

EMEA COMPANY OVERVIEW

Delivering Technically Complex Facilities
for the Life Science Industry



Knowledge, Skill & Passion • www.ipsdb.com

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Our cornerstones of Knowledge, Skill & Passion fuel our growth and cultivate a collaborative environment that drives our company.



IPS-Integrated Project Services, LLC, was founded in 1989 as a unique firm focused on aligning services with our client's business drivers and delivering projects on an integrated design-build platform. It was innovative and bold at that time. Since then, we have developed, executed, and advanced a number of strategies to reach our global status today.

IPS is one of the fastest-growing companies in the AEC industry, with a global reach that spans four continents. Our cornerstones of Knowledge, Skill & Passion fuel our growth and cultivate a collaborative environment that drives our company.

IPS-Integrated Project Services, Limited is strategically headquartered in Birmingham - UK, with offices in Manchester - UK, Dublin & Cork - Ireland, Frankfurt & Nürnberg - Germany, Basel - Switzerland, and Copenhagen - Denmark. These offices form an EMEA-based business with strong links to the management of IPS-Integrated Project Services, LLC, creating a truly global provider of technical consulting, architecture, engineering, project controls, construction management, and regulatory compliance services to support technically complex pharmaceutical development and manufacturing facilities.

The EMEA team leverages knowledge from our global Subject Matter Experts into projects and has grown to a staff of over 420 in the region. Our world-class expertise, knowledge, and understanding of industry trends place importance on time-to-market, plant flexibility, and cost control to avoid costly project delays and minimise risk while building, designing, constructing, and qualifying regulated facilities.



Founded in 1989



45+ Offices in 17 Countries and Growing



Biotech and Pharma Industry Focused



Projects Range from \$1,000 to \$1.5B



Over 2,700 Experienced Professionals



Internationally known SMEs



Best-in-class Technical Expertise



Many Employees Come from Client Side



Global Regulatory Knowledge



Trained 650+ FDA Inspectors



"A" Safety Conformance Rating



Incident and Injury-free Safety Culture

CORE INDUSTRIES

- Cell Therapy
- Gene Therapy
- Pharmaceutical
- Biotechnology & Biomanufacturing
- Animal Health
- Medical Device & Diagnostics
- Consumer Goods
- Science & Technology



HISTORY

Throughout IPS LLC's history, there have been many activities that had positively impacted the company, including the appointment of new executive leadership in 2023 when Jim Stephanou was placed at the helm of the organisation. This was a critical point in our business as Jim and his leadership team set their vision in place to spearhead our growth. IPS has moved from an execution-based company to a knowledge-based company and attracted internationally renowned subject matter experts (SMEs) that do not just design and construct facilities, but solve a client's problem. Our extensive roster of industry-recognised SMEs – a large number of whom have owner-side operating experience – possess deep global regulatory and best-in-class technical expertise.

Today, IPS remains at the forefront of new technologies and innovations in the industry. Clients reach out to us because of our recognisable brand of knowledge leadership. As we continue to grow, we do not lose sight of what has brought us here today: listening to the needs and challenges of our clients and providing integrated project and business solutions that help them create and manufacture life-impacting products worldwide.

IPS Limited was established in 2015 and is expanding as a focal point for all IPS project work in Europe, the Middle East, and Africa (EMEA). The current portfolio of projects spans throughout Europe for clients in Ireland, UK, Germany, Switzerland, Portugal, Spain, Denmark, the Netherlands, Austria, and France.

Internationally Recognised 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
- Serialisation & Traceability
- iCON™ / Flexible, Lean & Turnkey Modular
- Construction / Integrated Project Delivery

SERVICES



Technical Consulting

- Inceptioneering (Business Case Consulting)
- Real Estate Search Support & Test Fitting
- CGMP Compliance Consulting
- QMS Development
- CFD Modeling
- Strategic Master Planning
- Sustainability Planning & LEED Certification
- Lean Planning
- Calibration Programme Management



Architecture / Design

- Technology
- Process Engineering
- Process Architecture
- Automation
- Architectural
- Mechanical, Electrical, Plumbing
- Building Services
- Fire Protection / Life Safety
- Equipment
- Computer Process Simulation & Modeling
- Environmental
- BIM Technology / CAD
- 3D Simulation
- Conceptual Design / Engineering
- Detailed Engineering
- Energy / Sustainability / Conservation Management



Project Controls

- Cost Engineering
- Planning / CPM Scheduling
- Estimating
- Accounting Cost Analysis
- Earned Value Manpower Management
- Change Management
- Risk Management Assessment
- Document Controls
- Site Operational Support
- Software Integration
- Procurement
- PMO – Programme Management
- Engineering Support
- Project Management
- Project Engineering
- Construction Support
- Superintendents
- Project Controls
- Administration



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

SERVICES



Full Life Cycle CGMP Compliance / Commissioning, Qualification & Validation

- CGMP Facility Audits (Domestic / Int'l)
- CGMP Design Reviews / Design Qualification
- FDA 483 / WL / Consent Decree Remediation
- CQV Strategy / Validation Master Planning
- Facility, Equipment and System Qualification (IQ / OQ/PQ)
- Risk-based Qualification (ASTM E2500, ISPE BG5)
- CQV Execution
- CQV Project Management
- Project Information Management
- Specifications (URS / FRS / DDS)
- Commissioning Documents (Pre-Functional / Functional Checklists)
- Protocols / Test Plans / Test Scripts
- FAT / SAT Support
- Summary Reports
- Turnover Package Management
- Environmental Monitoring PQ
- Validation
- Process
- Cleaning / Sterilisation
- Computer Systems / Data Integrity
- Lab Equipment
- Quality Systems
- Policies
- Risk Assessments
- Standard Operation Procedures (SOPs)
- CGMP & CQV Training



IPS is a recognised leader of EPCMV services.

These services are provided on a stand-alone basis, as a fully integrated project delivery.

Construction Management

- Safety, Security & Environmental Compliance
- EPCMV
- Design / Build
- Programme Management
- Construction Management
- IPS Procurement Services & Strategies
- Facility / Process Equipment Expediting
- Project Controls
- Lean Construction Delivery
- Target Value Costing
- Preconstruction, Project Planning and Site Logistics
- Cost Management
- Estimating
- Scheduling, Pull & Takt Planning
- Open Book GMP
- Risk Analysis
- Sustainability / LEED
- Turnover

Technical Staffing

- Construction Managers / Field Engineers
- Project Managers
- Validation / Commissioning Engineers
- Project Controls Professionals
- Quality Systems Professionals
- Owners Representatives

SUBJECT MATTER EXPERTS & INNOVATIONS



Our subject matter experts include technologists, process engineers, architects, engineers, project management specialists, regulatory and compliance professionals, and business/operations consultants. Each possesses industry operating experience and understands underlying technologies, industry trends, construction and EHS practices, regulatory environment, and manufacturing processes to identify opportunities to streamline production and maximise efficiency.

- IPS has nearly 100 SMEs and technical experts across different specialties, such as cell and gene therapies, vaccine manufacturing, aseptic fill/finish, OSD, containment, continuous process, technology transfer, and sustainability
- IPS trains global regulatory agencies on new technology and advancements in the industry
- IPS contributes to ISPE® industry guidelines and educates the community

IPS Innovations:

- *i*CON™ Turnkey Modular Facility Platform Solution
- Aseptic Facility of the Future
- Inceptioneering™
- *i*LAB™
- ModulusEPCMV™
- CarTon™



2023

WuXi Biologics

CRDMO Facility *Dundalk, Ireland*

The WuXi Biologics leading CRDMO's facility in Dundalk has the largest single-use bioreactor capacity in Ireland and possibly all of Europe. It was designed using a "design-assist model," making it one of the first in Ireland to be delivered using this innovative methodology.

2023

Nexus Pharmaceuticals

New Aseptic Fill/Finish Facility *Pleasant Prairie, Wisconsin*

IPS designed the facility using design concepts that provide additional efficiency not seen before in pharmaceutical manufacturing. This multi-use facility features both the application of state-of-the-art process technologies and an aesthetically focused facility concept.

2022

Iovance Therapeutics

Clinical & Commercial Facility *Philadelphia, PA, USA*

This facility develops and commercialises novel cancer immunotherapies based on tumor infiltrating lymphocytes. Our experts qualified and validated the equipment and facility per the new ISPE C&Q Baseline Guide.



2021

Raymond G. Perelman Center for Cellular and Molecular Therapeutics

Clinical Vector Core, Research Lab, and Vivarium Lab CQV Services *Philadelphia, PA, USA*

IPS provided quick and cost-effective commissioning and qualification services for this cell and gene facility at the Children's Hospital of Philadelphia, including over 120 pieces of equipment.

2021

Locus Biosciences

CGMP CRISPR Facility CQV Services *Research Triangle Park, NC, USA*

IPS provided commissioning, qualification, and validation services, including program development, documentation deliverables, protocols, and verified architectural finishes for this facility that combines the safe delivery vessel of bacteriophage with the antibacterial power of CRISPR-Cas3 to create an innovative antibacterial platform.

2020

Sanofi

Digitally Enabled Integrated Continuous Biomanufacturing Facility *Framingham, MA, USA*

The project is a highly flexible modular facility that builds on widespread disposable technology to provide a platform to produce current products and, ultimately, a wide range of product modalities.

RECENT PROJECTS



Confidential Client

COGS United Kingdom

A fast-track project to support a global network programme for increasing competitiveness by driving down its COGS for manufacturing operations. Initially engaging to undertake Feasibility and Conceptual Design studies lead directly into an Enhanced Basic Design (EBD) phase. The EBD incorporated necessary Detailed Design and Procurement activities for those time-sensitive workflows affecting the challenging timeline to beneficial use. Following EBD, the project transitioned directly into its Execution phase, with IPS providing full EPCMV support to a multi-functional team.



Pfizer

Vaccine Production Facility Expansion Ireland

With the completion of the project Pfizer's production capacity will increase from 20MM doses/year to 30MM doses/year for the global marketplace. IPS delivered an exceptionally high standard basis of design (BOD) Report after an 8-week BOD period. The project is on an accelerated schedule to achieve mechanical completion in less than one year. All disciplines continued to work through the detailed design with a target to close the design phase within 26 weeks from the start of BOD commencement.



Bavarian Nordic

Fill & Finish Live Viral Vaccines Facility Denmark



The facility expansion is a multi-product plant designed and built to manage the formulation, filling, lyophilisation, inspection, packaging, and storage of several live attenuated viruses with complex, fragile structures and high value for clinical and large-scale manufacturing. It is world-class in terms of its project execution and efficient use of space within its limited footprint.

Confidential Client

Gene Therapy Conceptual Design Benelux

IPS developed the conceptual design of a new gene therapy facility, covering development labs, AAV manufacturing, QC labs, warehousing, clean utilities, building services, and integration into the client's campus. The project was a business transformation project, taking the client from a biopharmaceutical company to a gene therapy company. The technology used (single-use bioreactors with perfusion) was new to the client, and IPS used their network of SMEs in this field to work with the client in developing manufacturing solutions and design the facility.

INDUSTRY RANKINGS

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IPS is an award winning, global leader in the industry. Our company has been recognised by numerous industry trade groups and publications for growth and innovation, and our work has been honored or project execution, operational excellence, and equipment innovation.



ENR

Engineering News-Record

ENR Rankings

- Top 100 Design-Build Firms
- Top 225 International Design Firms
- Top 500 Design Firms in the US
 - Top 20 Industrial Process/Petroleum
 - Top 50 Designers in International Markets
- Top 400 Contractors
 - Top 20 - Industrial
 - Top 50 Contractors Working Abroad
- Top 100 Construction Management-for-Fee
- Top 100 Construction Management-at-Risk

Global Source Book

- Top International Design Firms & Contractors
 - Industrial Process List
 - Pharmaceuticals List
 - Chemicals (Non-Petroleum)

Design Source Book

- Top 500 US Design Firms in Manufacturing
 - Pharmaceuticals List
 - Industrial Process List
 - Chemical Plants List

Construction Source Book

- The Top 400 Contractors in Manufacturing
 - Industrial Process List
 - Pharmaceuticals List

ARCHITECTURAL RECORD

- Top 300 Architecture Firms



2021 Zweig Group Hot Firms List

Ranked as one of the 100 fastest-growing architecture, engineering, planning, and environmental consulting firms in the United States & Canada that have outperformed the economy and competitors to become leaders in our field.

BUILDING DESIGN + CONSTRUCTION

- Top 35 Engineering and Architecture Firms
- Top 70 Construction Management Firms
- Top 115 Contractor Management Firms
- Top 110 Reconstruction Engineering Firms
- Top 110 Reconstruction Construction Firms



- Top 300 Commissioning Giants
- Top 300 MEP & FP Giants



2020 Zweig Group Best Firms to Work For Award

The Best Firms to Work For award recognises the AEC firms in the US and Canada based on their workplace practices, employee benefits, employee retention rates, and much more. IPS ranked as #1 in the Design/Build category.

EMEA Leadership Team



Peter Higgins, Managing Director, EMEA

Mr. Higgins is a Managing Director with 25 years' experience in the blue chip Life Sciences, semiconductor, health care and commercial sectors. Senior positions held within the Operations & Capital Projects planning, design and engineering environments across a wide client base. Proven experience in project execution phases transitioning into operations including an in depth knowledge of procurement, contract management and regulatory processes.



Glen Slaymaker, Senior Director, EMEA - UK

Mr. Slaymaker is an experienced business leader with over 25 years of experience in the pharmaceutical, chemical, and food industries. Specialising in Project Management, he has successfully sponsored and delivered a diverse range of multidisciplinary Engineering, Procurement, Construction Management and Validation (EPCMV) projects from bid stage through to the delivery of the final product to the client. Prior to joining IPS as Senior Director, Glen held the position of Industry Director, Operations Director, Business Stream Director, and Senior Project Manager for one of the worlds largest professional services firms. Glen has also spent a number of years working within the construction industry, therefore understands the importance of health, safety, and well-being within regulated environments.



Helmut Steudel, Senior Director, EMEA - Germany

Mr Steudel is responsible for the establishment of an engineering, procurement and construction management operation based in and serving clients in Germany. With over 35 years' experience, Helmut is a senior-level Life Science Engineering & Constructions business expert and critical account leader. He has driven revenue growth in the Fortune 500 and government sectors. He expertly handles sales and project operations for customers in all aspects of the Life Science arena. He identifies hidden opportunities through precise market analyses. Helmut develops long-term strategic customer relationships, identifies winning commercial insights, leads effective proposal teams, and negotiates deals that satisfy the needs of all stakeholders.



Brian Peasley, Senior Director, EMEA - Switzerland

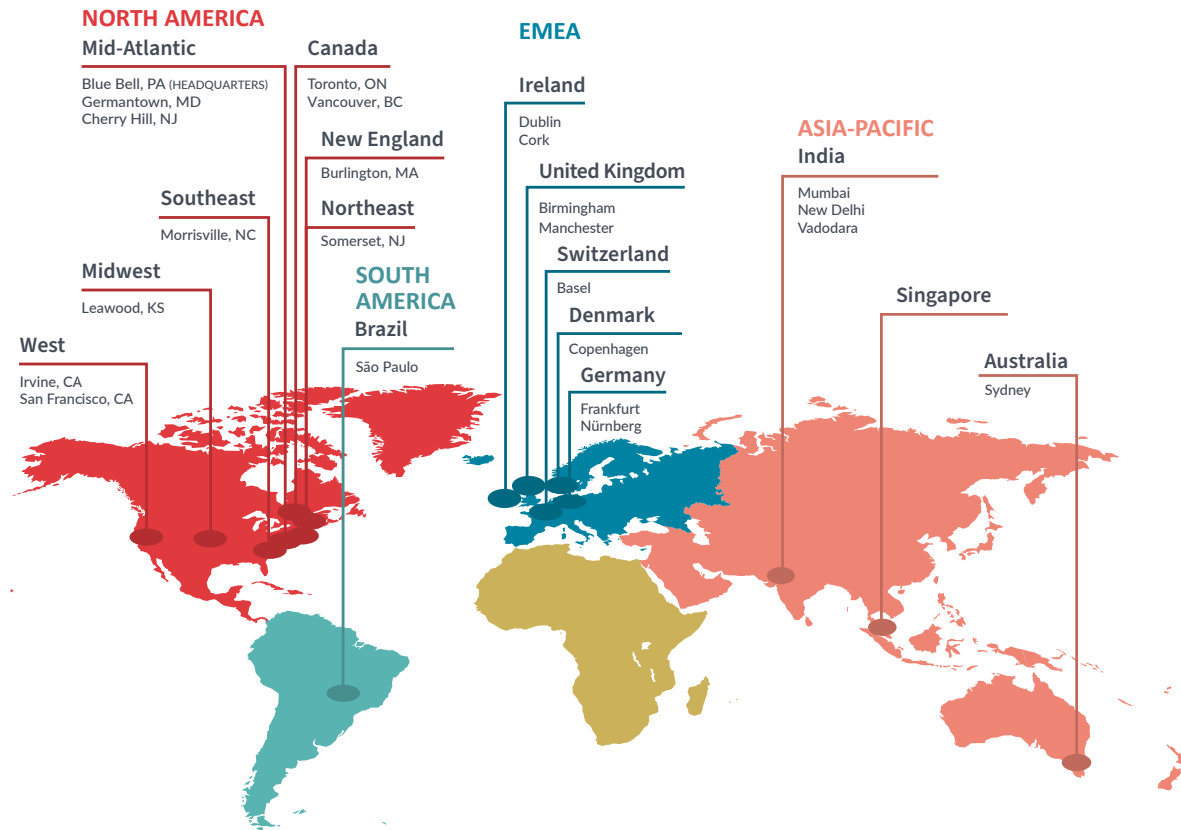
Mr. Peasley has over 20 years of experience in the biotechnology and pharmaceutical industries working for corporate, institutional and academic clients. Brian's areas of expertise include project management and project engineering, and he has a strong technical background in biocontainment, HVAC and mechanical system design for science and technology facilities. His background and understanding of laboratory design, utility system engineering and design, utility usage profiles, and energy optimization/conservation allows him to successfully estimate engineering and design costs, establish realistic schedules, and develop successful approaches.



Mark Miller, Senior Director, EMEA - Denmark

Mark has over 20 years of EPCMV project experience within pharmaceutical and biotechnology manufacturing and R&D. Mark has hands on experience in process design engineering, managing, and coordinating complex multi discipline projects from inception through to construction and CQV. He has design and management experience across a variety of processes covering Aseptic, API, OSD, Vaccines and Biotech. He has particular technical expertise in manufacturing facilities for potent compounds and sterile products utilising vials, barrier isolation technology, clean utilities and single use technology for formulation and fill/finish operations. Mark has experience of both greenfield and cut and carve brownfield projects in FDA & EMA GMP regulated environments.

IPS LOCATIONS



NORTH AMERICA

Mid-Atlantic

Blue Bell, PA (HEADQUARTERS)
Germantown, MD
Cherry Hill, NJ

Canada

Toronto, ON
Vancouver, BC

New England

Burlington, MA

Northeast

Somerset, NJ

Southeast

Morrisville, NC

Midwest

Leawood, KS

West

Irvine, CA
San Francisco, CA

SOUTH AMERICA

Brazil

São Paulo

EMEA

Ireland

Dublin
Cork

United Kingdom

Birmingham
Manchester

Switzerland

Basel

Denmark

Copenhagen

Germany

Frankfurt
Nürnberg

ASIA-PACIFIC

India

Mumbai
New Delhi
Vadodara

Singapore

Australia

Sydney

Pennsylvania

(Headquarters)

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Maryland

Germantown

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Massachusetts

Chelmsford

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Woburn

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Switzerland

Basel

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Germany

Frankfurt & Nürnberg

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Vadodara

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The locations listed herein are for IPS offices only; however, with the newest acquisition of Linesight, IPS has over 2,700 professionals in 45+ offices across 17 countries in the Americas, Europe, Asia Pacific, Southeast Asia, Australia, and the Middle East. Linesight specialises in cost, schedule, risk, program, and project management services in various market sectors, including data centers, life sciences, and high-tech industrial. With Linesight, IPS has become one of the AEC industry's fastest-growing organisations. www.linesight.com



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