trudell	Marketed; improves efficiency vs conventional nebulizers

Device/Brand Name	Device Type	Digital Feature	Integrated or Add-On	Developer / Company	Status and Key notes
AKITA® / AKITA2 APIXNEB	Nebulizer (vibrating mesh)	Automated aerosol control	Integrated	Activaero GmbH	Marketed; advanced nebulization control
Doser™	pMDI	Actuation recording	Add-On	Meditrack Inc.	Legacy device tracking doses & usage
Smart Mist®	pMDI	Inhalation & technique feedback	Add-On	Aradigm Corp.	Marketed; user feedback on inhalation strength
MDILog™	pMDI	Actuation and timing data	Add-On	Westmed Technologies	Marketed; records usage history
Hailie® Sensor Range (former Smartinhaler™)	pMDI / DPI	Bluetooth dose tracking + App	Add-On	Adherium Ltd.	Widely marketed; compatible with many inhalers; clinician dashboard available
Propeller Platform	pMDI / SMI	GPS + usage + environmental data	Add-On	ResMed / Propeller Health	Marketed; linked to mobile apps and analytics
FindAir ONE	pMDI	Usage tracking + environment info	Add-On	FindAir	Marketed (EU); improves patient contextual awareness
Intelligent Control Inhaler (ICI)	pMDI	Inhalation flow monitoring	Integrated	3M Drug Delivery Systems	Early/Legacy integrated smart MDI
Digihaler® (ProAir®, AirDuo®, ArmonAir®)	DPI	Pressure sensor, dose timing, reminders, app insights	Integrated	Teva Pharmaceuticals	Marketed digital DPIs; broader “connected DPI” family (MDPI)
RS01X DPI	DPI	Inhalation parameter recording	Integrated	Research device / developer	Under development / prototype (MDPI)
USSC-03 DPI	DPI	Pressure drop sensor + adherence logging	Integrated	Research / Developer	Under development; adherence focus
Inspiromatic™ DPI	DPI	Low-flow fluidization system + data logger	Integrated	Research device	Under development; optimized for low inspiratory flow
Diskus® + HeroTracker Sensor	DPI + Add-On	Usage logging + Bluetooth	Add-On	Cohero Health / Aptar	Marketed add-on for adherence
Verihaler	DPI / pMDI	Acoustic inhalation analysis	Add-On	Research developer	Under development; acoustic PIF analytics

REGULATORY CONSIDERATION IN THE AGE OF DPI DIGITAL HEALTH

DPIs are regulated as drug device combination products across major jurisdictions, and the incorporation of digital components has further increased regulatory complexity. In the European Union (EU), DPIs fall under the remit of medicinal product legislation, with oversight by the European Medicines Agency (EMA), while the device component must comply with the Medical Device Regulation (MDR, Regulation (EU) 2017/745). A key regulatory distinction is made between integral and non-integral drug device combinations. Integral devices are those in which the medicinal product and device form a single, non-reusable entity intended exclusively for combined use, such as preloaded multi-dose or blisterbased DPIs. In contrast, non-integral devices are supplied separately and include single-dose DPIs or reusable inhalers co-packaged with the medicinal product. For integral DPI combination products, marketing authorization dossiers must comply with Article 117 of the MDR, requiring demonstration of conformity of the device component with applicable general safety and performance requirements. This is typically achieved through submission of a declaration of conformity or certification issued by a notified body. Where such documentation is not available, a detailed justification addressing the relevant MDR requirements must be included in the marketing authorization application. Non-integral devices, by contrast, must independently bear the CE (Conformité Européenne – European Conformity) mark in accordance with medical device legislation. In all cases, EMA evaluation focuses on the quality, safety, and efficacy of the medicinal product, alongside verification of device performance and usability, particularly where device functionality directly influences dose delivery.

Digitalization introduces additional regulatory considerations, particularly where software is embedded in or associated with the inhaler. Under EU law, software may be classified as a medical device if it is intended for diagnosis, prevention, monitoring, or treatment of disease, a position reinforced by European Court of Justice rulings and now explicitly reflected in the MDR. Consequently, software incorporated into digital DPIs may fall within the scope of medical device regulation, requiring appropriate risk classification, validation, and lifecycle management. Despite this, detailed, DPI-specific guidance on software evaluation remains limited at the EU level, necessitating case-by-case regulatory interpretation [17].

In the United States, the Food and Drug Administration (FDA) provides more explicit guidance for combination products and software-based medical technologies. DPIs are regulated as combination products, with primary jurisdiction typically assigned based on the product's primary mode of action. Drug-specific digital inhalers are generally reviewed via a New Drug Application, whereas stand-alone or add-on devices may follow either a drug-led pathway or the 510(k) process through the center for devices and radiological health, depending on the regulatory status of the associated drug. Software components, including mobile medical applications, are assessed under established FDA guidance for device software functions, cybersecurity, and data integrity. Nevertheless, applicants frequently face challenges due to the involvement of multiple FDA centers and the need to align pharmaceutical and digital development timelines [18].

Globally, regulatory approaches to digital inhalers remain heterogeneous. In Japan, medical devices and combination products are regulated under comprehensive pharmaceutical legislation, but no dedicated framework currently exists for digitalized inhalation products, which are reviewed on a case-by-case basis. In the United Kingdom, post-Brexit regulatory divergence has introduced additional considerations for manufacturers supplying the EU and UK markets, including requirements for conformity assessment and batch release within the relevant jurisdiction. Comparative regulatory requirements for digital dry powder inhalers across major jurisdictions are presented in Table 3.

Beyond product approval, digital DPIs raise important considerations related to data protection, cybersecurity, and patient privacy. As these devices increasingly collect real-world and potentially sensitive health data, compliance with data protection frameworks and alignment with international recommendations on digital health governance are essential. Collectively, these evolving regulatory standards highlight the need for greater international harmonization and clearer guidance to support the development, approval, and lifecycle management of next-generation digital DPIs.

Table 3: Comparative regulatory requirements for digital dry powder inhalers across major jurisdictions

Regulatory Aspect	**European Union (EMA / MDR)**	**United States (FDA)**	**United Kingdom (MHRA)**	**Japan (PMDA / MHLW)**	**India (CDSCO)**	**Canada (Health Canada)**	**China (NMPA)**
Regulatory classification	Drug-device combination product regulated primarily as a medicinal product; device under MDR (EU 2017/745)	Combination product regulated by primary mode of action	Combination product under UK medicines and medical devices law	Drug-device combination under pharmaceutical/device legislation	Drug-device combination product under Drugs & Cosmetics Act and Medical Device Rules (MDR 2017)	Combination product regulated as a drug with device oversight	Drug-device combination product regulated by pharmaceutical and device regulations
Integral vs non-integral DPI	Explicit distinction defined under EU guidance	Not formally defined; pathway determined case by case	Follows EU-derived principles	No formal distinction	Not explicitly defined; assessed case by case	No explicit distinction	No explicit distinction

Regulatory Aspect	European Union (EMA / MDR)	United States (FDA)	United Kingdom (MHRA)	Japan (PMDA / MHLW)	India (CDSCO)	Canada (Health Canada)	China (NMPA)
Primary approval pathway	Marketing Authorization Application (MAA); MDR Article 117 for integral devices	NDA for drug-led DPIs; 510(k) / De Novo possible for device-led components	MHRA marketing authorization; UKCA conformity	Pharmaceutical approval with integrated device review	New Drug Application with device evaluation; import/manufacturing license	New Drug Submission (NDS) or Supplemental NDS	Drug registration with technical device review
Device conformity assessment	Declaration of Conformity or Notified Body certificate required	CDRH review when applicable	UK Approved Body assessment for UKCA marking	PMDA technical conformity review	Device compliance under MDR 2017; registration and licensing required	Medical Device License if applicable	Device registration with NMPA
Software regulation (SaMD)	Software classified as medical device if intended for diagnosis, monitoring, or treatment	Explicit SaMD and device software guidance	Aligned with EU MDR SaMD principles	SaMD recognized but limited inhaler-specific guidance	Software regulated as medical device if clinical decision support or monitoring	SaMD guidance available; risk-based classification	SaMD regulated with increasing scrutiny
Digital functionality assessment	Evaluated for safety, performance, usability, data integrity	Detailed expectations for software validation, cybersecurity, lifecycle	Similar to EU with evolving guidance	Evaluated case by case	Evaluated based on intended use and risk	Assessed as part of drug device submission	Evaluated during technical and clinical review
Cybersecurity and data integrity	Required under MDR general safety and performance requirements	Explicit FDA cybersecurity guidance	UK cybersecurity guidance aligned with global norms	Limited explicit guidance	Emerging expectations; limited formal guidance	Explicit cybersecurity expectations	Increasing focus; compliance required
Human factors and usability	Usability engineering expected	Human factors studies required for combination products	Required as part of device evaluation	Considered during review	Considered but limited formal guidance	Human factors data expected	Usability studies often required
Clinical evidence expectations	Demonstration of quality, safety, efficacy; device performance data	Clinical and real-world evidence depending on risk	Similar to EU	Clinical evidence required depending on novelty	Clinical trial data required for new drugs/devices	Clinical data required as applicable	Local clinical data often required
Post-market surveillance	Pharmacovigilance and post-market surveillance mandatory	Medical device reporting and post-market controls	UK vigilance requirements	Post-marketing safety surveillance	Pharmacovigilance Programme of India (PvPI)	Mandatory post-market vigilance	Post-market surveillance required
Data privacy considerations	GDPR compliance mandatory	HIPAA and federal/state data protection laws	UK GDPR	National data protection laws	Digital Personal Data Protection Act (India)	PIPEDA compliance	Personal Information Protection Law (PIPL)
Regulatory maturity for digital DPIs	Moderate - high; complex but structured	High; most explicit and mature	Moderate; evolving post-Brexit	Moderate; case-specific	Emerging; evolving clarity for digital health	Moderate-high; structured digital oversight	Rapidly evolving; increasing regulatory stringency

FUTURE PERSPECTIVES OF DIGITAL DPIS

The future of digital dry powder inhalers is closely aligned with the broader evolution of digital health, precision medicine, and data-driven regulatory science. Next-generation digital DPIs are expected to progress beyond passive adherence monitoring toward intelligent, adaptive systems capable of integrating inhalation analytics, patient-specific feedback, and clinical decision support. Advances in sensor miniaturization, low-power electronics, and artificial intelligence are likely to enable real-time assessment of inspiratory flow, inhalation technique, and dose emission, allowing personalized optimization of therapy across diverse patient populations. From a clinical standpoint, the increasing use of real-world evidence generated by connected DPIs may support improved disease phenotyping, earlier identification of poor disease control, and more informed treatment adjustments. Regulatory frameworks are also anticipated to evolve toward greater harmonization, with clearer guidance on software as a medical device, cybersecurity, data integrity, and lifecycle management of digital components in combination products. Additionally, integration of digital DPIs with electronic health records, telemedicine platforms, and population health tools may facilitate remote monitoring and decentralized care models, particularly for chronic respiratory diseases. While challenges related to cost, data privacy, interoperability, and user acceptance remain, continued collaboration among device developers, pharmaceutical companies, regulators, and healthcare providers is expected to accelerate the translation of digital DPIs into routine clinical practice, ultimately enabling more reliable, patient-centric, and outcome-driven inhalation therapy [5].

CONCLUSION

Dry powder inhalers have progressed from simple breath-actuated devices to more complex drug-device platforms; however, their real-world effectiveness remains limited by formulation constraints, device resistance, and patient-dependent factors such as inspiratory flow, inhalation technique, and adherence. The integration of digital health technologies marks a significant advancement, enabling objective monitoring of inhalation behavior, adherence, and treatment use, and supporting a shift toward data-driven and personalized inhalation therapy. At the same time, digitalization introduces regulatory challenges related to software qualification, cybersecurity, data integrity, and lifecycle management, extending beyond traditional pharmaceutical requirements. Although regulatory frameworks from agencies such as the FDA and EMA are evolving to address combination products and software as a medical device, DPI-specific guidance and global harmonization remain limited. Future progress will depend on coordinated advances in device design, validated digital functionalities, regulatory science, and clinical evidence generation to fully realize the potential of digital DPIs as reliable, patient-centric, and outcome-oriented inhalation therapies in the digital health era.

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