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Complexity of Selling Orally Inhaled and Nasal Drug Product CDMO Services

Selling Contract Development and Manufacturing Organisation (CDMO) services is a complex task that demands a versatile skill set, encompassing drug development expertise, technical and analytical knowledge in drug product manufacturing, equipment familiarity, and overall selling skills. Drug-device combination products bring an additional layer of complexity due to the variety of devices, intricate supply chains, and additional manufacturing processes for filling and assembly. This complexity is heightened in inhalation (nasal/pulmonary) product development, where device variability and rigorous analytical testing are significant challenges. This article explores the intricacies of selling these services and highlights the essential attributes of an exceptional business development professional.

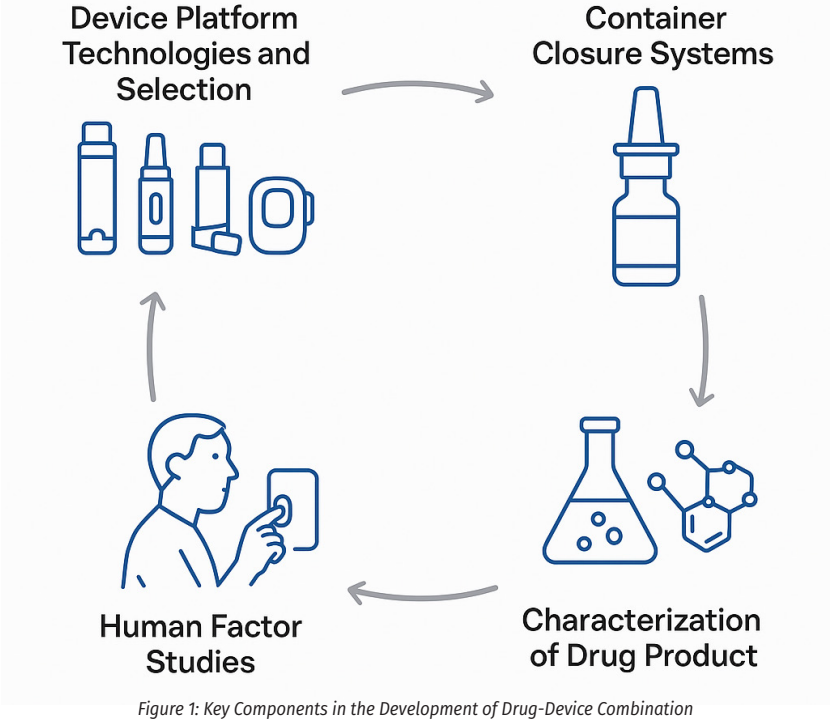


Figure 1: Key Components in the Development of Drug-Device Combination

The CDMO industry, as we know today, largely started in the late 1990s driven by multiple factors, amongst these the selling of excess manufacturing facilities by global pharmaceutical companies as older products went off patent.[1] The greatest growth driver, however, was the explosion of early-stage bio/pharma companies, thanks to the maturity of biotechnology and the availability of external funding.[1] Due to the cost of establishing owned manufacturing facilities, these emerging biopharma companies (EBPs) fuelled the CDMO industry by outsourcing all or part of their product development and/or manufacturing requirements.

Essential to the booming CDMO industry is the sales and business development (BD) function, which plays a pivotal role in driving revenue growth. Selling CDMO services is inherently complex and demands a unique blend of technical expertise and deep knowledge of the drug development process. Unlike traditional sales roles, BD professionals must understand intricate scientific concepts, regulatory requirements, and the nuances of pharmaceutical formulation and manufacturing. They must also be able to communicate effectively with cross-functional stakeholders and translate technical capabilities into strategic value. Adding to this is the need to tailor solutions amplified by the need to tailor solutions to each client's development stage, therapeutic area, and commercialisation goals, making the sales process highly consultative and relationship driven.

This complexity is significantly amplified when working with drug–device combination products. Unlike traditional pharmaceutical products such as oral solids, drug-device combination products are subject to more rigorous and multifaceted regulatory scrutiny, encompassing both drug and device requirements. As a result, navigating the development and approval process demands a deep understanding of cross-disciplinary standards. As shown in Figure 1, BD professionals must also be well-versed in drug delivery devices, the criteria for device testing and selection, and the scientific, technical, and regulatory requirements specific to drug–device combination products.

As of July 1, 2025, there were a total of 22,641 drugs (molecules) in development from pre-clinical through Phase III – thousands of these are drug-device combination products.[2] Of these, 457 were for orally inhaled and nasal drug products (OINDPs), all of which are drug/device combination products.

Figure 2: Types of Nasal Devices

1. Device Platform Technologies and Selection

OINDPs rely on a device to consistently generate an aerosol for the drug to be delivered to the patient. They are administered using a variety of device platforms, ranging from single dose to multi-dose systems designed for pulmonary or nasal delivery. Nasal administration devices support both liquid and dry powder formulations, and are available in unit-dose, bi-dose, and multi-dose formats to accommodate varying therapeutic and dosing requirements, as shown in Figure 2. Pulmonary drug delivery systems accommodate both liquid and dry powder formulations. Liquid formulations are typically administered via metered dose inhalers (MDIs), nebulisers or soft mist inhalers (SMIs) (Figure 3), while dry powder inhalation (DPI) products are delivered using a range of single-dose (sDPI) and multi-dose (mDPI) devices (Figure 4).

Figures 2–4 are generated by (Open AI, 2025) to depict common OINDP devices and are intended for illustrative purposes only.

The devices in Figures 2–4 represent a very limited subset of those that are commercialised or are currently under development. The choice of device depends on numerous factors, including drug formulation, the device's ability to deliver the intended dose, the drug's indication (emergency or chronic use), and various patient-related considerations such as patient age and ability to use the device correctly.[3] These factors can influence the lung or nasal deliverable dose, the distribution of the dose in the intended organ and, ultimately, determine the success of the treatment.[3]

For business development professionals, a thorough understanding of the full range of drug delivery devices, both approved and in development, is essential. This knowledge supports the selection of a device that aligns with the drug developer's specific needs.

Jet Nebulizer | Vibrating Mesh Nebulizer | Soft Mist Inhaler | Metered Dose Inhaler

Figure 3: Liquid Aerosol Delivery Devices

sDPI device | mDPI device | mDPI device

Figure 4: Common Dry Powder Inhalation Devices

2. Container Closure Systems

The FDA's definition of a container closure system is the sum of packaging components that together contain and protect the dosage form – these include both primary and secondary packaging.[4] Container closure systems (CCSs) are critical for maintaining the safety, efficacy, and quality of medical devices and pharmaceutical products throughout their lifecycle. The CCSs act as a barrier against contamination and degradation, ensuring product sterility and stability, and are essential for regulatory compliance.

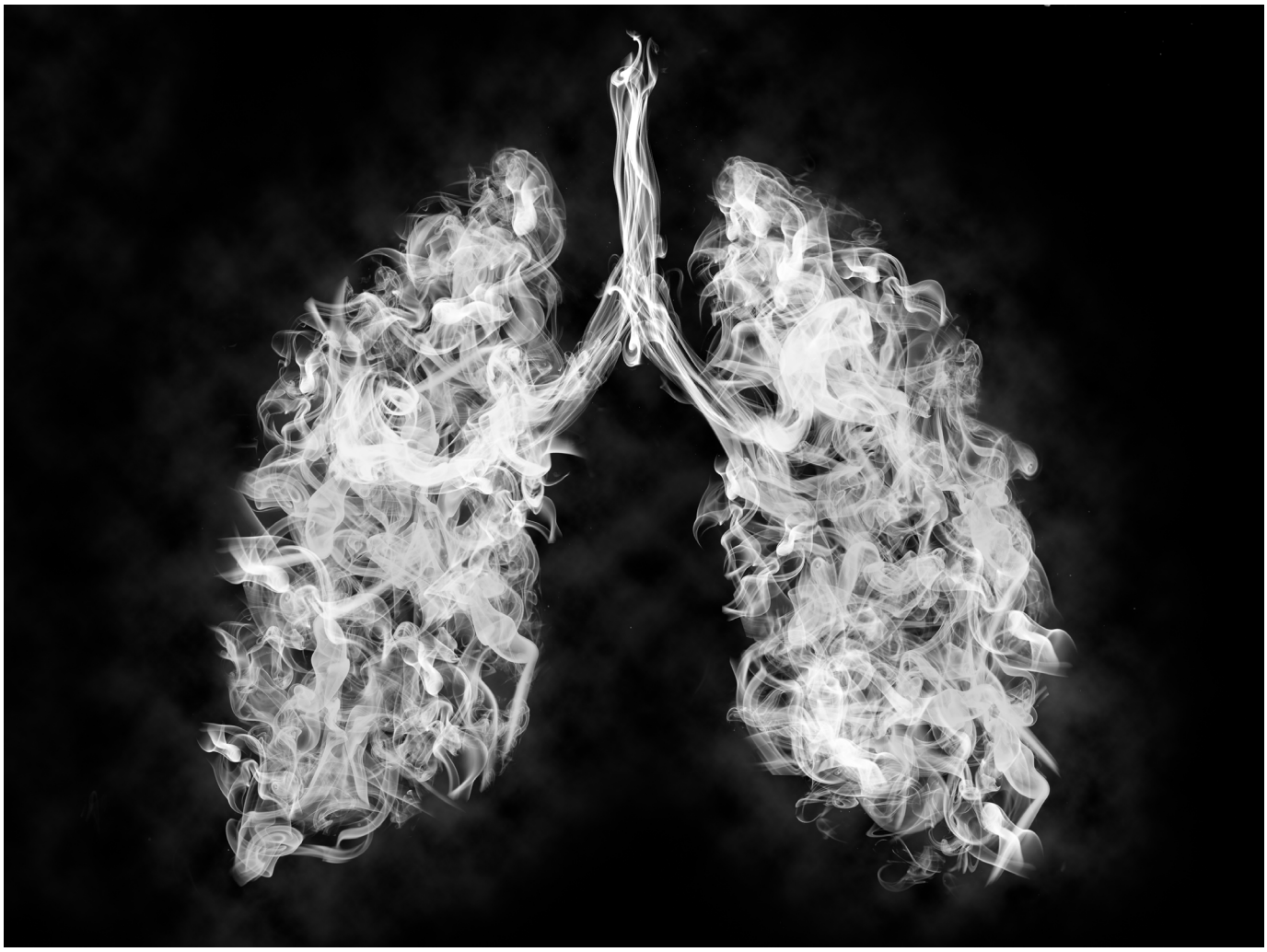
Primary packaging is considered any component that "is or may be in direct contact with the dosage form" whereas secondary packaging can provide additional protection to the product from humidity and other factors.[5,6] CCSs for OINDP products are extremely diverse and can range from blister packaging of capsules used in sDPI devices, metal or glass canisters used in SMIs, vials or nebules used for nebulisation, and the wide variety of containers, closures, and pumps used in nasal sprays. Table 1 summarises the FDA's guidance for industry regarding CSSs for DPIs, nasal sprays, inhalation solutions and suspensions, and oral tablets or capsules.

Given the potential for dosage form interactions in OINDPs, the FDA maintains heightened regulatory scrutiny and enforces more stringent requirements. For BD professionals, this translates into increased complexity due to the wide array of OINDP devices and CCSs available, some of which may be interchangeable. As such, BD professionals must not only have a deep understanding of the various CCSs types but also possess specialised knowledge of the manufacturing equipment specific to each device configuration.

Route of Administration	Degree of Concern*	Likelihood of Packaging Component-Dosage Form Interaction	Primary Packaging (Examples)	Protective Packaging (Secondary Packaging)
Inhalation powders	High	Medium	Foil pouch, blister device	Overwrap, carton, foil
Inhalation aerosols sterile powders and solutions	High	High	Container, closure, pump, and any protective packaging, if applicable	Foil overwrap
Nasal aerosols and sprays	High	High	Container, closure, pump, and any protective packaging, if applicable.	Foil overwrap, blister
Oral tablets and oral capsules	Low	Low	Plastic (usually HDPE) bottle with a screw-on or snap-off closure, pouch or blister package	Carton

*Refers to the level of FDA of concern given to the nature of the packaging components that may come in contact with the dosage form or the patient.

Table 1: FDA Guidance for CCSs for DPIs, Nasal Aerosol and Sprays and Inhalation Aerosols Sterile Powders and Solutions[4,5,6]



3. Characterisation Studies of OINDP Drug-Device Products

Product characterisation for OINDP is a crucial aspect of development, ensuring the product's quality, performance, and ability to deliver the drug effectively to the lungs or nasal cavity. This involves a range of studies to understand how the drug formulation and device interact and how the product performs under various usage conditions. Important components of these studies include drug product characterisation testing, stability testing and release testing.

Table 2 summarises the tests specific to OINDPs, which are designed to demonstrate the product's robustness and performance, and to support labelling instructions related to proper use (e.g., storage, cleaning, shaking.)[5,6] These tests are not applicable to oral solid dosage forms, as they are unique to drug-device combination systems.

Tables 3 and 4 provide a comparison of stability and release testing requirements needed for oral solid dosage forms and OINDPs.

Test	Dry Powder Inhalation	Nasals
In-Use Period	✓	N/A
Temperature Cycling	✓	✓
Priming and Repriming	✓	✓
Effect of Patient Use	✓	N/A
Effect of Orientation of the Device on Delivered Dose	✓	✓
Drug Deposition on Mouthpiece and / or Accessories	✓	N/A
Cleaning Instructions	✓	✓
Profiling of Actuation Near Device Exhaustion / Tail off	✓	✓
Effect of Flow Rate on Performance	✓	✓
Robustness	✓	✓
Effect of Resting Time	N/A	✓
In Vitro Dose Proportionality	N/A	✓
Effect of Storage on the Particle Size Distribution	N/A	✓
Plume Geometry	N/A	✓
Preservative Effectiveness and Sterility Maintenance	N/A	✓
Photostability	N/A	✓
Stability of Primary (Unprotected) Package	N/A	✓

Table 2: Drug Product Characterisation Studies[5,6]

Test	Oral Solid	DPI	Nasal (Liquid)	Nasal (Powder)
ID	✓	✓	✓	✓
Appearance	✓	✓	✓	✓
Assay/RS	✓	✓	✓	✓
Dissolution	✓	N/A	✓	✓
Content Uniformity	✓	✓	✓	✓
Microbial Limits	✓	✓	✓	✓
XRPD	✓	✓	N/A	N/A
APSD	N/A	✓	N/A	N/A
FPM (HIAC)	N/A	✓	✓	✓
Delivered Dose	N/A	✓	✓	✓
Impurities and Degradation Products	N/A	✓	✓	✓
Water/Moisture Content	N/A	✓	✓	✓
pH	N/A	N/A	✓	✓
Preservatives and Stabilising Excipients Assay	N/A	N/A	✓	✓
Leachables	N/A	N/A	✓	✓
Osmolality	N/A	N/A	✓	✓
Particulate Matter	N/A	N/A	✓	✓
Net Content	N/A	N/A	✓	✓
Weight Loss	N/A	N/A	✓	✓
Actuation Force	N/A	N/A	✓	✓
Fill Weight	N/A	N/A	✓	✓
Spray Content Uniformity	N/A	N/A	✓	✓
Plume Geometry	N/A	N/A	✓	✓
Pump Delivery	N/A	N/A	✓	✓
Droplet Size Distribution	N/A	N/A	✓	✓
Spray Pattern	N/A	N/A	✓	✓
Viscosity	N/A	N/A	✓	✓
Total	**7**	**10**	**22**	**22**

Table 3: Comparison of Stability Testing Requirements (Oral Solids vs. OINDPs)[5,6,7]

OINDP products require comprehensive testing to ensure the safety and efficacy of both the drug and its delivery device, as well as their interaction. This is illustrated in Tables 2–4, which highlight the significantly more extensive testing requirements for OINDPs compared to oral solid dosage forms. Not only are these tests more numerous, but they also tend to be more complex and costly. As a result, BD professionals must also be well-versed in all relevant testing protocols to effectively guide drug developers through each stage of the development process.

4. Human Factor Studies

Human Factor (HF) studies are required by the FDA to demonstrate that the device in a combination product can be used safely and effectively.[8] The term describes the usability of devices and how it "determines the efficacy, efficiency, and the ease of learning and satisfaction of the user".[8]

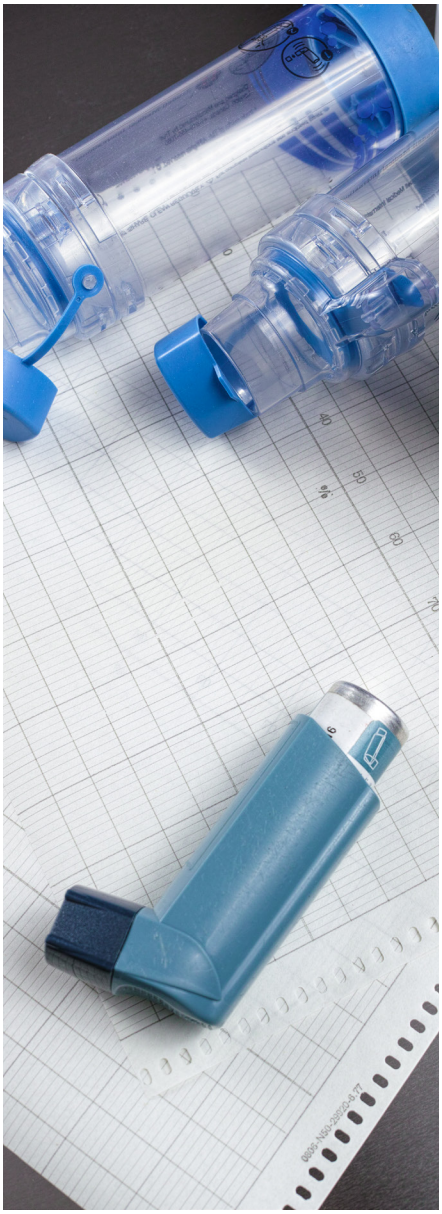
Not all CDMOs offer HF study services. For those that do, the BD professional will guide the client through the process, leveraging their expertise to align HF study offerings with the client's needs. For CDMOs that do not provide HF studies in-house, the BD professional will facilitate the process by coordinating the manufacturing, compliance, and logistics of the drug-device product for HF testing at a third-party provider.

5. Conclusion

The role of BD professionals is vital in the highly competitive and innovative CDMO market. Those focused on OINDP development and manufacturing face even more demanding tasks due to the unique and complex challenges these drug-device products entail.

Beyond their core responsibilities, BD professionals must possess a deep understanding of the drug delivery device landscape, including device design, functionality, and therapeutic compatibility. Moreover, they need to be familiar with the evaluation and selection processes for these devices, along with the intricate scientific, technical, and regulatory frameworks that govern drug-device combination products.

A highly skilled BD professional, especially in the inhalation field, is a valuable asset



Test	Oral Solid	DPI	Nasal (Liquid)	Nasal (Powder)
ID	✓	✓	✓	✓
Appearance	✓	✓	✓	✓
Assay/RS	✓	✓	✓	✓
Dissolution	✓	N/A	N/A	N/A
Content Uniformity	✓	✓	N/A	N/A
Microbial Limits	✓	✓	✓	✓
Valve Delivery (Shot Weight)	N/A	✓	N/A	N/A
Net Content (Fill) Weight	N/A	✓	N/A	N/A
Hardness	✓	N/A	N/A	N/A
Friability	✓	N/A	N/A	N/A
XRPD	✓	N/A	N/A	N/A
APSD	N/A	✓	N/A	N/A
FPM (HIAC)	N/A	✓	✓	✓
Osmolality	N/A	N/A	✓	✓
Delivered Dose	N/A	✓	✓	✓
pH	N/A	N/A	✓	✓
ID	N/A	✓	✓	✓
Spray Content U	N/A	N/A	✓	✓
Plume Geometry	N/A	N/A	✓	✓
Pump Delivery	N/A	N/A	✓	✓
Droplet Size Distribution	N/A	N/A	✓	✓
Spray Pattern	N/A	N/A	✓	✓
Viscosity	N/A	N/A	✓	✓
Pump Delivery	N/A	N/A	✓	✓
Droplet Size Distribution	N/A	N/A	✓	✓
Spray Pattern	N/A	N/A	✓	✓
Viscosity	N/A	N/A	✓	✓
Total	**9**	**11**	**15**	**15**

Table 4: Comparison of Release Testing Requirements (Oral Solids vs. OINDPs)[5,6,7]

to any CDMO operating in this space. They play a pivotal role in cultivating successful, collaborative partnerships – effectively balancing the priorities of both the CDMO and the client to ensure mutual success.

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