



ips

GERMANY, SWITZERLAND & AUSTRIA REGION

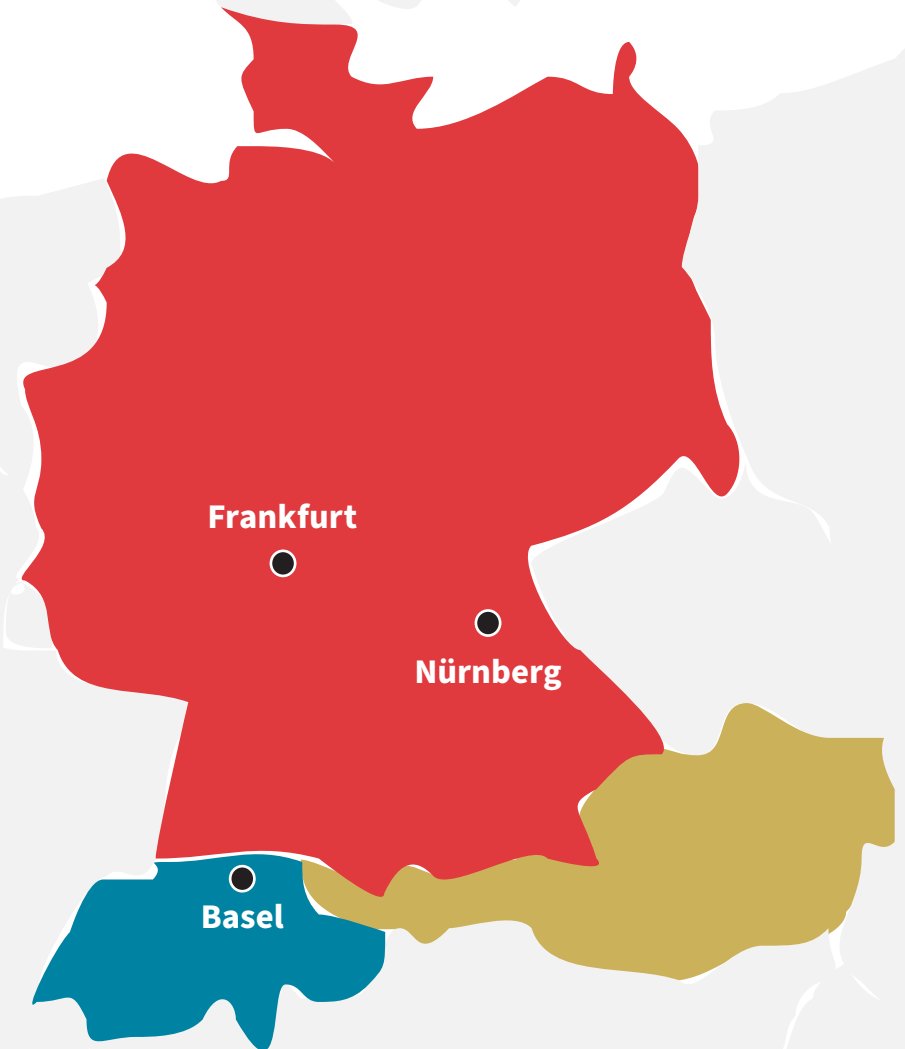
Professional Services Qualifications

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Knowledge, Skill & Passion | www.ipsdb.com

IPS IS AN INDUSTRY LEADER IN THE LIFE SCIENCE SECTOR

With accelerated growth in EMEA region over the past 8 years, IPS has established a significant presence, particularly within the Germany and Switzerland region. We have acquired top tier talent and have built an in-depth network of resources to fuel complex and intensive projects. Through the strategic development of our operations, we are fully capable of meeting client needs with our cultivated expertise.



LOCAL SUPPORT

Offices:

- Basel (Switzerland)
- Frankfurt, (Germany)
- Nuremberg (Germany)

Spoken Languages:

- We execute project in German, English and French.

Core Strengths:

- Aseptic Processing
- Bioprocess and ATMP Facility Design Leadership
- Biologics Drug Substance Manufacturing
- Process-Driven Solutions
- Complex Project Leadership

Local Capabilities:

- Early Design through Construction and Qualification
- Design: Project Management, Process &

- Process Architecture, Building Services
- Construction: Procurement, Construction Management, Field Engineering
- CQV: Master Planning, Design Reviews, Start-Up & Commissioning, GMP Compliance and Qualification
- EPCMV Integrated Project Delivery

Global Expertise:

- We leverage a global network of experts across the UK, Ireland, and the US, drawing on their specialized technical knowledge to enrich our projects. Through collaboration tools and digital platforms, we ensure seamless knowledge sharing and synergy.
- Projects can utilise the expertise of our design detailing resource located in the IPS India offices.



OUR COMMITMENT TO SAFETY

Safety is a core value at IPS and we incorporate it into all aspects of our business culture. We protect our most valuable assets, the employees, along with our clients, subcontractors, and vendor partners from injury and illness through our regimented and proven safety trainings, policies, and procedures.



Our Safety Program was established to ensure a safe and healthy environment for all IPS employees, subcontractors, suppliers and visitors.

Safety is a mindset. Safe projects require commitment at all levels of the organisation and promote safe behavior, positive attitudes, sound judgment, and good decisions.

Our team places safety above all other considerations in executing our work. We strive at all times to create a 100% safe work environment, on-site and in the office, with zero accidents and zero injuries.

To support our culture of safety, we created our 'Mission Zero Safety Program'. The purpose of the program is to ensure a safe and healthy environment for all employees. By developing expectations and standards, providing training and ensuring continual

education and improvement in construction job-site and workplace/office safety and health, we promote safety awareness and demonstrate safe behavior.

From a project standpoint, we insist that our contractors understand and share our values to ensure our clients receive the highest level of project safety. This is the backbone that inspires all of the safety procedures put in place for each location based on local requirement.

We continue to work strategically and collaboratively toward achieving a positive safety culture and creating safe workplace environments. Our core pillars of the Mission Zero Safety Program are:

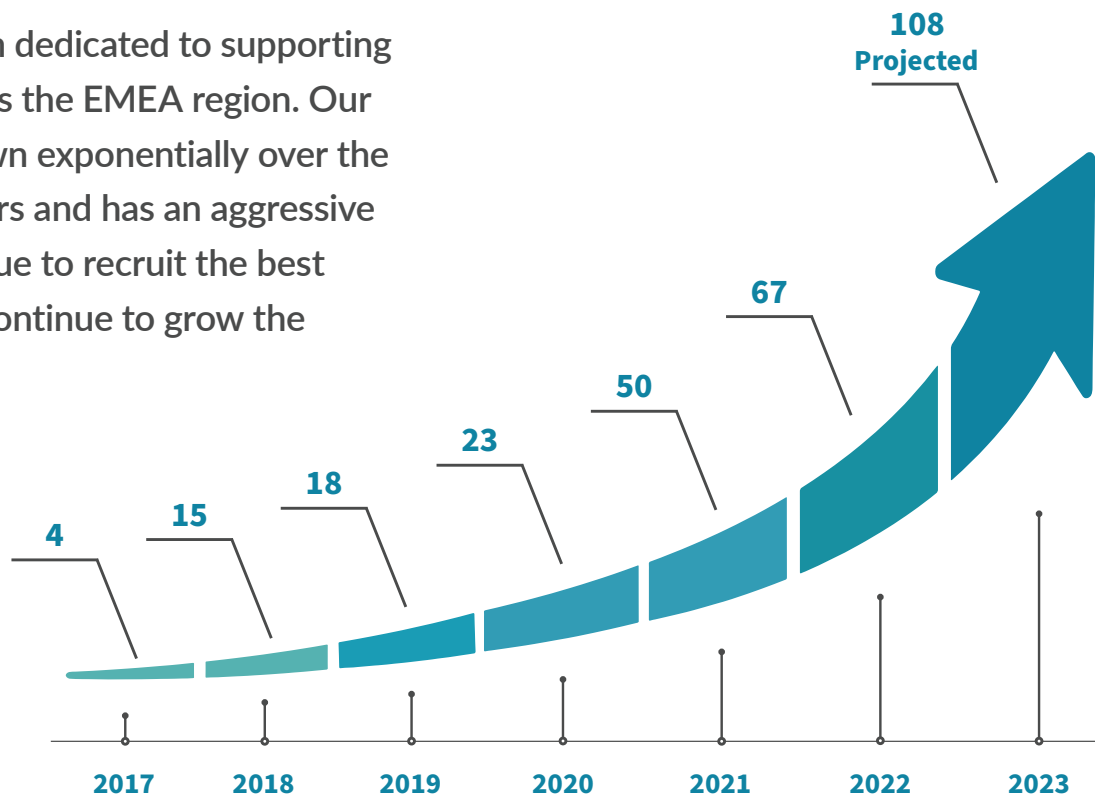
- Commitment to an incident and injury-free workplace from every employee
- Zero tolerance for safety inadequacies
- Continual development and advancement of safety training programs
- Promote safety with the first topic of discussion at every meeting
- Review ASAP, within 24 hours, every recordable incident for company and subcontractor employees

IPS EXPERTS

Over 100 employees in Germany and Switzerland, who are supported by over 2,000 technical experts globally.

IPS has a team dedicated to supporting projects across the EMEA region. Our team has grown exponentially over the last seven years and has an aggressive plan to continue to recruit the best talent as we continue to grow the business.

Employee Numbers in Germany and Switzerland



Our team is comprised of the following disciplines:

Discipline	Employee Total
Project Management	16
Design Management	3
Architectural, BIM, Piping	10
Process, Technology SMEs	20
Electrical, Automation	5
Mechanical, HVAC, Utilities	7
Procurement	2
Project Controls, Scheduling	9
Construction, HSE	6
CQV	8
Support Functions	7

CORE INDUSTRIES & EXPERTISE

IPS professionals apply their technical and operational expertise to help companies, across most major industries, create and manufacture life-impacting products around the world.

Internationally Recognized Technical Expertise

- Advanced Aseptic Filling / Barrier Technologies
- API / Small Molecule Manufacturing
- Oral Solid Dosage (OSD)
- Biomanufacturing, Cell & Gene Therapies, Vaccines
- Potent Compounds and Containment
- Scale-up / Tech Transfer
- Critical Utilities / Utility Design
- Laboratories / Vivariums
- Risk-based Commissioning & Qualification
- Serialization & Traceability
- i CON™ / Flexible, Lean & Turnkey Modular
- Construction Administration Support / Integrated Project Delivery

Core Industries

- Cell & Gene Therapies
- Pharmaceutical
- Biotechnology & Biomanufacturing
- Animal Health
- Medical Device & Diagnostics (Radiopharma)
- Science & Technology
- Advanced Therapy Medicinal Products

IPS EXPERTS

Our team of IPS Experts create and shape results-oriented strategies that yield practical, cost-effective business solutions to achieve your project and business objectives.

Our team has years of practical knowledge on topics and technologies that drive biopharmaceutical industry forward. Our experts bridge the gap between scientists, owners and users to deliver state-of-the-art facilities and labs that align with FDA, EMA and USP guidelines. Our core and management team includes the following individuals.

KEY PERSONNEL



Catherine Jomary

ATMP Subject Matter Expert

Catherine, a cell and gene therapy specialist, has 20+ years' experience in academia, biotech, CDMO, and pharma. Her work spans pre-clinical to commercial stages, including regulatory prep and launch processes. As a pivotal liaison, she bridges clients, supply chain, QC, business development, and regulatory authorities for successful manufacturing of therapy products.



Luis Martinez

Sr. Biotech Consultant

Luis's proficiency in biological product manufacturing stems from extensive production and QA experience. He has managed both antigen production for vaccines and diagnostic kits, and related QA activities, including audits and batch releases. His involvement in CMO tech transfers, coupled with his expertise in production, QA/QC, project management, and strong relational and linguistic abilities, makes him a key team member.



Cecilia Devlin

Lead Process Architect

With 27 years of experience, Cecilia specializes in managing large-scale architectural projects across biotech, pharmaceutical, food, and med-tech industries globally. Her involvement spans site selection, design, construction, and on-site acceptance. Cecilia's leadership, logical approach, and track record of delivering projects on time and budget showcase her competency in managing complex projects and teams.



Victorino Boavida

Head of Process Utilities

Leading IPS's Clean Utilities Team, Victorino orchestrates investment projects in the biopharmaceutical industry, encompassing pharmaceutical processes, plants, laboratory technology, and infrastructure. As a Senior Clean Utility Engineer with over 10 years' experience, he brings profound expertise in project engineering, production, qualification, and plant engineering.



Heiko Loeser

Process Engineering

Heiko has over 10 years experience in planning and execution of projects for drug / vaccine development and manufacturing. Heiko is experienced with leading cross-functional teams. His current focus is on fill & finish projects and secondary packaging. Has previously worked for a manufacturer of filling machines for the pharmaceutical industry.



Adam Isa

Process Engineering

With a decade's experience in engineering, project management, and strategic business growth, Adam excels in large-scale pharmaceutical and telecommunications projects. His focus on Process Engineering drives operational excellence in major pharmaceutical industrial projects, ensuring quality design, feasibility, fast-track execution, and cost-conscious alignment. His unique background leverages existing synergies for optimal outcomes.

KEY PERSONNEL



Victor Cotoranu

*Construction
Management*

Long-time Building Services Engineer, with more than 30 years project and construction management experience in medium to large commercial and industrial construction projects in various countries, with the mission to provide best results and added value to the customers in all design and execution phases until handover.



Rene Degens

*SiGeCo and HSE
Management*

Rene has many years of experience in the EHS sector and has also gained excellent in-depth knowledge of various specialist topics through permanent further training measures and certifications.



Hermann Schilling

*Regulatory Compliance &
Aseptic Processing*

Hermann, with 30 years in the pharmaceutical industry, specializes in sterile product production and facility engineering, from conceptual to detailed design and commissioning. A skilled leader, he's overseen teams of mechanics, operators, and engineers, managed complex projects, and has deep regulatory knowledge, preparing numerous companies for government audits.



Luca Paoletti

CAD BIM Manager

As a BIM Manager, Luca brings 8 years' experience optimizing BIM processes across pharmaceutical and healthcare projects. His roles span concept design to C&Q on 15+ projects, including biotech and cleanroom retrofit. Luca develops BIM setups, coordinates design and space, and manages process equipment. He's skilled in Revit ARC/MEP, Navisworks Manage, and other software.



Heike Zimmerman

Compliance/CQV Manager

Heike excels in the biotech industry, specializing in cleanroom concepts, system qualification, and auditing across production installations to warehouses. Her background in chemistry, process engineering, thermodynamics, and material science, combined with her 5-year experience at IPS leading CQV projects and applying modern CQV concepts like ASTM E2500, makes her an invaluable project asset.



Nesli Efecan

Validation

Nesli has is a well-organised and systematic person with 10 years experience in CQV. Good production equipment and validation knowledge and enjoys studying new projects and implementing procedures to ensure correctly placed equipment/ systems are used in projects.

KEY LEADERSHIP



Brian Peasley

Sr. Regional Director

Brian brings 25 years' expertise in biotech and pharmaceutical industries, specializing in project management, engineering, biocontainment, HVAC, and mechanical design for science facilities. His understanding of laboratory design, utility engineering, energy optimization, and cost estimation enables effective project scheduling and strategy development. Recently, he's managed large capital investments for major biopharmaceuticals expanding in Europe.



Helmut Steudel

Sr. Regional Director

Helmut joined the IPS's European Leadership Team, setting up the engineering procurement and construction management operation in Germany. With 35+ years' experience, he's an expert in life science engineering, driving revenue in Fortune 500 companies and government sectors. He fosters strategic relationships, leads proposal teams, negotiates deals, and transforms underperforming groups. His global experience spans industries and major clients like Amgen, Roche, and Pfizer.



Gabriele Vismara

Sr. Project Manager

Gabriele, a self-motivated, results-oriented professional, excels in end-to-end capital project delivery in pharmaceutical and biotech sectors, handling projects from 10 to 500 million Euros. With an MSc in Mechanical Engineering and 15+ years' experience in contracts, she's a hands-on leader adept at managing large, multicultural, and geographically diverse teams.



Patrick Pinede

*Project Director
Business Development
Lead*

Patrick possesses a 34-year diverse career in mechanics, energy, business administration, and project management. His varied roles include Global Engineering Vice-President, acquiring expertise in safety, engineering, and industrial development across multiple sectors and countries. Proficient in implementing strategic programs, Patrick excels in optimizing structures, simplifying processes, and accelerating transformation to enhance ROI and asset productivity.



Thorsten Friedrichs-Schmidt

Director, Design Operations

Thorsten brings 16 years of project management experience and international team leadership. His diverse roles include strategic consulting and department management. He's led various projects, from quality improvement and large-scale innovation plans to market entry studies and business process optimization.



Anna Jonasch

Project Manager

Anna Jonasch, with 9 years in engineering and project management, is a proficient bilingual communicator in German and English. She excels in critical thinking, problem-solving, and working within multi-disciplinary teams. Her client-side facilities and maintenance project management experience strengthens her collaboration among operations, maintenance, and engineering/design teams.

KEY LEADERSHIP



Sebastian Steinwarz

Procurement Lead

Sebastian, a procurement expert, specializes in highly specified engineering systems for industries like pharmaceuticals and semiconductors. His competencies include procurement route optimization, contract and supplier management. Recently, he's assessed needs across various companies and established new procurement and supply chains.



Patrick Eiche

BioProcessing & Project Lead

With 9 years in biotech and pharmaceuticals, Patrick excels in planning and implementing biotech processes for industrial production. Skilled in interdisciplinary coordination, tendering, decontamination strategies, and mechanical skid design, Patrick leverages his education and experience to efficiently manage design and execution phases in small to large investment projects.



Andrea Cura

Project Controls

Andrea has over 7 years of experience in project management and project controls. He has worked on complex projects across the pharmaceutical and oil&gas sectors. His technical and commercial background brings value in driving projects to reach their goals



Serdal Yuceel

Project Management

Serdal Yuceel has over 15 years of experience in project management & structural engineering. Ability to handle multiple tasks with excellent tracking and professional communication. Professional competency in MS Office – able to create professional project schedules. Excellent project management skills, organized and detailed oriented. With extensive experience in BIM/Revit engagement on projects.



William Craig

Process Engineering & Project Management

Knowledge, Skill & Passion

As a Process Engineer and Project Manager, Craig leverages 25+ years' experience in global capital project design, implementation, and validation. Initially in construction engineering, he transitioned into hygienic process. Craig has executed projects globally across food, dairy, drinks, and life sciences sectors. Known for innovative, economical, and safe solutions, he excels at multicultural team leadership and effective communication.



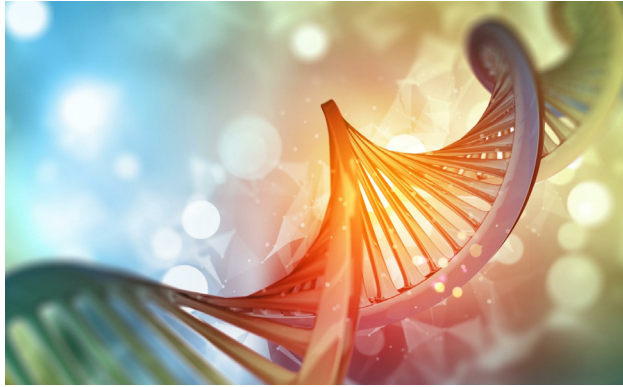
Prince John

Design Manager

A seasoned Design Manager with 19 years of diverse experience in spearheading large projects across industries like Biotechnology, Pharmaceuticals, Semiconductors, and Automotive Manufacturing. Demonstrates exceptional leadership, project management, and design skills, ensuring flawless, timely delivery. Experienced in managing global teams and overseeing master planning of facilities. Committed to results and maintains a strong passion for Design Management.

PROJECT REFERENCES

We support our clients regionally and around the globe and work on projects that utilize a wide spectrum of disciplines, technologies, tools, and subject matter expertise. We offer clients a single source, integrated approach to designing, constructing, and validating technically complex facilities that span across industries and facility types.



CelonicAG

ATMP HQ Renovation

Basel, Switzerland

5,700m² Renovation/1,000sqm Expansion | €40,000,000
| Consultation and Planning, Engineering/Design, Pre-
Consultation Management, CVQ

IPS were engaged by Celonic to use their industry-leading facility design and laboratory optimization expertise to develop the scope of their new headquarters. The new facility will house Celonic's Swiss ATMP Manufacturing, QC and R&D Laboratories and associated support spaces.

IPS' engagement started early in collaborations with Celonic to develop the user requirements (URB), defining how a flexible, state-of-the-art CDMO ATMP facility can be economically and practically achieved, transitioning into Basic Design to allow the project to progress through realization.

Celonic focus on GMP-compliant production of recombinant therapeutic proteins in mammalian cells and are diversifying into Cell and Gene Therapies, or ATMPs - Advanced Therapy Medicinal Products. This required a consolidation of Swiss operations to offer a highly flexible facility that offers malleability in the technical application as this area of the business develops. IPS were selected based on best in class laboratory expertise and a growing global reputation in innovating and flexibly working with Clients to achieve optimum project outcomes. A building on the Rosental campus was selected for the headquarters, and IPS worked together with Celonic to develop their preliminary vision for the consolidated operation into a facility renovation and expansion scheme.



Confidential Client

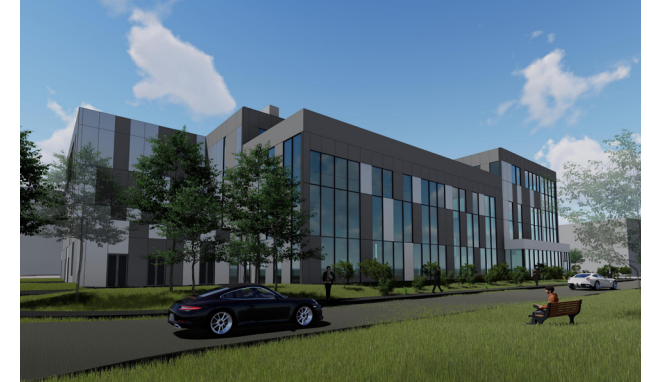
New Filler Addition (NFA) Project

Neuchâtel, Switzerland

5,000 m² | €60,000,000 | EPCM

The objective of this project is to build a new building with an aseptic Drug Product production line (buffer tank, filling line, freeze dryers, isolator, capping and printing machine, automated visual inspection and Control Closure Integrity Testing) in the Neuchâtel existing site.

The scope of the project was to design a new fill/finish facility capable of manufacturing both liquid and lyophilised product. The filling line was assessed for capability to fill both vials and syringes on the same line. The fill line is integrated with lyophilization capacity and finished product will be subject to automated inspection. The facility is to be provided in a purpose-built building on the existing site. The facility is comprised of four (4) levels housing Lyophilizer Technical/Utilities area on level 0 including gowning, with subsequent levels housing the fill/finish area, a technical area, additional production space, and an office area. Levels 1 and 3 each have a technical mezzanine space to support the immediate production spaces. The facility is designed in such a manner as to allow the phase future expansion of the facility. Levels 0, 1 and 2 are to be fitted out in Phase 1, and Level 3 in Phase 2.



Confidential Client

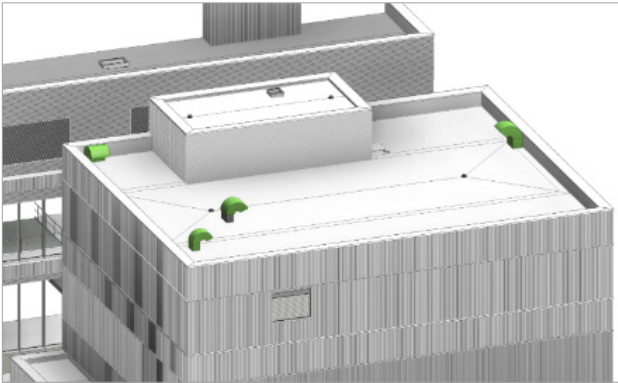
New Gene Therapy Facility

Benelux

15,000 m² | €150,000,000 | EPCMV

IPS provided EPCMV services for a new gene therapy facility, covering development labs, AAV manufacturing, QC labs, warehousing, clean utilities, building services and integration into client's campus.

The scope of the project was to build a 15,000sqm building, including QC labs, development labs, AAV manufacturing, offices, utilities and warehousing. Two fill-finish facilities were included in the design. IPS used our network of SMEs to work with the client in developing manufacturing solutions as well as designing the facility. The facility was designed with expansion in mind, with two areas of future expansion incorporated within the facility that could be developed seamlessly into the final facility with minimal disruption. Rigorous cost control and highlighting of impact of change in terms of final total installed cost enabled the client to stay on target with budget and time. IPS facilitated the client's decision making through provision of timely and accurate data. IPS undertook a value engineering exercise with the client where the project was descoped to ensure that the project met the business case. To quote the client, IPS was asked to design a Ferrari and did that brilliantly, but the client decided to build something more modest. IPS worked with the client to understand the key requirements and where the value for the client was and amended the design accordingly.



Carbogen Amicis

New API Facility

Hunzenschwil, Switzerland

4,300m² | €110,000,000 | Basic Engineering, Detailed Design

IPS was tasked to design a warehouse to support the main API Production Building. The project entailed the design of a new greenfield API manufacturing facility.

This involved the design of a production building which was supported by a warehouse laboratory and utility building. The building comprised of 4 levels, including a basement that was 6m below ground level.

The warehouse and production building were connected at the basement level via a link corridor. The warehouse consisted of an ambient controlled storage area, acid/base store, solvent store, packaging store and cold storage areas.

The building also used material sampling areas. Due to the nature of the products and materials being stored, large sections of the building were classified as ATEX zones.



Confidential Client

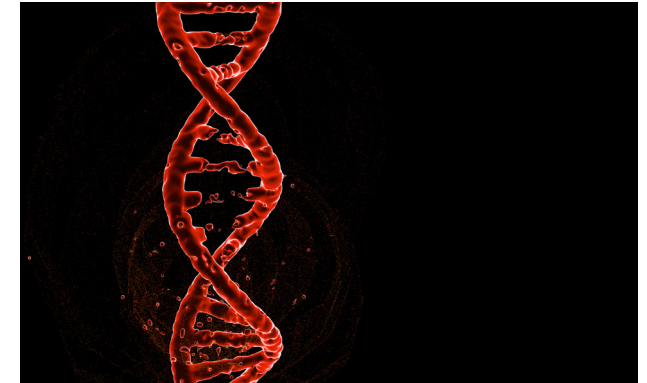
Viral Vector Manufacturing Facility

Germany

1,000 m² | €20,000,000 | EPCMV

The client was looking to increase production for their approved CAR-T product and produce clinical gene therapy clinical trial material. In support of these operations, the client desired to establish internal viral vector production capabilities, starting with a fast-track clinical facility located in an existing building.

IPS proposed their iCON delivery strategy, an off-site fabricated modular solution composed of a series of cleanroom "boxes" or PODs, engineered around the clients manufacturing process. The iCON team took their pre-engineered ÜBERcellFLEX24 modules and optionized them to meet the viral vector/gene therapy process requirements, effectively shaving several months off the design and fabrication schedule. The ÜBERcellFLEX units were constructed and FAT'd in a factory in Ireland before being shipped to the IPS construction site in Europe. The initial build was to meet clinical capabilities, with provisions to build out a 200L commercial operation. The new clinical and commercial facilities are designed to produce virus at 50L and 200L scale. IPS provided level of customization to fit the modules within the facility as well as rig them into place. The clinical and commercial programs required four ÜBERcellFLEX24 units. The PODs are BSL2 and autonomous from a ventilation, electrical and building automation and control perspective. The iCON team created a 3D model of the client's specific process train to verify the fitment in the ÜBERcellFLEX24 design. IPS attained an isolator for the filling operation within 3 months. Our customer was able to fast track their project in an adjacent model to their normal business operations.



WuXi Biologics Germany GmbH

Covid Viral Vector and Antibody Project

Wuppertal, Germany

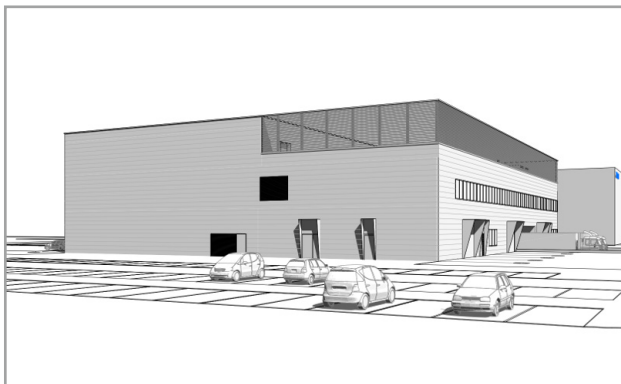
3,800m² | €70,000,000 | Project and Construction Management

IPS is providing project management support and engineering services as Wuxi rebuilds a former Factor 8 cell culture facility for vaccines production. This project entails complex facility and process changes to accommodate a portfolio of Wuxi products and CMO flexibility.

Wuxi has acquired two biologics production facilities from Bayer. The Wuppertal Plant is a fairly new plant that was developed to produce Factor 8 and consists of multiple trains of upstream and downstream biologics production equipment. Wuxi will retrofit the plant to manufacture its Covid vaccine and other viral vectors.

Wuxi is seeking support in Engineering Management, HVAC Systems and Construction Management, Permitting and Document Control. They also need an engineering and construction management team to develop a complete set of construction and permitting documents, and the team to manage the field works. Concept Process Design is done in Shanghai, China.

Challenges of the project entail a high volume of change management, a hyper busy market for resources and equipment, and transfer of technology from China to Germany.



Catalent Germany Schorndorf GmbH

New GMP Ambient Warehouse

Schorndorf, Germany

3,300 m² | €12,000,000 | Concept and Basic Design

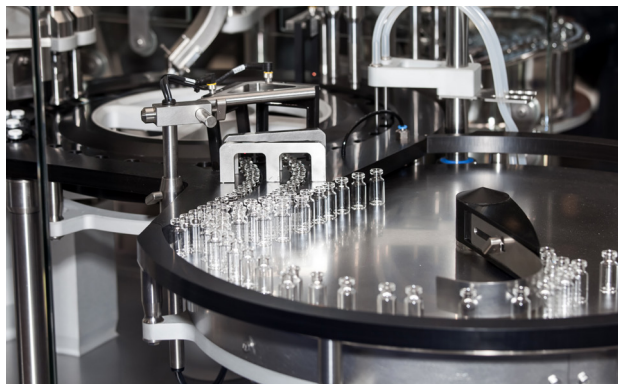
IPS was asked by Catalent Germany Schorndorf GmbH to develop a concept and a basic design along with construction support for a greenfield project in Schorndorf, Baden Württemberg.

IPS was asked by Catalent Germany Schorndorf GmbH to develop a master layout for a high-bay warehouse on the Schorndorf property with associated distribution and ancillary areas as part of a preliminary study, which would be based on the future expectations of Catalent developments.

The new high-bay warehouse with connected distribution building to hold around 4,300 pallets. A connection between the existing warehouse and the new warehouse was created. The height of the high-bay warehouse with the connected distribution building is based on the existing building.

The warehouse was designed to integrate to the existing material management system including a connection between the old and the new warehouse. Along the west side of the distribution building, a logistics yard/distributional area is attached to the new warehouse and ensures incoming and outgoing goods.

In addition to the building, a parking lot including a new truckload and streets are part of the design.



Recipharm Monts S.A.S

Aseptic Fill and Finishing Project

Monts, France

2,000 m² | €50,000,000 | Concept and Basic Design, CQV

IPS assisted Recipharm with a hyper fast-track project for the development of a new vaccine production facility in Monts, France to produce a COVID vaccine for the French market.

IPS provided concept design, basic design and qualification services on two sterile filling lines which includes formulation, sterile filling, inspection, and packaging.

Chinese equipment was used to facilitate the schedule and that presented unique challenges in compliance and documents management. Modular clean rooms were fabricated in Spain and shipped to site in France. The project will be completed in 20 months.



RECENT AWARDS



ISPE Facility of the Year Award Winner for the Operations Category

WuXi Biologics Large-Scale Manufacturing Facility in Mullingar, Dundalk, Ireland



ENR Rankings

#3 Design Sourcebook Pharmaceuticals List

#8 Construction Sourcebook Industrial Process Construction



ENR Global Best Projects Award of Merit

Bavarian Nordic - Fill & Finish Facility for Live Viral Vaccines

Kvistgård, Denmark



Pharma Innovation Awards

iLab - Intelligent Lean Labs



Zweig Group Hot Firm 2022

#2 Fastest Growing Firm

IPS Frankfurt

IPS-Integrated Project Services GmbH
Oberlindau 54-56,
60323 Frankfurt am Main, Germany
T:+49 172-577-1827

IPS Nürnberg

IPS-Integrated Project Services GmbH
c/o Design Offices, Nurnberg GmbH
Bahnhofstraße 2-4, 90402 Nürnberg
T:+49 172-577-1827

IPS Basel

IPS-Integrated Project Services GmbH
Picassopl. 4, 4052 Basel, Switzerland
T:+41 61-205-0990