

The Elastomeric Stopper as Part of a System: *Building Confidence Through Worst-Case Scenario Testing*

International Pharmaceutical Industry Journal speaks with Edouard Pagnoud, Product Line Manager – Vial Stoppers at Aptar Pharma, about the evolving expectations for elastomeric closures under USP <382>. The discussion explores the importance of evaluating closures as part of the complete Container Closure System (CCS), the value of worst-case scenario testing, and how system-level performance data can help pharmaceutical manufacturers build robust, risk-informed qualification strategies for sterile injectable products.

With USP <382> establishing a performance-based evaluation framework for elastomeric closures in sterile injectable production, passing a specification test is no longer sufficient. The standard requires evaluation within the full Container Closure System (CCS) – vial, stopper, cap, drug formulation, and access devices, and demands that performance be demonstrated not only at release, but throughout the product's entire shelf life and point of use. Edouard Pagnoud, Product Line Manager for Vial Stoppers at Aptar Pharma, explains Aptar Pharma's approach to providing pharmaceutical partners with confidence in how their products will perform when it matters most, including under worst-case scenarios.

Under USP <382>, primary responsibility for CCS qualification rests with the drug product manufacturer. What drives Aptar Pharma's decision to evaluate closures under worst-case conditions, beyond what is required of a primary packaging supplier?

Edouard: It comes down to a deliberate choice about the scope of our role. As an elastomeric closure solutions provider, our obligation is to deliver closures that meet performance requirements under recommended conditions. We have chosen to go further. Aptar Pharma evaluates its stoppers under worst-case scenarios, larger needle gauges, repeated multi-piercing, and aggressive sterilisation, to map precisely where performance begins to change.

Fragmentation and self-sealing results are not just compliance markers; they

tell you how the stopper's elastomeric structure actually responds under puncture stress. A drug manufacturer who reads those results that way can build a risk assessment on real mechanistic understanding rather than assumptions, and that changes every packaging decision they make downstream.

Which stopper properties most directly drive functional performance, and how do formulation, sterilisation, and geometry each contribute?

Edouard: Hardness and elasticity are the primary material drivers, determined by the rubber formulation and further influenced by sterilisation. Higher hardness increases penetration resistance, modifying piercing force, fragmentation behaviour, and self-sealing response. Gamma sterilisation amplifies these effects by hardening the elastomer. Within our portfolio, 6720GC (Bromobutyl) exhibits higher inherent hardness than 6422GS (Chlorobutyl). Geo-

metry adds a further dimension: increased piercing zone thickness raises piercing forces and increases sensitivity to needle gauge and repeated access. These effects are most significant under worst-case conditions; within intended use, all configurations remain fully compliant.

These parameters do not act in isolation. How does Aptar Pharma's worst-case programme characterise their combined effects on stopper performance?

Edouard: Under intended-use conditions, these interactions do not compromise stopper functionality; each configuration meets performance requirements as a system. Under worst-case conditions, however, combined effects become significant: material hardness, stopper geometry, and access conditions interact to amplify impacts on piercing force, fragmentation, and self-sealing. Mapping these combined effects, not just individual parameters in isolation, is precisely the value of a system-level evaluation approach.



Figure 1: Functional Testing of Rubber Stopper Components



Container Closure Integrity (CCI) must be maintained from sterilisation through to point of use, not simply confirmed at release. What does a lifecycle-based evaluation change about how manufacturers approach closure qualification?

Edouard: Release testing provides a snapshot; lifecycle evaluation tracks how the system performs under conditions it will actually encounter. A closure must protect the drug product against both microbial

contamination and environmental factors – oxygen, humidity, and light – throughout its entire shelf life. By considering the full system – vial, stopper, cap, and access tools – and how functional properties evolve across sterilisation processes, storage conditions, and access scenarios, a lifecycle approach ensures consistent performance from delivery through to point of use. This is the kind of evidence-based qualification that USP <382> now makes obligatory for the industry.

How should development teams integrate these findings into their USP <382> qualification strategy, from early-stage selection through to commercial supply?

Edouard: Treat this data as a development input, not a late-stage compliance output. Understanding how your CCS responds to different sterilisation modes, needle types, and access conditions enables informed packaging decisions before they become costly to change.

USP <382> creates the obligation to think systemically. Aptar Pharma provides the data and the technical partnership to make that thinking actionable from day one.

General Overview

Aptar Pharma's closure solutions for injectable drug vials is supported by a comprehensive in-house testing strategy designed to exceed regulatory requirements. By characterising stopper performance across a comprehensive matrix of conditions, formulations, sterilisation modes, needle gauges, stopper geometries, and multi-piercing sequences, Aptar Pharma provides pharmaceutical manufacturers with the evidence base needed to implement USP <382> with confidence and to build robust, risk-informed qualification strategies.

We will gladly provide you with further information on request. https://aptar.com/en-us/contact-us?utm_campaign=52778154-USP382-IPI-0%2F2026&utm_source=tradejournal&utm_medium=IPI



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Edouard Pagnoud is Product Line Manager for Vials Solutions at Aptar Pharma's Injectables Division. A graduate in Chemical Engineering from Université Technologique de Compiègne, he brings over ten years of experience across the cosmetic and pharmaceutical industries. Before joining Aptar Pharma in 2021, he held technical and industrial roles focused on product development and lifecycle management. In his current position, Edouard oversees the vials solutions platform and supports customer development projects across the injectable packaging value chain.