



Client BioMarin
Location Novato, CA

Baby Biotech Grows Up with Foster Wheeler Biokinetics

Starting with a scientist and only a handful of employees in a lab, today BioMarin has four products in the market and is a fully-integrated multinational corporation providing innovative therapeutics to patients with serious unmet medical needs.

Situation

In 1997, BioMarin was an emerging biopharmaceutical company with a vision for developing and commercializing innovative biopharmaceuticals for serious genetic diseases and medical conditions. At the time, BioMarin was a 20 person, single product business, which had just gone public and had only one Phase I cell culture product in their pipeline - an “orphan” drug developed specifically to treat a rare medical condition. Orphan drug status was issued to BioMarin by the FDA and the drug was included in the FDA’s Fast-Track Program, which expedites the development and review process of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs.

Foster Wheeler Biokinetics’ first contact with BioMarin was with their head R&D Scientist. Like other early stage biotechs made up largely of R&D types, BioMarin was challenged with taking their

Background

BioMarin is a multinational corporation headquartered in Novato, California. They were founded in 1997 and currently have over 1,000 employees worldwide. BioMarin develops and commercializes innovative biopharmaceuticals for serious diseases and medical conditions. They have commercialized four products since 1997 and have multiple clinical and preclinical candidates in the pipeline. This is a remarkable accomplishment in the biopharmaceutical industry, and a testament to the company’s passion and dedication to patients with serious unmet medical needs.

drug candidates from the lab through the complex challenges of designing and building their first scale-up cGMP facility toward the commercialization of their new product – from the bench to the bank.





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Results

Foster Wheeler Biokinetics won the client’s confidence quickly. BioMarin was impressed with Foster Wheeler Biokinetics’ technical professionals from the outset and sole-sourced their Mammalian Cell Culture facility project. We went quickly to work providing feasibility studies for a new scale-up facility. Our process engineers, experts in cell culture, worked directly with the scientists to assist in the scale-up of the process. We designed, built and started-up BioMarin’s first scale-up facility within 28 weeks. We assumed the role of Design-Build lead with the project architect, MEP, and structural all reporting to us.

Later in 2002, Foster Wheeler Biokinetics completed an \$18 million Phase II renovation expansion of the existing Mammalian Cell Culture facility.

In 2009, Foster Wheeler Biokinetics led the facility and process design for the Novato facility expansion for commercial manufacturing. The \$60 million project included the retrofit of a 3 story facility which included major seismic work and included upstream

and downstream processing areas including (8) 200 liter bioreactors.

Since 1997, Foster Wheeler Biokinetics has enjoyed a successful relationship with BioMarin. We are proud of the role we have



played in partnership with BioMarin in bringing these life saving therapies to patients with serious unmet medical needs. We look forward to leveraging this success with similar early stage biotech companies as we bring the lessons learned and best practices from our past projects.



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