

OFICHEM

CPHI Milan

6th – 8th Oct 2026



What sets us apart, in practice

Four strengths, one way of working.



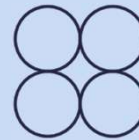
1. With us beside you

A partner, not just a supplier

We work as an extension of your team, aligning to your goals, timelines and challenges from day one.

What this means

You get consistency, transparency and a team that stays accountable through every phase, not just the easy ones.



2. Let's keep it moving

Big enough to deliver. Small enough to adapt.

We combine scale with flexibility, adjusting quickly as priorities shift without slowing your program down.

What this means

Faster decisions, fewer delays and steady progress, even when plans change.



3. Big on the little things

Quality built in, not added later

During development, we embed compliance, precision and control into every process, every batch and every interaction.

What this means

Confidence that everything is inspection-ready, without needing to chase it.



4. This is the place

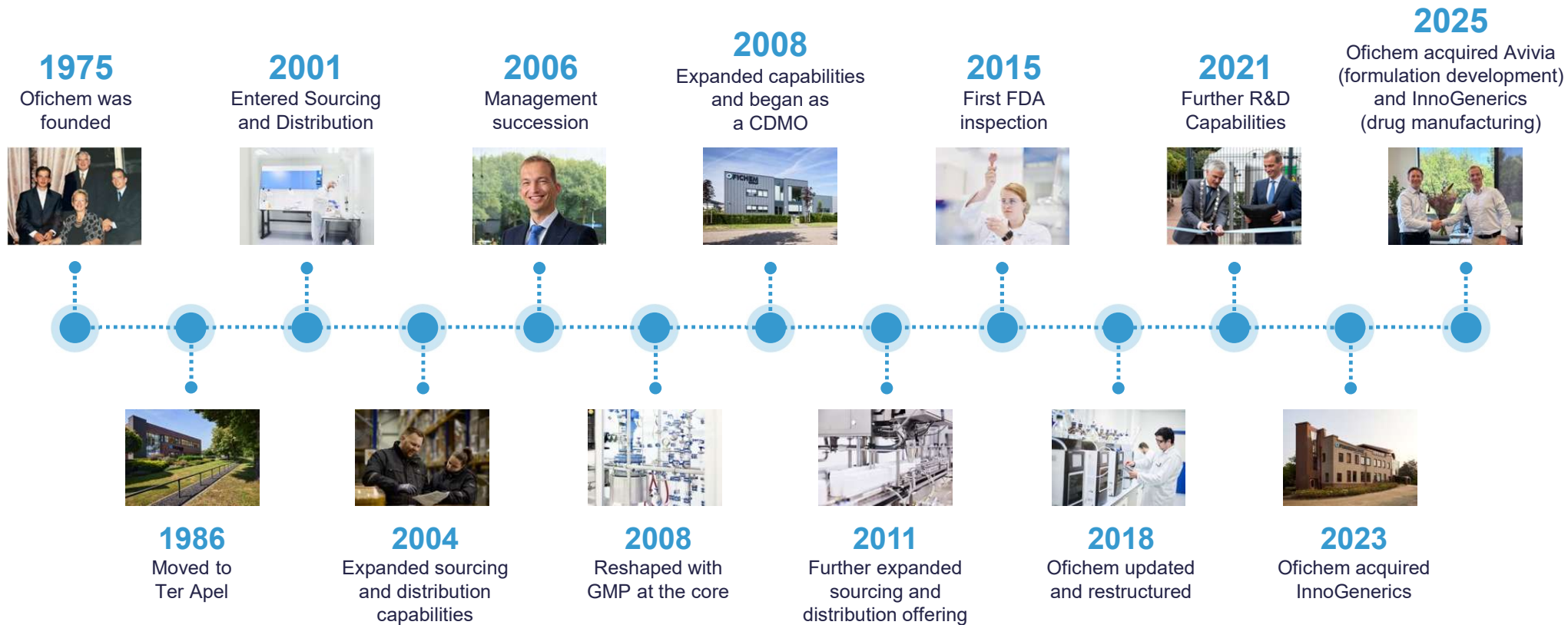
A trusted European alternative

Our EU-based operations bring security, reliability and regulatory clarity in an increasingly complex global landscape.

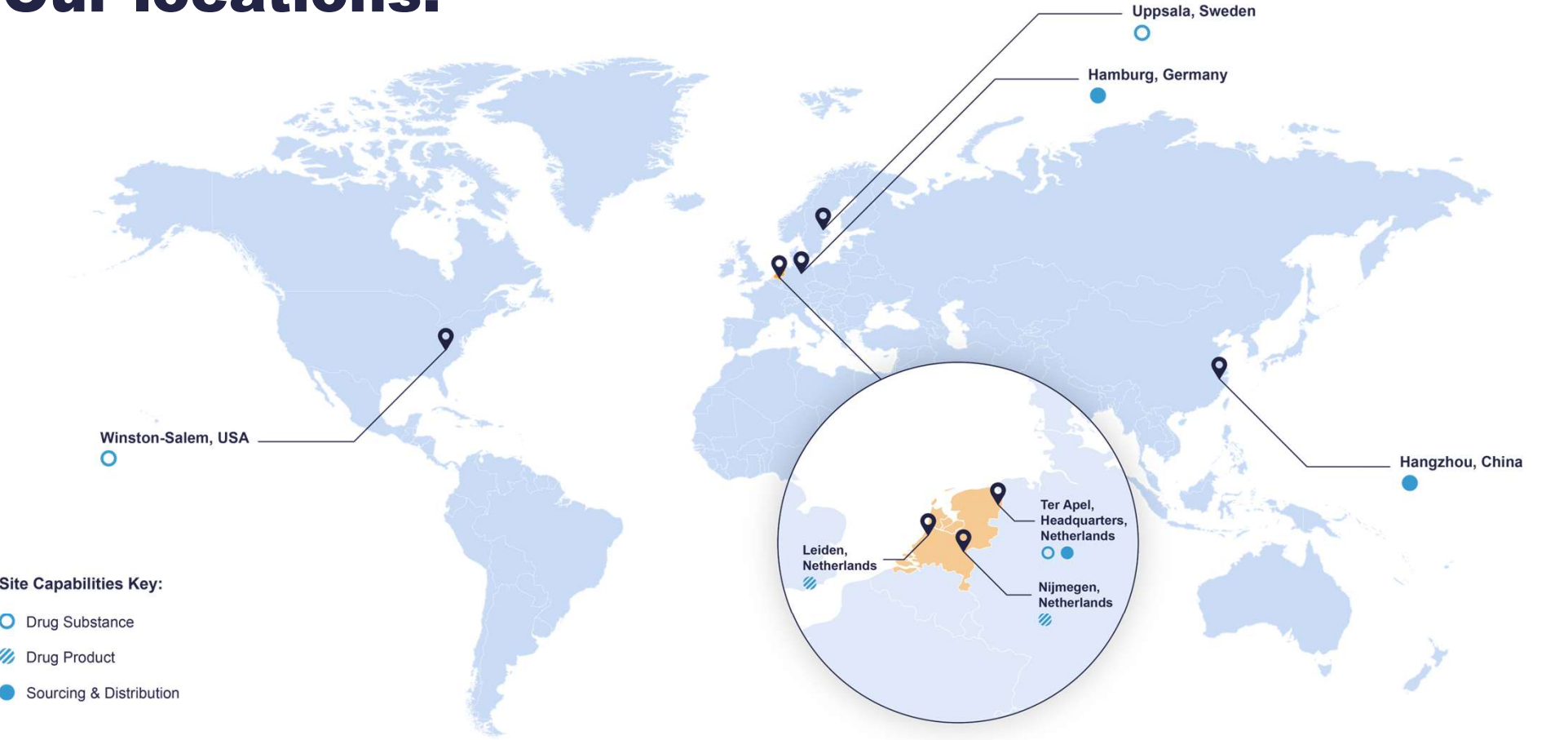
What this means

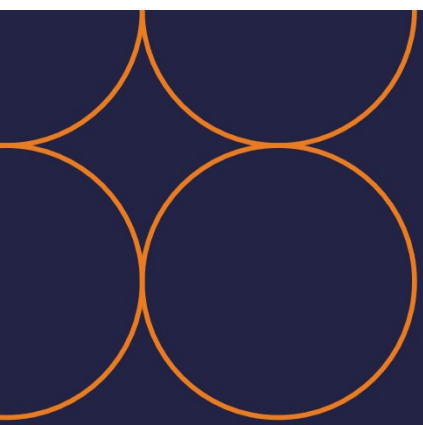
Stronger supply chains, reduced risk and greater control over your program.

The Ofichem story so far



Our locations:





Drug substance development and manufacturing

With us beside you from molecule to market

 **OFICHEM**





Drug Substance Uppsala, Sweden

Where insight becomes progress

We combine advanced analytical capabilities with hands-on development expertise to solve complex challenges and move your program forward.

Synthesis equipment

- Small scale and large-scale labs with reactors (10mL – 60L)
- Parallel reactors for DoE experiments
- Automated preparative HPLCs
- Automated flash chromatograph & ÄKTA purifier
- Reaction & Adiabatic calorimetry
- Pressure hydrogenator (2L)

Analysis equipment

- LC-UV-TOF & LC-MS/MS (High Resolution Instruments)
- HPLC-UV (Agilent 1100 series)
- GC/MS & GC/TOF
- Eppendorf Liquid Handling Systems
- Spectrophotometer and Nano Drop2

Drug Substance manufacturing in Ter Apel, the Netherlands.

From early-phase batches to commercial production, our facilities are designed to adapt to your needs without compromising quality or control.

cGMP and FDA approved, providing material for phase I, II, III, IV and commercial purposes via multiple regulatory pathways (NDA, 505b2, ASMF, DMF, CEP, JMF)

Small scale production

- 5 multi-purpose production suites with temperature range -75 to +250 C
- Fully glass (lined) manufacturing equipment (20L - 100L)
- Fluidized bed drying, flash chromatography, isolator, jet milling options

Mid scale production

- 4 multi-purpose production suites with temperature range -50 to +150 C.
- Fully glass lined manufacturing equipment (200 - 700L)
- Micronization & particle size distribution (jet milling and sieving)

Large scale production

- 5 multi-purpose production suites with temperature range -50 to +250 C / +15 to +90 C.
- Several glass lined (250 - 750L) and stainless steel (1000-2000L) manufacturing equipment
- Fluidized bed drying, nutsche filtration, hammer/jet/oscillating milling capabilities



Analytical services, made to measure up

Process Development Analytical Services

- Raw materials, excipients, API and FDF testing (Extractables & Leachables)
- ICH Q2(R2)/Q14 Full method development, verification and validation of RSMs, Intermediates & APIs
- Impurity profiling, identification & reference standard qualification
- Determination of logP, log D and pKa
- ICH Q1A (R2) / Q1B Stability studies – accelerated and real-time and photostability
- ICH Q3C - Residual solvent analysis

Analytical Third-Party Services

- All equipment in house for Pharmacopeia testing (BP, EP, USP)
- Compatibility studies with filters and medical devices
- Medical cannabis testing

Quality

- EU GMP
- EU GDP
- GLP
- Opiate license
- ISO9001

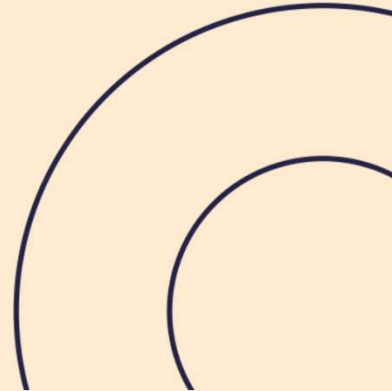
Quality isn't a checkpoint. It's how we work.





Drug product development and manufacturing

Built around your program



Formulation development in Nijmegen, the Netherlands

Straight to the solution

Each phase brings its own distinct challenges, so we tailor our support to ensure steady progress.

- 25+ years of formulation development and analytical experience
- Expertise across a wide range dosage forms and technologies:
 - Tablets & Capsules
 - Injectables
 - Oral solutions
 - Gels & sprays
 - Controlled-release
 - Fixed dose combinations
 - Hot Melt Extrusion
- Comprehensive analytical services including method development
- Reverse engineering specialists
- Unique excipient analysis platform
- Designed to deliver precision and control through every stage





Drug product manufacturing in Leiden, the Netherlands

European manufacturing

From clinical batches to commercial supply, our Leiden site is built to keep your production moving, reliably and efficiently.

Tableting and film coating

- Manufacturing area of 4200 m²
- Annual capacity of 2 billion tablets per year
- 6 tableting areas, speeds up to more than 200.000 tablets per hour
- Manufacturing tailored to customer needs with staff and equipment suited for small and large quantities
- High shear wet granulation and direct compression production
- Film coating and sugar coating
- Clinical trial GMP production of tablets, powders and granulates
- R&D scale equipment for faster tech transfer and process optimization

Packaging

- Packaging area of 1,200 m²
- Annual packaging capacity of 1 billion tablets in bottles and 1.5 billion tablets in blisters (>200.000 per tablet press)
- 4 high speed blister lines
- 1 bottle line
- Serialization via Trace Link
- Packaging for small (clinical) batches and commercial product quantities
- Flexible capacity aligned to your demand
- Seamless scale-up from development to production
- Consistent quality across every batch

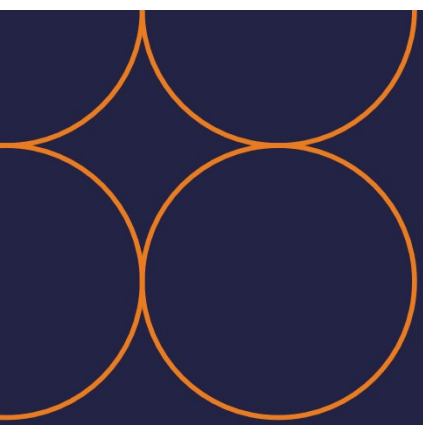


Advanced analytical support that underpins reliable drug product development.

We handle analytical method transfer into GMP, supporting seamless integration into final quality testing.

Our capabilities at a glance:

- Method development, qualification and validation
- Drug product assay and purity (HPLC/GC)
- Particle size distribution (laser diffraction, sieve analysis)
- Size exclusion chromatography
- Excipient compatibility testing
- Stability testing
- Solubility studies
- Reverse engineering of existing drug products
- Dissolution testing (USP I, II, III and IV)
- Excipient analysis
- Nitrosamine method development and analysis
- Leachables and extractables
- Compatibility testing and in-use studies



Sourcing and distribution

Keeping your supply moving

 **OFICHEM**



We are the stabilising partner in the value chain

Acting as a buffer function within our customers' APIs and feed additives supply chains

As an API supply partner, our daily world is shaped by availability, documentation, GMP expectations, logistics, price volatility and geopolitical disruption.

We deliver value where sourcing, quality, regulatory support, logistics, market intelligence and global developments come together.



Sourcing partner

Finding and qualifying reliable global sources, creating steady supply relations.

Risk monitor & buffer

Monitoring market signals, pro-acting on expected disruptions, price movements and supplier constraints.

Documentation partner

Supporting GMP, WC, LOA, LOC and supplier qualification processes.

Knowledge partner

Strengthening decision making across the value chain, through market intelligence, strategic sourcing, and regulatory expertise.

Repacking Services

Built for high-mix, low-volume pharmaceutical supply chains



Global Sourcing

- Direct relationships with qualified global suppliers
- Full visibility on market pricing and trends



Quality and Compliance

- QA-driven release according to monographs
- GMP retesting and regulatory expertise
- Specialized in controlled substances & opiates



Flexible Packaging

- EU-GMP & WinAp approved repackaging
- From 200 mg to 25 kg (high-mix flexibility)



End-to-End Partnership

- Private label & stock solutions
- Full service: sourcing → delivery



Extensive portfolio. Ready when it matters.

From essential APIs to specialised veterinary products,
we provide access to a broad and reliable portfolio.

Example: Human Pharma product portfolio		Example: Veterinary product portfolio	
• Allergy & Antihistamines • Anti-infectives (Antibiotics, Antivirals, Antifungals) • Cardiovascular System • Central Nervous System (CNS) • Dermatology • Endocrine & Metabolic • Gastrointestinal	• Hematology (Coagulation) • Hormonal Therapies • Immunology & Inflammation • Musculoskeletal • Oncology • Pain Management • Respiratory	• Amino Acids • Analgesics • Anthelmintics • Anti-Inflammatories • Antibiotics (Non Penicillins) • Antibiotics (Penicillins) • Coccidiostats • Corticosteroides	• Hormones • Intramammaries • Iron Compounds • Minerals • Sedatives • Theileriosis • Trypanosomiasis • Vitamins