



IPS Company Overview

Knowledge, Skill & Passion

COMPANY OVERVIEW

IPS-Integrated Project Services, LLC is a global provider of technical consulting, architecture, engineering, project controls, construction management, and CGMP compliance services for technically complex pharmaceutical development and manufacturing facilities worldwide. 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 minimize risk while building, designing, constructing and qualifying CGMP regulated facilities.

About Us

 Founded in 1989	 22 Offices in 10 Countries and Growing	 Biotech and Pharma Industry Focused	 Projects Range from \$1,000 to \$1.5B
 Over 1,500 Experienced Professionals	 Internationally Known SMEs	 Best-in-class Technical Expertise	 Many Employees Come from Client Sites
 Global Regulatory Knowledge	 Trained 650+ FDA Inspectors	 "A" Safety Conformance Rating	 Incident and Injury-free Safety Culture

Core Services

 Technical Consulting	 Architecture	 Engineering	 Project Controls
 Construction Management	 CGMP Compliance / CQV	 EPCMV	 Technical Staffing

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
- iCON / Flexible, Lean & Turnkey Modular Construction / Integrated Project Delivery

Technical Consulting

- Business Case Consulting
- Operations Strategies
- CGMP Compliance Consulting
- Operational Excellence and Planning
- Strategic Master Planning
- Technology Transfer
- Lean Approaches to Capital Projects
- Calibration Program Management
- Energy Audits / Conservation/ Management
- Environmental Impact Analysis / Assessment

Design / Engineering

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

Full Life Cycle CQV

- CGMP Audits (Domestic/Int'l)
- Project Design Reviews (Design Qualification)
- Early Stage Planning
- Validation Master Planning
- ASTM E2500 Implementation
- Validation Program Development
- Project Management
- Quality System Implementation
- Risk Assessments / FMEA / HACCP / Other
- FDA 483/WL/Consent Decree Remediation
- Validation & CGMP Training
- Project Information Management
- FAT/SAT Support
- Facility, Equipment and System Qualification (IQ/OQ/PQ)
- Process Validation
- Cleaning Validation
- Automation and Computer Systems Validation
- Lab Equipment and Analytical Methods Validation
- Environmental Monitoring
- Specifications (URS/FRS/DDS)
- Bid Packages/Bid Evaluations
- Submittal Reviews
- Commissioning Documents (Pre-Functional/Functional Checklists)
- Risk/Impact Assessments
- Protocols/Test Plans/Test Scripts
- Summary Reports
- Turnover Packages
- Standard Operation Procedures (SOPs)

Construction Management

- EPCMV / Design-Build
- Program Management
- Construction Management
- Preconstruction
- Cost Management
- Estimating / Scheduling
- Target Costing
- Open Book \$GMP
- Risk Analysis
- Facility / Process Equipment Expediting
- Procurement Strategies
- Project Management
- Risk Analysis
- Turnover Packages
- Safety / Environmental Compliance


Project Controls

- Cost Engineering
- Planning / Scheduling
- Critical Path Methodology
- Manpower Requirements
- Earned Value Management
- Change Management
- Risk Management Assessment
- Estimating
- Document Controls

Technical Staffing

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

BioManufacturing	Aseptic	OSD	API	Compliance	Construction
 Tom Piombino, PE	 Sterling Kline, RA	 Sam Halaby	 Jerry Cerulli, PE	 Vince Cebular, LEED AP	 Tom Chapman
 Gene Martini, PE	 Jason Collins, AIA	 Brian Egan	 Narendra Prasad	 Michael Westerman	 Dan Leorda, PE
 Tim Schuster	 Rob Roy, PE	 Mike Vileikis	 Steve Tom	 Aaron Weinstein	 Britton Wolf
 Mark Miller, C.Eng, MChemE	 John Lyons	 Angus Dagnall	 Patrick Wong, PE	 Mark Rezac, PE	 Kevin Batche
 Doyle Johnson	 Paul Valerio	 Russ Somma, PhD	 Robert De Sonier, PhD	 Alicia Riesgo	 Steve Huntzinger, MBA

 **United Therapeutics** - Dinutuximab-Dedicated Oncology Medical and Analytical Laboratory (DDOMAL) Silver Spring, MD

This monoclonal antibody facility overcame the challenges of its urban site location, passing zoning legislation, building and maintaining community relationships, and the atypical cylindrical shape.

 **Sanofi** - Digitally Enabled Integrated Continuous Biomanufacturing Facility Framingham, MA

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.

 **Pharmalucence** - EPCMV New Aseptic Filling Facility Billerica, MA

This facility received industry recognition for the execution and entrepreneurial spirit demonstrated by the construction of the new aseptic filling facility by the consolidation of generic and contract manufacturing operations into a single, state-of-the-art facility.

 **Merck** - Global Clinical Supplies Manufacturing, Packaging and Warehouse Expansion Summit, NJ


A three-phased hybrid-build design construction approach was undertaken to consolidate global clinical supplies operations into a single, state-of-the-art clinical manufacturing, packaging and distribution facility.

 **BMS** - Clinical Supplies Manufacturing and Drug Product Technology Expansion New Brunswick, NJ

IPS brought early and late phase CGMP clinical manufacturing and development scale-up areas together within a single facility allowing BMS to develop and deliver increased compliance, productivity and technical innovation to meet present and future drug development pipeline.

 **Janssen Pharmaceuticals and Legend Biotech** - CAR-T Clinical Manufacturing Facility Somerset, NJ


Retrofit of 38,000sf within an existing open shell space. IPS expedited the GMP manufacturing facility for early-clinical trials with iCON™ to deliver off-site-constructed modular environments (PODs) and executed an Inceptioneering™ study.

 **Cook Pharmica** - Flexible Filling Line Bloomington, IN


This complex manufacturing upgrade was executed within an existing operation, to complement its existing syringe and vial lines with first-of-its-kind flexible filling technology. This facility was recognized for its novel approach to combine three filling lines into one under barrier isolation in a single filling suite.

 **Eisai** - Knowledge Centre Vizag, AP, India

The facility was recognized for designing and building of a Greenfield, state-of-the-art manufacturing and process research complex.

 **Biogen Idec** - LSM Facility Upgrade, Phase II Research Triangle Park, NC

The project scope included the renovation and upgrade of a 250,000sf biological bulk manufacturing facility. This facility received industry recognition for its exceptional design, innovative modular construction methods, and safety record.

 **ISPE** - 2005 Company of the Year

IPS received recognition for our contribution to the industry.



Industry Rankings

PHILADELPHIA BUSINESS JOURNAL

- Top 25 Engineering Firms
- Top 25 Architectural Firms
- Top 25 Contractors
- Top 100 Major Employers

ENR Engineering News-Record

ENR Rankings

- Top 100 Design-Build Firms
- Top 225 International Design Firms
- Top 400 Contractors
 - Top 50 Contractors Working Abroad
- Top 500 Design Firms in the US
 - Top 50 Designers in International Markets

Design Source Book

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

Global Source Book

- Top International Design Firms
 - Industrial Process List
 - Pharmaceuticals List
- Top International Contractors
 - Pharmaceuticals List

Construction Source Book

- Top 500 Design Firms in Manufacturing & Telecommunications
 - Industrial Process List
 - Pharmaceuticals List

ARCHITECTURAL RECORD

- Top 300 Architecture Firms

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

CONSULTING - SPECIFYING engineer

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



2020 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.



2020 Zweig Group Best Firms to Work For Award

The Best Firms to Work For award recognizes 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.

Inc. 500 | 5000

2014 Inc. List of the Fastest-Growing Private Companies in America

IPS received recognition for a 131% growth in the past 3 years.

Internationally Recognized Technical Expertise

IPS has integrated state-of-the-art knowledge and project execution around the world.

- IPS India provided a detailed HAZOP study for solvent storage tanks for an API manufacturing client. A nitrogen blanketing automation system was designed to surround over 800 tanks and vessels in accordance with CGMP and the client's internal standards. The system was designed for safe storage, handling, transfer and process operation, as well as minimizing vapor loss.
- Created a large-scale pharmaceutical manufacturing facility for OSD and injectable products for Lupin. This technically complex project set a quality standard and template for how future projects in India should be executed and constructed to compete in the global market place. This project won ENR's 2019 Global Best Projects Award of Merit for Manufacturing.
- Designed a greenfield aseptic manufacturing complex with the commitment of QBD, CGMP compliance, safety, efficiency, sustainability, and aesthetics. The facilities in the complex ensure a supply of liquid vials and ampoules as well as lyophilized vials to domestic and global markets.
- IPS used the iCON™ solution to deliver viral vector manufacturing and cell therapy production units to a facility in Germany. Once delivered, the facility started commercial production at the 50L and 200L scale using iCON units for inoculum prep and Grade D upstream and downstream processing.
- IPS was retained by a CMO in Ireland to prepare a concept design for a laboratory and manufacturing facility dedicated to manufacturing a vaccine in lyophilized vial dosages for a BSL-3 designated virus.

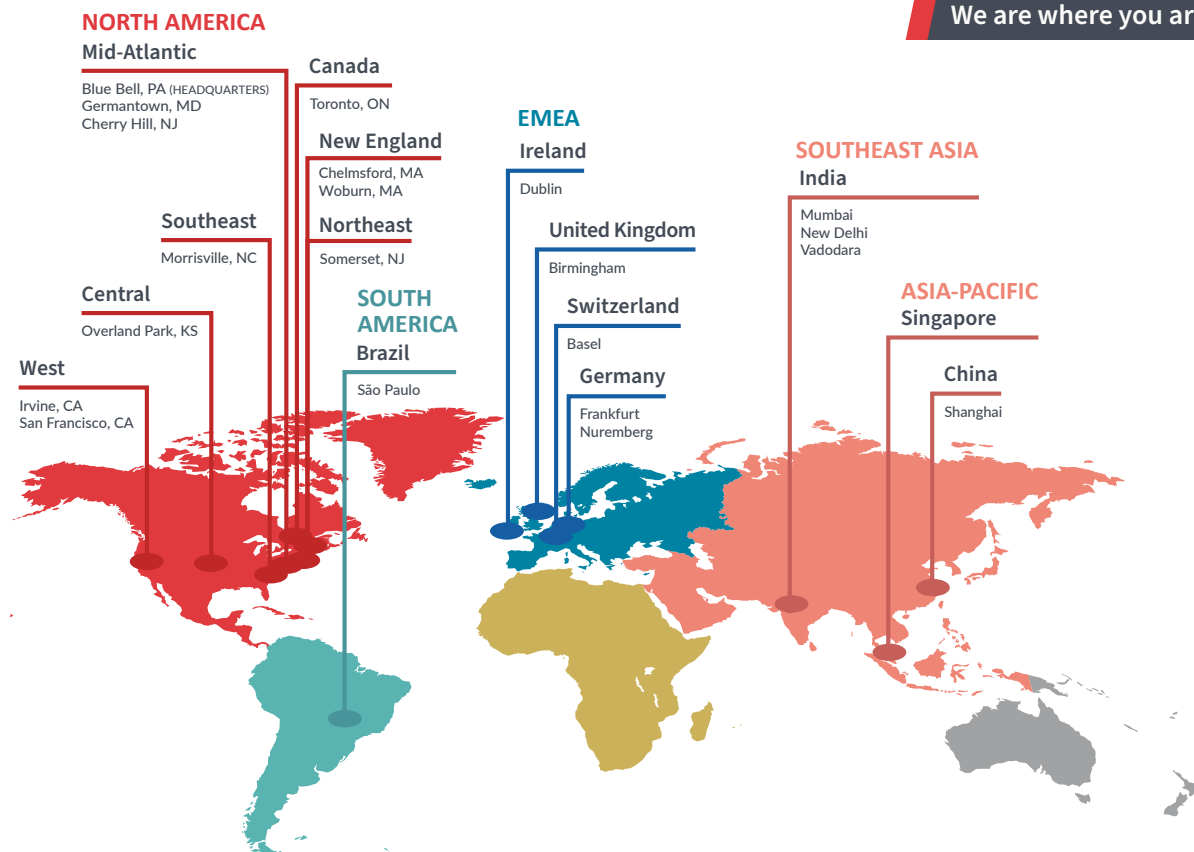


IPS provides services across the world



COMPANY OVERVIEW

Locations



We are where you are

Blue Bell (Headquarters)

P: 610.828.4090
F: 610.828.3656

California

Irvine &
San Francisco
P: 949.679.4682
F: 949.679.4683

Kansas

Overland Park
P: 913.345.9084

Maryland

Germantown
P: 240.839.3620

Massachusetts

Chelmsford
P: 978.954.5450

Woburn
P: 617.799.6987

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Somerset
P: 732.748.1990
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