

#### **Customer Profile**

# BioMarin Enhances GMP Compliance and Workflow with Infor FAM



#### Facts at a glance.

Solution: EAM

Products: Infor™ EAM, Infor™ EPAK Industry: Chemicals & Life Sciences

Country: USA

"We're very encouraged by Infor's desire to serve biopharmaceutical customers. We worked closely with their development team to address certain functional concerns for the next upgrade, and they came back with outstanding resolutions."

—Jim Kroyer, Principal Engineer, Equipment Reliability, Biomarin

## About the company.

Based in Novato, California, BioMarin develops and commercializes biopharmaceuticals for rare, serious diseases and medical conditions. The company occupies 500,000 square feet within 10 buildings in its main Novato operations, and it has a presence in 40 countries. BioMarin has a product portfolio of four marketed products and multiple clinical and preclinical product candidates, but its core business lies in developing enzyme replacement therapies. To learn more, visit www.bmrn.com.

### Challenges.

- Achieve targeted maintenance for plant optimization, or rolling shutdowns, even in the face of explosive growth, through the creation of a reliability-centered maintenance (RCM) system.
- Improve GMP (Good Manufacturing Practice) compliance, develop controlled business processes, and eliminate paper documentation.
- Provide a single source of truth to improve equipment and maintenance data management, as well as calibration histories.

#### Benefits.

- Gained configuration tools such as KPIs, dataspies, status changes, e-signatures, and calibration that aligned well with the needs of a biopharmaceutical company.
- Demonstrated continuing Good Manufacturing Practices (cGMP) to regulators as required of biopharmaceutical companies by developing software development lifecycle (SDLC) documents, user acceptance testing, and validation.
- Identified and resolved potential compliance issues by developing standardized business processes and work order types that would ensure proper workflow and protect status changes.
- Eliminated paper documents by developing cloned work order screens to replicate paper forms and retain familiarity for users.
- Managed inventory more effectively by standardizing inventory part descriptions, resulting in less downtime and fewer costs associated with rush orders.
- Standardized training requirements for new and infrequent users with Infor EPAK, which allowed the company to develop 175 scripts that mirrored its business workflows.

"Infor EAM has helped us meet increasing demand for maintenance services and our customers' rising expectations, boost our level of GMP compliance, and significantly reduce paper documents."

—Jim Kroyer, Biomarin

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