

Say yes to what's next

Your partner for pharmaceutical
development and manufacturing with
fast, flexible and personalised solutions
for worldwide markets.

 **NextPharma**

Global contract development and manufacturing

Being a preferred outsourcing partner means being ready to support the challenges our customers face today and tomorrow.

15bn tablet capacity

600m finished packs produced each year
100+ audits each year
15,000+ batch releases each year

More than 75

highly skilled scientists specialised in NCE, line extension and generic development using our diversified technologies

7 of the top 10

pharma companies are partners for the worldwide market

2,400 employees

>25% working in quality & regulatory roles

Value added approach

NextPharma's mission is to provide a best value service to its customers. We combine our core competencies with the right skilled people and demonstrate that every day. Our characteristics valued most by our customers are:

- Technical expertise and excellent quality
- Flexibility and responsiveness
- Commercial competitiveness
- Reliability
- Speed in execution
- Communication – always well informed

Experts in solids, semi-solids and liquids. Specialised containment and unrivalled know-how for:

• Penicillins

• Cephalosporins

• Hormones

• Lipid-based formulations

• Ophthalmics

• Pediatric formulations

• Controlled substances

• High Potent

• Consumer Health & Nutritional

Smart every time

The people at NextPharma provide a unique combination of scientific, technological and market knowledge.

Whether as a start up, virtual pharma or one of our world leading multinational customers,

we take each project and apply an innovative and customised approach to match your specific requirements and standards.

High calibre expertise

Our objective advice and expert guidance will make the difference in getting to the next trial phase or launching faster and more efficiently.

At NextPharma, we have established centres of excellence across all of our locations, each operating globally with common processes to ensure that best practice in project

management and scientific knowledge are applied consistently to meet your deadlines.

Speak to one of our experts to hear first hand how we can help your products succeed or ask to see some of our customer success stories.

NextPharma's core values summarise our 'smart every time' approach:

Service

One global team, with our customer at the centre of everything we do.

Passion

Proud of our skills and technologies. Passionate about how we apply them.

Speed

Always aware that our agility and flexibility are a competitive advantage for our customers.

Centres of excellence

Capacities and capabilities

Our roots go back more than 75 years. With the recent acquisition of our Tampere site, we have added a new centre of excellence in Ophthalmics to our six traditional centres of excellence.

Goettingen Centre of Excellence for Solids

Mixing/Blending	2,000 tonnes
Granulation	1,700 tonnes
Tableting	4,000m tablets
Coating	1,200m tablets
Blistering	225m blisters
Sacheting	35m sachets
Bottling	15m bottles
Filling in glass bottles	20m20m bottles
Manufacturing	5,600 m ²
Regulatory status	Anvisa (Brazil), EMA, FDA (USA), audited by Russian authorities

Goettingen Centre of Excellence for Cephalosporins

Mixing/Blending	600 tonnes
Granulation	400 tonnes
Tableting	630m tablets
Hard capsules	200m capsules
Coating	168m tablets
Blistering	47m blisters
Bottling	2.52.5mm bottles
Manufacturing	900 m ²
Regulatory status	EMA

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 m ²
Regulatory status	Anvisa (Brazil), EMA, FDA (USA)

Berlin Centre of Excellence for Penicillins

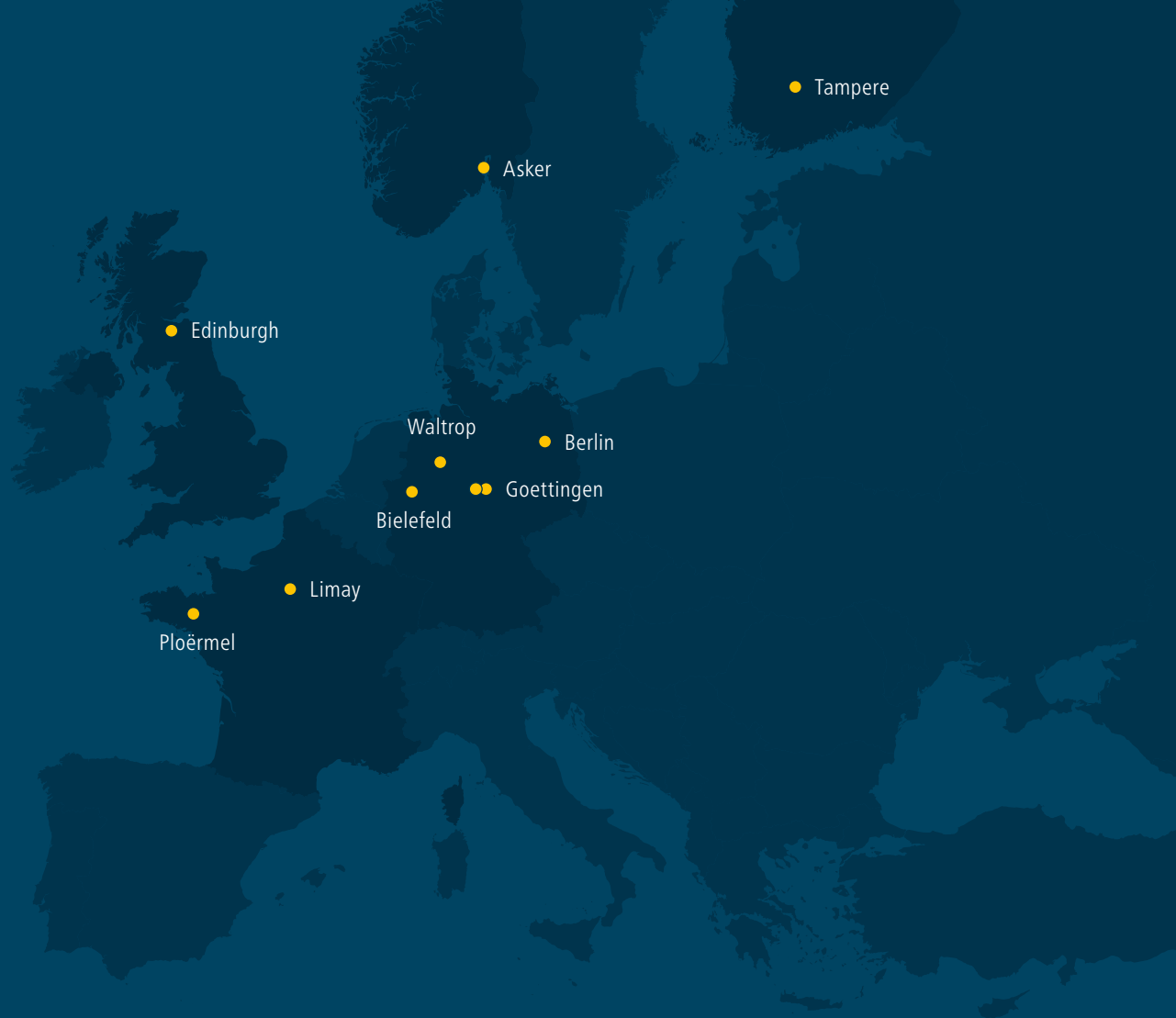
Mixing & Blending	270 tonnes
Tableting	200m tablets
Coating	300m tablets
Blistering	30m blisters
Sacheting	17m sachets
Bottling	3m bottles
Manufacturing	1,700 m ²
Regulatory Status	EMA, FDA (USA)

Bielefeld Centre of Excellence for Modified Release

Mixing/Blending	600 tonnes
Pellets	500 tonnes
Tableting	800m tablets
Encapsulation	350m capsules
Coating	600 tonnes
Stick Packs	50m packs
Manufacturing	3,400 m ²
Regulatory status	Anvisa (Brazil), EMA, FDA (USA)

Limay Centre of Excellence for Liquids & Semi-Solids

Liquids manufacturing	Batch size from 200 liters to 10 000 liters
Packaging activity in blisters	75m blisters
Syrups and oral solution	45m bottles from 50 ml to 500 ml
Double-point ampoules	100m
Drops	5m units from 5 ml to 30 ml
Suppositories	20m suppositories
Manufacturing	8,500 m ²
Regulatory status	Anvisa (Brazil), EMA, audited by Russian authorities



Ploërmel 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
Suppositories	20m suppositories
Xcelodose	1.5 million capsules
Nutritional certificates	ISO22000, FOS (Friend of the Sea), Ecocert, Hallal
Regulatory status	Anvisa (Brazil), FDA (USA), EMA, audited by Russian authorities

Asker Centre of Excellence for Chewable Tablets

Granulation/Blending	4,000 tonnes
Chewable Tablets	2.8 billion tablets
Packaging	40 million bottles
Manufacturing	8,000 m ²
Nutritional certificates	Kosher
Regulatory status	EMA

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 m ² total (400 m ² dedicated to HP production)
Regulatory status	MHRA approved and FDA (USA) inspected

Tampere Centre of Excellence for Ophthalmics

3P bottles	40m bottles
PFMD	5m bottles
BFS single dose	30m ampoules (strips of 10)
BFS single dose	200m ampoules (strips of 5)
BFS multi dose	7m bottles
Manufacturing	5,000 m ²
Regulatory status	EMA, FDA (USA), audited by Russian authorities

Commercial manufacturing

Our manufacturing centres of excellence provide our customers with reliable product supply in facilities that include European, US FDA and ANVISA approvals.



From launch to commercial supply

With an agile approach and wealth of experience, we ensure our customers obtain the right value through our collaboration. We excel across a range of dosage forms, as well as specialised technologies such as modified release (including pellets and bi-layer tablets). We also have a strong track-record with drugs requiring containment areas (hormones, penicillins, cephalosporins, ophthalmics, high potents and controlled substances) and specific solvent handling.

Technology transfer

Always driven by your deadlines and flexible in our approach, you can be confident that our strong Project Management team is fully skilled to make sure that transferring your finished product to our facilities will be managed seamlessly.

A broad range of highly tailored or large-scale primary and secondary packaging solutions for:

- Blister packs
- Sachets
- Tubes
- Stick packs
- Glass or plastic bottles
- Pump sprays
- Drinkable ampoules
- BFS Unidoses and multidoses, PFMD
- 3P Bottles



Flexible capacity from our integrated network of world-class GMP facilities.

NextPharma has a strong track record across a range of dosage forms:

Solids



- Tablets
- Chewable tablets
- Capsules
- Granules
- Powders
- Orodispersible tablets
- Pellets
- Coating
- Dry syrups
- Soft gels
- Liquid-filled hardshells

Semi-solids



- Suppositories
- Ointments
- Gels
- Creams

Liquids



- Solutions
- Drops
- Sprays
- Suspensions
- Syrups
- BFS Unidoses and multidoses, PFMD
- 3P Bottles

Pharmaceutical development

At NextPharma we combine scientific, regulatory and product development expertises to support a wide range of projects. You can rely on our drive, transparency and innovation.



Formulation and Process Development

Our personalised project management will nurture your product from development through to scale-up and commercial manufacturing. Fully aligned manufacturing technologies from early-stage development to industrial scale provide the basis of success of your development and optimise time to market. Our very experienced and motivated team is demonstrating every day its extended expertise in multiple and also niche areas such as pediatric formulation development. As early in your project as possible, our goal is to establish a process that sets you up for commercial success.

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

NextPharma, your partner from early-stage development to commercial manufacturing.



Our latest acquisitions add to our development platform early-stage development of lipid-based formulations, helping our customers to overcome bioavailability challenges of poorly soluble APIs.

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)

Product optimisation



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

Scale-up and process delivery

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

Clinical trials services and analytics

From our dedicated centre for clinical trials and analytics, we reliably deliver flexible, tailor-made solutions to customers worldwide.



Our highly skilled and competent team will provide for your clinical trials the best value for the following services:

- IMP creation and matching placebo manufacturing
- Packaging and labeling
- Randomisation
- IMPD
- Blinding
- Special label design and printing
- Return, reconciliation, destruction
- Comparator sourcing
- Worldwide distribution

Analytical Services

- Analytical testing is carried out at the state-of-the-art NextPharma laboratories
- Rapid testing of drug products to registration stability and commercial release
- Outstanding technical support and problem-solving experience
- Dedicated microbiology laboratory with over 40 years' experience



NextPharma is your one-stop-shop partner to better support your clinical trials.

It's time for your **next** chapter

NextPharma

Mail info@nextpharma.com
Web nextpharma.com

