

CAPABILITIES PRESENTATION:

Your success is our priority.

Reagents.

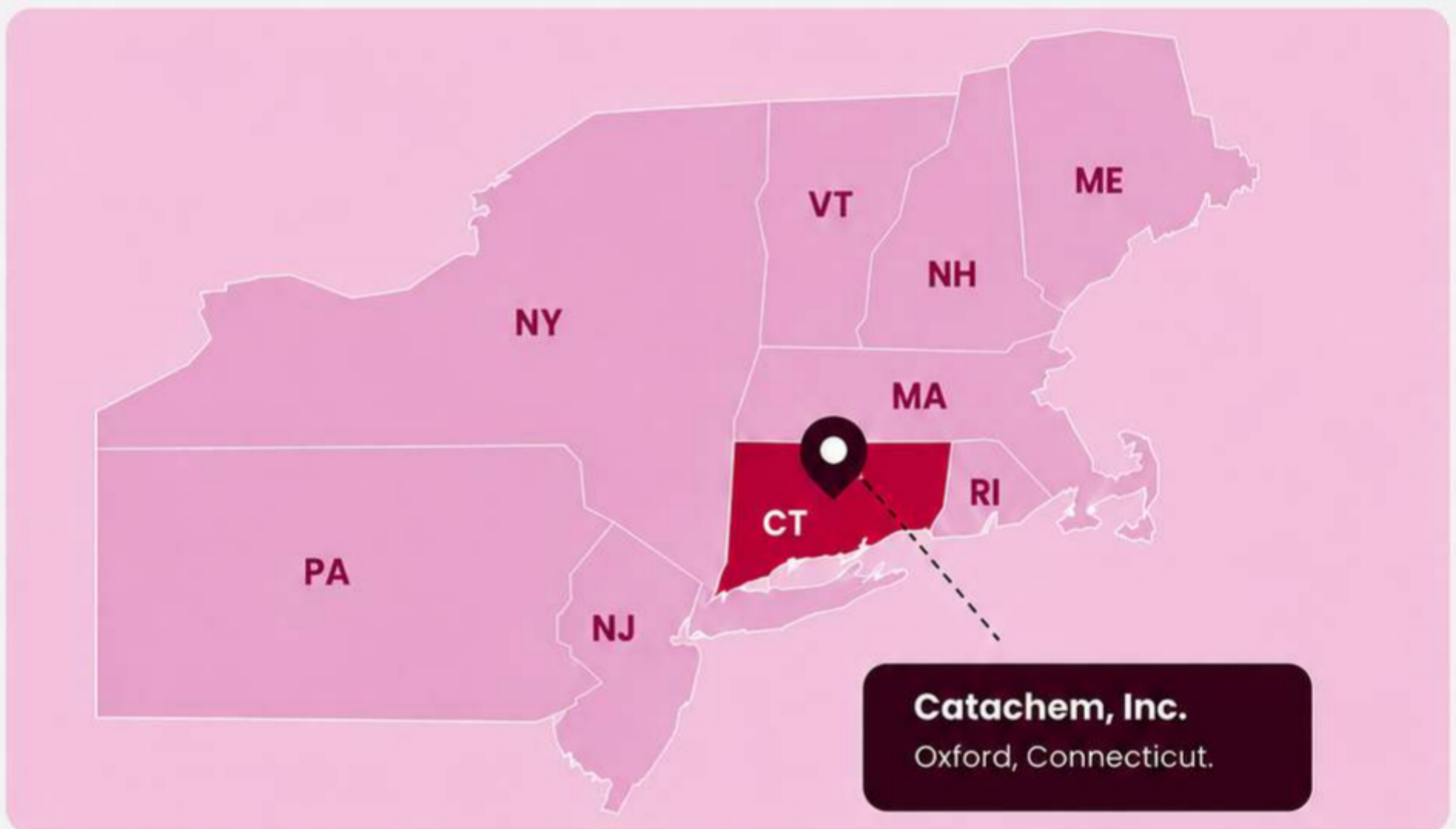
Lyophilization.

Contract Manufacturing.

Catachem Background.

History:

Catachem was founded in 1984 and is 100% US operated, specializing in enzyme-based chemistries, contract manufacturing, lyophilization services, and human/veterinary diagnostic test kits. Reagent manufacturing has been a core focus since the 1980s, with lyophilization and contract manufacturing capabilities added in the early 2000s.



Company:

7,000

SQ. FT. FACILITY.

15

YEARS LYOPHILIZATION
EXPERIENCE.

80+

PRODUCTS MANUFACTURED.

Catachem currently occupies 7,000 sq. ft. in Oxford, Connecticut and manufactures 80+ products.

Catachem is independently owned (not PE) and has been revenue & cash flow positive for 10+ years.

Catachem is stable, independent, and designed for long-term production.

Certifications:

Catachem, Inc. is ISO 13485 certified and an FDA-registered Medical Device manufacturer.

ISO 13485. CERTIFIED

FDA-REGISTERED.

cGMP IN PROGRESS.

Capabilities.

Medical Devices — Diagnostic Reagents & Kits:

Catachem, Inc. is a biotech contract development and manufacturing organization (CDMO) providing lyophilization and other biopharma services. We manufacture specialty bioprocessing materials and diagnostic reagents, including culture media, custom buffer systems and buffer solutions, assay reagents, controls and calibrator standards, positive and negative controls, ion transfer/electrolyte solutions, test kits, lyophilized materials, recurring lab-use products, linearity sets, and custom HPLC/UPLC reagent formulations.

Lyophilization:

Traditional · Lyobeads · Bulk.

Research & Development:

Proof of concept, formulation, and excipient/cryoprotectant identification and optimization. Recipe optimization: no batch too small. Exceptional customer service and turnaround time on every project.

Production:

Small to medium production runs up to 1.6M vials annually. Ambient or inert gas backfill available, with automated and manual filling, capping, and crimping options.



Contract Manufacturing:

- Manufacturing volumes up to 240L in a single batch/vessel.
- Filtering down to 0.22 microns with UVC sterilization (@ 254 nm).
- Customized SOPs, batch records, medical device records, reports, and documentation as required for each product/project.
- In-house quality control measurements with numerous metrics and reporting options. Catachem can implement, validate, and perform additional QC as required.
- Manual and automated processes for labeling, cartoning, packing, and packaging, plus shipping of finished product.

Planned cGMP Capabilities

Upon completion of our cGMP expansion, Catachem plans to offer:

Pharmaceutical Drug Products.

Aseptic fill-finish, lyophilization, and contract manufacturing using customer-supplied drug substances. Small-molecule drug products, sterile formulations, and other compatible pharmaceutical products.



Biologics.

Aseptic fill-finish and lyophilization using customer-supplied biologic drug substances. Monoclonal antibodies, recombinant proteins, enzymes, and other compatible non-viral biologics.



Bioprocessing Materials & Specialty Reagents.

Contract manufacturing, sterile filtration, filling, and lyophilization of buffers, cell culture media, and reagents for PCR and other molecular applications.



Animal Health Products.

Aseptic fill-finish, contract manufacturing, and cGMP lyophilization of compatible animal-health drug products, including sterile injectables. All programs are subject to technical and facility compatibility assessment.



For more information, visit [Catachem.com](https://catachem.com) or call +1-203-262-0330.

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