

Taking Risk Out of Device Development Through Regulatory Strategy

Sandra Schaerer and Karolina Snajdarova are Regulatory Affairs Managers at Ypsomed. We spoke with them about where programmes actually slow down on the device side, and what a different approach looks like.

Device development isn't usually where sponsors expect their programme to stall, but it often does. Why?

Sandra Schaerer: Because the risk tends to be invisible until it isn't. Sponsors understandably focus first on the molecule, formulation, and clinical strategy, and the device gets treated as something you sort out later. The issue is that "later" is exactly when your options narrow. If you discover a regulatory gap when the design is already fixed, closing it means creating additional documentation, repeating verification work, adding usability and bridging studies, and losing time. That is why regulatory thinking needs to start early, while there's still room for flexibility in the device and submission strategy.

What does that early regulatory involvement look like in practice?

Sandra Schaerer: We run what we call a regulatory radar, continuously tracking global regulatory requirements and authorities' feedback, and contributing to standards like the ISO 11608 series, so that when requirements change, we've anticipated them rather than absorbed them. For sponsors, that means fewer late surprises, stronger device documentation, and submissions that behave more predictably. This is especially important in fast-moving market areas such as biologics, biosimilars, GLP-1s, peptides, and therapies shifting toward at-home administration. That predictability and readiness have real commercial value.

So the starting point is getting ahead of regulatory risk. What's the foundation that actually makes that possible?

Sandra Schaerer: The foundation is the use of well-established and mature platform

devices. When the device platform is already well characterised and supported by validation and verification evidence, manufacturing experience, expertise in risk management and human factors, and is also based on current regulatory requirements, a new project doesn't need to start development from scratch.

It also means that when something shifts, whether a formulation moves to a higher viscosity or a fill volume change, you're not creating a compliance burden on top of an already complex programme. You're working within a known platform context.

And then there's the weight of track record. More than 40 years of self-injection experience, over 80 combination products, and devices that already support more than eight million people across multiple therapeutic areas. Regulators and patients have seen these devices perform. That's not just a credential. It's a form of de-risking that no amount of documentation alone can replicate.

GLP-1s and peptide therapies are driving significant demand right now. What does Ypsomed bring to that part of the market?

Sandra Schaerer: Something that shapes how we work across the whole pen business, not just one part of it. For our reusable pen platforms, YpsoPen and ServoPen, we hold full legal manufacturer responsibility. This means we deal directly with notified bodies and competent authorities, are responsible for certifications and approvals, as well as for the entire device lifecycle. Branding customisation is, of course, determined by the customer.

In volume terms, though, most of the pen programmes we support are integral combination products like UnoPen or YpsoMate autoinjectors. That's the more typical model, and it's where the depth of our own experience from reusable pens pays off. Because we've lived the full regulatory lifecycle from the inside, we know what authorities look for, where submissions tend to meet resistance, and

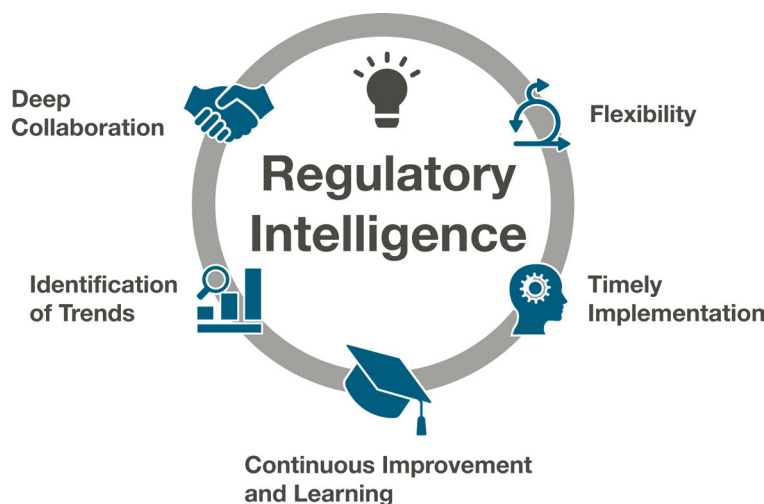


Figure 1: Regulatory activities and competences at Ypsomed



Figure 2: Ypsomed's portfolio consists of 15 platforms, supporting 80+ combination product launches

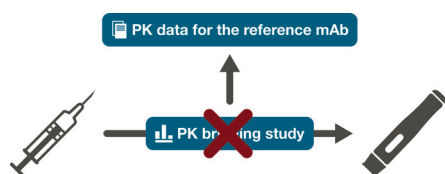


Figure 3: MIDBA approach enabling omission of a dedicated PK bridging study between manual injection and autoinjector

how to structure documentation to anticipate that. Our partners on combination product programmes benefit from that knowledge directly. It's built into how we approach the device-related part of the submissions, input on regulatory strategy, risk management evidence, verification and validation data, human factors input, labelling support, and lifecycle impact assessments. This distinction is important. We do not replace the MAH or the customer's regulatory responsibility, but we help ensure that the device part is ready, consistent, and aligned with the relevant regulatory expectations.

The foundations of that expertise were built over more than 40 years in diabetes care. Bringing insulin delivery and connected diabetes solutions to market required us to navigate approvals, lifecycle management, risk management, human factors requirements, post-market surveillance, and evolving regulatory expectations across multiple jurisdictions. That experience now informs how we support today's GLP-1 and peptide programmes, from clinical development through commercialisation.

Moving to autoinjectors, traditionally timelines here can stretch. Is that still true?

Karolina Snajdarova: It doesn't have to be. With pre-configured clinic-ready devices that are already pre-qualified and pre-verified, you can cut a standard development window in half to around six months. The lengthy device development timelines stop being what holds up your clinical submission. Because the devices cover the wide range of fill volumes and viscosities, you can enter Phase IIb easily, then pick or switch between devices as the formulation evolves. At the cost of a Phase IIb or III programme, that kind of flexibility matters enormously.

But the timeline is only part of the story. The less-discussed cost-related aspect is the PK bridging study. Under the traditional model, introducing an autoinjector late in development requires a pharmacokinetic study to bridge the manual injection used early in the trial to the autoinjector. Short development timelines enable the use of

the pre-developed autoinjector early in the clinical trial, which may eliminate the need for a PK bridging study. This allows you to reach the market sooner and with lower overall spending.

There's a specific bridging approach that takes this further in the EU. What does MIDBA change for a sponsor?

Karolina Snajdarova: MIDBA, the molecule-independent device bridging approach qualified by the CHMP (Committee for Medicinal Products for Human Use), is one of the most significant regulatory advancements in recent years. In the EU, under specific conditions, you may omit a dedicated PK bridging study between manual injection and an autoinjector altogether for new monoclonal antibodies. Instead, you may use PK comparability data from reference monoclonal antibodies. This scientifically-justified and evidence-based approach supports efficiency, time-to-market, and patient access to innovative treatments.

The validity of the MIDBA has been demonstrated using the Ypsomate 2.25mL and 1.0mL autoinjector and with omalizumab and gantenerumab as reference mAbs. The pharmaceutical companies using the Ypsomate platforms can leverage this approach with reduced regulatory uncertainty to lower development burden, and shorten the development timelines for new drug products.

Applying the MIDBA to a different autoinjector and/or changing any of the proposed specifications need to be supported by additional data and/or justification, along the lines presented for Ypsomate 2.25 and 1.0 in the qualification opinion. Sponsors using alternative platforms may therefore

need to establish an additional reference evidence base before leveraging a MIDBA-based strategy across similar mAbs.

And what exactly are the specific conditions which need to be met in order to omit a dedicated PK bridging study?

Karolina Snajdarova: The qualification opinion for MIDBA clearly defines the conditions that must be met for MIDBA to be accepted. When transitioning from manual injection to an autoinjector, the monoclonal antibody, dose and formulation, injection volume (0.5–2 mL), and injection site(s) must remain unchanged. The exposed needle length was determined as an additional potential factor that influences the outcome of the pharmacokinetic (PK) comparability study and must remain between 4 and 8 mm. The monoclonal antibody must demonstrate slow absorption after subcutaneous (SC) injection and have similar physicochemical properties to at least one reference mAb. MIDBA is a good example of the kind of efficient, science-led approach with the potential to influence future global regulatory frameworks and facilitate acceptance of similar approaches in other markets.

Which brings us to the geography question. Regulatory requirements may differ from market to market. How do you maintain a consistent approach while navigating different regions?

Sandra Schaefer: The principle is the same in every region: get ahead of requirements rather than react to them. What changes is the regulatory landscape, and that's where local expertise becomes critical. China is a good example. Success there requires more than understanding global regulatory principles.

Two Wings. One Partnership.



Figure 4: Ypsomed's "two wings" framework in China

You also need people on the ground who understand local requirements, expectations, and regulatory processes. Our local regulatory team helps multinational companies translate global development programmes into submissions that meet Chinese requirements, while supporting Chinese companies as they prepare products for international markets.

That local commitment extends beyond regulatory expertise. In June 2025, we opened our manufacturing facility in Changzhou, built to global standards and certified to ISO 13485 by TÜV SÜD. Together with our local teams, it demonstrates our long-term investment in supporting customers in one of the world's most important pharmaceutical markets. The same model applies across our global network. We combine local regulatory

knowledge with globally consistent quality and development standards, helping partners coordinate programmes across the US, Europe, China, Japan, and other markets without having to navigate each region in isolation.

So if you pull all of this together, platforms, regulatory strategy, methodology, global footprint, what's the single thing a senior leader should take from it?

Sandra Schaerer: That the device should not become a bottleneck in a development programme. Everything we've talked about is in service of the same idea: make the device predictable, so you can focus on the drug development. Proven platforms mean you're not re-proving fundamentals. A continuous

regulatory thread from concept to end of life means you're not absorbing surprises. A footprint that now spans Europe, Asia, and, from 2027, a US site at Holly Springs means you're not re-engineering your approach for each market.

What partners ultimately rely on is the combination: depth of collaboration and expertise, the insight that comes from running a high volume of submissions, and the agility to implement new requirements quickly. In a market that never stands still, that's what turns complexity into opportunity.



**Karolina
Snajdarova**

Karolina Snajdarova is Regulatory Affairs Manager, Associate Director and Team Lead Autoinjectors at Ypsomed. She is responsible for regulatory affairs for the company's autoinjector platforms and provides strategic regulatory support for customer-specific projects, including global registration activities, and supports a variety of corporate strategic initiatives. Karolina holds a Master's degree in Chemistry for Medical Applications. She has a strong background in analytical chemistry and extensive regulatory expertise in various product categories.

Email: karolina.snajdarova@ypsomed.com



**Sandra
Schaerer**

Sandra Schaerer is Regulatory Affairs Manager at Ypsomed, supporting strategic regulatory projects for pen injectors and drug-device combination products. Her regulatory career began in the pharmaceutical sector, preparing CTDs and managing medicinal product submissions, before expanding into MedTech. Her expertise spans MDR CE marking, Article 117 assessments, FDA CFR regulations, and global market registrations. With a background in chemistry and bioprocess engineering, she now focuses on lifecycle management, technical documentation, and guiding cross-functional teams.

Email: sandra.schaerer@ypsomed.com

Making the complex feel straightforward.



**Over 40 years dedicated to selfcare
and self-injection solutions.**

- More than 80 combination products and 24 indications served, covering both originators and biosimilars.
- Improving the quality of life of over 8 million people around the globe.
- Over 130 large, medium and small biopharma and biotech customers worldwide.
- Scalable business models for clinical trials and full-scale production.
- 100% electricity from renewable sources since 2021.



**For more information visit
www.ypsomed.com or scan
the QR code**

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



**Edouard
Pagnoud**

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.

The Global Harmonisation of Contamination Control Strategy Regulations and Enforcement

Holistic, risk-based contamination control and risk management expectations have evolved from a regional regulatory expectation to a globally recognised cornerstone of sterile pharmaceutical manufacturing. Regulatory authorities and standards organisations are increasingly converging on a risk-based, lifecycle approach to proactive contamination prevention, driven by the need to ensure product quality, patient safety, and supply continuity. Recent updates to key frameworks including ICH Q9(R1), EU GMP Annex 1, PIC/S PE 009, and WHO Technical Report Series (TRS) 1044 reflect a shared emphasis on end-to-end contamination control strategies that extend across facility design, manufacturing operations, supplier management, environmental monitoring, and ongoing process oversight.

This global harmonisation signals a shift away from traditional, compliance-focused assessments toward evaluations of how effectively manufacturers identify, mitigate, and continuously manage contamination risks throughout the product lifecycle. Regulatory inspections increasingly scrutinise the robustness of risk management practices, the effectiveness of supplier oversight programmes, the investigation of recurring deviations, and the scientific justification underpinning contamination control decisions. Concurrently, international standards and compendia bodies, including ISO and USP, are embedding lifecycle contamination control principles into evolving industry guidance, further reinforcing expectations for proactive, integrated quality systems.

As authorities worldwide adopt or align their good manufacturing practice (GMP) requirements with these emerging standards, the principles embodied in EU GMP Annex 1 are becoming a de facto global benchmark rather than a solely European regulation.

In recent years, global regulatory authorities have renewed their focus on patient safety by requiring enhanced risk mitigation from manufacturers. This focus has expanded beyond the finished product to both upstream (supplier

management, manufacturing, sterilisation, etc.) and downstream (distribution, lifecycle management, etc.) processes. International regulatory and standard updates worldwide are increasingly aligned around common principles, raising expectations for comprehensive, lifecycle based risk management and contamination control that apply broadly across markets.

Specifically, the convergence of key initiatives including implementation of International Council for Harmonization (ICH) Q9, Quality Risk Management (R1), and the harmonised adoption of EU GMP Annex 1; the Pharmaceutical Co-Operation Scheme (PIC/S) Guide to GMP for Medicinal Products (PE 009 17); and the World Health Organization (WHO) Technical Report Series 1044 Annex 2: WHO good manufacturing practices for sterile pharmaceutical products, have established a new global benchmark for sterile injectable drug manufacturing.^{1,2,3,4} These developments have substantially redefined best practices and generated industry wide ripple effects. Since their introduction, regulators have intensified scrutiny of supplier qualification, cGMP compliance, and the adequacy of investigations and effectiveness of corrective actions related to recurring contamination issues, with greater enforcement actions where deficiencies are observed.

EU GMP Annex 1 originated within specific European Union frameworks; however, it is now widely recognised as the new global standard for contamination control. While compliance to EU GMPs is already applicable to any global territory exporting to the EU, due to the harmonisation with the PIC/S and WHO, regulators internationally are increasingly expecting manufacturers to demonstrate alignment with these principles regardless of whether products are intended for the EU market. This alignment between the WHO, PIC/S and EU reflect a broader regulatory consensus that the contamination control and risk management principles articulated in EU GMP Annex 1 represent appropriate, modern expectations for sterile manufacturing globally. As a result, individual countries are increasingly codifying these requirements into national law or integrate them into local GMP regulations to make them enforceable. In terms of risk management, this was already an international inspection focus however,

the updated ICH Q9 has significantly shifted from an individual process/product driven checkbox toward driving organisations to identify, assess, justify, and continuously manage risks across the full product and global supply lifecycle regardless of jurisdictional origin of the product.

Since 2023, many countries/territories have already moved to strengthen their GMP frameworks by aligning national requirements with the contamination control and risk management principles established in ICH Q9(R1) and EU GMP Annex 1, either through direct adoption or through functionally equivalent national requirements. The current adoption status internationally includes the following:

- EU Member States – All EU member states are required to comply with EU GMP Annex 1.
- Non EU Countries Recognising EU GMP – Countries such as Canada, Iceland, Israel, Liechtenstein, New Zealand, Norway, Switzerland, Ukraine, and the United Kingdom formally recognise EU GMP compliance and therefore expect adherence to Annex 1 to utilise the international recognition schemes.
- PIC/S Adoption – Countries including Australia, Canada, Egypt, Indonesia, Hong Kong, Japan, Jordan, Saudi Arabia, Malaysia, Pakistan, Singapore, Taiwan, and Türkiye have issued national guidance adopting PIC/S PE 009 17.
- WHO Alignment – Countries such as Paraguay, Venezuela and others generally align GMP expectations with WHO guidelines.
- Equivalent Contamination Control Requirements – The United States, India, Eurasian Economic Union (EAEU) and China have not formally adopted EU or PIC/S guidance but have implemented or proposed comparable contamination control requirements within their national GMP frameworks.

In the United States, although not directly harmonised with EU GMP Annex 1, existing regulations, along with recently released guidance, stress the importance of contamination control principles such as robust risk management, the clinical impact



Unrivalled quality with additional features

CPHI | October 6–8, 2026 | Fiera Milano, Italy | Booth 11A11

Gx[®] Elite Vials



Optimum drug product protection

- Industry-leading strength
- Drug protection in cold storage (-80°C)

De-risking fill-finish operations

- Smoother handling, fewer line stoppages and interventions
- Engineered to ensure CCI & excellent capping performance

Optimized total cost of ownership (TCO)

- Reduced cost of non-conformity
- Increase line speed

Available in non-sterile bulk & pre-sterilized RTF packaging formats

of particulate, and holistic mitigation plans.^{5,6,7} Specific to end-to-end risk management, the Food and Drug Administration (FDA) agency's view is clear with the adoption of ICH Q9 (R1), but risk is also woven into almost all recent guidance related to quality. For example, The FDA guidance Risk Management Plans to Mitigate the Potential for Drug Shortages (May 2022) notes, "Effective quality risk management can facilitate better, more informed decisions; can provide FDA with greater assurance that stakeholders understand and can manage the associated risks; and can potentially affect the extent and level of direct regulatory oversight."⁷ In practice, recent FDA Inspections and Warning Letters indicate expectations in line with this statement. Approximately 39% of all drug recalls from the FDA are related to visible foreign particulate.^{8,9} Heightened supplier qualification scrutiny is also evident since 2023, with emphasis on data reliability, cGMP compliance, and adequacy of qualification procedures.¹⁰

When FDA inspection data are isolated to regulations associated with sterility assurance, contamination control, investigations, laboratory controls, and container closure systems, a pronounced post-2023 increase is observed.¹¹ Following implementation of EU GMP Annex 1 in August 2023, Voluntary Action Indicated (VAI) findings increased from 104 in FY2023 to 172 in FY2025 (+65%), while Official Action Indicated (OAI) findings increased from 61 to 103 (+69%) over the same period. FY2026 year to date remains directionally consistent, with 66 VAI and 42 OAI findings already identified, although FY2026 should be interpreted cautiously because it represents partial-year data. The trend suggests heightened regulatory scrutiny of contamination control and sterility assurance systems, with deficiencies increasingly identified in inspection outcomes requiring regulatory action. The pattern is consistent with industry-wide challenges in meeting evolving Annex 1 expectations, particularly around investigations, microbiological control, and container-closure assurance.

Communication from the FDA emphasises not only the importance of contamination control but the real-life consequences of a manufacturer's inaction. The data suggest that FDA observations tied to Annex 1-adjacent topics are not merely routine inspection findings. Of the 220 target-regulation FDA Form 483s identified from FY2020 through FY2026, approximately one in five was followed by a Warning Letter.¹¹ This reinforces the regulatory importance of contamination control, sterility



assurance, laboratory controls, investigations, and container closure integrity as areas where inspectional findings may escalate beyond observation into formal enforcement action.

Expectations are clear from the FDA that manufacturers have a deep understanding of their end-to-end products, processes, and suppliers. Specifically, to particulate contamination, the agency expects manufacturers to conduct studies on particulate levels and understand the impact of every individual process step (e.g. handling, incoming materials, processing including sterilisation, etc.) that could lead to particulate generation.⁶ Overall, the main objective of US applicants is to gain agreement from the FDA that the evidence provided in their submission and/or pre-approval inspection substantiates that the target product is safe and effective. It is clear from all available communication and enforcement trends that the FDA views contamination control as a key part of that evidence.

In China, the National Medical Products Administration (NMPA) issued a revised draft of the Sterile Drug Annex to the GMP for Drugs (2010 Revision) in March 2025.¹² The draft largely aligns with EU GMP Annex 1 while incorporating regional and technical requirements, such as enhanced material transfer controls and references to national pharmacopoeia standards (e.g., steam sterilisation condensate meeting Chinese water for injection specifications). China has continued to update its GMP framework, including publication of the Pharmaceutical Packaging Materials Annex (No. 1, 2025),

reinforcing risk management expectations and regulatory enforcement.¹³ Finalisation of the Sterile Drug Annex is anticipated in the near term and underscores how Annex 1 principles are being globally embedded and adapted, reinforcing their relevance as international benchmarks rather than region specific requirements.

Beyond China, several countries including Algeria, Brazil, Iran, Lebanon, Mexico, North Macedonia, Serbia, and South Africa are proposing or consulting on the implementation of enhanced contamination control measures, signalling further global alignment by tightening of requirements in the coming years.

In parallel with regulatory changes, standard setting organisations are also undergoing revision. Recent updates include ISO 14644 5:2025, Cleanrooms and associated controlled environments, Part 5: Operations and proposed USP chapters addressing contamination control and particulate mitigation. These standards embed holistic risk management principles across the product lifecycle, from initial development and facility design to equipment selection, materials, manufacturing processes, packaging, labelling, and supplier management.

Across both regulations and standards, expectations now reinforce integral aspects for effective contamination control strategies including robustness of risk governance, organisational accountability, data-driven decision making, improved supplier oversight, deviation recurrence handling, and continual improvement mechanisms

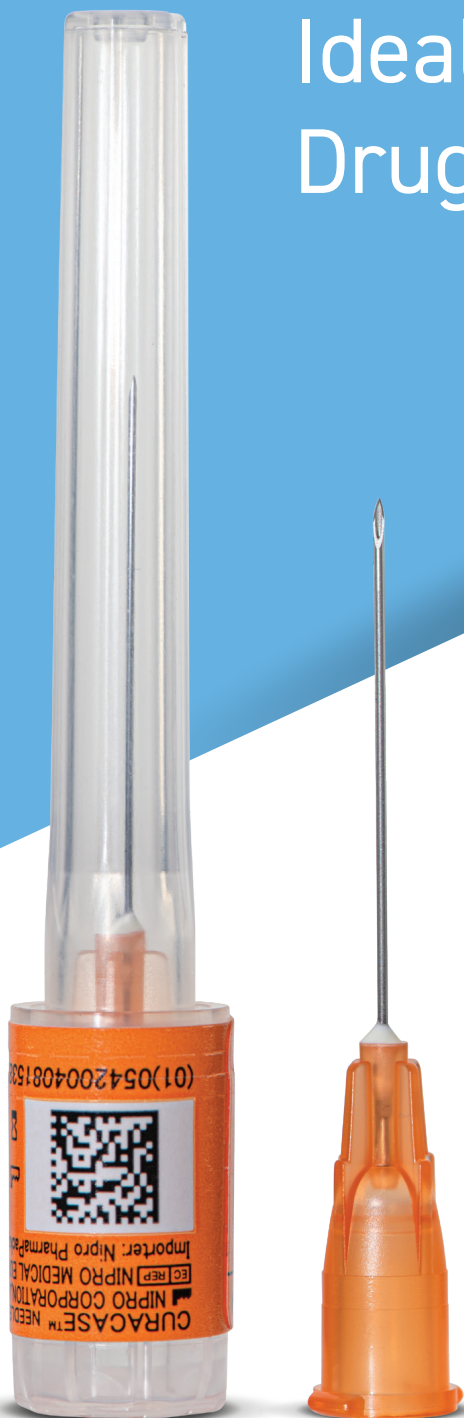


HYPODERMIC NEEDLES

Ideal to By-pack with
Drug Products!



[Visit our website](#)



**Each needle is sterile packed
individually in a hard case unit pack**

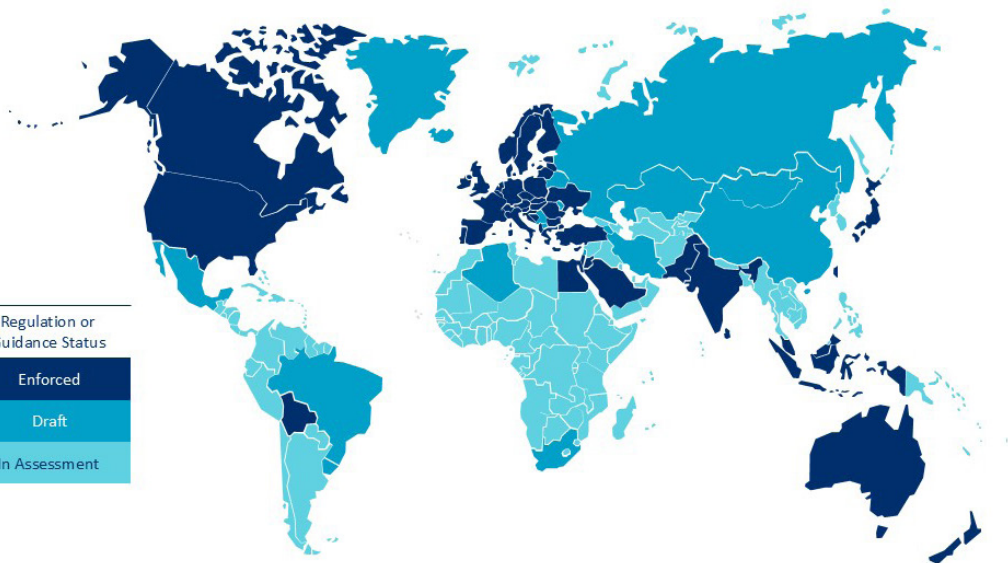
**Packaging design supports
compatibility with automated pick-
and-place systems/feeders**

**Color-coded labels and barcode
on label enable in-line product
identification**

Global Harmonization of Contamination Control Strategy Regulations, Guidance & Enforcement



Estimated Enforcement Timing	Regulation or Guidance Status
Current	Enforced
1-2 Years	Draft
3-5 Years	In Assessment



This analysis is provided solely as a courtesy and is an estimation based on information available at the time of preparation. It is the user's responsibility to interpret GMP regulations applicable to their business or offerings. West Pharmaceutical Services, Inc. and its affiliates do not assume any responsibility for the user's regulatory strategy, product classification, risk management activities, technical documentation, conformity assessment, or any determination regarding the applicability or interpretation of Annex I requirements.

Overall, in the relatively short period since these initiatives were introduced, enhanced lifecycle risk management and contamination control expectations are becoming firmly established as a global norm that extends beyond compliance with any single guideline or geographic region. For jurisdictions that already have these enhanced regulations in force, manufacturers must quickly adapt processes, quality culture and documentation to remain in compliance. For jurisdictions with regulations not yet in force, manufacturers that implement comprehensive, risk-based contamination control strategies and demonstrate sustained effectiveness through continuous improvement will be better positioned to meet regulatory expectations, maintain inspection readiness, and support reliable supply of sterile products in an increasingly harmonised regulatory environment.

REFERENCES

1. ICH Q9, Quality Risk Management, 18 January 2023
2. The Rules Governing Medicinal Products in the European Union Volume 4 EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, Annex 1, Manufacture of Sterile Medicinal Products, 22 August 2022
3. Pharmaceutical Co-Operation Scheme (PIC/S) Guide to GMP for Medicinal Products (PE 009 17), 25 August 2023
4. World Health Organization (WHO) Technical Report Series 1044 Annex 2: WHO good manufacturing practices for sterile pharmaceutical products, 31 October 2022
5. FDA Guidance, Q9 (R1) Quality Risk Management, May 2023
6. FDA Guidance, Inspection of Injectable Products for Visible Particulates, Dec 2021
7. FDA Guidance, Risk Management to Mitigate the Potential for Drug Shortages, May 2022
8. U.S. Food and Drug Administration. Drug Recalls. Accessed February 2026.
9. U.S. Food and Drug Administration. Recalls for
10. Biologics. Accessed February 2026.
11. U.S. Food and Drug Administration. Warning Letters. Accessed July 2026.
12. U.S. Food and Drug Administration. Inspections Database. Accessed July 2026.
13. Public Opinions Solicitation of Department of Comprehensive Affairs, Planning, and Finance Affairs of the National Medical Products Administration for the Sterile Drug Annex of the Good Manufacturing Practice for Drugs (2010 Revision) (Exposure Draft), March 17, 2025
14. Announcement of the National Medical Products Administration on Issuing the Appendices for Pharmaceutical Excipients and Drug Packaging Materials and Containers of the Good Manufacturing Practice for Drugs (2010 Revision) (No.1, 2025), January 2, 2025



Lauren Orme

Lauren Orme has more than 24 years of experience in pharmaceutical packaging, medical devices, and analytical services. She leads Regulatory Affairs Intelligence and Policy at West Pharmaceutical Services, overseeing global regulatory monitoring and compliance activities. Previously, she held technical and commercial roles supporting customer adoption of West's products and services. Lauren holds a B.S. in Biology from West Chester University and is a PMP-certified professional.





Make the next transition feel seamless

The transition to next-generation propellants raises the bar for sustainability, while demanding proven performance and dependable commercial supply.

Kindeva supports the seamless transition to next-generation propellants, helping ensure tomorrow's MDIs match the performance of today's inhalers.

See how Kindeva supports your MDI

kindevadd.com

Redrawing the Delivery Map: The Next Dosage Form Is One That Patients Barely Notice

In recent years, drug discovery has advanced rapidly to yield increasingly sophisticated medicines, yet our primary method of administering these drugs remains remarkably unchanged. Many of these new and advanced macromolecules still rely on standard liquid injections, a dependence that imposes a significant physical and financial burden on patients and healthcare systems alike. Liquid injections frequently require cold-chain transport, clinic visits, administration by trained professionals and the physical discomfort of a needle.

Translating complex molecular science into patient-centric healthcare requires drug developers to pair therapeutic innovation with equally advanced, patient-directed dosage forms. Dermal drug delivery through microneedle array patches (MAPs) offers a viable solution to these translational challenges. This approach restricts penetration to the non-vascular outer layer of the skin to avoid the pain and anxiety associated with injections and remove the safety risks that require professional clinical administration. This transition away from legacy drug delivery methods can directly improve patient compliance, clinical outcomes and global accessibility.

The Legacy of Liquid Injection

Biologics now represent approximately 40% of the global drug development pipeline and account for nearly half of all new drug approvals.¹ These complex macromolecular therapies are transforming treatment across chronic therapeutic areas, including autoimmune diseases, cancers, endocrine disorders and genetic conditions. Despite their therapeutic promise, these complex structures cannot survive oral administration, as gastric enzymes and the acidic environment of the stomach degrade the molecules before they can enter the bloodstream.²

While bypassing this gastric barrier has long made liquid subcutaneous or intramuscular injections the default pathway for systemic biologic delivery, this approach carries physical and logistical challenges:

- Clinic visits require travel, consume patient time and increase the overall cost of care.
- Self-injection demands a high degree of manual dexterity and patient training.

Beyond these administration challenges, liquid formulations often present significant shelf-life limitations due to their molecular instability at room temperature. These formulations remain highly vulnerable to thermal fluctuations, light and mechanical stress. This sensitivity necessitates a continuous cold chain from manufacture to administration, which limits medicine distribution in developing regions, increases carbon footprints and generates substantial waste when temperatures slip outside of safe limits.

How Direct Dermal Penetration Unlocks Large Molecule Therapies

Traditional transdermal patches rely exclusively on passive diffusion to slowly seep small-molecule drugs through the stratum corneum, the highly resilient outermost layer of the skin. Because the stratum corneum is designed to keep foreign substances out, only a very narrow class of lipophilic, low-molecular-weight drugs can use this route, making transdermal delivery unsuitable for large macromolecules, proteins and vaccines.³

MAPs operate on a fundamentally different delivery principle. A MAP uses an array of microneedles to create precise, microscopic gateways directly into the underlying epidermal and dermal layers of the skin, physically bypassing the stratum corneum. These needles do not reach the deeper pain receptors or blood vessels located in the lower dermis, allowing for a painless delivery experience.

The dermal layer itself is a valuable target for drug delivery. It is highly vascularised and rich in antigen-presenting cells, such as Langerhans cells and dermal dendritic cells, making it the ideal site for vaccine delivery.⁴ When an antigen is delivered directly to this immunologically active environment, the response is often far more robust than when the same antigen is injected into muscle tissue. Clinical studies also suggest that dermal vaccine delivery can support dose sparing, which allows developers to use less active

ingredient to achieve the same protective effect.⁴ It may also reduce or eliminate the need for adjuvants, which can be the cause of local injection-site reactions.

Beyond vaccines, the rich vascular network of the dermis enables rapid systemic absorption of therapeutic peptides and proteins, making it an excellent path for daily or weekly biologic regimens.

At-Home Autonomy: Overcoming Needle Anxiety

Needle phobia is a highly prevalent condition that affects a significant portion of the global population.⁵ This anxiety often leads to treatment avoidance, missed doses and eventually complete non-adherence. In chronic diseases such as severe osteoporosis or diabetes, inconsistent dosing can accelerate disease progression and increase hospitalisations.

By removing the needle from view and eliminating associated pain, microneedle patches redefine the patient experience through a simple and intuitive application process. Patients apply the patch to the skin using a customised applicator device that automatically ensures the correct force and velocity of insertion, resulting in only a sensation of slight pressure. This straightforward ease of use supports patient autonomy and allows individuals to manage chronic conditions in the comfort of their home.

This opportunity for self-management is particularly advantageous for therapeutic classes that traditionally demand highly frequent, invasive dosing regimens to achieve therapeutic efficacy. In the rapidly expanding field of glucagon-like peptide-1 (GLP-1) receptor agonists, patient adherence remains highly dependent on overcoming the physical discomfort and anxiety of needles. Introducing a daily or weekly microneedle patch for GLP-1 delivery eliminates the need for regular subcutaneous injections, converting a potentially painful medical task into a routine wellness habit. Similar clinical benefits apply to daily therapies for osteoporosis, where elderly patients often struggle with the physical demands of preparing and administering liquid injections. By simplifying the administration process across these diverse indications, MAPs

empower patients to take control of their health, which directly leads to higher adherence and better long-term clinical outcomes.

The Potential for Solid-State Stability

One of the most profound advantages of solid-coated microneedle technology is the transition from liquid to solid-state chemistry. To create a solid-coated MAP, formulation scientists transfer a biologic from a liquid format to a specialised coating solution that can then be deposited as droplets on the tips of the microneedles. Once dried, the active biologic molecule is held in a stable, solid-state matrix.

Liquid formulations are highly dynamic environments where molecules are free to move, aggregate and degrade. The solid-state matrix of a coated microneedle immobilises the biologic, which restricts molecular movement and drastically reduces the rate of chemical degradation. Through this immobilisation, biologics that would normally denature within hours at room temperature can remain stable on a patch for months or even years without refrigeration.⁶

The commercial and humanitarian implications of this stability are vast. From a logistics perspective, eliminating the cold chain simplifies the distribution network. Pharmaceutical companies can ship vaccines and biologics through standard postal services directly to patients, bypassing the expensive infrastructure of refrigerated shipping and specialised clinic storage. In developing nations or disaster zones where refrigeration is unavailable, room-temperature stable patches can be distributed safely to remote populations. This stability also reduces the risk of medicine waste, ensuring that stockpiles of critical therapies remain viable for extended periods without ongoing energy costs.

Designing for the Patient Experience

Creating a successful patient-centric MAP requires a deep understanding of both formulation chemistry and mechanical design. The physical design of the microneedle array must be optimised for both skin penetration and drug release. At Kindeva, this micro-architecture is engineered using a proprietary liquid crystalline polymer (LCP) platform. LCP is an exceptionally strong, biocompatible material that maintains its structural integrity during skin insertion, ensuring that the needles do not bend or break during use.

Every aspect of the array architecture can be customised to suit the specific therapeutic target:

- **Needle length:** Determining the precise length ensures the needles target either the shallow epidermis for local therapies or the deeper dermis for rapid systemic absorption.
- **Needle spacing and density:** Optimising the distance between needles ensures the application force is concentrated effectively to penetrate the skin barrier without causing unnecessary tissue displacement.
- **Formulation concentration:** Maximising API concentration in the coating droplet allows us to deliver the target dose within a very limited physical surface area.

While customising this micro-architecture optimises the patch, clinical success ultimately relies on pairing the array with an applicator device that overcomes natural variations in skin physiology. Because skin elasticity varies significantly across age groups and body types, a reusable or single-use applicator is essential to ensure consistent drug delivery. By applying the patch at a standardised velocity and force, this integrated mechanism guarantees that the microneedles penetrate the skin to the exact target depth every single time, regardless of whether the user is an elderly patient or a young caregiver.

The Industrial Horizon

Scaling microneedle arrays beyond laboratory benchtop environments represents a sizable industrial challenge, as many early architectures performed reliably in controlled R&D settings but proved impossible to reproduce consistently at high volumes.

To overcome this industrialisation bottleneck, developers must design with manufacturability in mind from the very beginning of a programme. This means understanding the constraints of commercial assembly lines and engineering backward to the early design phase. Translating this early design philosophy into a scalable reality requires specialised, highly automated production lines that integrate advanced robotics, isolated cleanroom environments and machine vision systems to guarantee that every patch meets strict regulatory and quality standards.

By establishing this end-to-end manufacturing pathway, developers can significantly de-risk the scale-up process. Biopharma companies can initiate feasibility studies with the confidence that the same formulation and process can be scaled seamlessly to commercial production. This industrial maturity is the final, essential step in turning

the promise of microneedle technology into a commercial reality.

Embracing the Future of Patient-Centric Medicine

Prioritising the patient's daily experience is becoming the defining requirement for modern drug delivery. By combining the clinical efficacy of injections with the ease and stability of a dry patch, MAPs offer an unparalleled opportunity to modernise healthcare. This technology eliminates needle pain, enables at-home self-administration, can remove cold-chain restrictions and ensures precise, automated dosing.

For biopharma innovators looking to differentiate their products, serve patients more effectively and secure their pipelines, MAPs represent the path to progress. The dermal revolution is here, and the future of medicine is ready to be applied.

REFERENCES

1. "The Future of Biologics and Bio-betters: A Strategic Deep Dive into Next-Generation Therapies." Drug Patent Watch, 2026. <https://www.drugpatentwatch.com/blog/the-future-of-biologics-bio-betters-and-the-dawn-of-next-generation-therapies/>
2. Zhu, Quangang, Zhongjian Chen et al. "Oral delivery of proteins and peptides: Challenges, status quo and future perspectives." *Acta Pharmaceutica Sinica B*. 11.8 (2021): 2416-2448. Print. <https://pubmed.ncbi.nlm.nih.gov/34522593/>
3. Bos, Jan and Marcus Meinardi. "The 500 Dalton rule for the skin penetration of chemical compounds and drugs." *Experimental Dermatology*. 9.3 (2000): 165-169. Print. <https://pubmed.ncbi.nlm.nih.gov/10839713/>
4. Menon, Ipsita, Priyal Bagwe, et al. "Microneedles: A new generation vaccine delivery system." *Micromachines*. 12.4 (2021) Web. <https://pmc.ncbi.nlm.nih.gov/articles/PMC8070939/>
5. McLenon, Jennifer and Mary Rogers. "The fear of needles: A systematic review and meta-analysis." *Journal of Advanced Nursing*. 75.1 (2019): 30-42. Print. <https://pubmed.ncbi.nlm.nih.gov/30109720/>
6. Nguyen, Thuy Trang, Yujeong Oh, et al. "Progress in microneedle array patch (MAP) for vaccine delivery." *Human Vaccines & Immunotherapeutics*. 17.1 (2020): 316-327. Print. <https://www.tandfonline.com/doi/full/10.1080/21645515.2020.1767997>



Andrew Riso

Andrew Riso, Vice President, Dermal Delivery and Licensing at Kindeva.

What if you could know more about your syringe system earlier?



From component expertise to system-level understanding.

Aptar Pharma combines deep elastomeric component expertise with integrated testing and performance data to evaluate how syringe components work together as an assembled system. Our system-level framework supports earlier, more informed development decisions, stronger risk management and greater confidence before late-stage scale-up.

Discover a more integrated approach to injectable drug delivery systems.



Contact our team to discover
the findings.

You can also meet with our experts at:

CPHI Milan | 6–8 October 2026
[Hall 11 Booth 11A43](#)

PDA PFS Palm Springs | 6–7 October 2026
[Booth 411](#)

Injectable components delivering confidence in every injection.



Aptar 
pharma