FSP solutions

PPD Functional Service Partnership (FSP) Global Clinical Supplies solutions

Extensive global clinical supplies services with the ease of a single partner

For biopharmaceutical, biotech and medical device organizations, process and expertise are critical components of any successful supply chain strategy. Whether you need expert supply chain management or an end-to-end global supply solution to complement your existing infrastructure, you want an experienced global clinical supply partner offering proven processes and a global logistics network.

The PPD™ clinical research business of Thermo Fisher Scientific helps manage all aspects of your clinical trial supplies lifecycle through the flexibility of a functional service partnership (FSP) model. Offering unique clinical site and patient insights and the ease of a single partner, **PPD™ Functional Service Partnership (FSP) Global Clinical Supplies solutions** provide unmatched expertise to deliver customizable solutions and an uncompromising commitment to quality — while providing much-needed resource flexibility, reliability and continuity.

Proven track record

- **30+ years of drug and device development experience, with 47% growth over the last three years**
- **Services delivered for 800+ studies across 270+ individual clients**
- **600+ staff across 38 countries, including 100+ experienced global supply project managers**
- **Global depot footprint of 31 locations**
- **36-hour shipment turnaround time**
- **7,500+ devices provisioned across 51 projects**
- **Extensive experience with Top 10 IRT providers**

Keep your studies well stocked with global clinical supplies services

Our PPD FSP Global Clinical Supplies solutions have a proven track record managing tens of thousands of shipments per year with dedicated experts, extensive standard operating procedures (SOPs), and detailed process training to ensure the onsite delivery of trial supplies with maximum efficiency.

Our teams include project managers that nimbly manage your entire clinical supply chain; operational teams of logistics, import/ export and procurement experts; and quality assurance teams comprising GMP-qualified persons, quality auditors and quality associates.

In addition, our extensive team of qualified persons (QP) provide expertise in release of many different dosage forms, as well as support for auditing facilities, hosting regulatory inspections (EU & FDA), supply chain quality assurance and quality assurance for complex biologics / advanced therapy medicinal products (ATMP) batch review. We continuously adapt to new and evolving requirements, patient needs, technologies, pandemics and new types of drugs in development.

We specialize in protocol and/ or portfolio-level supply management for:

- **Investigational product**
- **Commercial comparator**
- **Auxiliary medicinal products**
- **Equipment**
- **Ancillaries**
- **Digital devices (tablet, handheld, wearables)**

Our integrated services include:

- **Project management**
  Study operational leadership, consultancy, project coordination and forecasting for global clinical supplies and interactive response technology (IRT)
- **Depot services**
  Global distribution through Thermo Fisher-owned and third-party management depots (or audited and approved vendors) to support sites worldwide
- **Trade compliance**
  Sophisticated network of regional trade experts and importer of record (IOR) responsibility
- **Vendor management**
  Identify and select third-party providers with oversight of contracting, finances and performance delivery
- **Device provisioning and management**
  Internet of Things (IoT) integration into clinical study procurement, configuration, logistics and data
- **Inventory management**
  System for drug accountability through final reconciliation, including handling of returns and destruction activities
- **Clinical logistics monitoring**
  Specialized logistics/chain of custody associated with unique needs of cell and gene therapy studies
- **IRT design**
  Customizable web-based portal for randomization and inventory management

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Clinical supply lifecycle management

A single point of contact for clinical supply management, from bulk product forecasting through expiry date monitoring and destruction, shipment request and inverse logistics.

Forecasting

Providing efficiencies for regulatory submission, label development, forecasting and procurement of goods required

Global procurement and inventory management

Offering product receipt, storage, distribution, relabeling, return, accountability and destruction coordination services

Packaging and labeling

Supporting materials printing and package labeling, country submission, and automatic creation and translation of country label text with a validated audit trail

Proven processes and expertise to manage entire clinical supply chains

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We provide expertise across all clinical supply chain markets, including:

- **Direct-to-patient (and direct-from-patient)**
- **Digital**
- **Cell and gene therapy / atmp**
- **Biotech and biopharma**
- **Vaccines**

Global logistics network and advanced systems to drive traceability and efficiency

Through Thermo Fisher Scientific's global logistics network and infrastructure, combined with advanced systems, process maps and SOPs, PPD FSP Global Clinical Supplies solutions provide streamlined workflows to enhance global quality, traceability and efficiency. Our solutions leverage well-established partnerships with third-party vendors that have passed rigid vendor qualification processes, are fully integrated into our supply chain network, and managed and monitored through routine audits.

Our experience running program-level pooling across global studies also minimizes overages of expensive comparators, equipment and ancillary product. We engage local import/export experts to standardize pro forma invoices and preclear shipments, where possible, to reduce distribution time per shipment and enable central sourcing consistency across study sites. Consolidation of investigational product, lab and other required supplies needed also significantly reduces costs.

Flexible and rapid deployment of personalized partnership models

- Custom rates, qualification and implementation via quality technical agreements (QTAs) and master service agreements (MSAs)
- Personalized mix of systems, processes, oversight and facilities — either yours or ours

- We can embed our staff within your workforce, using your systems and processes

OR

- We can take your projects fully in-house, using our innovations and technologies

Innovative pricing models:

- Full-time equivalent (FTE) models
- Unit-based models
- Time & materials models
- Hybrid models

Our global clinical supplies expertise, by the numbers

27,000+ imports and exports annually, with more than **30%** growth year-over-year as Importer of Record in 2023

29 purpose-built cGMP facilities and more than **250** packaging rooms strategically located in emerging regions

75% reduction in cost associated with freight, broker fees and overall customs frequency of operations

50-75% reduction in time spent by CRAs and Site Coordinators on supplies administrative tasks

Overage of expensive comparator, equipment and ancillary product minimized to **<10%** through focused inventory management and program-level pooling across global studies

Talk with your account representative or visit ppd.com/fsp-global-clinical-supplies to learn more about how PPD FSP Global Clinical Supplies solutions can help optimize your clinical trial supply chain.

Learn more at **ppd.com/fsp-global-clinical-supplies**