



## Podcast Transcript

# Regulatory Horizons: Supply Chain Sovereignty: How U.S. and E.U. Regulatory Priorities Are Reshaping Life Sciences Manufacturing

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**Kattman:** Welcome to Regulatory Horizons, delivering strategic insights for the future of global life sciences regulation. This podcast is your guide to the evolving policies, global frameworks, and innovations shaping the compliance landscape across biotech, pharma, medical devices, and even foods. I'm Amy Kattman, and you're listening to BakerHosts.

Today's episode is focused on one of the biggest strategic shifts we're seeing right now, supply chain sovereignty. In the U.S., we're hearing a lot about onshoring, friendshoring, and national security-driven oversight, from the BIOSECURE Act to the FDA's increasing scrutiny of foreign manufacturing. In the E.U., we're seeing parallel, but not identical, moves through the Critical Medicines Act. Expanded shortage reporting obligations, and tighter expectations around manufacturing resilience. The big question for Global Life Sciences Company is this: How do you comply with two systems that are aligned in their goals, but diverging in execution? Let's listen in.

**Kirton:** Hello, friends. My name is Winston Kirton, and I'm the leader of BakerHostetler's FDA practice and co-leader of the firm's Life Science Industry team and the host of the Regulatory Horizons podcast. Over the last few years, life sciences companies have learned a hard lesson. Your supply chain is no longer just an operating model. It is a regulatory position. Here in Washington, supply chains are now tied to national security, resilience, and public health. We're seeing that

play out in FDA policy, inspection priorities, and legislation like the BIOSECURE Act. Now, across the Atlantic, the story is similar but not identical.

The European Union is advancing its own framework through the Critical Medicines Act, shortage prevention mandates, and new expectations around manufacturing resilience. The result is a new reality for global companies. U.S. and E.U. regulators are aligned in objective, but increasingly divergent in execution. Today, we're going to unpack what that means in practice, how onshoring, friendshoring, and supply chain sovereignty are reshaping compliance, approvals, and enforcement on both sides of the Atlantic.

To help us unpack that, I'm joined today by my friend and E.U. life sciences attorney, Tomáš Čihula. He is a partner at Kinstellar in Prague, Czech Republic, and Kinstellar is a leading independent full-service law firm operating across Central and Eastern Europe, Southeast Europe, and Central Asia. Tomáš serves as the firm's sector leader for life sciences and healthcare. His practice focuses among other areas on regulatory matters in the life sciences, and healthcare industries. Tomáš, welcome to the Regulatory Horizons podcast.

Čihula: Thank you, Winston. It is great to be here and thank you for inviting me. I think you framed it exactly right. Supply chains used to be viewed as a purely operational or commercial issue, but I think that is no longer true. In Europe, regulators now see supply chain resilience as a patient safety issue, but also as a public health issue, and I think increasingly also as a strategic autonomy issue.

Kirton: Yeah, Thomas, that sounds very familiar from the U.S. perspective. So, at FDA, we're seeing heightened inspection focus on foreign manufacturing sites, more probing questions during application review about upstream suppliers. And even at the legislative level, an explicit concern about reliance on certain geographies. So, tell me, Tomáš, and tell our audience, how is this conversation showing up in the E.U. regulatory framework?

Čihula: That is interesting to hear. In the E.U., the shift is most visible, I think, through the Critical Medicines Act and related pharmaceutical reforms that were proposed in March 2025, and then the European Parliament later on adopted its position in early 2026. The objective is not to require that everything should be manufactured in Europe, but rather to reduce single point dependencies, especially for APIs, key starting materials, and also sterile injectables.

So, then regulators, they are asking sponsors very pointed questions. For example, they might ask, where are your critical manufacturing steps? They also ask, do you have alternative E.U.-based suppliers? Or also, can you withstand disruptions? Or they may also ask how quickly can you scale production within the E.U. if global supply is disrupted? So, lifecycle requirements exist, but they are mostly focused on shortages, reporting, and diversification, not a generalized lifecycle framework.

Kirton: Oh, that is interesting. That lifecycle element is critical, right? In the U.S., we're seeing FDA connect supply chain transparency directly to post-marketing

compliance, including field actions and even enforcement discretion during shortages. And what is striking, Tomáš, is that neither system is explicitly banned in foreign manufacturing, right? Neither U.S. or E.U., but both seem to be clearly disincentivizing over-concentration in high-risk regions, right?

So more on this onshore and friendshore and FDA scrutiny. On the U.S. side, companies are navigating a layered environment. Part of that layering is FDA policy signaling favoring domestic or allied nation manufacturing. Another layer is legislative pressure through mechanisms like the BIOSECURE Act. And then one is even practical realities, right? Like longer approved timelines or approval timelines or deeper audits for certain foreign sites. So, from your conversations with multinational clients, Tomáš, how are companies reacting to these U.S. signals?

Čihula: Yeah, very interesting topic indeed. What I'm seeing is that many companies are remapping their global manufacturing footprint in real time. What I'm seeing is not wholesale relocation, but rather a strategic redundancy. So, for example, secondary fill-finish capacity in the E.U. for U.S.-approved products, or dual-sourcing for APIs where one supplier is in a geopolitically low-risk jurisdiction. Or for example, earlier engagement with both FDA and EMA to align on acceptable supply chain configurations. The regulatory conversation now often happens before clinical development is complete, which I think is a big change.

Kirton: That is great insight. I want to shift a little to where companies are getting caught, right? So, if there is one pain point I see repeatedly, it is misalignment between regulatory strategy and corporate strategy, right? The two are definitely not the same, right? So, a company may lock in a low-cost manufacturing partner overseas, but only to discover that it raises serious approval or inspection risk in both jurisdictions. So where do you see E.U.-focused companies getting tripped up?

Čihula: Yeah, indeed. I think two areas in this regard stand out, at least from my perspective and that is, first, underestimating the documentation and disclosure expectations, particularly around supplier qualification and contingency planning. And maybe second, assuming that compliance in one jurisdiction automatically translates to the other. FDI and E.U. authorities are increasingly sharing information, but they still, on the other hand, expect independent justifications under their own legal frameworks.

Kirton: Yeah, I think that is important, this independent justification under the local framework. And as we transition and we look at what is going to happen, this podcast is Regulatory Horizons, right? So, as we look ahead and we look at what is going to happen in the rest of 2026 and beyond, do you see this trend towards supply chain sovereignty accelerating, Tomáš, or stabilizing?

Čihula: Yeah, that is a tricky question. I would say I expect acceleration but with more nuance. So, regulators, they recognize the cost implications of reshoring. So, the focus is shifting towards resilience over relocation and companies that can

demonstrate credible risk management without full geographic duplication will be in the strongest position for sure.

Kirton: Yeah, that resonates strongly with what we're hearing in the U.S. as well. This isn't about abandoning global supply chains, not in the least. It is really about defending them intelligently, in my mind, and intelligently in a more fragmented, uncertain regulatory world.

Alright, so this was very short and brief and to the point. Tomáš, this has been an incredibly helpful cross-border perspective. We didn't want to boil the ocean here, so to speak, using American colloquialisms. We wanted to give folks something to consider, and I think we've achieved that. So, thank you for joining us. And to our listeners, it is important if your company is operating both in the U.S. and the E.U., now is the time to treat supply chain strategy as a core regulatory function, not an afterthought. We're going to continue this conversation in future episodes. There is a lot to unpack, and we're going to break it down piece by piece in future as things develop, and especially as both FDA and the E.U. authorities refine their approaches to what is now being deemed manufacturing resilience. So, until next time, Tomáš and our listeners, this has been Regulatory Horizons. Be well.

Kattman: Thank you, Winston and Tomáš. If you have any questions for Winston, his contact information is in the show notes. As always, thanks for listening to BakerHosts.

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