PPE intelligence
translating process into facility
powered by DORR

Biotech & Pharma

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IS YOUR GMP FACILITY READY FOR ANNEX 1, HIGH POTENCY, ADCS, ROBOTICS, AND MAXIMUM FLEXIBILITY?

High potent molecules, ADCs, robotics, stricter regulatory expectations e.g. Annex 1 compliance, and volatile product portfolios are reshaping Biotech & Pharma. Success starts with integrated Functional Planning aligning process, containment, CCS, material flows, and energy efficiency from day one.
We combine strategic management perspective with engineering depth: robust OEB and containment strategies, flexible multi-product layouts, brownfield transformations, and sustainable operating concepts.

Fig. 1: Together we are the heartbeat that moves process forward

WHAT?

The Process area consists of specialized teams that cover the full spectrum of Biotech & Pharma process design. The Process department develops overarching methods and standards for process planning.
Drug Substance includes Chemical API and Biotech API teams, focusing on reactor systems, bioreactors, purification and related equipment.
Drug Product covers sterile and non-sterile dosage forms, addressing formulation, filling, isolators, lyophilization, solid dosage and packaging technologies.
Additional teams such as Process & Clean Utility, Automation & IT, and GMP Compliance support all processes.

PROCESS

Team Biotech & Pharma defines a clear, experience-driven set of key assumptions that gives every project early direction and confidence. By validating options, feasibility, and cost impacts from the start, we enable transparent, sound decision-making. The PPE intelligence subject-matter experts turn initial complexity into aligned focus and shared understanding.

Meaningful progress always begins with trust.

DRUG SUBSTANCE

Drug Substance development is accelerating as HPAPIs, ADC payloads, biologics and targeted small molecules redefine pharmaceutical manufacturing.
Innovators and CDMOs focus on QbD, ICH Q8–Q12 alignment, CCS, Annex 1 compliance and strong data integrity within fully GMP-controlled environments. Robotics, isolator-based high containment, single-use technologies, continuous manufacturing, PAT, RTRT and digital twins are driving the shift to Pharma 4.0. Modular multi-product facilities, flexible ballroom concepts and adaptive clean-utility systems support volatile pipelines. Our subject matter experts help transform these trends into competitive advantage through integrated functional planning, OEB-aligned containment, energy-efficient HVAC zoning and inspection-ready, resilient facility concepts.

DRUG PRODUCT, FILL&FINISH

Drug Product and Fill & Finish operations are undergoing rapid transformation driven by biologics, mRNA platforms, cell & gene therapies, and highly potent formulations.
Across manufacturers, CDMOs and innovative equipment suppliers, current industry discourse emphasizes Annex 1 compliance, holistic Contamination Control Strategy (CCS), and advanced aseptic processing with barrier technologies such as isolators and RABS.
Robotics, gloveless interventions, and fully automated filling lines reduce human interaction and support sterility assurance. Single-use systems, ready-to-use (RTU) components, nested vials and prefilled syringes enhance flexibility and speed to clinic.

OUR AREAS OF EXPERTISE

- Biotech & Pharma
- Research & Laboratory
- Advanced Industries & Logistics

PPE intelligence is a multidisciplinary consulting and engineering firm combining Process Engineering with Facility Design & Delivery. At our core, we translate complex operational processes – whether highly regulated or not – into built environments. This conviction defines our identity and is captured in our guiding principle:
Translating Process into Facility.

Fig. 2: Our areas of expertise

WHAT'S IN IT FOR YOU
We are leveraging centuries of experience combined with cutting-edge manufacturing and Pharma 4.0 technologies. You gain higher OEE, lower total cost of ownership, robust GMP compliance, faster tech transfer, and future-proof, scalable operations.

Digital batch records, MES integration, PAT, environmental monitoring 4.0 and data integrity frameworks enable real-time oversight. Modular cleanroom concepts, ballroom layouts and energy-efficient HVAC designs ensure scalable, inspection-ready, and future-proof aseptic manufacturing environments.

PACKAGING

Drug Product packaging operations are evolving under cost pressure, serialization mandates and increasing supply chain complexity. Manufacturers and CDMOs focus on OEE optimization, lean manufacturing, and total cost of ownership while ensuring full GMP compliance and data integrity. Current industry discussions highlight EU FMD/DSCSA serialization, aggregation, track & trace, and end-to-end supply chain visibility. Smart packaging lines integrate inspection, AI-driven rejection management, and real-time performance analytics.
Modular, scalable line concepts and rapid format changeovers support small batch sizes and personalized medicines. Sustainable packaging, recyclable materials, reduced plastic use and carbon footprint transparency are key conference themes. Robotics, cobots and digital twins enhance line balancing, while MES integration ensures inspection readiness and operational excellence.

NON-STERILE, SOLID DOSAGE FORMS

Non-sterile Solid Dosage Forms operations are experiencing a technological renaissance. "**The tablet is not dead**".

Despite growth in biologics, tablets and capsules remain the backbone of cost-efficient, high-volume pharmaceutical supply. Manufacturers and cost-driven pharma companies emphasize OEE optimization, lean production, and right-first-time performance within fully GMP-compliant environments. Current industry buzz centers on continuous manufacturing, direct compression, high-shear granulation optimization, and advanced coating technologies. Process Analytical Technology (PAT), real-time release testing (RTRT), and Quality by Design (QbD) enable robust control strategies and reduced cycle times.

Equipment suppliers showcase modular, flexible manufacturing platforms, contained handling for HPAPIs, dust management concepts, and energy-efficient HVAC zoning. Digital twins, AI-driven process monitoring, predictive maintenance, and MES integration support Pharma 4.0 strategies. Sustainability initiatives like solvent reduction, continuous drying and reduced footprint facilities are increasingly prominent.
Multi-product facilities, rapid changeover concepts, and scalable architectures ensure resilience against volatile demand while safeguarding competitiveness and regulatory compliance.

Fig. 4: Annex 1 compliant set up

PROCESS & CLEAN UTILITY, AUTOMATION & IT, AND GMP-COMPLIANCE

Cross-functional integration and GMP Compliance is a decisive success factor in regulated pharma environments. Manufacturers recognize that siloed engineering increases cost, compliance risk, delays, and operational inefficiency. Industry focus highlights holistic system architecture, Quality Risk Management (QRM), and life cycle approaches aligned with ICH Q8–Q12 guidelines.

Process design is tightly connected with clean utilities – WFI, clean steam, gases, and HVAC zoning – to ensure energy efficiency, sustainability, and robust contamination control. Automation & IT strategies emphasize MES/SCADA integration, data integrity (ALCOA+), CSV, cybersecurity, and advanced Pharma 4.0 analytics.
GMP compliance is embedded from concept through CPV using digital validation and eBR, enabling inspection readiness and resilient, scalable, cost-optimized manufacturing ecosystems.

OUR DELIVERY OPTIONS

E
Engineering

AGILE EPCM(V)
Agile Engineering, Procurement, Construction Mgmt, Validation

EPC
Engineering, Procurement, Construction

IPD
Integrated Project Delivery

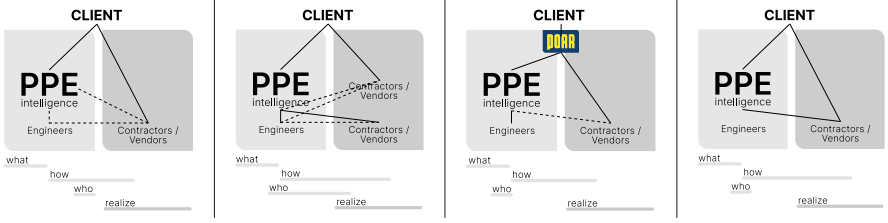

Fig. 3: Our delivery options

HOW?
We establish an early, experience-based assumption management framework. It validates potential solutions, technical feasibility, and cost implications at an early stage. This provides transparency and confidence for all stakeholders.
It all starts with understanding and trust.
We then structure process functions with careful consideration of all interfaces, containment, EHS requirements, and logistics efficiency. We also ensure a robust GMP envelope tailored to local site conditions, including available resources, utilities, and the relevant authority framework.
Integrated design is achieved through dedicated workshops and interdisciplinary collaboration.
Systematic 3D/BIM-based checks align all trades and safeguard compliance across every project phase.
To integrate "quality by design" from the start, we embed risk assessments and review procedures, and capture all content with AI tools

PPE.bot

TRUST
A reliable guiding lead is a defining success factor in engineering ventures, particularly when diverse stakeholders must align on complex functional, technical, operational, and organizational decisions. Early, consistent direction establishes confidence and ensures that all parties advance with clarity. PPE intelligence reinforces this foundation by assuming full coordination responsibility and integrating all contributor inputs transparently and on schedule.

A central pillar of this trust is process engineering within the Biotech & Pharma Area of Expertise. PPE intelligence bases decisions on a long-standing, in-depth understanding of pharmaceutical and laboratory environments, shaped by extensive industry practice and senior subject-matter insight. This includes comprehensive knowledge of functional requirements and the core processes behind research, development, and production. Such expertise enables precise interpretation of process needs, sound assessment of alternatives, and early identification of risks, dependencies, and potential constraints.
Trust grows further through disciplined communication, confidentiality, and integrity in handling sensitive information. These principles PPE intelligence regards as non-negotiable. Transparent workflows, predictable leadership, and aligned interfaces create an environment where clients and partners rely on stable, well-founded decisions. Psychological safety, respectful collaboration, and clearly structured roles reinforce a culture in which stakeholders contribute openly and constructively.

Together, this combination of trusted leadership, deep process insight, and long-term expertise transforms engineering ventures into shared success stories.
At PPE intelligence, senior SME leadership is not a luxury. It is embedded in our identity. Every project team is supported by top-tier experts with a proven record across high-visibility, high-stakes initiatives, valued by clients for dependable delivery. This concentration of senior excellence ensures that from day one, each engagement benefits from decades of process mastery, GMP proficiency, and facility-engineering know-how across all discipline interfaces.

> **DEVELOP TAILORED, HIGH-QUALITY BEST-FOR-PROJECT VARIANTS CONSIDERING DIFFERING PRIORITIES (TIME, COST).**
>
> *PPE intelligence: The Variant Makers*

Fig. 7: Holistic process design, safer therapies

Fig. 5: One spine powering modular Biotech & Pharma

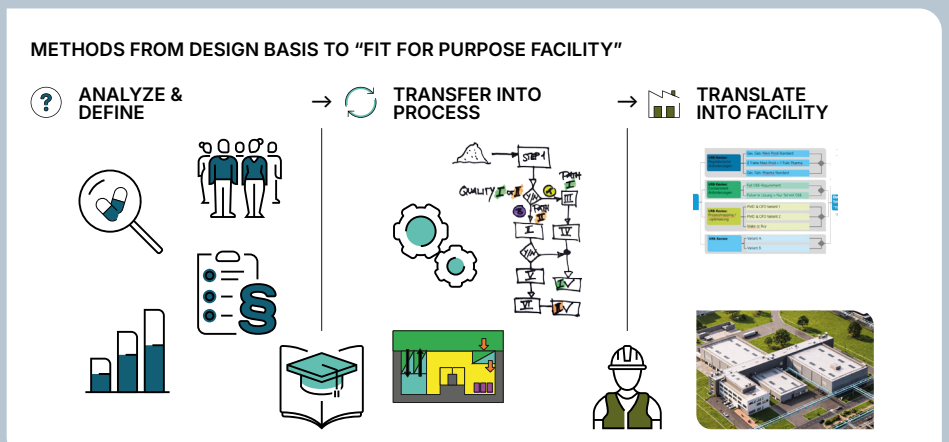

Fig. 6: From initial request to optimal outcome – our end-to-end workflow makes it happen

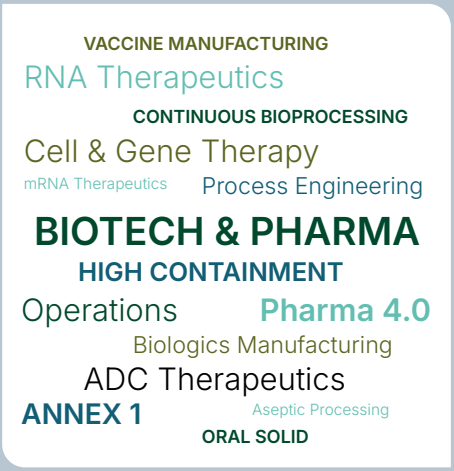

Fig. 8: Biotech & Pharma trends

THE PPE INTELLIGENCE PROJECT METHOD DESIGNED TO DELIVER

A consistent end-to-end process design approach ensures that regulated manufacturing workflows are clearly defined and stable. Establishing process logic, sequencing, flow requirements, and GMP-aligned operational principles from the start creates a reliable engineering basis. Following the "form follows function" principle, process design defines steps, flows, cleanability, containment, and automation needs. Iterative development enables flexible, scalable technical solutions, while interfaces to logistics and facility design are addressed where essential such as material flows, spatial needs, or utility demands to ensure supporting layouts follow the process.

PHASE 1: DEFINING SCOPE & REQUIREMENTS

Every project in regulated industries begins with a clear definition of the intended scope and operational expectations. This includes identifying required functions, performance levels, compliance needs, cleanliness or contamination-control strategies, automation depth, and any risk factors that must be addressed. The outcome is a concise technical requirement specification aligned across Quality, Operations, Engineering, R&D, and Regulatory teams.

PHASE 2: THE FRONT-END PLANNING & CAPACITY ANALYZE

This phase translates the defined requirements into a cohesive operational concept. It includes process flow development, zoning strategies based on risk and Cleanliness classes, structured risk assessments, the creation of process concepts, and capacity modeling for stable, compliant operations. The result is a functional conceptual design that meets regulatory expectations and forms a solid basis for detailed engineering.

PHASE 3: DETAIL DESIGN & ENGINEERING

Detailed engineering develops precise layouts, selects compliant and robust equipment, and embeds design-for-cleaning and design-for-inspection principles. Utilities, automation strategies, and digital validation tools such as simulation and digital twins are defined to ensure efficient, safe, and compliant operation under regulated conditions.

PHASE 4: TENDERING & SUPPLIER COORDINATION

In regulated industries, supplier selection requires documented audits, compliance verification, and proof that equipment and systems meet applicable standards. Documentation for qualification readiness and adherence to design guidelines are evaluated to ensure that all partners support the project's regulatory requirements.

PHASE 5: CONSTRUCTION, INSTALLATION & COMMISSIONING

Execution includes controlled construction practices, equipment installation, and full qualification activities such as FAT, SAT, IQ, OQ, and PQ. Utilities and cleaning processes are verified, and baseline system performance is confirmed before the operation enters its regulated environment.

PHASE 6: HANDOVER TO OPERATIONS & RAMP-UP

The final phase ensures that operational teams are fully prepared through training, KPI monitoring, and process stabilization. Regulatory readiness is verified, including documentation, audits, and compliance reviews, ensuring a smooth transition into steady-state operations within a fully regulated framework.

Clear interfaces, aligned workflows, and validated processes are essential to secure project stability and ensure smooth transition from design to full operations.

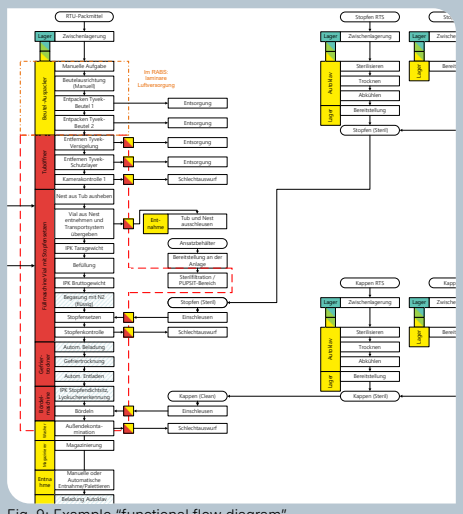
Fig. 9: Example "functional flow diagram"

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**.

Our monthly Tech Sheet