



## RETRAINEE - JOB CREATION

### Critical Proposal for:

### BioMarin Pharmaceutical Inc. Agreement Number: ET16-0152

Panel Meeting of: August 28, 2015

ETP Regional Office: San Francisco Bay Area      Analyst: D. Woodside

#### PROJECT PROFILE

Contract Attributes:	Critical Proposal Retrainee Job Creation Initiative Priority Rate	Industry Sector(s):	Manufacturing Biotechnology/Life Sciences  Priority Industry: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Counties Served:	Marin	Repeat Contractor:	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Union(s):	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		
Number of Employees in:	CA: 1,500	U.S.: 2,000	Worldwide: 2,500
<u>Turnover Rate:</u>	7%		
<u>Managers/Supervisors:</u> (% of total trainees)	6%		

#### FUNDING DETAIL

Program Costs	-	(Substantial Contribution)	(High Earner Reduction)	=	Total ETP Funding
\$900,000		\$56,700 15%	\$0		\$843,300

In-Kind Contribution:	100% of Total ETP Funding Required	\$1,530,750
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**TRAINING PLAN TABLE**

Job No.	Job Description	Type of Training	Estimated No. of Trainees	Range of Hours		Average Cost per Trainee	Post-Retention Wage
				Class / Lab	CBT		
1	Retrainee Priority Rate	Continuous Improvement, Business Skills, Computer Skills, Advanced Technology, Manufacturing Skills, PL-Mfg.	700	8-200	0-100	\$459	\$18.60
				Weighted Avg: 30			
2	Retrainee Job Creation Initiative Priority Rate	Continuous Improvement, Business Skills, Computer Skills, Advanced Technology, Manufacturing Skills, PL-Mfg.	435	8-200	0-100	\$1,200	\$18.60
				Weighted Avg: 60			

**Minimum Wage by County:** Job Number 1: \$16.44 per hour for Marin County; Job Number 2 (Job Creation): \$13.70 per hour Marin County.

**Health Benefits:**  Yes  No This is employer share of cost for healthcare premiums – medical, dental, vision.

**Used to meet the Post-Retention Wage?:**  Yes  No  Maybe

Although employer provides health benefits, they are not being used to meet the Post-Retention Wage.

Wage Range by Occupation		
Occupation Titles	Wage Range	Estimated # of Trainees
Production Worker/Operator		600
Engineer		300
Scientist		70
Administrator		101
Manager/Supervisor		64

**Critical Proposal**

This proposal for BioMarin Pharmaceutical Inc. (BioMarin) has been designated a Critical Proposal by the Governor’s Office of Business and Economic Development based on the Company’s planned expansion and commitment to adding new jobs in California.

## **INTRODUCTION**

Founded in 1997, BioMarin ([www.biomarin.com](http://www.biomarin.com)) is headquartered in San Rafael and has its manufacturing facilities in Novato. BioMarin develops and manufactures pharmaceuticals for rare but serious autoimmune and inherited metabolic diseases. The Company specializes in the development and production of medications targeted for populations of 200,000 patients or fewer.

The Company's FDA-approved products include Naglazyme, Aldurazyme, Kuvan, and Firdapse. Naglazyme and Aldurazyme are used to treat patients with MPS, a debilitating, life-threatening genetic disease for which no other drug treatment currently exists. Kuvan treats an inherited metabolic disease that affects at least 50,000 diagnosed patients under the age of 40 in the developed world. Firdapse treats patients with LEMS, which is a rare autoimmune disease with the primary symptoms of muscle weakness.

The Company proposes to train 700 currently employed, frontline employees and 435 newly-hired, frontline workers. Training and hiring will occur both in Novato and San Rafael. This is BioMarin's second ETP project. Any Incumbent workers in Job Number 1 trained under a previous Agreement will receive different training courses based on new technology, processes, and equipment. Due to the complexity of manufacturing its products, it is critical that BioMarin be able to manufacture drug products at a scale large enough to support their respective commercial markets. This ETP-funded training will assist BioMarin to remain competitive globally, meet the demands of expanding markets, and retain its manufacturing workforce in California.

### **Retrainee - Job Creation**

The Panel offers incentives to companies that commit to hiring new employees. Training for newly-hired employees will be reimbursed at a higher rate and trainees will be subject to a lower post-retention wage.

To meet future commercial and clinical product needs, manufacturing operations will expand to meet long-term anticipated demand. Infrastructure improvements at the Novato manufacturing facility include adding a cell culture and fermentation capacity to support seven clinical and commercial biological products. BioMarin is also building a new three-story, 85,000-square-foot research and development facility in San Rafael. This San Rafael facility is set to open in late 2015. In addition, BioMarin invested over \$300 million in research and development in 2014 resulting in the creation of a robust pipeline of new products.

In this proposal, BioMarin has committed to hiring 435 new employees over the next two years, largely in production but potentially across all occupations. The date-of-hire for all trainees will be within the three-month period before contract approval or within the term-of-contract. The Company also represents that these trainees will be hired into "net new jobs" as a condition of contract.

## **PROJECT DETAILS**

BioMarin is requesting the Panel's assistance to provide classroom/laboratory, computer-based training (CBT), and Productive Lab (PL) training hours in the following areas:

**Continuous Improvement Skills (14%):** Training in Quality Master Plan will provide trainees across occupations with skills to make significant improvements in: quality, decision-making, corrective and preventative actions, management controls, process validation, and compliance

management. This training will also enable employees to reduce costs, work in teams, lead teams, improve productivity, and find root causes of problems.

**Computer Skills (3%):** Trainees in all occupations may receive training in advanced desktop applications, computer-assisted design software, productivity software applications, and BioMarin's in-house software applications for inventory, account management, and manufacturing control. All basic desktop training such as Microsoft Word, Excel, and PowerPoint will be delivered at BioMarin's own expense.

**Business Skills (2%):** Training will be provided to personnel interacting with customers (primarily Administrators) and to Supervisor/Managers. Classes will include project management; marketing; communications; finance; and preparing effective oral and written presentations to customers. FDA regulations, including the complexity of BioMarin products and business transactions, dictate that effective customer communications and order accuracy be achieved.

**Manufacturing Skills (5%):** Training will be provided to frontline Production Workers and Operators who need to operate specialized equipment used in BioMarin's production facilities. Trainees will also learn cross-functional production skills to use several different pieces of equipment and manufacturing assembly techniques. Manufacturing skills training (class/lab and PL) will be taught by a combination of highly skilled internal production supervisors, chemists, scientists, production trainers, production associates and/or engineers. These instructors will oversee an employee's use of special biotech equipment, which will provide the employee highly transferable skills to other biotech employers.

**Advanced Technology (10%):** Training will be delivered to Engineers and Scientists in the following: bio-analytical, sterility, and stability testing; DNA/Viral filtration theory; cell culture, fermentation, harvest, and purification; microplasma and in vitro testing; cell culture density and operations; and other advanced bioscience topics. This type of training, entirely provided by in-house and external trainers, will cost more than \$100 per trainee hour. Trainees slated to receive training have previous training and experience in biotechnology and/or electronic technology measurement but lack specific skills in new product technologies, equipment, and processes. The trainer-to-trainee ratio will be capped at 10 trainees to one instructor to allow in-depth coverage and personal attention from the instructor.

### **PL-Manufacturing Skills (66%)**

Only frontline manufacturing employees, including Production Workers employed as Operators who directly interface with a new and/or improved manufacturing process, will attend PL training. The proposed PL training will provide manufacturing employees cross-training opportunities on the many production lines/procedures used throughout the manufacturing facility. Rather than create live classroom training sessions for each new standard, BioMarin is using PL training as the most logical alternative to deliver the substantial quantity of critical manufacturing skills to its frontline manufacturing workers.

The projected number of employees who will attend productive lab training is 600. Each trainee will receive an average of 47 PL training hours, not to exceed 60. This training methodology is needed for the newly hired trainees in Job Number 2 but will also be a significant training methodology for production workers in Job 1 because of the nature of its manufacturing business and its focus on training frontline workers on the manufacturing floor. The Company's Novato facility must demonstrate compliance with Good Manufacturing Practices (GMPs) to the satisfaction of the FDA, the European Commission (EC) and health agencies in other countries for the commercial production of Aldurazyme, Naglazyme and Vimizim. To sustain GMP status, BioMarin is subject to periodic inspections confirming compliance with applicable law and must

pass inspection before drug protection and sales. A major compliance review item is the competency of worker skills operating the biotech machines throughout BioMarin's clean room facilities. All PL training will occur in a cleanroom manufacturing setting, conducted by a qualified trainer. During ETP-funded training, the trainer's time will be dedicated to the delivery of PL to the trainee. The trainer-to-trainee ratio is 1:1. These parameters meet the Panel's standards for PL training. This training will provide specific bio-tech manufacturing skills on the latest machines, tools, and techniques to produce FDA-regulated products. A trainee observes real production procedures demonstrated by the lab trainer and will practice their skills under the supervision of the lab trainer. Upon certification of their competency, the trainee is able to independently produce goods that are for sale.

PL training certificates and attendance records are stored in PDF format in the Learning Management System (LMS) using ComplianceWire software. The course content is also stored in LMS along with individual training plans.

### **Impact/Outcome**

The majority of the training under this proposal will be delivered to frontline manufacturing workers who will be trained to use state-of-the-art biotech machines, tools, and techniques in a clean room environment. BioMarin representatives report that the life sciences industry is the most regulated in the State, and trainees who are knowledgeable in performing their job to the current manufacturing operating procedures acceptable under FDA standards attain highly transferable skills.

Trainees will receive certifications in such areas as: Quality Control, Biochemistry, Operation and Maintenance of VITEK 2, Glassware Wash Process, Swab Sampling, HVAC Sampling, Single Use Bioreactor, Tubing Welder, Freezing of Microorganisms, Bioburden Testing, Endotoxin, Validation of Microbial Recovery, Buffer Preparation, Processing of Samples for Microbial Identification and others depending on work order requirements.

### **Commitment to Training**

ETP funds will not displace BioMarin's existing financial commitment to training. The Company's statewide training expenditures in California for non-ETP related training is in excess of \$1,300,000. Further, the proposed ETP-funded training is different in content and format than the Company's ongoing training. The proposed customized ETP curriculum will build on, but not overlap, basic instruction and orientation training already provided by the Company.

BioMarin currently funds all training in OSHA and FDA-mandated safety regulations; rudimentary job skills; basic desktop training in Microsoft Word, Excel, and PowerPoint; and executive development. BioMarin will continue to fund such training, and any training hours delivered beyond the 200 hours per trainee cap in this project. Safety training is, and will continue to be, provided in accordance with all pertinent requirements under state and federal law.

### **Recordkeeping**

Staff has reviewed and approved the use of a Learning Management System for recordkeeping.

### **RECOMMENDATION**

Staff recommends approval of this proposal.

**PRIOR PROJECTS**

The following table summarizes performance by BioMarin under an ETP Agreement completed within the last five years:

Agreement No.	Location (City)	Term	Approved Amount	Payment Earned \$ %
ET13-0209	Novato	11/26/12– 11/25/14	\$457,920	\$452,822 (99%)

**DEVELOPMENT SERVICES**

Herrera & Company, of Stockton, provided application development services at no cost.

**ADMINISTRATIVE SERVICES**

Herrera & Company will also perform administrative services for an amount not to exceed 13% of payment earned.

**TRAINING VENDORS**

To Be Determined

**Exhibit B: Menu Curriculum****Class/Lab Hours**

8-200

**CONTINUOUS IMPROVEMENT SKILLS**

- Process Modeling and Analysis
- Good Laboratory Practices
- GxP Compliance Training
- Quality Fundamentals/Core Skills
- Leadership / Coaching Skills
  - Facilitating Groups
  - Efficiency Workflow
  - Facilitation Skills and Mentorship
  - Strategic Sales Negotiation Techniques

**BUSINESS SKILLS**

- Project Management
- Master Scheduling Presentation
- Product Knowledge and Market Validation
- Finance and Accounting Skills
- Marketing Promotion and Position

**COMPUTER SKILLS**

- Management and Manufacturing Control Systems
- Materials and Logistics Software Development
- Advanced Desktop Applications
- Programming Languages
- Project Management Software Tools
- Operating System Programming Language

**ADVANCED TECHNOLOGY**

- Cell Data Modeling and Architecture
- Advanced Programming Development Applications
- Application Bioscience Engineering
- Factory Automation Tools and Techniques
- Instrument Modeling/Integration Software Development
- Measurement Biosciences Practice and Theory

**MANUFACTURING SKILLS**

- Production and Equipment Operations
- Manufacturing Process Cross Training
- Machine Operations, Calibration, and Maintenance

**Productive Lab Hours**

0 - 60

**MANUFACTURING SKILLS (1:1 Ratio)**

- Production and Equipment Operations
- Manufacturing Process Cross Training
- Machine Operations, Calibration, and Maintenance
- 125 ml, 500ml Shaker Flask Inoculation
- Assembly, Compression and Filter Flush Millipore Pod System
- Automated SIP of Equipment Using SCADA
- Butyl Strip through Storage
- Butyl Washes (Wash 1 to Wash 2)
- Charcoal Filtration of UF Concentrate
- Cleaning & Maintenance of Hoses in Galli West Mfg. Facility
- Determination of Cell Density & Viability During Cell Culture
- Equipment Flow for Kitting and Sampling Room at Pimentel
- Execution of Oracle EBS for Commercial Manufacturing
- Expansion to 1/3/8 L Flasks
- Final Filtration of UF Concentrate
- Gowning & Equipment Flow for Kitting & Sampling Room at Pimentel
- HiCap Washes (Wash 1 to Wash 2)
- In-Process Sampling for rhIDU Production
- Material, Equipment & Process Flow for Galli East Non-MFG Staff
- Navigation to Control Windows
- Operation & Preventative Maintenance of the QC Fume Hoods
- Operation & Maintenance of the Adv. MicroOsmometer 3300
- Operation & Maintenance of the Beckman 350 pH Meter
- Operation & Maintenance of the Bellco Spinner Plate
- Operation & Maintenance of the DU 730 UV/Vis
- Operation and Maintenance of the pH/Conductivity Meter
- Operation and Maintenance of the Sartorius Sartocheck 3 Integrity Tester Including Filter Usage and Testing
- Preparation of Snap Frozen HCCF Samples for Mycoplasma Production Media Preparation Using VE-2200 and VE-2210
- QC Accessioning
- Recalibration of Probes
- Sampling Post-DNA/Viral Filtration
- Barcode Gun Scanner for EBS Transactions for Commercial Mfg.
- Viable Air Monitoring Using the Settling Plate Method
- Washout/ Perfusion and Harvest Collection

- WFI Drops Sanitization and Usage
- Working Cell Bank Distribution
- Zinc Elution and Adjustment

**CBT HOURS**

0 - 100

**COMPUTER-BASED TRAINING (CBT)\*****Computer Skills**

- Management and Manufacturing Control Systems (1 hr)
- Single-Vendor Enterprise Resources Planning (1 hr)
- Customer Relationship Management Systems (1 hr)
- Advanced Desktop Applications (2 hr)

**Business Skills**

- Customer Communications and Awareness (1 hr)
- Sales and Negotiation Skills (1 hr)
- Finance and Accounting Skills (1 hr)
- Marketing Promotion and Position (2 hr)

**Continuous Improvement**

- Quality Management Systems (QMS) Procedures (1 hr)
- Manufacturing Quality and Reliability (1 hr)
- Process and Capability Mapping (1 hr)
- Problem Solving Tools and Techniques (1 hr)

**Manufacturing Skills**

- Production System Procedure Review (0.5 hr)
- Manufacturing Procedures and Protocols (1 hr)
- Machine Instrumentation and Troubleshooting (1 hr)

\*An Excel list will be provided to ETP with CBT course titles and standard times per module. The list includes codes which will correspond to the CBT topics listed above. CBT will be capped at 50% of total training hours per trainee.

Note: Reimbursement for all retrainees is capped at 200 total training hours per trainee, regardless of training delivery method.
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