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As global pharmaceutical supply chains face cost inflation, geopolitical instability, and new frameworks such as the EU's Critical Medicines Act, the industry is redefining what resilience means. Today, we speak with Dr. Max Lauwiner about how quality, supply chain security, and agility can coexist-not as trade-offs, but as mutually reinforcing pillars of a modern pharma ecosystem.

Quality has always been central in pharma. How is the definition of quality evolving today?

Quality remains our industry's non-negotiable foundation, but its scope has expanded significantly. It is no longer enough to deliver a compliant product at the end of the process. Today, quality is evaluated across the entire value chain-raw-material traceability, supplier robustness, process reproducibility, digital documentation, and even sustainability expectations.

We now speak of "systemic quality". If an API cannot be delivered reliably because a key starting material depends on a politically unstable region or because logistics networks lack resilience, then quality is compromised-no matter what the analytical results show.
At Valsynthese, we see quality emerging from three interconnected elements:

1. Process understanding and control, enabled by scientific development and digital tools.
2. People and culture, where every decision reflects responsibility toward patients.
3. Transparency across the supply chain, extending to suppliers, logistics partners, and customers.

This holistic view is essential as molecules grow more complex and regulatory expectations tighten.

Supply chain disruptions have become more visible since COVID-19. How should the industry rethink supply chain security?

For decades, global pharmaceutical supply chains prioritized cost and efficiency. The pandemic merely exposed vulnerabilities that had been accumulating for years. We now face geopolitical tensions, energy volatility, and heavy concentration of essential raw materials in a handful of regions. The key question has changed from *"Can we afford resilient supply chains?"* to *"Can we afford not to have them?"*.
The EU's Critical Medicines Act highlights this shift toward strategic resilience. For CDMOs and fine chemical manufacturers, this means:

- Expanding regional production capacity for critical intermediates and APIs.
- Ensuring vertical traceability-including second-tier suppliers and their risk profiles.
- Building redundancy into key steps and materials.
- Strengthening energy resilience, especially for energy-intensive chemical processes.

At Valsynthese, being located in Switzerland gives us advantages in regulatory stability and energy reliability. But geography is only part of the puzzle. True security requires:

- Strategic partnerships rather than transactional relationships
- Early joint risk assessments with customers
- Technology and knowledge sharing across supply networks

Security is not static-it is a dynamic ecosystem built on transparency, trust, and long-term collaboration.

Pharmaceutical pipelines are becoming more complex. Why is agility now such a critical differentiator?

Agility has moved from a "nice to have" to a competitive necessity. Companies expect their CDMOs to scale processes from grams to multi-ton volumes, navigate rapid demand fluctuations, and integrate new regulatory constraints and even mid-development. Agility directly influences time-to-market-and therefore patient access.

Infrastructure plays a key role. At Valsynthese, our "Vista" investment program-which includes new hydrogenation capabilities, debottlenecking measures, and modernization of multipurpose assets-was designed specifically to increase operational flexibility.

But agility is not simply about equipment. It is fundamentally a mindset, requiring:

- Fast and empowered decision-making
- An entrepreneurial culture
- Highly skilled technical teams
- Transparent risk-benefit discussions with partners

Agility must flow through the entire organization-from operators to senior management. In an environment where molecules evolve, regulations evolve, and customer priorities evolve, static systems are no longer viable.

Some believe that prioritizing agility, quality, and supply chain security simultaneously creates conflicts. Do you see these elements as competing or complementary?

They are absolutely complementary when approached intelligently. In fact, their interdependence strengthens the resilience of the whole system.

Quality reinforces security:
Deep process understanding reduces variability. Strong compliance builds trust with authorities and customers, which in turn stabilizes supply relationships.

Security reinforces quality:
Stable raw materials, reliable energy supply, and robust production networks prevent deviations and emergency interventions-two major sources of quality risk.

Agility reinforces both:
Agile organizations respond faster to deviations, market shifts, and regulatory changes. They prevent issues from escalating into disruptions and ensure continuous medication availability.

So rather than seeing these pillars as trade-offs, we need to treat them as a strategic triangle-each vertex strengthening the others.

What steps must the broader industry take to strengthen its resilience in the coming years?

The challenges we face-geopolitical shifts, climate-related disruptions, regulatory evolution-require systemic, not incremental, solutions. Several industry-wide actions are essential.

1. **Regional diversification**
   We must reduce reliance on highly concentrated global sources for essential intermediates and key starting materials.
2. **Investment in sustainable, energy-efficient production**
   Not only for environmental reasons, but to reduce vulnerability to volatile global energy markets.
3. **Long-term partnerships instead of transactional procurement**
   Shared development models and transparent risk discussions lead to better and more resilient outcomes.
4. **Regulatory harmonization**
   Diverging national frameworks slow development and increase compliance complexity. Streamlining them would strengthen global resilience.
5. **Workforce development**
   We need chemists, engineers, and operators equipped for advanced processes, digitalization, and high-throughput technologies.
6. **Adoption of digital tools**
   Predictive quality systems, demand forecasting, and supply-risk management tools can detect issues early and prevent disruptions.

Resilience should no longer be treated as a cost center-it is a strategic advantage.

How does the EU's Critical Medicines Act influence future strategies for CDMOs and fine chemical producers?

The Act is a strong signal that access to essential medicines is becoming a matter of strategic autonomy. It pushes companies-and governments-to rethink supply chain structures and bring critical capabilities closer to home.
For CDMOs, this means:

- Increased expectations for regional manufacturing capacity
- Stricter requirements for supply transparency and documentation
- Greater emphasis on dual sourcing and redundancy
- More collaborative frameworks involving regulators, industry, and customers

Ultimately, it aligns with what many of us have been advocating for years: a shift from cost-optimized global supply chains to resilient, strategically diversified ecosystems.

Looking ahead, what does the future belong to? Which companies will thrive in this new environment?

The future belongs to companies that excel simultaneously in quality, security, and agility. These are no longer optional capabilities-they are the foundation of the industry's license to operate.

At Valsynthese, our strategy and investments are guided by this conviction. We see our role not just as a supplier, but as a partner in ensuring medicine availability, patient safety, and technological progress. The companies that thrive will be those that understand resilience as a shared responsibility and act on it through innovation, collaboration, and long-term thinking.

Closing Statement

We are entering a new era for the pharmaceutical supply chain-one defined by rapid change, higher expectations, and greater strategic scrutiny. But these pressures also create opportunities. By aligning quality, supply chain security, and agility, we can build a stronger and more sustainable pharmaceutical ecosystem. For the sake of patients and society, coexistence of these pillars is not only possible-it is essential.