

When the Ground Shifts, So Must the Materials

Why converging regulation, sustainability and biologics are rewriting the specification for pharmaceutical materials – and why no company will solve it alone

The pharmaceutical industry is experiencing not one disruption but several at once. PFAS restriction, the propellant transition, expiring device patents and the relentless rise of biologics are colliding – and each is quietly asking the same question of the components that touch our medicines. The answer will not come from a single supplier, but from an ecosystem willing to innovate together.

Walk the halls of CPHI or the Drug Delivery to the Lungs (DDL) conference this autumn and one theme follows you from stand to stand: change. For two decades the materials in our inhalers, injectors, vials and filling lines were treated as settled science. That stability is ending. A cluster of regulatory, environmental and clinical pressures is arriving at once, and beneath every one lies the same question: is the material of construction still fit for what we now ask of it?

The honest answer is rarely “exotic materials everywhere.” For most components, metals, elastomers and commodity plastics remain perfectly adequate, and high-performance polymers have historically been reserved for a device’s few genuinely demanding corners – the high-pressure dosing chamber of a soft mist inhaler being the classic example. What is changing is that those corners are multiplying. A useful rule of thumb: when three demanding requirements must be met at once – strength, say, with chemical inertness and a tight, stable tolerance – a specialist polymer such as PEEK (polyetheretherketone) begins to earn its place. It is worth holding that test in mind through what follows – asking not only what each pressure breaks, but what might quietly fix it.

PFAS: From the Seal to the Coated Stopper

Fluoropolymers such as PTFE and PVDF are everywhere in pharmaceutical operations – in valve seats, seals, gaskets and O-rings on filling lines, in non-stick coatings, and, critically, in



Figure 1: Inhalers, injectors and line components – the materials of construction now under simultaneous regulatory, clinical and environmental pressure.

the spray-coated stoppers and plungers that protect injectable biologics. As PFAS restriction tightens across Europe, forward-looking teams are mapping where those chemistries sit in their bill of materials. Substitution is not uniform: where PTFE is chosen for its lubricity and non-stick behaviour, it is hard to match without real development work. But where a fluoropolymer is doing a sealing or chemical-resistance job, credible non-fluorinated options exist. PEEK, for example, is used for seals, valves and connectors across temperature extremes – from cryogenic handling to high-temperature aseptic processing – and its very low leachables suit it wherever purity in contact with the drug matters most. The lesson: a bill of materials can be unpicked function by function, not all at once.

The Propellant Transition

Greenhouse gas emissions from the pressurised metered-dose inhalers (pMDIs) segment account for a significant proportion of the carbon emissions from the inhalers devices (ref – Asthma and Lung UK. How inhalers affect the environment. Available at: <https://www.asthmaandlung.org.uk/conditions/asthma/how-inhalers-affect-environment>); however, for 30% of patients, it is not possible to replace them with other inhalers (source – IPI Issue 3 of Volume 17 from Autumn 2025). With the Kigali Amendment entered in force in 2019, the segment is undergoing its second most significant transition towards

sustainability since the Montreal Protocol in the 1980s, moving to low-global-warming-potential propellants such as HFO-1234ze(E) and HFA-152a.¹ Each differs from the incumbents in density, vapour pressure and solvating power, altering spray force, valve behaviour and – crucially – the extractables and leachables profile of every polymer and elastomer it touches.² In short, changing the propellant can silently change the requirements of the valve, the seal and the canister lining. Here the material, not the propellant, becomes the variable worth changing: a component that stays inert against a more aggressive chemistry, and sheds few leachables of its own, absorbs uncertainty that would otherwise land on the valve and seal. It is one reason PEEK is increasingly discussed for canister linings, valve components and coatings that must hold up against an unfamiliar propellant.

Patent Cliffs and the Pull Toward Precision

As originator patents lapse, the differentiated engineering migrates from the molecule to the device – and to the materials that make it work. Soft mist inhalers are a case in point: by using a mechanical spring rather than a propellant, they sidestep the propellant debate while improving lung deposition, but that benefit is bought with engineering. The dosing components must withstand pressures of the order of hundreds of bar, hold micron-level tolerances, and remain inert in direct contact with the formulation.



Figure 2. Larger volumes and higher viscosities demand more force through finer needles – pushing conventional device materials to their limits.

From Material Supplier to Innovation Partner

By this stage PEEK has surfaced in almost every story, which is rather the point: it is not a universal answer but an unusually versatile tool in the kit, combining strength, chemical resistance, low moisture absorption, dielectric stability and high-temperature performance with injection-moulding to micron tolerances – and, as a non-fluorinated thermoplastic, standing in for certain fluoropolymers in specific sealing and thin-film roles.⁵ What turns those properties into advantage is evidence: a pharmaceutical-contact grade tested against USP Class VI, USP <87> and USP <661> reassures manufacturers that the part will meet end-part compliance testing, reducing risk and, potentially, time to market. The clearest proof is already in patients' hands. In one class-defining soft mist inhaler, a metal dosing chamber that had to withstand roughly 340 bar was re-imagined in PEEK, preserving the performance of metal while remaining safe in direct contact with the formulation⁶ – and, on a life-cycle basis, consolidated moulded parts can carry a markedly lower carbon footprint than the machined metal they replace. The more important shift, though, is one of posture. The old model – specify a material, buy it by the kilogram, move on – sits poorly with an era in which changing one component can trigger extractables and leachables re-testing, stability restarts and regulatory resubmissions across a whole product. What is needed is not simply a supplier but a development partner: one that brings decades of evidence from other regulated sectors and engages early enough to de-risk the choice rather than merely fulfil it.

It Takes an Ecosystem

None of these pressures can be solved by any single link in the chain: the drug owner controls

This is a corner where high-performance polymers already have a quiet track record: the dosing components of a class-defining soft mist inhaler were among the first places PEEK was adopted, because it could hold those tolerances under pressure, resist wear across thousands of actuations, and replace an assembly of small machined metal parts with one consolidated moulded component – taking out cost, weight and machining steps. As precision devices proliferate, that experience becomes more relevant, not less.

The Biologics Effect on Injectors

Nowhere is the pressure more visceral than in injectable delivery. The biologics boom – monoclonal antibodies, bispecifics and GLP-1 therapies – is pushing self-injection well beyond its comfort zone. Where autoinjectors once delivered up to 1 mL of a low-viscosity solution, developers now target 2.0–2.25 mL of formulations reaching 50 centipoise or more.³ Higher volume and viscosity mean one thing mechanically: more force, applied for longer, through finer needles. Device engineers describe conventional drive springs as reaching their practical limits, prompting ultra-thin-wall cannulae and alternative energy sources.⁴ Two things follow, and both play to a polymer's strengths. First, thin-walled, load-bearing parts need a high strength-to-weight ratio, and properties can be tuned to the task: carbon-fibre-reinforced PEEK adds stiffness and strength without adding bulk, where every millimetre of device real estate is contested. Second, as these devices migrate from clinic to kitchen table, they must stay robust and dimensionally stable through drops, temperature swings and repeated use. Connectivity compounds

it: as devices gain onboard electronics for adherence telemetry and charging, designers want to cut metal content, free up space and manage the electrical interface – another set of simultaneous demands a strong, dimensionally and dielectrically stable polymer can reconcile.

Five Pressures, One Question

Step back and the pattern is unmistakable. The surface questions differ – can our seals and packaging be re-specified? our valves tolerate new chemistries and forces? our components survive higher forces and viscosities? – but underneath lies the same one: are the materials of construction still fit for purpose, and if not, what can safely take their place? The recurring answer: a material chosen to satisfy several demands at once, not to optimise just one.



Figure 3. High-performance polymers earn their place where three or more demanding requirements – strength, chemistry, precision, temperature, compliance – must be met at once.

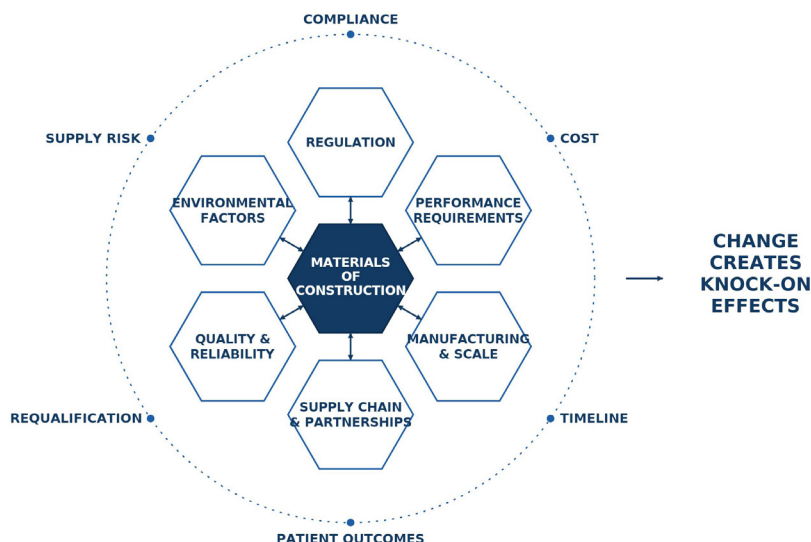


Figure 4. Controlled innovation: change coordinated across drug owner, device developer, CDMO, packaging and material partners – so the whole ecosystem is enabled to adapt.

the formulation and dossier, the device developer the mechanism, the CDMO scale-up and fill-finish, the suppliers the parts that touch the drug, and the material scientist what a given polymer can, and cannot, be asked to do. Re-specifying a material ripples through all of them at once – attempt it in isolation and you invite delay, failed qualification or supply risk; approach it together and disruption becomes orderly progress. That is the essence of controlled innovation: change introduced deliberately, evidenced thoroughly and coordinated across the value chain, so uncertainty is reduced at every step rather than transferred downstream.

weather system, whose common denominator is the component that touches the medicine. Teams that treat material selection as a strategic, early and collaborative decision – not a late procurement line item – will convert that turbulence into differentiated, compliant and more sustainable products. The industry does not have to face this alone: the materials, the evidence and the manufacturing routes largely exist. Handled deliberately and early, this upheaval becomes the moment the ecosystem chooses to innovate in a controlled way – moving from disruption to genuine confidence about the medicines, and the patients, that depend on getting the materials right.

From Disruption to Confidence

The market is telling us, from several directions, that materials of construction can no longer be an afterthought: PFAS, propellants, patents and biologics are not separate storms but one

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