

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

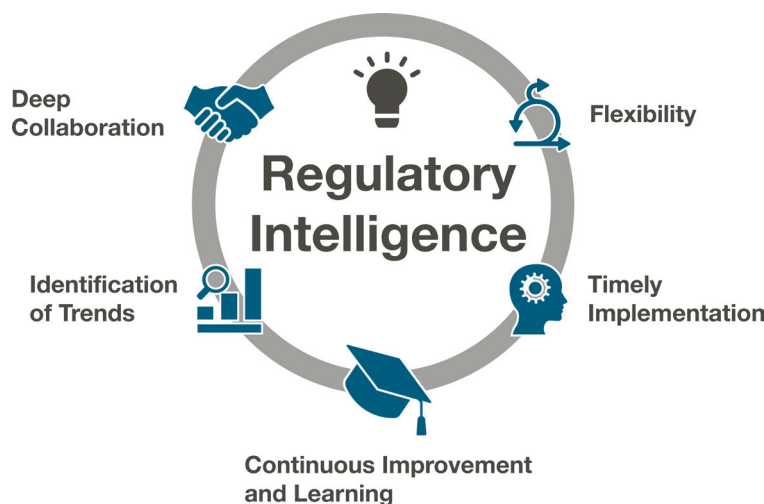


Figure 1: Regulatory activities and competences at Ypsomed



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

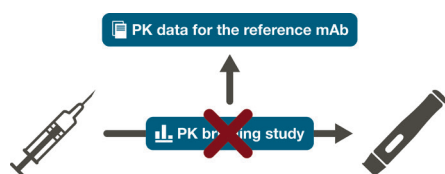


Figure 3: MIDBA approach enabling omission of a dedicated PK bridging study between manual injection and autoinjector

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