〈Passion for
pharma engineering〉

PHARMA PLAN

One strong brand of TTP GROUP

TTP GROUP

〈 Passion for **engineering** 〉

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ABOUT TTP GROUP

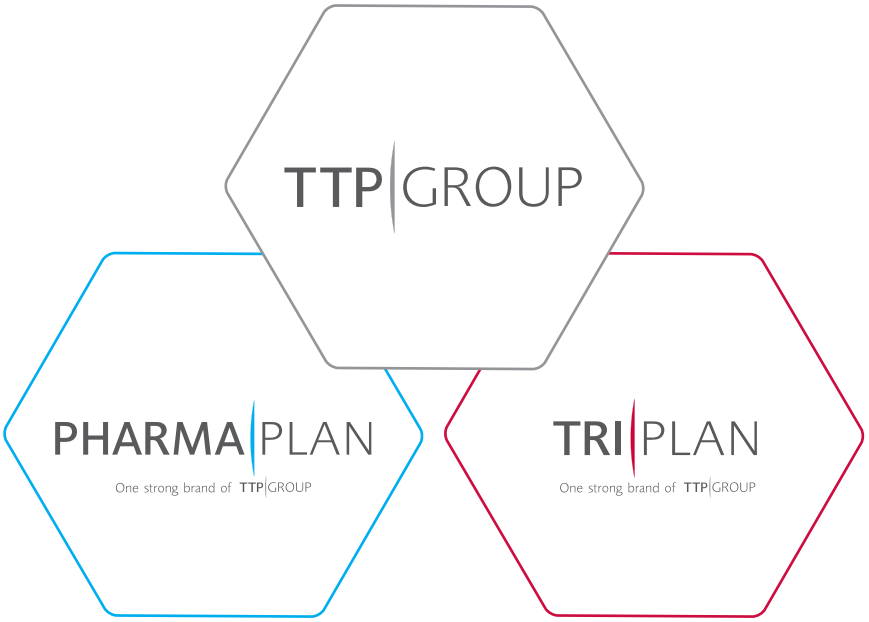
PASSION FOR ENGINEERING

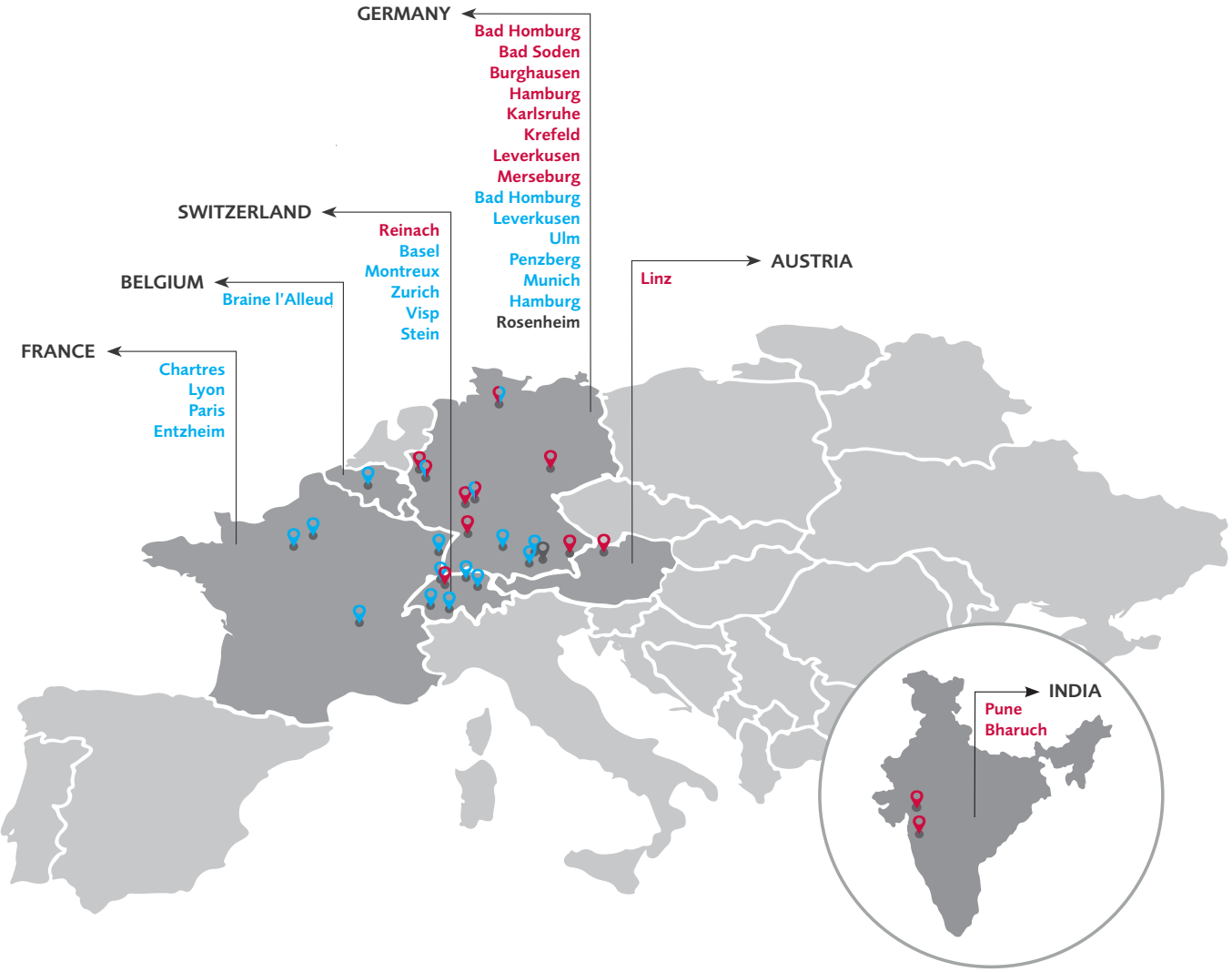
⟨ Design and project execution for the process industry ⟩

As a group of companies, TTP Group specializes in consulting and engineering services for the process industry.

Since 2019, TTP Holding GmbH as parent company, combines the Triplan and Pharmaplan brands under one roof. With these companies, TTP Group occupies an outstanding position in consulting and engineering for the chemical, pharmaceutical, and biotech industries.

The operating brand Triplan offers engineering services for plant construction, primarily in the chemical and petrochemical industries. As an independent general design contractor, Triplan undertakes technical development for new construction and refurbishment projects, as well as modernization and optimization of existing plants.
Pharmaplan is one of the leading engineering companies for the GMP regulated industry in Europe. Highly recognized for integrated and holistic planning, Pharmaplan designs and realizes research buildings and production facilities for its customers. Pharmaplan covers the entire value chain of pharmaceutical engineering, from consulting to EPCMV projects and upgrades to local site support. Pharmaplan sets the course for the global supply of medicines of tomorrow.





More than 1,000 employees work at 29 offices in Austria, Belgium, France, Germany, India, and Switzerland. The operational brands Triplan and Pharmaplan complement each other in their service portfolio. The two fast-growing and dynamic companies handle challenging projects of all sizes within budget, time, and required quality targets. With their international and long-standing expertise serving companies of all sizes, Triplan and Pharmaplan offer future-proof solutions for long-term customers.

STRONG REGIONAL PRESENCE

〈 EPCM(V) project execution and on-site engineering partner 〉

TTP Group offices are located close to the customers.

As a group of companies focusing on Europe, a strong regional presence is part of the strategy. With offices close to the customers site, TTP Group can manage projects most efficiently with local teams. TTP Group branches cover all relevant disciplines as EPCM(V) partners and site engineering providers for the pharma, biotech, and chemical industry. Project teams composed of dedicated and permanently employed architects, engineers, and scientists take care of initiation, planning, design, construction management, commissioning, and qualification for new and existing sites. In-house subject matter experts (SME) are involved in the projects to support customers with specific issues on site.

COMPLETE AND RELIABLE

〈 Exceptional services throughout the project life cycle 〉

TTP Group is the asset lifecycle service partner for the pharmaceutical, biotech, and chemical industries.

From early consulting to project initiation, planning, execution, and project closeout, Triplan and Pharmaplan provide high-performance services throughout the project lifecycle, including, if necessary, qualification support – from the start to the end of a project and beyond. TTP Group combines the experience of its Triplan and Pharmaplan brands with the size and range of capabilities needed to respond competently and flexibly to changing customer requirements and those of the market.

By working with key chemical and pharmaceutical players, TTP Group companies are up-to-date on the latest industry trends. Through its cross-group network, TTP Group is always up to date with regulatory requirements, best practice industry standards, as well as state-of-the-art technologies. This enables the engineers to support the customers in meeting their demanding challenges in the best possible way.

DIGITALIZATION

⟨ From virtual construction to real factory ⟩

Digital engineering runs under the credo "From virtual construction to real factory."

Digitalization is of prime importance to TTP Group. Within the group, the individual companies offer diverse services in digital engineering via BIM methods as well as manufacturing IT & OT (information technology & operational technology). These range from manufacturing IT consulting to classic automation tasks – from integrated project planning and monitoring to interactive training or mockups in virtual & augmented reality.

Implementing this digital transformation requires a good understanding of the business and project delivery processes and the information exchanged within them, IT/OT know-how, and in-house change management skills. The key to the successful planning of complex pharma projects is integrated engineering of all disciplines in the digital space.

SUCCESS HAS A HISTORY

⟨ Modern corporate management with profound roots ⟩

Modern corporate management knows the past, understands the present, and shapes the future.

For more than 50 years, the operational brands of TTP Group have been trusted as partners for the industry. By continually developing our range of services, TTP Group has been able to respond optimally to ever-evolving customer needs. The history of TTP Group shows consistent growth over time. Founded in Germany, we today offer our services throughout the D-A-CH area, as well as in Belgium, France, and India.

FOUNDATION OF OUR BRANCHES

2021	Triplan Austria
2019	TTP GmbH
2014	Triplan India
2012	Pharmaplan Belgium
2004	Pharmaplan France (Chartres)
1998	Pharmaplan Switzerland (Basel)
1974	Pharmaplan Germany
1970	Triplan Switzerland
1967	Triplan Germany

SUSTAINABILITY

⟨ More than an agenda ⟩

TTP Group and its operating brands are aware of their responsibility towards the environment and are committed to responsible and sustainable growth.

The internal Corporate Social Responsibility policy defines non-negotiable points for all members of the group. It codifies the values and makes clear what is expected of all TTP Group employees.

To this end, a cross-group team develops guidelines to ensure TTP Group is contributing to achieving the United Nations sustainable development goals (SDGs) through our work.

As an active member of the UN Global Compact, TTP Group is committed to conducting business and to reporting in accordance with internationally recognized sustainability standards. TTP Group integrates fundamental principles such as human rights, environmental stewardship, and anti-corruption into our strategy, culture, and day-to-day operations.

To establish verifiable KPIs related to business ethics, corporate social responsibility (CSR), and sustainability, Triplan and Pharmaplan branches underwent an external TfS (Together for Sustainability) audit by ECOVADIS and another by the auditing company Intertek.

WHAT TTP GROUP STANDS FOR

⟨ The five core values ⟩

They are our "high five" that result in our unique corporate culture. Our values express what we stand for within the whole TTP Group, but also as individuals.

#OWNERSHIP

Success lies in our hands

We have it in our hands. We own our tasks and take personal responsibility for our company's success. We can rely on each other, are committed and empowered to do our work. We act mindful with resources.

#PROXIMITY

We know our people and the market

We are close to our customers and colleagues and anticipate their needs. Our communication is frequent, transparent, and open.

#EXCELLENCE

Our high quality is based on our knowledge, that we daily expand

We are experts in our business, striving for continuous expansion of knowledge and steady improvement. Our long-term experience is our engine. We commit ourselves to lifelong learning and deliver high quality work results.

#RECOGNITION

Mutual appreciation is motivation for further growth

We appreciate and praise each other for our excellent work. We celebrate professional development and strong performance. Open feedback supports steady growth. We encourage and support each other to succeed.

#TOGETHER

We stand together and have fun

We are one team and we stand together. Our team is built upon the diversity and competence of its individual members. With engagement and fun, we create a motivating working atmosphere in which we trust and support each other.

PHARMA|PLAN

〈Passion for
pharma engineering〉

ABOUT PHARMAPLAN

ABOUT PHARMAPLAN

〈 For more than 45 years: passion for pharma engineering 〉

Pharmaplan designs and realizes world-class research and production facilities for our customers in GMP-regulated and related industries.

〉 **Founded in 1974**

〉 **One of the largest engineering companies focused on the GMP-regulated market in Europe**

〉 **All disciplines for successful project execution under one roof**

EPCMV partner and general design contractor

〉 **Always close to our customer**

Offices in Belgium, France, Germany, and Switzerland

〉 **Pharmaplan clients come from GMP-regulated and related industries**

Pharma and biotech
Research centers and laboratories (GMP and non-GMP)
Diagnostics
Medical devices
Cosmetics and food and beverage
Universities
Pharmacies and hospitals

ABOUT PHARMAPLAN

〈 Pharmaplan is the strategic engineering partner for the GMP-regulated industry 〉

LEADING EUROPEAN PHARMA ENGINEERING COMPANY 〉

Since our founding in 1974, we have continuously grown and extended our expertise in architecture, process engineering, and science. Today, Pharmaplan is a leading engineering company focused on the GMP-regulated industry in Europe.

ALL DISCIPLINES IN-HOUSE 〉

As a general design contractor and EPCMV partner, our devoted team of long-time colleagues is equipped to cover all relevant disciplines in-house. Our *agile*-EPCMV model offers a lean communication approach for customers where Pharmaplan acts as a single point of contact, in charge of the entire project scope. This approach has been key to our long-term success: Pharmaplan has been delivering comprehensive, challenging projects on time and within the budget for over 45 years.

DISTINGUISHED EXPERTS 〉

We are proud to employ globally recognized experts at Pharmaplan regional offices. Together with our partners in international organizations, our team members drive excellence and innovation for future production sites, setting new horizons for world-class process facilities.

STRONG REGIONAL PRESENCE 〉

Having a strong regional presence is a pillar of our execution strategy. With 16 Pharmaplan offices in Belgium, Germany, France, and Switzerland, we staff projects with regional teams who are familiar with the local regulations and our customers' requirements. Our teams are fluent both in the local language and in English because we know that good communication is essential for a successful project.

OUR BUSINESS AREAS

〈 Three strong business units for successful projects 〉

FRONT END PROJECTS 〉

Front end design marks the beginning of every investment project and lays the foundation for strategic decisions and further planning. Pharmaplan's Front End Projects business area focuses on consultative engineering, capability reviews, site master planning, feasibility studies, and conceptual design studies. Innovative expert teams develop and evaluate future-proof solutions in close relationship with our customers.

INVESTMENT PROJECTS 〉

Pharmaplan assumes responsibility for the entire execution of projects of all sizes as an EPCMV partner or general design contractor for revamps as well as greenfield projects. This also includes construction management and commissioning and qualification support. Experienced project and construction managers coordinate Pharmaplan's teams of architects, engineers, and scientists as well as equipment vendors and all contractors directly on the construction site, in close collaboration with the customer. We have decades of experience in the successful fast-track execution of large projects, according to our proven project management methodology. Our group of companies has a huge in-house pool of seasoned project managers and engineers, who work according to proven project execution standards and ensure project delivery within budget, time, and quality target.

SITE PROJECTS 〉

Once a project is completed and the assets are operational, Pharmaplan's Site Projects business area continues to support the customer site operations with a broad service portfolio. The services include the engineering required for product changeover, capacity optimization, operational excellence initiatives, all types of facility upgrades or refurbishments, automation upgrades or integration of digital solutions into existing plants, (re-)qualification, and validation services. We are familiar with our customers' local standards and systems because we are their strategic engineering partner. In this role, we continue to support their full plant lifecycle through long-term assignments, fully embedded in their organizations.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FULL-SERVICE ENGINEERING PARTNER

〈 Providing all disciplines in-house 〉

Pharmaplan is equipped to oversee projects from end to end as a general design contractor and EPCMV partner. We serve our customers as a single point of contact, which means we handle the complexities across the disciplines, with the key disciplines executed in-house.

PROJECT MANAGEMENT 〉	PMI standards Cost control and time scheduling Document management
CONSTRUCTION MANAGEMENT 〉	Zero accidents/Health Safety Environment (HSE) BIM to field Coordination and quality control
PROCESS ENGINEERING 〉	Biotech Fill & finish OSD Chemical active pharmaceutical ingredients (API) Assembly and packaging Simulation and modeling
DIGITAL FACTORY 〉	BIM and PIM Virtual reality and augmented reality (VR, AR) Digitalization strategy
AUTOMATION 〉	Process automation Building automation Enterprise architecture
ARCHITECTURE AND LOGISTICS 〉	Civil, structural, architectural (CSA), and interior design Sustainability Warehouse and logistics
LABORATORIES 〉	Laboratory design GMP laboratories BSL 1-3
PROCUREMENT SERVICES 〉	Procurement strategy Vendor negotiation and handling Claim and change management
BUILDING SERVICES AND CLEAN MEDIA SUPPLY 〉	HVAC Clean and black utilities Piping
QUALITY AND GMP COMPLIANCE 〉	Installation qualification, operational qualification, and performance qualification (IQ/OQ/PQ) Computer system validation (CSV) Risk analysis

PROJECT MANAGEMENT

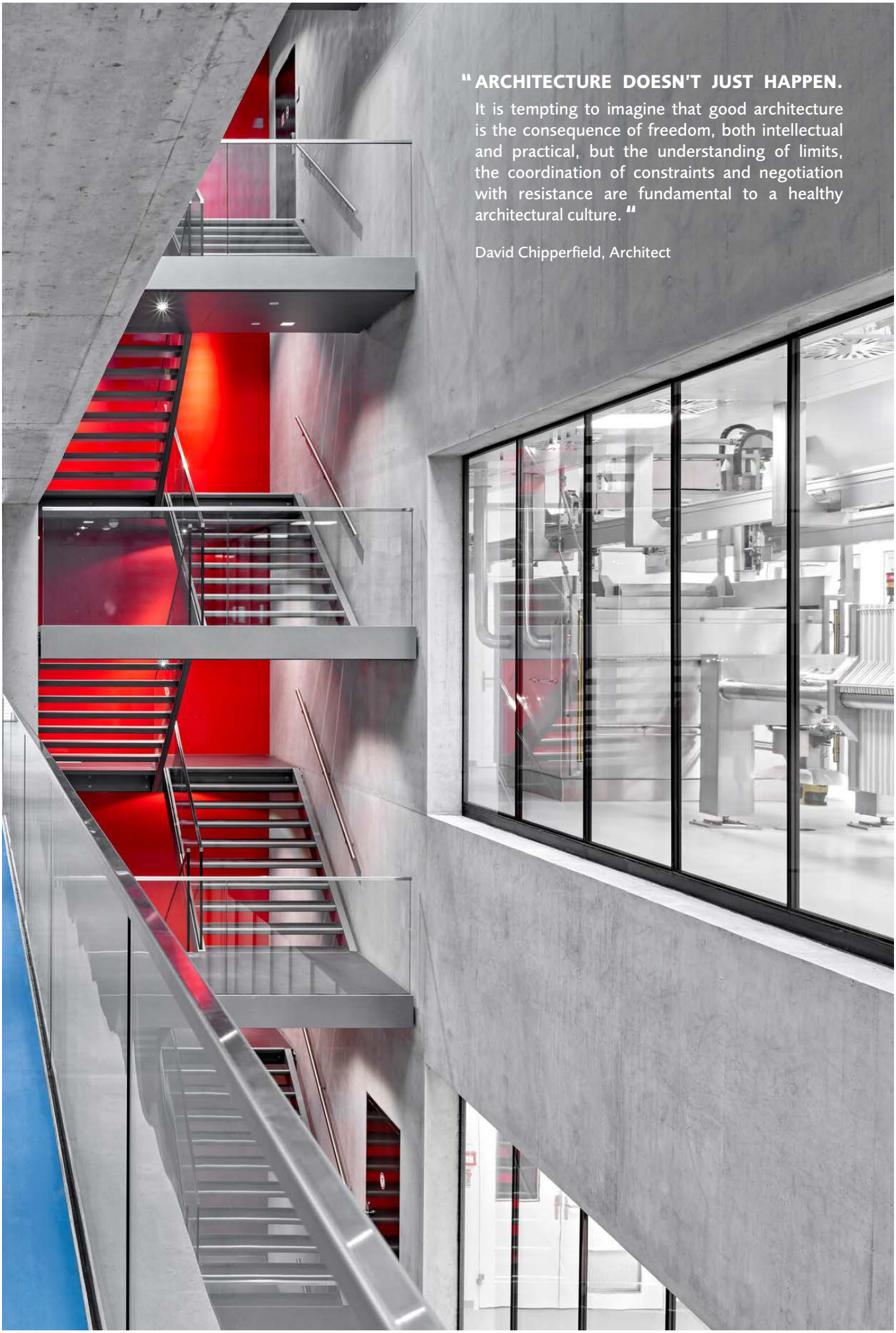
〈 Strong project management: the key to meeting quality, schedule, and budget targets 〉

- 〉 PMI standards
- 〉 Schedule planning and controlling in Primavera P6 and MS Project
- 〉 Cost calculation and monitoring
- 〉 Procurement, from purchasing strategy to contract close-out
- 〉 Qualitative and quantitative risk management
- 〉 Cloud-based solutions (e.g. digital project room, BIM environment)
- 〉 Document management

More than ever, schedule and budget constraints drive projects. Pharmaplan optimizes for these constraints across the entire project lifecycle.

Our project management experts support projects of all sizes, communicating the customer's input to the technical disciplines, contractors and authorities involved.

Our customers benefit from our many years of experience in engineering and execution, as well as from our internal expert groups and our global network. Our proven project delivery model allows us to meet quality, schedule, and budget targets.



" ARCHITECTURE DOESN'T JUST HAPPEN.

It is tempting to imagine that good architecture is the consequence of freedom, both intellectual and practical, but the understanding of limits, the coordination of constraints and negotiation with resistance are fundamental to a healthy architectural culture. "

David Chipperfield, Architect

ARCHITECTURE AND LOGISTICS

〈 Translating process into architecture 〉

- 〉 Coordination of all civil, structural, architectural (CSA) subdisciplines
- 〉 Interior fit-out
- 〉 Clean rooms
- 〉 Space management
- 〉 Laboratories (including biosafety level up to 3)
- 〉 Logistics and warehouses
- 〉 Visualization

ARCHITECTURE 〉

Thanks to our roots in the pharmaceutical industry, our process architects, engineers, and logistics professionals design efficient buildings and infrastructure, whether new greenfield buildings or brownfield modernizations and upgrades. Our process architects are competent partners for constructing complex facilities, with extensive experience in the following areas: site master planning, process architecture, bio-containment and biosafety, clean room, plant design, workplace design, and laboratory design. We have extensive experience in local architectural planning, applying for building permits, handling procurement, benchmarking for cost estimates, and executing fast-track project implementation and construction during operation.

LOGISTICS 〉

A successful site design facilitates the interaction between processes, storage, material flows, supply facilities, and workstations. Our logistics specialists stay abreast of new technologies and regulatory requirements and support our customers in the following areas: site master plans, traffic and material flows, warehouse design, process logistics, and definition of supply chain interfaces.

WAREHOUSE AND PACKAGING 〉

Pharmaplan designs and realizes warehouses and packaging centers for secondary packaging. Thanks to their broad knowledge of different packaging machine providers, our specialized logistics experts and architects can help clients choose the provider and equipment that best suits their specific production program.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CONSTRUCTION MANAGEMENT

〈 Our safety policy for zero accidents 〉

- 〉 Supervision of all construction site activities
- 〉 Electronic T-card system
- 〉 Quality control in BIM to field
- 〉 Creation, implementation, and monitoring of comprehensive HSE concepts

Pharmaplan's construction management approach is to increase efficiency and construction quality from the constructability review through to mechanical completion.

We follow two methods: On the one hand, we organize construction processes according to lean management principles (avoid waste, increase added value), and on the other hand, we digitalize the construction value chain via model-based planning (BIM) to support integral cooperation among all stakeholders during construction projects.

Our customers benefit from our transparent processes including execution plans, detailed staffing and progress reports, and cost tracking. For construction sites with limited space, Pharmaplan manages the delivery of materials for just-in-time installation. This reduces stock levels and storage costs while preserving the quality of the building materials.

Our safety vision is an essential part of the Pharmaplan construction management philosophy:

At Pharmaplan we are convinced that every accident is preventable. We are committed to delivering safe buildings, developed at safe construction sites. It is our top priority to achieve zero accidents, and we therefore establish fundamental processes as early as in the design phase to minimize risks during implementation and installation, and to ensure a high level of safety in day-to-day operations (e.g. EHS plan).

LABORATORY DESIGN

〈 Inspiring work environments for agile research and development 〉

- 〉 Laboratory programming to ensure planning and cost certainty
- 〉 Continuous research on generic laboratory modules for maximum flexibility
- 〉 Assured compliance with the bio-ethical requirements for animal research facilities
- 〉 Experience in the development of laboratories for genetically modified organisms (GMO)
- 〉 Competence in the design of biosafety levels 1-3 (BSL 1-3) laboratories

An unknown future is today's reality: Nobody fully knows what kinds of research technology tomorrow's laboratories will need to support.

Nevertheless, how can companies translate this challenge into future-proof laboratory designs? The solution lies in designing new laboratories with high flexibility and a modular approach. We build laboratories that are adaptable to meet tomorrow's research needs, process development demands, and ever-developing quality control standards. Modular laboratories make it possible to evolve with the science and continue to act as a hub for innovation – one that attracts top talent from around the world.

Pharmaplan is committed to delivering holistic solutions that go beyond GLP and GMP requirements. We know that research and development are social endeavors and that teams flourish in work environments that are designed to foster individual well-being, creativity, and collaboration.

Flexibility, functionality, regulatory compliance, and a safe working environment are of prime importance when it comes to laboratory design. Pharmaplan employs international experts from all areas of laboratory design – from natural scientists to specialized architects – to define requirements and develop customized solutions that will ensure flexibility in the future.


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PROCESS ENGINEERING

〈 Process engineering champion 〉

- 〉 Biotech: upstream and downstream processing/ single-use equipment/ADC production/cell and gene therapeutics/ATMP
- 〉 Fill & finish/lyophilization/OSD/containment/ blow-fill-seal
- 〉 Semi-solid preparation and filling
- 〉 Manual, semi-automated, automated visual inspection
- 〉 Processing of highly active products
- 〉 Layouts and flow design
- 〉 Production planning and dimensioning
- 〉 Continuous processes/continuous manufacturing
- 〉 Medical devices/assembly and packaging
- 〉 Washing, sterilizing, and final packaging

Interdisciplinarity is the key to successfully planning complex projects in which the pharmaceutical process is critical.

Our subject-matter experts bring in-depth knowledge of current technologies and concepts across process engineering and strive to find the best solution for each customer and their unique product portfolio.

We aim to expand the limits of what is possible and work together with customers to forge innovative solutions for process engineering's most pressing challenges.

In our project design, we always focus on finding the right balance of time, cost, and quality, while minimizing product loss and maximizing system efficiency. We support our clients in finding the right equipment suppliers for their needs, based on our broad network of contacts with all large process equipment suppliers in the pharmaceutical and biotech industry. Pharmaplan takes responsibility for the complete procurement process, FAT, SAT, installation management, and commissioning.

Our process engineers are united in their commitment to ensuring health and safety in all process designs. As an engineering company specialized in the pharmaceutical industry, Pharmaplan incorporates all relevant local and global regulations into the process design. We integrate health, safety, and environment best practices for products and employees, including specific precautions for processing highly active substances.

BIOTECH

Pharmaplan's bioprocess specialists design and optimize client facilities for state-of-the-art systems that use microorganisms, mammalian or plant cells to express and purify the product of interest. Pharmaplan oversees the entire pharma and biotech project lifecycle, from project initiation to final documentation. Our bioprocess experts draw on extensive knowledge of upstream and downstream production processes, including fermentation, separation and purification methods and chemical modification. Our bioprocess know-how includes active pharmaceutical ingredients such as antibiotics, vitamins, enzymes, antibodies, and other biochemicals, as well as blood plasma fractionation processes. We are also happy to contribute with our experience in the field of advanced therapy medicinal products (ATMP) such as cell and gene therapy and plasma/blood fractionation including viral vectors, CAR T-Cells, and pDNA.

FILL & FINISH/FREEZE DRYER

The fill & finish market has been changing, e.g. from bulk production of high-volume pharmaceuticals to personalized medical treatment. Therefore, new, flexible concepts and technologies are required to fulfill dynamic patient and market needs. Our innovative engineering approach and in-house tools optimize the planning processes and enable our customers to engage in the personalized medicine revolution. Pharmaplan expertise covers the complete manufacturing process, from weighing and compounding, filling and closing, freeze-drying, and inspection to secondary packaging, as well as the washing and sterilization of equipment and components. We implement best-practice solutions such as unidirectional flows, state-of-the-art barrier technology, and containment strategies.

OSD

OSD products are the dominant pharmaceutical product form. They address a wide range of diseases, are convenient for patients, and are shelf-stable. Pharmaplan's OSD experts and engineers are distinguished by their vast experience, which facilitates different kinds of OSD production. From low-cost, large batch production to small-scale pilot plants for highly potent or oncological products, Pharmaplan delivers infrastructure for the latest technologies in the solids' formulation sector, e.g., high containment or continuous manufacturing.

CHEMICAL APIs

Chemical active pharmaceutical ingredients (APIs) are the active substance in the final drug product and are produced by chemical processes. Pharmaplan is familiar with the most relevant processes, including synthesis and extraction, and can offer consulting for the right equipment as well as support in transferring technologies from one facility to another.

MEDICAL DEVICES

The medical device sector includes a very wide range of products such as implants, transdermal patches, catheters, stoppers and caps for syringes and vials, infusion and transfusion sets, injection systems, inhalers, and electromedicine equipment. Pharmaplan designs and realizes automated or semiautomated production facilities for the medical device sector.

BUILDING SERVICES, UTILITIES, HVAC, ENERGY

〈 Utilities, HVAC, and energy 〉

- Heating/cooling/ventilation/air conditioning/ climate control
- Black utilities generation and distribution
- Clean utilities generation and distribution
- Technical gas supply
- Process wastewater decontamination
- Cleanroom finishes

Pharmaplan executes greenfield, modernization, and optimization projects for the pharmaceutical industry.

We start with the core of the facility – the process. Our technical teams define and calculate all support functions to enable the process requirements. Depending on the product and process properties (product form, BSL or OEB constraints, process equipment needs, etc.), Pharmaplan engineers define HVAC, clean utilities, black utilities, electrical, and cleanroom finishes. We reconcile the regulatory requirements, customer standards, and project drivers in our technical decisions to achieve the design goals.

The focus areas of the building services activities depend on the project phase:

- Concept definition: strategies, redundancy policy, sizing according to current and future process needs, HSE constraints
- Basic and detailed study: PFD, P&ID, drawings, technical specifications, interfaces definition, execution
- Schedule and cost estimates
- Tendering support: tender packages preparation, suppliers' list proposal supplier prequalification, invitation to tender, technical and commercial, comparison and alignment of bids, recommendations
- Design review and spatial synthesis of suppliers' execution studies: securing suppliers' studies, aligning them with the design, reviewing change propositions, and resolving clashes
- Construction management: following-up on suppliers' work during construction, including financial and cost aspects, and managing change requests submitted by contractors
- Commissioning and qualification support: writing or reviewing protocols and reports, organizing, guiding, and witnessing commissioning and qualification operations (FAT, SAT, IQ, OQ, metrology), supporting the customer and the suppliers to clear C&Q punch lists
- Handover operations support: organization of the handover visit, handover report, assistance to punch list clearance, as-built documents collection, and verification
- Operational support and expertise: technical audit, optimization study, etc.

QVA AND GMP COMPLIANCE

〈 Seamless qualification and validation concepts through interdisciplinary cooperation 〉

- 〉 Regulatory compliance
- 〉 Operational readiness, audit, and inspection readiness
- 〉 Gap analyses
- 〉 Commissioning and qualification concepts and sequencing
- 〉 VMP/DQ/SIA/CIA/FAT/SAT/IQ/OQ/PQ
- 〉 Process validation
- 〉 Cleaning validation
- 〉 Sterilization validation
- 〉 Environment validation
- 〉 Cross-contamination control strategy
- 〉 Computer system validation
- 〉 Quality risk analyses

QUALIFICATION AND VALIDATION 〉

Pharmaplan offers seamless qualification and validation services, from the earliest project stages to handover and even during operations, e.g., by creating or modifying standard operating procedures for customers. We work closely with our customers and across all disciplines to define qualification and validation activities specific to each project using guideline documents such as system-level impact assessment and validation master plan. Depending on our clients' needs, we can support each commissioning and qualification step (design qualification, quality risk management, factory acceptance tests, site acceptance tests, installation qualification, operations qualification, performance qualification) either as writers or as reviewers and coordinators. We work with customers to deliver a complete documentation package. Our qualification experts have extensive experience with the quality systems used by renowned pharmaceutical manufacturers, and Pharmaplan employs a flexible approach, developing tailor-made solutions for each customer.

REGULATORY COMPLIANCE EXPERTISE 〉

The global regulatory environment is changing rapidly. Meeting the increasing GMP requirements is a challenge for many companies. With our knowledge of the latest international GMP regulations and the relevant industry standards, we help customers successfully pass inspections and audits, and we support them with compliant technology transfers. To secure GMP compliance in all functions and phases, we offer our customers consulting services throughout the entire product lifecycle. Whether introducing or optimizing a quality management system (QMS), we attach great importance to the balance between regulatory requirements and practical operational needs. Our experts tailor their approach to the client's specificities, from process type to size of the customer's QVA team, without compromising quality.

Our GMP compliance experts are dedicated to fulfilling GxP requirements specified by the countries in which we work and oversight organizations such as the FDA, EU, ICH, and PIC.

Our extensive service offering includes:

- 〉 Front end GMP consultancy
- 〉 Quality risk management
- 〉 Gap analyses
- 〉 Audits and inspection preparation
- 〉 GxP training
- 〉 Process validation
- 〉 Qualification and validation concepts
- 〉 Implementation or optimization of quality management systems
- 〉 Seamless CQV strategies

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Finale Version

AUTOMATION AND AMITS

〈 Advanced know-how in automation and AMITS 〉

- 〉 Business process mapping
- 〉 Design of manufacturing automation and IT architecture
- 〉 Design of stationary and mobile HMI applications, MES, and data historian software
- 〉 Shop floor integration as connectivity service
- 〉 Robotics, AGV, and material handling optimization
- 〉 Digitalization of manufacturing process and supply chain
- 〉 Pharma 4.0

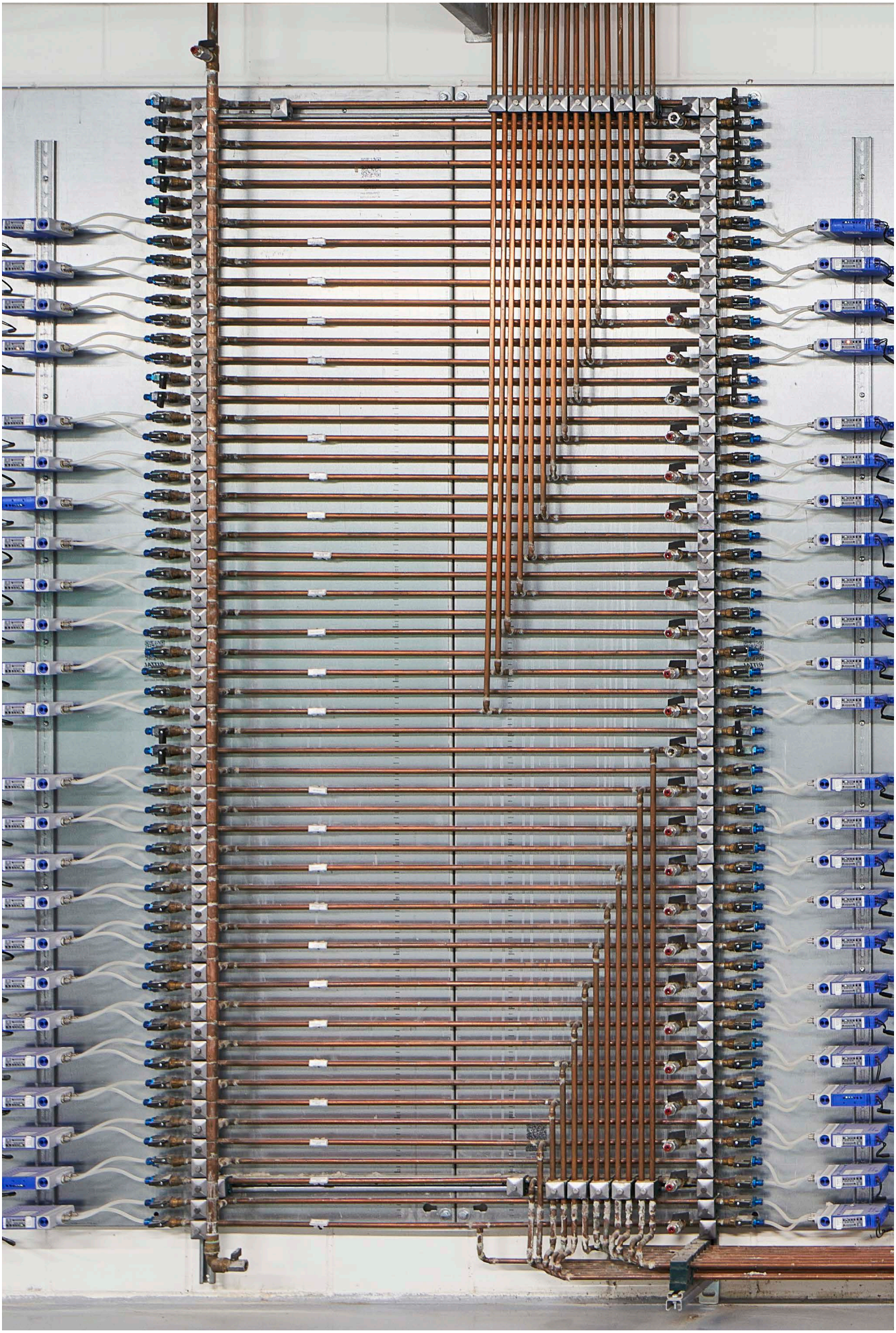
AUTOMATION, MANUFACTURING, AND IT STRATEGIES

With technical expertise in automation (electrical, instrumentation, plant control) and AMITS (automation, manufacturing, and IT strategies), Pharmaplan is perfectly placed to provide all engineering services relevant to greenfield and brownfield facilities. Pharmaplan's AMITS division designs the roadmap and the architecture for Pharma 4.0 production facilities according to international regulatory standards. The AMIT division conducts the gap analysis for manufacturing processes and the automation landscape in general and delivers the basic and detailed design for automation applications. With this broad portfolio of AMITS services, we support our customers' goals to harmonize business processes and interfaces. This approach leads to advantages, including optimized technology transfer, a complete electronic batch record, and the ability to test "by exception."

ELECTRICAL, INSTRUMENTATION, AND FACILITY AUTOMATION

Pharmaplan's understanding of a successful electrical, instrumentation, and facility automation project is based on a modular engineering approach that reduces risks and is crucial for effectiveness and efficiency. Pharmaplan draws on extensive GMP experience to provide expertise in electrical, instrumentation, and facility control for new construction and modernization projects, as well as for modifications in the process, building and utilities, and energies supply areas.

Pharmaplan automation specialists collaborate closely with internal experts for pharma-specific manufacturing processes and utility supply. Our solutions are therefore the result of interdisciplinary cooperation, and this is a major advantage for project planning and execution.



SUSTAINABILITY

〈 Ambitiously energy-efficient and sustainable 〉

〉 Sustainable building shell designs, with emphasis on durability and environmental compatibility
〉 Resource-saving materials and construction
〉 Energy-efficient technical installations, e.g. alternative cooling methods

The Society, the environment, and the economy are the three basic elements of sustainability. We support our customers to achieve sustainable production and climate-neutral plants.

Our sustainability approach to any project is based on an assessment of risks and requirements. It begins during early project phases with impact assessment and continues with updates and reviews of assessment during the life cycle of the project. In a workshop approach, we bring in our extensive knowledge and develop together with our customer strategies that address the individual project need.

During the design phase, we utilize our expertise to translate the predefined energy and sustainability requirements into future-proof engineering solutions. We rely on sustainable innovation to build facilities that fulfill ambitious energy efficiency and sustainability objectives.

With the latest energy consumption tools and software, we help pharmaceutical production companies and CDMOs elaborating energy concepts for their plants. Our main objective is reducing energy consumption, optimizing energy supply, managing on-site energy production and storage, to finally improve the energy efficiency of processes, installations, and whole buildings.

Our architecture department develops projects following the guidelines of the Swiss Sustainable Building Standard (SNBS), Swiss Society for Sustainable Real Estate (SGNI), Minergie, Leadership in Energy and Environmental Design (LEED), Deutsche Gesellschaft für nachhaltiges Bauen (DGNB) and BREEAM (Building Research Establishment Environmental Assessment Methodology).

BIM AND VR

〈 A customized BIM approach, from a basic 3D model to a complex digital twin 〉

〉 BIM management from concept design to execution
〉 Space management
〉 Cloud data exchange
〉 Virtual and augmented reality
〉 BIM to field
〉 BIM to facility management

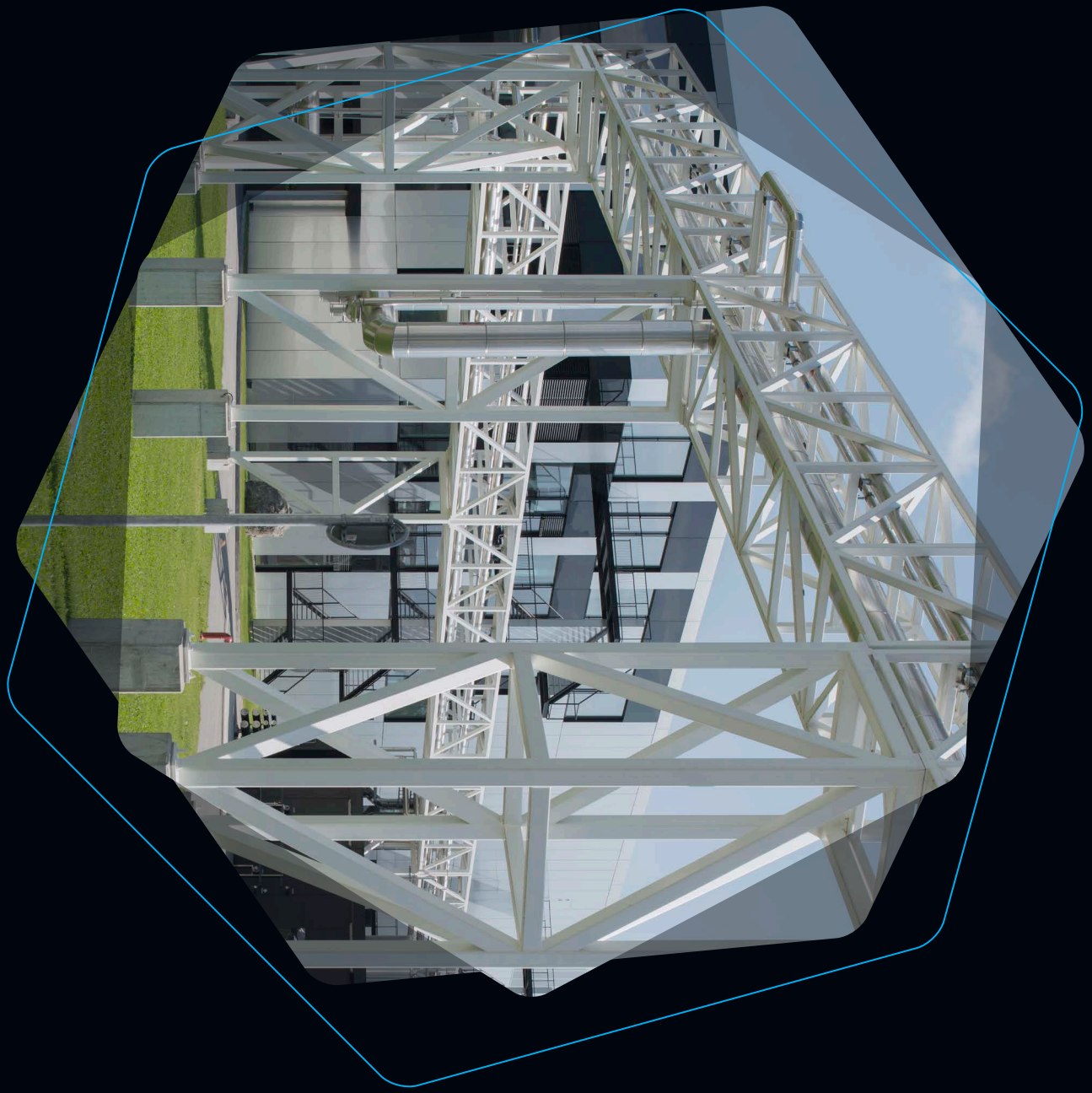
Pharmaplan's preferred methodology for the design and realization of new facilities is building information modeling (BIM) software. BIM is part of our standard setup for collaboration and innovation for all engineering projects.

A BIM model consolidates data on design, construction, logistics, operation, maintenance, budgets, schedules, and much more. Information created in one project phase can be passed on to the next to be developed further. BIM 3D database systems support engineering services in a simple and agile way, and the cloud-based platform Autodesk Construction Cloud (ACC) allows us to share work beyond regional borders in all our Pharmaplan offices. All relevant building data are digitally recorded, connected, and integrated. The building is visualized geometrically as a virtual federated model, and the information and space data are retained in a live database. Based on standards and experience, we work side by side with our customers to help create tailored BIM requirements for every project, defining the scope and the benefits of BIM application. These benefits are enhanced when the process is considered as a whole, and the information/data requirements are coordinated. Through the BIM approach, changes in all phases of the building's lifecycle are immediately visible for all parties involved, and the effects are synchronized immediately. During construction, BIM allows contractors to clarify the design and to provide shared "live" data, which improves the ability to track both time and costs (4D and 5D). All construction managers can monitor construction progress via augmented reality, integrated claim management, and remote field applications.

BIM FOR INDUSTRY 4.0 〉

Pharmaplan designs intelligent, networked buildings for the "fourth industrial revolution"— Industry 4.0. Tools for BIM and augmented/virtual reality are integrated into our daily business: They ensure seamless 3D planning across all disciplines, facilitate automation, minimize replanning effort, enable virtual design reviews, and allow us to set up a digital twin for a facility. A digital twin is a virtual copy of a facility that is paired with real-time information from the facility. The digital twin can then be used to plan and optimize a variety of operational processes (maintenance, trouble-shooting, operators' training, etc.)
As a general design contractor, our BIM approach allows us to coordinate communication among all stakeholders and so to ensure the success of a correct BIM database implementation for the full project lifecycle, including facility management.

REFERENCES PHARMAPLAN



PHARMA PLAN

〈Passion for
pharma engineering〉


Kohlenmonoxid
Stickstoff
Sauerstoff
Prozessluft
21
Airflow Controller

PROJECT 〉 Bovenau Expansion
TECHNOLOGY 〉 Biotech
LOCATION 〉 Germany
CUSTOMER 〉 Confidential
DURATION 〉 2020 – ongoing
TIC 〉 Confidential
SCOPE 〉 EPCMV

PROJECT DESCRIPTION

New multi-production facility for microbial products including QC laboratory and warehouse for capacity expansion of the site.

PROJECT 〉 New ATMP facility
TECHNOLOGY 〉 ATMP
LOCATION 〉 Germany
CUSTOMER 〉 Confidential
DURATION 〉 2020 – ongoing
TIC 〉 Confidential
SCOPE 〉 EPCMV

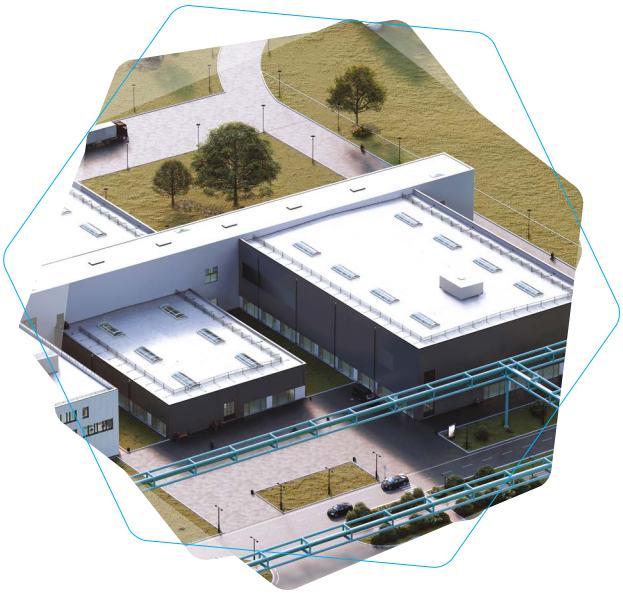
PROJECT DESCRIPTION

New facility for the production of individual-specific therapies. Production of individualized vaccines for several thousand patients per year for both clinical phases and commercial production.

PROJECT 〉 pRED
TECHNOLOGY 〉 Technical and laboratory installations
LOCATION 〉 Basel, Switzerland
CUSTOMER 〉 F. Hoffmann-La Roche AG
DURATION 〉 2019 – ongoing
TIC 〉 1,200 million CHF
SCOPE 〉 Construction management

PROJECT DESCRIPTION

The new pRED (Pharma Research and Early Development) Innovation Center will be the hub of Roche's research activities in Basel. The project consists of two high-rise buildings (Buildings 6 and 7) housing flexible and state-of-the-art laboratories for life science and pharmaceutical chemistry with an associated office zone for 1,800 researchers. A conference and an office building are also part of the project. The four buildings share a common basement with service areas and parking spaces. For more than 20 years, Pharmaplan has been designing and building pharmaceutical facilities for Roche in Basel. We are the preferred engineering partner of Roche. For the new pRED project in Basel, Pharmaplan serves as construction manager for technical and lab installations, responsible both for the two largest laboratory buildings in Switzerland as well as for the building services for all four new buildings (overall construction management by ARGE SB+IB).



PROJECT 〉 Modular solids launch facility
TECHNOLOGY 〉 OSD
LOCATION 〉 Germany
CUSTOMER 〉 Confidential
DURATION 〉 2019 – ongoing
TIC 〉 Confidential
SCOPE 〉 EPCMV partner for process design

PROJECT DESCRIPTION

New greenfield facility and new highly modular brownfield facility for launch products on an approx. 10,000 square meters gross floor area. With this project, the customer gets flexibility and modularity for product launches (process) and simple future changes, adjustments, and reorganizations (facility).

PROJECT 〉 RIOM2 – Greenfield
TECHNOLOGY 〉 Injectables
LOCATION 〉 Riom, France
CUSTOMER 〉 CARBOGEN AMCIS
DURATION 〉 2017 – 2023
TIC 〉 45 million EUR
SCOPE 〉 EPCMV

PROJECT DESCRIPTION

CARBOGEN AMCIS is building a new 9,500 square meters facility dedicated to injectables. These new premises will enable CARBOGEN AMCIS to expand their services portfolio, notably with complex formulations using various chemical and biological agents. Pharmaplan designed an evolutive facility and conducted a containment risk assessment, aiming to define the right strategy to handle High Potent products. Expert teams developed a flexible process design to deal with clinical and commercial batches: development, formulation, and filling of freeze-dried and liquid products. The building will also include research and development and quality control laboratories, as well as administrative functions.

PROJECT 〉 B93
TECHNOLOGY 〉 Packaging and warehouse
LOCATION 〉 Bern, Switzerland
CUSTOMER 〉 CSL Behring AG
DURATION 〉 2020 – 2021
TIC 〉 Confidential
SCOPE 〉 E(P)CM

PROJECT DESCRIPTION

CSL Behring is expanding its secondary packaging area and warehouse capacities. Pharmaplan was awarded the general design and construction management to convert an existing building into a new packaging center and high-bay warehouse. The future building will house visual inspection booths, a high-speed packaging line, and room for future expansion for two packaging lines, as well as a logistics center with a high-bay warehouse.

Pharmaplan's scope included all tasks as a general design contractor, from conceptual design to detail design. Our own architects were in charge of the CSA package. During the design phase, we followed our internal proven safety methodology, ensuring an accident-free construction site, for which Pharmaplan was in charge as construction manager.

PROJECT 〉 Capacity increase and ergonomics and process efficiency improvement
TECHNOLOGY 〉 Fluid bed drying for Ionic exchange resin
LOCATION 〉 Chauny, France
CUSTOMER 〉 DSP SAS, Group DuPont
DURATION 〉 2019 – 2021
TIC 〉 4 million EUR
SCOPE 〉 EPCMV

PROJECT DESCRIPTION

DSP SAS produces Ionic Exchange Resin (IER), used in the pharmaceutical industry as API or excipient. The purpose of the project was to increase production capacity by adding a second dryer (fluid bed technology) within a building extension and improving ergonomic aspects and process efficiency (loading, cleaning, and transfer). Pharmaplan consolidated the preliminary study done by the customer and followed the entire design and execution, with a strong focus on the process: supplier selection, trials at suppliers' manufacturing sites, design qualification, installation, commissioning, IQ, OQ.

PROJECT 〉 F²VE – Greenfield
TECHNOLOGY 〉 Veterinary vaccines
LOCATION 〉 Lyon, France
CUSTOMER 〉 Boehringer Ingelheim Animal Health
DURATION 〉 2017 – 2021
TIC 〉 62 million EUR
SCOPE 〉 EPCMV

PROJECT DESCRIPTION

Pharmaplan conducted the complete detailed design, construction, and qualification of a new large-scale facility for formulation and filling of inactivated virus vaccines for farm animals. Boehringer Ingelheim Animal Health's new production unit covers three levels and a total of 6,000 square meters. It includes a formulation area, high complexity transfer, and CIP/SIP systems, an aseptic filling line, areas for storage, support functions, and an administrative area.

PROJECT 〉 New biotech production facility
TECHNOLOGY 〉 Monoclonal antibody production
LOCATION 〉 Visp, Switzerland
CUSTOMER 〉 Confidential
DURATION 〉 2017 – 2021
TIC 〉 Confidential
SCOPE 〉 EPCMV

PROJECT DESCRIPTION

With Pharmaplan in the role of EPCMV partner, our customer expanded its production capacity with the first facility within its new biotech areal. Pharmaplan handled the complete project scope as an EPCMV partner, from feasibility study to construction, and supported the customer during commissioning and qualification. Our scope included the disciplines of project management, architecture, process, and building services. Planning of electricity and automation were managed by the customer. A main objective was high flexibility throughout the entire building. Future modernizations and expansions should be possible without disrupting ongoing production. To overcome this challenge, Pharmaplan's in-house architects designed the core and shell of the building with a cleanroom-approved facade, which guarantees partial removal. Successful project execution was possible thanks to the utilization of a cloud-based BIM environment with all disciplines fully integrated, and BIM 360™ Field was used as a tool during construction management.

PROJECT 〉 Protinus
TECHNOLOGY 〉 Bulk manufacturing lines
LOCATION 〉 Bern, Switzerland
CUSTOMER 〉 CSL Behring AG
DURATION 〉 2017 – 2021
TIC 〉 Confidential
SCOPE 〉 general design contractor, construction management, commissioning & qualification lead

PROJECT DESCRIPTION

With Pharmaplan as general design contractor, construction management, commissioning & qualification lead, CSL Behring is expanding its production capacity to keep up with global demand for its market-leading immunoglobulin products. The new building accommodates two additional manufacturing lines for immunoglobulin products. This extension is a multi-story building with three basement levels. The new building is connected to the already existing service and logistics center at the site. Its core includes immunoglobulin bulk manufacturing, space for future sterile filling line, and utility and logistics rooms. Pharmaplan took on the role of general design contractor to support the production expansion. A fast-track approach was applied in all project phases to meet the strict timeline. The basic design, for instance, was executed in just six months. The new production building and the building envelope had to be built within a limited time frame and without any interruption to the existing site operations. Also, with the footprint of the new buildings taking up the majority of the remaining site area, there was very limited space for the kind of construction site that this type of project usually requires.

PROJECT 〉 New solids launch facility
TECHNOLOGY 〉 OSD
LOCATION 〉 Ingelheim am Rhein, Germany
CUSTOMER 〉 Boehringer Ingelheim Pharma GmbH & Co. KG
DURATION 〉 2016 – 2021
TIC 〉 90 million EUR
SCOPE 〉 EPCMV

PROJECT DESCRIPTION

The pharmaceutical company Boehringer Ingelheim Pharma GmbH & Co. KG wanted to establish a new central launch and production facility with containment requirements (OEB4) within the Boehringer network in Ingelheim am Rhein. The new facility should on the one hand be highly flexible and modular for the manufacturing of launch products, and on the other hand implement "state-of-the-art" containment technologies. To be flexible to future needs, the complete design of the facility has to be very easily adaptable to other manufacturing processes and room for expansion should be planned in.

PROJECT 〉 Six-storey laboratory building
TECHNOLOGY 〉 Scalable modular laboratories
LOCATION 〉 Visp, Switzerland
CUSTOMER 〉 Confidential
DURATION 〉 2018 – 2020
TIC 〉 Confidential
SCOPE 〉 EPCM

PROJECT DESCRIPTION

With Pharmaplan as an EPCM partner, our customer was building a large multipurpose laboratory for different uses of its manufacturing complex. Pharmaplan was responsible for the complete EPCM scope. The core and shell of the building were designed by Pharmaplan's in-house architects. The complete facility is based on a modular laboratory concept, which allows both maximum utilization and maximum flexibility to adjust to changing requirements in terms of room size and arrangements for a multipurpose laboratory for different uses. The engineering scope included the preparation of the complete URS. The fast-track approach and the strict budget meant that overall there was only 1.5 years from putting pen to paper to the hand-over to the operators. Pharmaplan is currently assigned the fit-out of the remaining floors as an EPCM partner.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PROJECT 〉 Pegasus III – Capacity increase
TECHNOLOGY 〉 Medical devices
LOCATION 〉 Pringy, France
CUSTOMER 〉 Allergan
DURATION 〉 2017 – 2019
TIC 〉 17 million EUR
SCOPE 〉 EPCM

PROJECT DESCRIPTION

To increase capacity, Allergan planned to modernize and extend its existing medical device manufacturing plant. The overall project is approx. 4,000 square meters and encompasses a new receiving warehouse, a new packaging line, the upgrade of the bulk area, and all associated utilities, energies, and technical areas. Allergan developed a conceptual design and then asked Pharmaplan to plan, consult, design, and produce all documentation and coordinate the implementation of the project.

PROJECT 〉 B098 IVR
TECHNOLOGY 〉 In-vivo research laboratory
LOCATION 〉 Basel, Switzerland
CUSTOMER 〉 F. Hoffmann-La Roche AG
DURATION 〉 2014 – 2019
TIC 〉 250 million CHF
SCOPE 〉 EPCM

PROJECT DESCRIPTION

As a general design contractor, Pharmaplan has contributed significantly to F. Hoffmann-La Roche receiving the Facility of the Year Award 2020 in the category "Equipment Innovation". Pharmaplan was the general design contractor of this highly automated laboratory facility with a focus on flexibility, functionality, automation, and security. Roche will centralize all of its Basel in vivo research units into this new building, which covers present and future needs. The equipment innovations that are found in every part of the project aim to protect researchers and animals, drive efficiency, and set new industry standards for animal research.

PROJECT 〉 New f&f facility for high potent / cytotoxic ADC products
TECHNOLOGY 〉 Fill & finish
LOCATION 〉 Germany
CUSTOMER 〉 Confidential
DURATION 〉 2012 – 2019
TIC 〉 Confidential
SCOPE 〉 EPCMV partner for process design

PROJECT DESCRIPTION

As part of its pharma manufacturing strategy, the client set a strategic goal in 2012 to establish a multi-purpose lyo-liquid line ("multi-purpose production unit pharma - infrastructure") in Germany. This provided the necessary capacities for the transfer and launch of new products, as well as a strategic "agility reserve" within the biologics drug product network.

PROJECT 〉 New fast track OSD production facility
TECHNOLOGY 〉 OSD
LOCATION 〉 Ingelheim am Rhein, Germany
CUSTOMER 〉 Boehringer Ingelheim Pharma GmbH & Co. KG
DURATION 〉 February 2016 – July 2017
TIC 〉 Confidential
SCOPE 〉 EPCMV

PROJECT DESCRIPTION

The pharmaceutical company Boehringer Ingelheim Pharma GmbH & Co. KG needed a partner who would help them design and realize an OSD production facility in a time frame of just 18 months – from the first sketch until the start of commercial production. High flexibility and modularity were further demands, as commercial production will run for a limited time only before the facility is remodeled for other production purposes. In addition to time and flexibility, simplification was the third design driver, and lessons learned were to be collected to be considered in future projects.

PROJECT 〉 New aseptic production facility
TECHNOLOGY 〉 Fill & finish
LOCATION 〉 Reinbek, Germany
CUSTOMER 〉 Allergopharma GmbH & Co. KG
DURATION 〉 2012 – 2016
TIC 〉 Confidential
SCOPE 〉 EPCMV

PROJECT DESCRIPTION

Allergopharma wanted both a representative and functional production building. However, the existing area was rather limited, and local restrictions in the industrial area had to be considered. In a challenging design and execution process, we could implement all requirements into a representative and fit-for-purpose building.

PROJECT 〉 Greenfield aseptic filling
TECHNOLOGY 〉 Injectables
LOCATION 〉 Gerland, France
CUSTOMER 〉 Aguettant
DURATION 〉 2011 – 2015
TIC 〉 Confidential
SCOPE 〉 EPCMV

PROJECT DESCRIPTION

Pharmaplan supported Aguettant in designing and realizing a new aseptic filling facility, from conceptual design studies up to qualification activities. The new building encompasses a new filling line, line transfer, laboratories, and packaging activities, and aims to secure Aguettant's production capacity while simultaneously remaining compliant amid high pharmaceutical standards, all in a cost-effective manner. Aguettant also sought Pharmaplan's support to review its engineering service to ensure compliance in all processes and piping and instrumentation diagrams for another production site.

PROJECT 〉 Edelweiss
TECHNOLOGY 〉 Microbial production facility
LOCATION 〉 Bulle, Switzerland
CUSTOMER 〉 UCB Farchim AG
DURATION 〉 2011 – 2014 (2017 capacity increase)
TIC 〉 172 million CHF
SCOPE 〉 EPCMV

PROJECT DESCRIPTION

With Pharmaplan as a skilled EPCMV partner, UCB Farchim has successfully built a new greenfield microbial production facility for Cimzia™ production in Bulle, Switzerland. Pharmaplan designed and built one of the largest biotech production facilities in Europe within 28 months. Two years after successful hand-over, Pharmaplan supported UCB again in increasing the production capacity for Cimzia™ to 1,000 kg/year. UCB's new greenfield facility for antibody production against rheumatoid arthritis is the main production center for Cimzia™. It is fitted with ultramodern laboratories and a highly automated production line. One of the main challenges was the ambitious schedule that aimed at fast-track finalization in 28 months.

PACKAGING AND WAREHOUSE

CORE & SHELL

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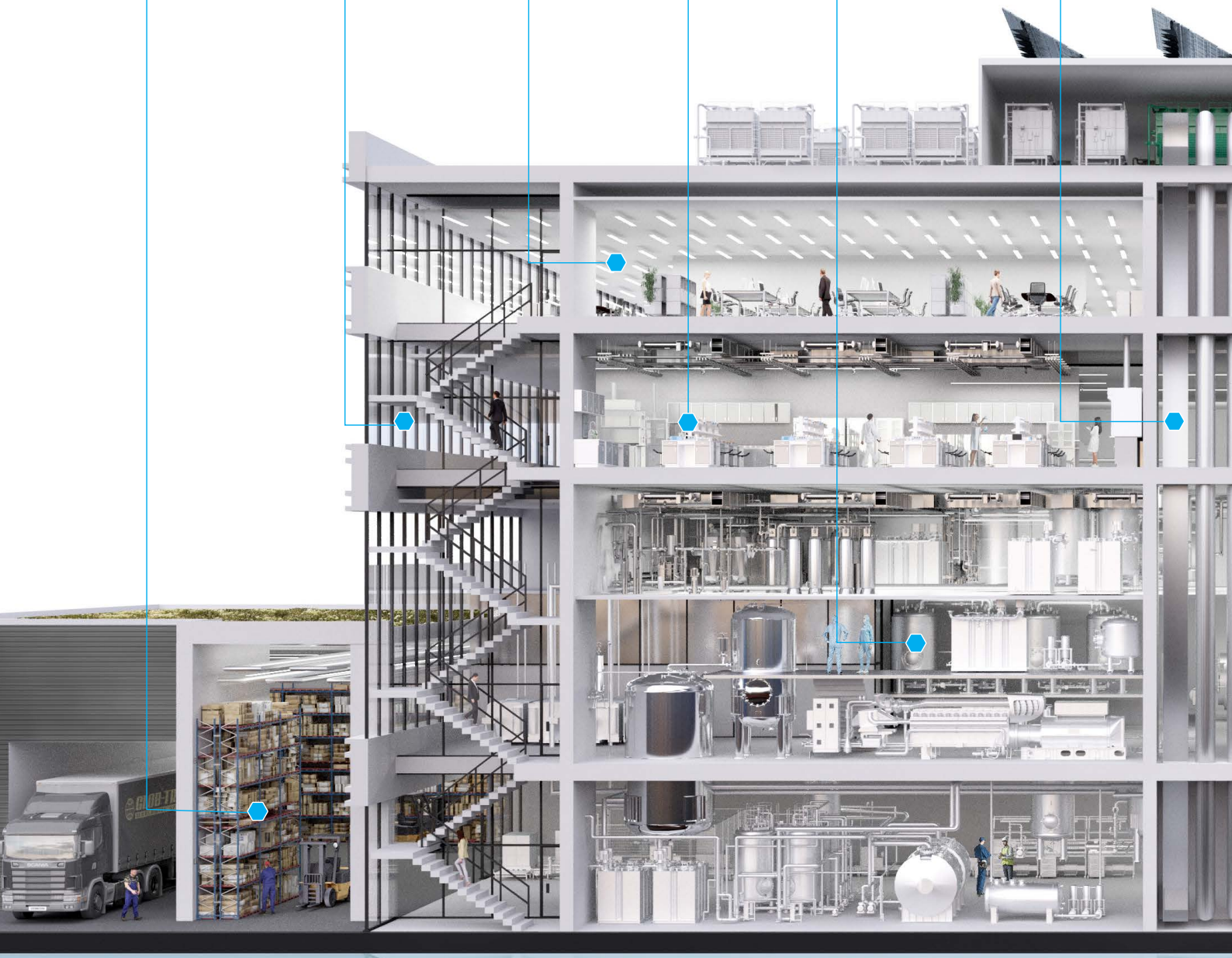
LABORATORIES

PROCESS

BUILDING INFORMATION MODELING



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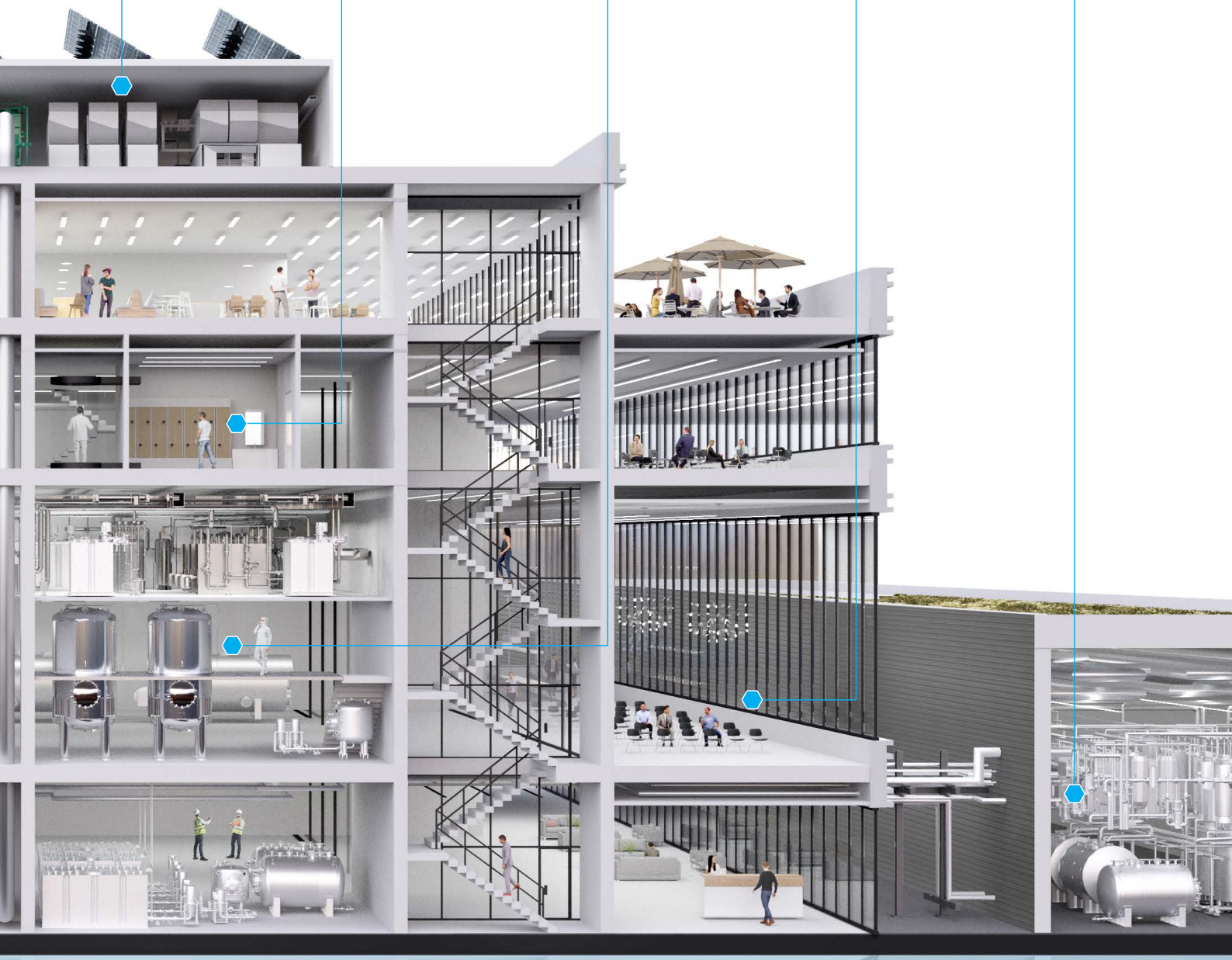

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