

Hovione's 3,000m<sup>2</sup> Technology Transfer Centre (TTC) in East Windsor, New Jersey, USA, initiated operations in September 2002. The site serves as Headquarters for Hovione's US Operations, and consist of process chemistry R&D labs, cGMP kilo and scale-up labs a cGMP pilot plant and a cGMP Spray Dryer. The TTC is also the home of Hovione's commercial offices and provides for cGMP storage and repackaging of finished goods. The TTC offers Hovione's US based customer's process development and scale-up services, along with quality control/assurance and regulatory support. The cGMP facility is designed to prepare small quantity NCE's to support customer's pre-clinical and early-phase clinical development, demonstrating the customer's processes locally before transferring them to Hovione's full scale manufacturing plants, in Europe and Asia.

In 2005 the TTC increased its technologies portfolio to handle highly potent compounds with an Occupational exposure limit of 0.5 µg/m<sup>3</sup> TWA 8 hr.

The technical capability of the TTC mimics that of Hovione's fully commercial facilities for seamless transition to commercial scale production. The TTC is fully integrated into Hovione's global quality network offering US customers real-time data and regulatory support for on-going production in the manufacturing plants. Operating under the same procedures, company culture, and team management, the New Jersey located TTC will benefit customers with efficient, seamless and cost-effective technology transfer.

- The development labs, staffed with multi-disciplinary project teams, allow fast turn around in producing small quantity pre-clinical APIs and investigates emerging technologies for scale-up for incorporation into Hovione's core capabilities. Process R&D and scale-up studies, carried out in glassware to 22 lt, will help to identify potential problems for eventual industrialization of the synthetic process.

- The Kilo Lab has a capacity to 200 lt in glass-lined reactors and 100 lt Hastelloy® C-22 cryogenic reactors. The kilo lab continues to develop the process and produces pre-approval quantities for clinical studies in compliance with strict cGMP procedures.
- The Pilot Plant, equipped with a 400 Lt Hastelloy® C-22 cryogenic reactor and 800 Lt glass-lined vessels, produces kilo quantities of API under cGMP. From the pilot plant, a seamless technology transfer can be done to industrial scale quantities.
- The Mobile Minor Spray Dryer allow to process DOE, scale up and manufacture under cGMP with greater flexibility in controlling and optimizing the particle attributes of pre-formulated APIs.
- The Finished Goods storage allows to stock up all Hovione API's for US customers in compliance with the cGMP regulations.
- Sales, Marketing and Administrative offices communicating via a global IT connection provide a permanent presence and service to US customers, a market that already represents over 60% of Hovione Group sales.

The TTC is located on an 8 acre parcel of land just off exit 8 of the New Jersey Turnpike, and is ideally located close to nine of the world's major pharmaceutical companies. The TTC employs 49 people.

This USD18M investment demonstrates the Company's commitment to constant but secure expansion in the business of APIs and addresses a growth strategy directed at strengthening Hovione's leading position to service the Pharma Industry.

The TTC was approved as a VPP (Voluntary Protection Program) Star participant by the US Department of Labor. This award recognizes sustained excellence in all areas of safety and health management.

The TTC has been inspected by the FDA in October 2007 and through this successful PAI with no 483, has now its commercial manufacture line.



Hovione is a specialist in the development and compliant production of active pharmaceutical ingredients (APIs), serving exclusively the pharmaceutical industry. With four FDA inspected sites in the US, Portugal, Ireland and China, Hovione is committed to the highest levels of service and quality. Specializing in complex chemistry, Hovione offers integrated API, particle design and formulation development and manufacturing. In the inhalation area, Hovione is the only independent company offering such a broad range of services.

Active anticipation, assured results.

[www.hovione.com](http://www.hovione.com)

Exclusives

Inhalation

Particle Design

Generics



The TTC is fully integrated with Hovione's global quality network offering customers' real-time data and regulatory support for on-going production at all our manufacturing plants.

Hovione's longstanding experience and commitment to Pharma customers is characterized by four key factors:

- Focus on API development and manufacture
- Wide and flexible range of research, development and production facilities that deliver robust cGMP solutions
- Project management skills that ensure we get it right first time, every time
- Reliable long-term customer relationships



**For further information, please contact:**

**Dave Hoffman**, President of US Operations - [dhoffman@hovione.com](mailto:dhoffman@hovione.com)  
**Doug Hecker**, Business Development Particle Design Director- [dhecker@hovione.com](mailto:dhecker@hovione.com)  
**Steve Barr**, Particle Design & Exclusives Sales Director - [sbarr@hovione.com](mailto:sbarr@hovione.com)  
**Carla Vozone**, Marketing & Business Development Director - [cvozone@hovione.com](mailto:cvozone@hovione.com)  
**Mayra Reyes**, Head of Process Chemistry - [mreyes@hovione.com](mailto:mreyes@hovione.com)  
**Filipe Tomás**, Head of Process Engineering - [ftomas@hovione.com](mailto:ftomas@hovione.com)

Hovione LLC  
 Technology Transfer Centre  
 40 Lake Drive  
 East Windsor, NJ 08520  
 USA  
 Tel: + 1 609 918 2600  
 Fax + 1 609 918 2615  
 Toll free: 877 909 0506  
[weblink@hovione.com](mailto:weblink@hovione.com)

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