



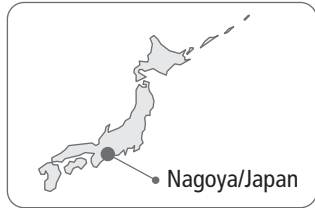
For product development, clinical trials services, contract manufacturing and cold chain and logistics services partner with NextPharma – **Next Generation Pharma Solutions**

www.nextpharma.com

Next Generation Pharma Solutions

NextPharma Technologies, headquartered in the UK and founded in 2000, is a world class outsourcing partner to the pharmaceutical and biotechnology industry.

We offer a full range of services from early phase product development, through clinical trial packaging to high volume commercial manufacturing. We are a world leader in lyophilization, sterile fill finish and pellet technologies and in specialist product manufacturing including cytotoxics, hormones, penicillins, cephalosporins and narcotics. Our sterile development and production offers a full range of drug delivery technologies including pre-filled syringes, vials and ampoules.



NextPharma operates globally with seven product development centers, seven manufacturing plants and six storage and distribution sites across Europe and North America. We have 1,200 employees dedicated to servicing over 200 customers world wide. NextPharma has a proven track record in almost all pharmaceutical technologies and product forms and in addition to the specialist areas above, has capabilities in solids, semi-solids, liquids, sprays and dry dosage form technologies.

All of NextPharma's sites are either FDA inspected, in the process of upgrade for inspection or targeted for upgrade for inspection.

Many faces – one shared goal:

maximizing your efficiency.



Quality at NextPharma

Our integrated approach to quality through our Quality Management System and strategic quality plan, together with our culture of continuous improvement ensures compliance with the ever changing global regulatory requirements. Our objective is to ensure total transparency of our quality processes.

Peace of Mind through Project Management

NextPharma has a focus on effective project management which we define as the discipline of organizing and managing our resources in such a way that your projects are completed within defined scope, quality, time and cost constraints. At NextPharma your project, whether new business or a product transfer, will be assigned a dedicated Project Manager who will be responsible for managing your project from inception to completion ensuring that critical time lines are met, technical formulation and production issues are resolved quickly and efficiently and regulatory requirements are met in full.

NextPharma's Full Service Approach

Product Development Services (PDS)

- Formulation development / design
- Analytical services
- Stability testing
- Microbiology
- Dossier development
- Registration
- Lyophilization cycle optimisation
- Non-Clinical Trial and Clinical Trials
- Materials Manufacturing
- Packaging services

Cold Chain and Logistics Services (CLS)

- Cold chain storage
- Storage of narcotics and biologics
- Order processing
- Electronic data transfer
- Warehousing
- Pick, pack and ship
- Invoicing
- Customers sales statistics
- Debt collection and reminder system
- Handling and processing of returned goods
- IT Interfaces

Clinical Trials Services (CTS)

- Blinding
- Randomization
- Packaging and Labeling
- Special label design and printing
- Distribution and Destruction
- Patient Kits
- Return & Reconciliation of Drug Products

Contract Manufacturing Services (CMS)

- Hormones (solid forms only)
- Sterile
 - Cytotoxics: solutions / freeze dried
 - Non-cytotoxics: solutions / freeze dried
 - Eye and ear drops
- Penicillins and cephalosporins
- Tablets, capsules, film coating
- Oral and topical liquids
- Suppositories, ointments, gels, creams and lotions
- Immediate release (effervescent)
- Controlled release (pellets)
- Packaging into all relevant presentations
- Visual Inspection Services
- Medical Device Assembly
- EU importation release for Non EU country products

Product Development Services (PDS)

NextPharma PDS operates globally with seven customer focused PDS centres in Europe and North America. PDS services include formulation, design, lyophilization cycle development and optimization, manufacturing for clinical trials, analytical and microbiological testing, stability testing according to ICH guidelines and product dossier development and registration.

Our recently expanded business now includes sterile product development capabilities in both San Diego, California and Braine-l'Alleud, Belgium where we are able to support non-clinical through Phase III development of sterile products including biologics and cytotoxics. In addition, our San Diego facility is ISO 13485:2003 certified for Medical Devices and manufactures medical devices from R&D to commercial.

Our world class PDS team gives you the confidence and knowledge that your products will be produced to meet your requirements. An additional benefit is our ability to provide a seamless process from non clinical product formulation to commercial scale manufacturing.

PDS Capabilities

| | Pharmaceutical Development | Analytics and Stability Studies | Clinical Trial Packaging (CTP) | Regulatory Services | Microbiology |
|--|----------------------------|---------------------------------|--------------------------------|---------------------|--------------|
| Sterile cytotoxics | ✓ | ✓ | ✓ | ✓ | ✓ |
| Sterile biologics | ✓ | ✓ | ✓ | ✓ | ✓ |
| Sterile forms, conventional (injectables, eye drops, nasal sprays) | ✓ | ✓ | ✓ | ✓ | ✓ |
| Hormones and steroids (oral and topical) | ✓ | ✓ | ✓ | ✓ | ✓ |
| Antibiotics (oral) | ✓ | ✓ | ✓ | ✓ | ✓ |
| Controlled release pellets and modified release forms | ✓ | ✓ | ✓ | ✓ | ✓ |
| Effervescent and chewables | ✓ | ✓ | ✓ | ✓ | ✓ |
| Semi-solids (emulsions, suspensions, creams, gels, suppositories) | ✓ | ✓ | ✓ | ✓ | ✓ |
| Conventional solids (tablets, capsules, dragees) | ✓ | ✓ | ✓ | ✓ | ✓ |
| Conventional liquids (solutions – aqueous and alcohol, syrups) | ✓ | ✓ | ✓ | ✓ | ✓ |
| Packaging (sterile, oral and topical) | ✓ | ✓ | ✓ | ✓ | ✓ |



Clinical Trials Services (CTS)

NextPharma has extensive expertise in manufacturing and packaging clinical trial supplies. Our highly experienced team handles a variety of pharmaceutical forms for Phase I-IV clinical trials in accordance with Annex 13 of the EU-GMP guidelines. This includes handling specialized products including cytotoxics, hormones, penicillins, cephalosporins and narcotics.

Clinical Trials Services

- Manufacturing
 - Blinding
 - Matching placebos

- Packaging and labeling
 - Primary packaging
 - Secondary packaging
 - Randomization
 - Special label design and printing

- Storage, distribution and destruction
 - Storage under cGMP conditions (controlled room temperature and refrigerated)
 - Distribution of drug products and patient kits (controlled room temperature and refrigerated)
 - Return and reconciliation of drug products
 - Manage destruction of drug products
 - Waste Management

- Analytical, stability and microbiological testing services



Contract Manufacturing Services (CMS)

To meet our customers' needs NextPharma has established significant capabilities in specialist pharmaceutical technologies such as lyophilization, sterile fill finish and pellet technologies and also in specialist product areas such as cytotoxics, hormones, penicillins, cephalosporins and narcotics as well as in conventional dosage forms. By providing high levels of customer service and quality, accurate documentation and delivery on time, NextPharma allows you to manage your supply chain efficiently and effectively. Our scale of operations enables us to produce a wide variety of products in batch sizes to meet your needs and readily supply markets around the world.

Sterile Capabilities

- Cytotoxics – lyophilization and solutions
- Non-cytotoxics – lyophilization and solutions
- Vials, ampoules
- Eye and ear drops
- Visual inspection services

Hormone Expertise

- Solids forms (tablets – film and sugar coated, pellets)
- Packaging in blisters (also diary packs) including alu/alu sachets (flow packs)
- Semi-solids
- Tubes and stick packs

Solid Beta Lactam Antibiotics

- Penicillins and Amoxiclavulanic acid
- Cephalosporins

Customized Release Formulations

- Pellets (extrusion and layering)
- Double core tablets, film coated tablets
- Effervescent tablets, soluble tablets

Conventional Pharmaceuticals

- Organic, aqueous and dry granulation
- Tablets and capsules
- Liquids and semi-solids
- Suppositories
- Sachets (including micro filling)
- Packaging in relevant presentations
- Special handling areas for sensitive products (humidity/temperature)

Packaging

- Blister (PVC, CoC, Triplex and Alu-Alu)
- Bottles (glass/plastic)
- Tubes (alu/plastic)
- Secondary packaging
- Special application like kits, pre packed patches
- Special handling areas for sensitive products (humidity/temperature)

Qualified Person Services

For those customers wishing to import product into Europe, we offer qualified person services (QP) in conjunction with any required analytical testing.



Cold Chain and Logistics Services (CLS)

NextPharma controlled temperature storage and distribution services are supported by state-of-the-art technology appropriate for the pharmaceutical industry. Whether your product requires controlled room temperature storage of down to minus 80 °C, we have the capabilities to meet your needs. Our pick, pack and ship systems ensure the correct product reaches its destination according to your requirements.

NextPharma offers one-stop logistics solutions tailored to meet the needs of the global pharmaceutical industry under the rigid standards of cGSP/GDP regulations. This pre-wholesaling business delivers directly to pharmacies, hospitals, doctors, sales representatives and wholesalers. Customers also benefit from NextPharma's economies of scale.

- Controlled Temperature Storage at -20°C and at -80°C
- Controlled Temperature Storage at 2-8°C (short term and long term)
- Paperless picking process (pick by light) performed in cold store
- Packing either in polystyrene containers with coolpacks (ambient forwarder) or in cardboard shippers (cold chain forwarder)

Specialities and Equipment

| | Bielefeld Germany | Limay France | San Diego USA | Stockerau Austria | Turbenthal Switzerland | Waltrop Germany |
|--------------------------------|-----------------------------|------------------------|-------------------------|-----------------------------|----------------------------------|---------------------------|
| Temperature Controlled Storage | ✓ | - | ✓ | ✓ | ✓ | ✓ |
| Storage of narcotics | - | - | - | ✓ | ✓ | ✓ |
| Air-conditioned warehouses | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Manufacturing authorisation | ✓ | ✓ | - | ✓ | ✓ | ✓ |
| Pick-by-light system | ✓ | - | - | ✓ | ✓ | ✓ |

Logistics Services

Logistics services include importation, receipt of goods, storage, order administration, processing of returns, pick, pack, ship/dispatch, accounting, invoicing and debt collection. Our sophisticated Information Technology (IT) systems provide customers seamless communication with our sites.

Cross-Border Presence

Our sites are ideally located to ensure efficient Continental European wide distribution and our site in Stockerau, Austria is ideally placed to facilitate distribution to the fast growing Eastern European marketplaces. Our site in Limay, France also offers logistic services to North African markets.



Contact NextPharma today to find out more about how we can meet your pharmaceutical, biotechnology and medical device needs at www.nextpharma.com or by contacting one of our sites.

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