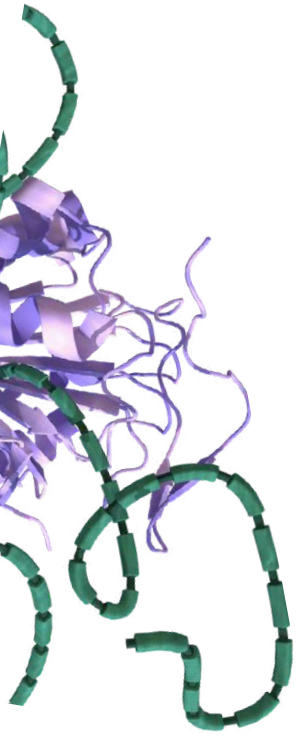
CURAPATH



CDMO Services

SCAN ME!

REACH OUT

RESOURCES

SOCIAL MEDIA

CURAPATH

More than a CDMO

About Curapath

Curapath is a **specialized CDMO** focused on **advanced drug delivery technologies using precision lipid- and polymer-based systems.** We provide end-to-end support, from early formulation and process development to GMP manufacturing of Drug Substance and Drug Product (F&F), delivering tailored, reliable, and regulatory-ready solutions.

Our expertise in LNPs, PNPs, and next-generation polymers enables the delivery of genetic material, peptides, small molecules, and more, supporting the development of innovative therapeutic products.

Curapath is more than a CDMO, it is your trusted partner driving innovation in non-viral delivery for gene therapy and beyond.

Our sites

GMP Production Site

Av. Benjamin Franklin, 19
46980 Paterna, Valencia, Spain

R&D Innovation Site

Alexander Graham Bell, 6
46980 Paterna, Valencia, Spain

Commercial offices

One Broadway, 14th floor
02142, Cambridge, MA, US

The team

Employees per team

Your Trusted CDMO Partner for your GMP needs

From preclinical to commercial Curapath empowers your non-viral delivery journey with proven GMP expertise in polymer and lipid-based therapeutics.

Novel Excipients

Innovativelipids & polymers including PEG alternatives

GMP Manufacturing

Manufacturing of lipid, polymers & Bioconjugates from R&D up to GMP

Nanoparticle Formulation

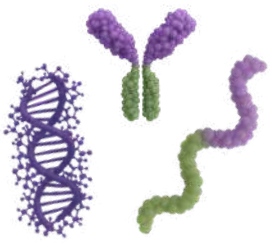
End-to-end solutionsfor nanoparticle drug product manufacturing

Product Catalog

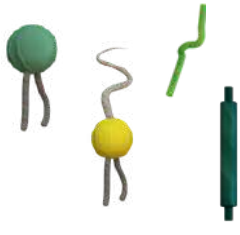
Off-the-shelf components to accelerate your clinical research

Our integrated CDMO offer:
GMP Manufacturing and Formulation Development to Fill & Finish

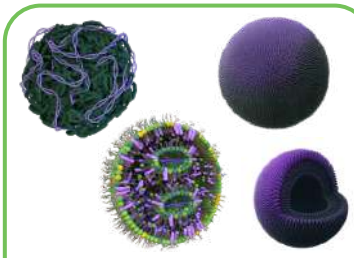
Drug substance | **Excipients** | **Drug Product** | **Packaging**



Customer API



High purity *off the shelf* and custom polymers and lipids



Formulation Development & adaptable workflow to your process needs

Fill & Finish: liquid and lyophilized

Comprehensive support on your journey to market authorization

Preclinical Development

From discovery to preclinical, we support early-stage development.

- Process development
- Formulation screening
- Pilot batch manufacturing for non-clinical and GLP tox studies
- Analytical method development

Clinical Supply

Accelerating your path to clinic, from candidate optimization to GMP production.

We enable smooth progression toward IND filing for novel excipients, drug substances, and drug products.

- Clinical supply of investigational products
- Fill & Finish
- Process & Method validation
- Quality by Design
- Regulatory support for clinical trial submission

Commercial Manufacturing

From late-stage development to global market launch, we deliver quality at scale.

We offer fully integrated GMP manufacturing with regulatory support to ensure timely, compliant, and reliable supply.

- Commercial batch release
- End-to-end tech transfer, scale-up & commercial readiness
- Regulatory support for NDA/BLA submissions across major markets

Supporting
+15
Ongoing Clinical Programs

+100
Customers worldwide

2
Life changing therapies
(FDA license ongoing)

61
Customer NPS
Industry average <20

% Project per clinical phase

36% Preclinical
17% Phase 1
3% Phase 2
20% Phase 3
24% Commercial/ recurrent manufacturing

% Project per payload type

73% Nucleic Acid
20% Small molecule
6% Biologics

Product type

44% Polymer excipient
8% Conjugate
3% Lipid excipient
9% LNP
8% PNP
16% Polymer drug
13% Other

Service

32% Analytical Service
12% DP Manufacturing
17% DS Manufacturing
11% Formulation Development
10% Regulatory support
18% Other

Analytics

Analysis, Testing Capabilities, and Milestones

Curapath's QC scientists support the development of Drug Substances and Drug Products through the entire project life-cycle. Quality control an analytical characterization will be an intrinsic part of your project. Equipment and skills are especially suited but not limited to method development, validation and stability studies. Allanalytical work is performed using qualified equipment within state-of-the-art GMP & GLPcertified facilities.

Curapath Analytical Experts Offer

- Routine characterizations.
- In-process and quality control.
- Identity, quantitative & limit tests.
- Impurity profiles.
- Analysis according to current monographs (e.g., Ph. Eur., USP).
- Method development and validation.
- Comprehensive cGMP documentation and release certificates.

250
Non-compendial Analytical Methods Developed

>200
Analytical Methods Validated (ICH Q2)

>50
Formal ICH Stability Programs

Method Development & QC

- Analytical method development for release, raw material control, in-process controls, and cleaning verification.
- Compendial and non-compendial methods.
- Method qualification and validation (ICH Q2).
- Forced degradation studies & ICH formal stability program including placebos.

Relevant Assays

Lipid & Polymer Nanoparticle Characterization
(Drug Product, Aseptic F&F)

- Particle Size, distribution, Z-potential & disparity
- API Identity & total concentration
- API % encapsulation
- Total API purity
- Lipid and polymer excipient
- identity & concentration
- Appearance, viscosity, osmolality, pH, VIC
- Residual solvents
- Endotoxin, bioburden, sterility, SVP, content uniformity
- Target Degree for targeted Nanoparticles

Polymer & Lipid Excipients
(Functional Excipient, Bulk Solid Release)

- Lipid & polymer identity and purity
- Polymer Mw, polydispersity and degree of polymerization
- Residual solvents
- Water content
- Mw & DP by end group analysis
- Impurities (elemental, process and degradation related)
- Enantiomeric excess
- And End Group functionalisation degree Characterisation

Polymer-Drug Conjugates
(Drug Substance, Bulk Solid Release & Drug Product)

- API identity & total concentration
- API conjugation % & free API
- Residual solvents
- Polymer Mw, polydispersity and degree of polymerization
- Enantiomeric excess
- Impurities (elemental, process and degradation related)
- Appearance, viscosity, osmolality, pH, VIC
- Endotoxin, bioburden, sterility, SVP, content

Manufacturing Capabilities from Pre-clinical to Commercial

To reduce scale-up time and regulatory risk, this process will be based on our strong know-how of precision polymers and in our comprehensive understanding of production processes.
Curapath bridges the gap between small to medium quantities (grams to multiple hundred kilograms per year) and the highest GMP-compliant manufacturing standards.

Manufacturing Facilities

- Four qualified clean-rooms
- Reactors up to 100 L
- Temperature range from −5 °C to +200 °C
- Freeze dryers
- Distillation equipment
- Nutsche filters
- Tangential Flow Filtration (TFF)

Polymer & Lipid Drug substances

- Ring-opening polymerization (NCA-ROP, Cationic-ROP...)
- Reversible Addition–Fragmentation Chain-Transfer (RAFT)
- Step-growth polymerization (Michael Addition, polycondensation...)
- Free-radical polymerization

Bioconjugations

- Polymer Drug Conjugates
- Polymer Protein Conjugates
- Polymer Excipients
- Glycopolymers
- Linking Chemistry Optimization
- Activated Polymers

Drug Products

- Polymeric Non-viral Vectors
- Lipid Nanoparticles
- Polymer Nanoparticles Colloidal Nanoparticles
- Hydrogels
- Hydrophilic Drug Conjugates

Our company provides proven scale-up capabilities, analytic development and a comprehensive CMC package, including

Preclinical Development

GMP Manufacturing

Method Development, Validation & ICH stability studies

Technology Transfer

Drug Product Formulation, Fill & Finish services to support clinical development

CMC Regulatory support for IND & BLA submission

GMP CERTIFIED

0.5-10/kg batch
For clinical and commercial stage supply
Capacity increase plan (during 2026-2027)

+200 GMP batches Manufactured
+250 Non-Compendial Methods Validated

Fill & Finish capabilities

Our Aseptic Filling operations are ideal for Gene and Cell Therapies and Orphan Drug trials

In additionto the development of drugdelivery systems, Curapathdevelops customized Fill & Finish approaches based on your request. As a CDMO, we can perform sterile Fill & Finish activities for a wide range of substances such as biologicals, DNA, RNA, proteins, nanocarriers, and controlled substances.

Aseptic Fill & Finish

Flexible formats

Semiautomatic filling line

- 2-20R Vials, up to 1500 vials/Batch
- 100-500mL Bottles
- 1-5L Bags

Automated line (through qualified partner network)

- Up to 10,000 liquid vials/batch, 2R, 10R, 20R, 50R
- Up to 4,000 lyophilized vials/batch (for 10R)

Environmental Monitoring, Sterility Assurance & Qualified Person release

Bulk Formulation up to 50L batch (Bioburden reduction available for shipment to third parties F&F)

Production following each **market's regulatory requirements:**

- Controlled rooms for **medical-device ingredients**
- ICH Q11-guided **excipient development**
- GMP / ICH Q7-aligned **drug-substance** manufacturing

Complete set of technologies to accelerate clinical development and go-to-market strategies

	Lab	Tech batch	GMP clinical & commercial
Manufacturing			
Non-GMP reactors up to 50 L	✓	✓	
GMP reactors for Drug Substance up to 100 L			✓
GMP Reactors for Drug Product Formulation up to 100 L			✓
Downstream			
TFF / Tangential Flow Filtration (Cassettes, hollow fiber) up to 15L	✓	✓	✓
Flash Chromatography	✓	✓	✓
High Pressure Preparative Chromatography	✓	✓	✓
Crystallization / Precipitation	✓	✓	✓
Lyophilization Drug Substance	✓	✓	✓
Lyophilization Drug Product	✓	✓	Established Partnership
Knauer mixing device for LNP / PNP	✓ HTS	✓	✓
Fill & Finish capabilities up to 1500 vials / batch		✓	✓
Sterile filtration	✓	✓	✓
Analytics			
Analytical methods development and validation (HPLC/MS, HPLC/CAD, SEC-MALS-RI, SLS, IC, KF, ATR-FTIR…)		✓	
Stability studies / ICH guidelines		✓	
Compatibility studies		✓	
Particle characterization (CE, qPCR, Fluorescence, PSD Malvern, DLS, Zpot, UV-Assay, LC)		✓	
In vitro testing (cells bank: liver, kidney, …)		✓	
In vivo testing / Tox studies		Established partnership	

With this capabilities Curapath can cover all steps from preclinical to commercial phase

Clinical, Product and Process Development lifecycle

Clinical Development Phases

Product and Process Development Stages

QbD Risk Assessments & Milestones

1. Target Product Profile (TPP) identification
2. Quality Target product profile (QTTP) definition
3. Critical quality Attributes (CQA) risk assessment
4. Initial process risk assessment (pCPPs)
5. Process risk assessment
6. Design space definition
7. Control Strategy risk assessment
8. Control strategy definition
9. Ongoing improvement and support

For Polymers, Lipids & Nanoparticle formulation

What our customers say

61
Customer NPS
Industry average <20

9.2 AAA
Most Reviewed CDMO
Best Lipid nanoparticles formulation supplier
Best Lipid Excipient Supplier
SciRank

ORPHA TRADE

We only have a small project with Curapath, but communication have always been impeccable. They are easy and quick to understand what I as a customer want and need, they come up with proposals and solutions, they are always responsive, and well-prepared for The R&D team works diligently, with proper care of the product, and the holistic project strategy in mind.
Claudia Turetscheck Director of R&D

Iris Biotech

We have found with Curapath a partner who has a profound know-how in both technical aspects of developing and manufacturing real innovative carriers in the field of polymer therapeutics and, furthermore, a deep understanding of the administrative and documentation necessities in the pharma world.
Both are extremely important and valuable, as new developments in the field of biopharmaceuticals require a solid technical understanding from chemistry to pharmacology to biochemistry and medicinal chemistry, as well as the special regulatory aspects, which have to be matched by any party acting in the health industry.
CSO & VP BUSINESS DEVELOPMENT
Thomas Bruckdorfer, Iris Biotech GMBH, Germany

Macro Biologics

Curapath has proven itself to be a capable and reliable partner. Over the past four years we have been repeatedly impressed by their knowledge and professionalism. The Curapath team has been both skilled and responsive to our needs, as well as innovative in meeting ne
llenges. Simply stated, Curapath has brought real value to our programs and to company. We look forward to the next phases of our relationship.
DANIEL J. HUANG & MICHAEL BEVILACQUA
Vice President of Operations & MD., PhD
CEO, CSO, Director & Co-Founder on Macro Biologics

CURAPATH

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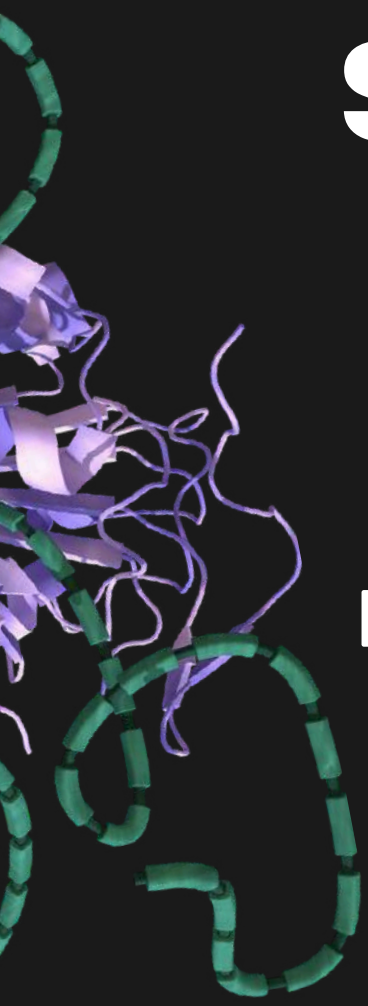

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