NextPharma

Say yes to what’s next

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NextPharma at a glance

NextPharma

Leading European pharmaceutical CDMO focused on attractive technology niches

9 Manufacturing facilities

4 Logistics sites

€299 million

2020PF LFL Revenue*

14%

2020A **organic** revenue growth

60+

End markets served

~2,000

Employees

~25%

In Quality roles

Products

- Solids / Pellets
- Hormones
- Liquids / semi-solids
- Penicillins / Cephalosporins
- Ophthalmics / Blow-fill-seal
- Softgels/Liquid-filled Hardshells
- High potent
- Nutritional

Regulated by

FDA (USA)

EMA (Europe)

Anvisa (Brazil)

ROW

*2020PF, like-for-like for the acquisition of Lonza assets

Manufacturing network

Strong production platform underpinned by best-in-class quality

Production Platform

- Nine state-of-the-art centres of excellence
- Capable to produce 8 billion tablets per annum
- ~25% of employees work in quality control and assurance
- 100 customer and authority audits p.a.
- >10,000 batch releases
- Clinical trial services (Göttingen)
- Analytical services (Bielefeld)
- Strong development capabilities

Centres of Excellence

	1 Berlin	2 Bielefeld	3 Waltrop	4 Göttingen	5 Göttingen	6 Limay	7 Tampere	8 Ploermel	9 Edinburgh
Key Competences	• **Penicillins**	• **Pellet dosages**	• **Hormones**	• **Cephalosporins**	• **Oral solids**	• **Oral liquids** • **Suppositories**	• **Sterile ophthalmics**	▪ **Softgels***	▪ **Liquid filled hard capsules***
Illustrations									
Size	• 1,300m²	• 3,400m²	• 4,300m²	• 900m²	• 5,600m²	• 3,600m²	• ~4,000m²	acquired March 2021	

Healthcare logistics services

Pre-wholesaling logistics services to the pharmaceutical industry

Logistics Platform

- Goods-in and dispatch (pick and pack)
- Warehousing (ambient to -80°c)
- Delivery to wholesalers, pharmacies, hospitals
- Controlled substance storage
- Repacking and relabelling in accordance with GMP
- Storing and shipping
- Distribution for clinical trials
- Customer service desk handling

Warehouse Overview

	1 Werne[1]	2 Munich	3 Vienna	4 Schaffhausen
Storage Capacity	• **24,200 pallet spaces**	• **4,000 pallets spaces**	• **14,100 pallet spaces**	• **9,000 pallet spaces**
Illustrations				
Ownership	• Leased until Dec-25	• Leased until Oct-21	• Leased until Aug-29	• Leased until Aug-35

1 New project to open an additional site near Werne approved in Q1 2021

New acquisitions of Lipid Based Technologies sites

Adding softgel capsules and liquid-filled hard capsules to NextPharma's capabilities

- NCEs, 505 (b)(2), Generics & OTC in both sites - CH&N in Ploermel

Edinburgh, UK

CORE CAPABILITIES

- Lipid-based Formulations
- Liquid-filled Hard Capsules

SPECIALTIES

- High Containment / HPAPI
- Controlled Substances
- Colonic delivery
- Capsule-in-capsule technology
- Abuse deterrent formulations

Ploermel, FR

CORE CAPABILITIES

- Lipid-based Formulations
- Liquid-filled Hard Capsules
- Softgels capsules
- API-in-Capsule Studies / Micro-dosing

SPECIALTIES

- High Containment / HPAPI
- Hormones
- Microdosing for FIH study

Service offering along the entire product lifecycle

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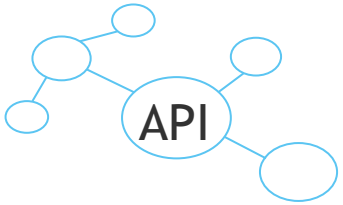

Pharmaceutical development

- Formulation and process development
- Analytical method development
- Stability testing

Clinical supply

- Clinical batch manufacture
- Phase I – IV clinical trials supply

Commercial

- Validation batches
- Technology transfer
- Launch and supply

CMC regulatory affairs

Commercial Manufacturing

Experts in solids, semi-solids and liquids (including sterile blow-fill-seal)

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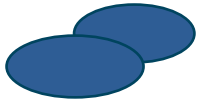
Solids

Powders and Granules	Pellets	Tablets	Film Coated Tablets	Hard Gelatine Capsules	Softgels
Paediatric Formulations					
Modified Release					
					
• Dry syrups • Bottles • Sachets	• Taste masking • Modified release of API • Protection of API	• Compressed Powder • Compressed Granules • Compressed Pellets • Bi-layer (2 different blends compressed in one tablet) • Modified release matrix tablets • Orodispersible • Mini-tablets	• Coating for taste masking • Coating for modified release of API • Coating for protection of API	• Powder blend in capsules* • Granules in capsules • Pellets in capsules • Tablets in capsules • Liquid in Capsules *incl. microdosing	• Pharmaceutical • Hormones • Health & Nutritional

Semi Solids

- Topical gels & creams
- Ointments
- Suppositories

Liquids

Non-sterile	sterile
• Buccal sprays, topical sprays • Nasal sprays • Oral solutions & Suspensions in bottles or ampoules	• Eye drops • sterile Blow Fill Seal Single Dose • Multi Dose 3P & PFMD bottles
	

Regulatory status

Centres of Excellence responding to global quality standards

	Anvisa (Brazil)	EMA	FDA (USA)
Berlin		✓	✓
Bielefeld	✓	✓	✓
Göttingen	✓	✓	✓
Limay	✓	✓	
Waltrop	✓	✓	✓
Tampere		✓	✓
Ploermel	✓	✓	✓
Edinburgh		✓	✓

How NextPharma has successfully grown organically

NextPharma

Positive differentiators of NextPharma in our industry

Customer-focused
reputation

Financial
stability

Project management
& excellent product transfers

Synergies
between production & development

Flexible partner
fast to act / lean

Local and global
perspective

Skills and Capabilities

Equipped and ready to support you along the entire product lifecycle

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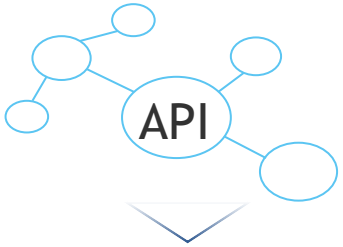

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Pharmaceutical Development Services

NextPharma

Always tailored to your precise needs

In Summary
API, comparator, excipient sourcing and testing
Pre-formulation and formulation development
Analytical method development
Microbiological testing
Manufacture, packaging and distribution of clinical supplies
Scale-up and process development
Analytical method validation and stability registration
Technology transfer to production
Compilation of CMC modules for CTAs, CTDs, NDAs, INDs dossier submission and variations
QP release

- ✓ Depth of scientific knowledge applied to your project
- ✓ Seamless links to your clinical and commercial supply
- ✓ Direct, fast communication through your dedicated project manager
- ✓ Flexible approach to your evolving needs
- ✓ Scientific and regulatory advice

Pharmaceutical Development Services

NextPharma

With diversified services

Product Optimisation

- Optimisation of composition and manufacturing process
- Analytical method development and method validation
- Scientifically guided setup of product specifications
- Supportive stability and stress studies on prototype formulations

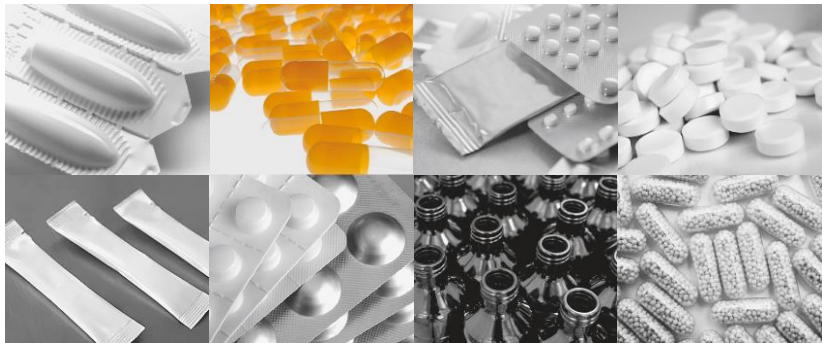
Product Development

- Formulation and manufacturing process strategy tailored to individual project requirements
- Quality by design including quality target product profile, gap analysis and risk assessment
- Full characterisation / reverse engineering of related products (if required)

Scale-up and process delivery

- Process development and validation
- Full ICH validation of analytical methods
- Manufacturing of registration batches
- ICH stability studies

Our across-site highly-skilled development team enables us to provide a maximum level of service and competence for every single project.



Analytical Services

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Key Services
Analytical Chemistry for raw materials, bulk and finished products
QP Release
Method development, validation and transfer
Stability storage and testing
Microbiology

- ✓ Depth of scientific knowledge
- ✓ State-of-the-art laboratory and equipment
- ✓ Direct, fast communication through your dedicated project manager
- ✓ Consistent high quality to EMA, FDA, ANVISA, ICH
- ✓ High flexibility to your evolving needs
- ✓ Scientific and regulatory advice
- ✓ >25 years experience as Analytics provider

Clinical Trials Supply services

From an experienced CTS partner who understands your needs may evolve

NextPharma CTS
A truly flexible approach to ensure your project keeps right on track
Seamless links to development and commercial supply
Always reliably informed with an experienced and dedicated project manager

Modu-C station | Göttingen, Germany

Clinical Trials Supply services

NextPharma

Our full services offer

Clinical Manufacturing Packaging & Labelling

- Blinding/Encapsulation capabilities for all major dosage forms
- Primary and secondary packaging of solids, semi-solids, liquids
- Labelling and secondary packaging of injectables and other dosage forms
- Kit packaging
- Randomisation
- Manufacturing capabilities for IMPs and placebos

Storage & Distribution

- Logistics solutions meeting CGSP/GDP regulations
- Storage at controlled temps 15-25°c | 2-8°c | -20°c
- Storage of controlled substances
- Worldwide distribution at controlled temperatures
- Return and reconciliation

Regulatory Support

- Creation of IMPD/IND
- QP Auditing / QP Release
- Import and export of IMPs and controlled substances from and into third countries
- Randomisation lists and emergency letters
- Also, comparator sourcing

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					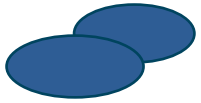
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Commercial Manufacturing

NextPharma

Unique niche services

Specialised containment and unrivalled know-how

- Penicillin
- Cephalosporin
- Hormone
- Lipid based formulation
- Ophthalmic
- High Potent
- Controlled substance
- Paediatric formulation

Capacities and Capabilities

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Berlin Centre of Excellence for Penicillins

Mixing/Blending	1800 tonnes
Granulation	1800 tonnes
Tabletting	570m tablets
Coating	250m tablets
Blistering	50m blisters
Sacheting	13m sachets
Bottling	2m bottles
Manufacturing	1,300 m²
Regulatory status	EMA, FDA (USA)

Bielefeld Centre of Excellence for Modified Release

Mixing/Blending	600 tonnes
Pellets	500 tonnes
Tabletting	800m tablets
Encapsulation	350m capsules
Coating	600 tonnes
Stick Packs	50m packs
Manufacturing	3,400 m²
Regulatory status	Anvisa (Brazil), EMA, FDA (USA)

Waltrop Centre of Excellence for Hormones

Hormonal solids	1,800m tablets
Hormonal semi-solids	200 tonnes
Hormonal solids blistering	55m blisters
Standard liquids	1,8m litres
Filling of oral and topical liquids	25m units
Standard semi-solids	200 tonnes
Standard solids blistering	25m blisters
Manufacturing	4,300 m²
Regulatory status	Anvisa (Brazil), EMA, FDA (USA)

Goettingen Centre of Excellence for Solids

Mixing/Blending	2,000 tonnes
Granulation	1,700 tonnes
Tabletting	4,000m tablets
Coating	1,200m tablets
Blistering	225m blisters
Sacheting	35m sachets
Bottling	5m bottles
Filling in glass bottles	8m bottles
Manufacturing	5,600 m²
Regulatory status	Anvisa (Brazil), EMA, FDA (USA), audited by Russian authorities

Goettingen Centre of Excellence for Cephalosporins

Mixing/Blending	600 tonnes
Granulation	400 tonnes
Tabletting	630m tablets
Coating	168m tablets
Blistering	47m blisters
Bottling	2,5m bottles
Manufacturing	900 m²
Regulatory status	EMA

Limay Centre of Excellence for Liquids & Semi-Solids

Liquids manufacturing	3.0m litres
Liquids filling	45m bottles
Double-point ampoules	100m
Drops and pump sprays	5m units
Encapsulation	750m capsules
Suppositories	20m suppositories
Manufacturing	3,600 m²
Regulatory status	Anvisa (Brazil), EMA, audited by Russian authorities

Tampere Centre of Excellence for Ophthalmics

3P bottles	40 Mio bottles
BFS single dose	3,2 Mio ampoule stripes (10)
BFS multi dose	8 Mio bottles
Manufacturing	4,000 m²
Regulatory status	EMA, FDA (USA), audited by Russian authorities

Ploermel Centre of Excellence for Lipid based formulation & Soft Gels

Nutritional Softgel	1.8 billion capsules
Pharmaceutical Softgel	1.4 billion capsules
Rx Hormonal Softgel	0.7 billion capsules
Pharmaceutical Licaps	0.2 billion capsules
Xcelodose	1.5 million capsules
Nutritional certificates	ISO22000, FOS (Friend of the Sea), Ecocert, Hallal
Regulatory status	Anvisa (Brazil), US FDA, EMA, audited by Russian authorities

Edinburgh Centre of Excellence for Liquid-Filled Hard Capsules

API size reduction	Impact milling
Bulk mix preparation	20L, 200L and 400L vessels
Capsule filling and banding	Bench to commercial scale, up to 100k capsules/hour
Drum coating	Multiple scales, up to 120k capsules/batch
Capsule printing	Off-set roller printing, up to 80k capsules/hour
Blister packing and cartoning	Thermoform capability with full lid foil printing
Serialisation	Level 4 system with tamper evident closure
Containment	High containment API handling in dedicated suites
Manufacturing	900 m² total (400 m2 dedicated to HP production)
Regulatory status	MHRA approved and FDA inspected

Why select NextPharma as your partner?

NextPharma

Service

- ✓ Strong, secure foundations
- ✓ Demonstrating innovation and world-class technical skills
- ✓ Modern outlook / facilities
- ✓ Competitive

Passion

- ✓ Proven excellence creating client specific solutions
- ✓ Depth of understanding and flexible approach
- ✓ Application of enthusiastic scientific expertise
- ✓ Proactive communication

Speed

- ✓ Recognised by customers for delivering a fast response
- ✓ Ability to react and deliver the ‘smart’ solution

Smart every time

NextPharma

It’s time for your next chapter

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