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MANAGING COMPLEXITY: FACTORY PLANNING IN REGULATED ENVIRONMENTS

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ABSTRACT

Planning in regulated environments such as Pharma, Food & Nutrition, Cosmetics and Defense is characterized by a high degree of technical, regulatory, and economic complexity. Production processes, logistics, buildings, and organizational structures are tightly interconnected – each decision influences the entire system. If individual areas are optimized in isolation, interface risks quickly emerge, which can impact efficiency, compliance, and operational safety.

In contrast, integrated, process-driven planning creates reliable decision-making foundations because it reveals interdependencies early and enables holistic solutions. This results in factory concepts that not only meet current requirements but are also robust, auditable, and scalable in the long term.

Fig. 1: Precision-driven pharmaceutical manufacturing with automated conveyor systems and quality inspections

REGULATED ENVIRONMENTS

Regulatory requirements significantly shape the scope of design flexibility and demand a high level of traceability and documentation, along with a clear separation of relevant functional and process areas. As a result, we strongly recommend integrating audit and inspection logic early in the planning phase, as late changes can introduce unnecessary risks by disrupting multiple disciplines at once. Regulation not only sets boundaries; it also establishes a strategic framework that shapes layout, logistics, and technical systems, enabling resilient, future-ready, and fully compliant facilities.

Regulation might lead to a competitive advantage – providing the strategic framework that shapes smarter layouts, safer logistics, and resilient technical systems.

COMPLEX PRODUCTION

Multistage production processes with multiple product and packaging levels significantly increase manufacturing complexity. Product variety, format changes, and short life cycles boost this dynamic. Strong interdependencies between production, packaging, quality, and logistics mean bottlenecks often arise at interfaces rather than individual equipment.

Over the past several years, we've noticed that hidden constraints increasingly arise from cross-functional interactions. Therefore, transparent processes and material-flow models expose key constraints and empower factory designs that are both scalable and efficiently manageable.

Fig. 2: Highly automated handling module for pharmaceutical manufacturing areas

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ECONOMIC OBJECTIVES

Economic objectives are shaped by the tension between substantial investment needs and rising cost pressure. At the same time, trade-offs between compliance, throughput, flexibility and space efficiency must be balanced early in the planning process. Within many projects we identify incorrect assumptions in early phases quickly lead to costly retrofits or operational disruptions in later phases. We urge for a holistic consideration of investment, operating and lifecycle costs is essential to minimize risks and ensure sustainable, future-proof factory models.

INTEGRATED FACTORY PLANNING

Based on our extensive experience in regulated production environments, we advise prioritizing fully integrated planning, as compliance, traceability, and risk control consistently define the boundaries of every design decision and determine long-term operational effective.

Fig. 3: End-to-end alignment of regulatory requirements, design, and processes

From the outset, processes, logistics, buildings, and technology are aligned holistically to ensure that all flows – material, personnel, waste, and information – meet GMP, biosafety, and audit requirements. By linking top-down regulatory and operational objectives with bottom-up validation of process workflows, capacities, and equipment needs, the approach creates full transparency of interdependencies across all disciplines.

Iterative planning variants and structured evaluations make regulatory gaps, bottlenecks, and risks visible early, significantly reducing the likelihood of costly redesigns or validation issues. This integrated framework enables consistent, compliant decision-making and coordinated execution, resulting in strong, regulatory-ready, and next-generation production facilities that remain adaptable as regulations, technologies, and business needs evolve.

ROBUST, AUDITABLE, AND FLEXIBLE FACTORY CONCEPTS

Robust, auditable, and flexible factory concepts are characterized by their resilience to disruptions, changes, and growing requirements. Verifiability is achieved through clear process logic, transparent material flows, and consistent, comprehensive documentation – essential elements, especially in regulated industries. At the same time, well-designed scalability enables flexible adaptation to changing product portfolios and volumes, supported by modular layouts, defined expansion options, and flexible logistics and packaging concepts.

In many cases we see, such concepts ensure long-term usability across product and volume changes while significantly reducing operational and project risks. They strengthen planning reliability, improve operational efficiency, and support sustainable success even in highly dynamic market environments.

Fig. 4: Complex building cross-section of a modern industrial and logistics system

Integrated, process-driven planning uncovers interdependencies early and delivers holistic, and scalable factory solutions – empowering confident decisions and long-term operational success.

WHAT'S IN IT FOR YOU

Integrated planning for regulated industries reduces interface risks and ensures compliant, well-founded decisions. It replaces isolated optimization with a holistic system view.
The result: compliant by design, scalable by default!

PREVIEW

Mar 26 | Vol #4: The Hierarchical Lab

Laboratory efficiency and worker´s satisfaction is largely determined by the suitable lab- and workplace design.
Our next issue will cover this topic in a historic context.

NICE TO KNOW

PPE intelligence is an independent consulting and engineering company within the PORR Group. We focus on biotech & pharma, research & laboratory, as well as logistics & advanced factory planning. The PORR Group employs around 21,000 people, including more than 1,000 engineers.

Together, we combine **Engineering Agility** with **PORR Stability**.