



## RETRAINEE - JOB CREATION

### Training Proposal for:

**Boehringer Ingelheim Fremont, Inc.**

**Agreement Number: ET17-0232**

**Panel Meeting of:** September 23, 2016

**ETP Regional Office:** San Francisco Bay Area

**Analyst:** R. Jackson

### PROJECT PROFILE

Contract Attributes:	Priority Rate Retrainee Job Creation Initiative	Industry Sector(s):	Manufacturing Biotechnology/Life Sciences  Priority Industry: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Counties Served:	Alameda	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: 340	U.S.: 340	Worldwide: 45,500
<u>Turnover Rate:</u>	7%		
<u>Managers/Supervisors:</u> (% of total trainees)	4%		

### FUNDING DETAIL

Program Costs	-	(Substantial Contribution)	(High Earner Reduction)	=	<b>Total ETP Funding</b>
\$408,800		\$34,160 15%	\$0		\$374,640

In-Kind Contribution:	100% of Total ETP Funding Required	\$408,800
-----------------------	------------------------------------	-----------

**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	Business Skills, Computer Skills, Commercial Skills, Continuous Improvement, Mfg. Skills, PL-Mfg. Skills	280	8-200	0	* \$688	\$17.02
				Weighted Avg: 45			
2	Retrainee Priority Job Creation	Business Skills, Computer Skills, Commercial Skills, Continuous Improvement, Mfg. Skills, PL-Mfg. Skills	130	8-200	0	\$1,400	\$17.02
				Weighted Avg: 70			

\* Reflects Substantial Contribution

**Minimum Wage by County:** \$17.02 for Alameda County for Retrainees; \$14.19 for Job Creation.

**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 Post-Retention Wage.

**Wage Range by Occupation**

Occupation Titles	Wage Range	Estimated # of Trainees
<b>Job Number 1</b>		
Production Staff		100
Engineers		80
Administrative Staff		55
Manager		15
Supervisor		30
<b>Job Number 2</b>		
Production Staff		130

**INTRODUCTION**

Boehringer Ingelheim Fremont, Inc. (BIFI), is a subsidiary of the family owned parent corporation, Boehringer Ingelheim, [www.boehringer-ingelheim.com](http://www.boehringer-ingelheim.com), a global pharmacology corporation founded in 1885 in Ingelheim, Germany. The Company researches and produces

human and animal pharmaceuticals and employs over 42,000 people worldwide in 15 countries, including the US and Canada.

BIFI is a contract pharmaceutical manufacturing business offering customers the entire drug product manufacturing chain comprising of filling, visual inspection, labeling and packaging. BIFI produces commercial products such as colon cancer drugs and numerous other pharmaceuticals for Phase I and Phase II clinical trials.

BIFI's 100,000 square-foot, multi-product manufacturing facility in Fremont is primarily dedicated to the manufacture of monoclonal antibody therapies and other proteins from cell culture technology. The facility contains process development labs, a pilot plant, and large-scale bioreactors for manufacturing biologics for clinical studies as well as for clinical manufacturing. Training will occur in the Fremont facility and also inside a second new facility located adjacent to the existing Fremont facility.

BIFI is eligible for standard retraining under the Out-of-State Competition Provisions as a company engaged in an industry facing out-of-state competition (Research and Development in Life Sciences). The Company is also a manufacturer of biopharmaceutical products and is eligible as a priority industry.

### **PROJECT DETAILS**

The goal of this training project is to;

- Increase the Company's competitiveness with new product initiatives and plant expansion in Fremont,
- Improve and expand employee skills
- Meet increased production demands in Fremont facilities, and
- Achieve cost savings through improved efficiency.

Production volume and staffing level increases are occurring due to consumer demands worldwide for products made by BIFI in Fremont. Due to the launching of a new line of products the company must upgrade worker skills to operate new biotech machines. Cross-training employees on new functions is critical in helping BIFI to meet plant capacity increases and its successfully implement new procedures. New procedures will improve efficiency, increase production yields, and reduce losses.

Some courses in this proposal were delivered in prior ETP agreements; however, course content has been refreshed. No trainee trained in prior ETP Agreements will duplicate training in this proposal. All training will occur at the Company's two Fremont locations, delivered by in-house subject matter experts.

### **Training Plan**

The training plan in this proposal differs from previous Agreements. This proposal will focus on new work related equipment and new technology-based skill upgrades (software, manufacturing processes, and ISO requirements). Class/lab and PL training will be provided.

**Business Skills (1%):** The training topic Sales and Planning will be provided to Administrative Staff and Supervisors/Managers. BIFI's expansion into commercial manufacturing is impacting BIFI's marketing and communications. Training will support BIFI's commercial manufacturing of new products.

**Commercial Skills (4%):** This training will be offered to all occupations. BIFI maintains periodic Procedure and mandatory Good Manufacturing Practices training to keep workforce

skills current. Training is being offered in Clinical Trials, Process Development, Program Management, R&D, Production, and Quality Control. This training helps meet steady compliance with FDA and other requirements.

**Computer Skills (5%):** Training will be provided to Engineers, Managers/Supervisors in topics from desktop applications, such as advanced levels of computer assisted design software, advanced desktop applications, and personal productivity software applications, the Company's in-house computer applications for inventory, account management, and manufacturing control.

**Manufacturing Skills (70%):** Training will be provided to Production Staff and Engineers. Trainees will learn to operate new machines. Topics such as Equipment Operation and Cross Training Production will be provided. Courses like Testing and Troubleshooting Cells, Clean Room, Restricting Hazardous Substances are designed to ensure the Company will meet quality standards. Given the Company's expansion and rapid hiring plan within the production staff occupation, Manufacturing Skills represents the majority of the training.

**Continuous Improvement (20%):** Training will be offered companywide. BIFI has a quality control program which spans all occupations. Additionally, frontline employees including Managers and Supervisors, will be provided with leadership training. Training on decision making, quality processes, team skills, and compliance management will help BIFI meet or exceed performance expectations.

### **Productive Laboratory**

Trainees may produce goods for profit as part of the Productive Lab (PL) training in the courses identified under the Curriculum. The instructor will be dedicated to training delivery during all hours of training.

### **LMS**

BIFI will utilize an LMS to track training. The LMS was approved for use in the prior ETP Agreement. BIFI represents no significant changes have been made to the LMS since the last ETP Agreement.

### **Retrainee - Job Creation**

In support of 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.

BIFI has committed to hiring 130 new employees (Job Number 2). The date-of-hire for all trainees will be within the three-month period before contract approval or within the term-of-contract. These trainees will be hired into "net new jobs" as a condition of contract.

The second facility opening adjacent to the existing Fremont location consists of an additional 30,000 square feet. This new facility will be operational within the contract term, and employ an estimated 130 additional new employees through 2018. The primary activity at the new facility will focus on new commercial manufacturing initiatives mostly for Full-Finish operations. New and existing manufacturing equipment and software, such as full-finish operations, supports the need for training for the newly hired staff.

## **Commitment to Training**

BIFI currently offers a combination of elective and mandatory training including safety, OSHA, company orientation, basic computer skills, sexual harassment prevention and executive development. BIFI provides government mandated training to meet the Food and Drug Administration (FDA) requirements.

ETP funds will not displace the existing financial commitment to training. Safety training is, and will continue to be, provided in accordance with all pertinent requirements under state and federal law.

### ➤ Training Infrastructure

BIFI is ready to begin training in October 2016. The Company is spending an estimated \$50M on manufacturing equipment and software, prompting the need for training. The Company has two dedicated training coordinators and has retained an experienced Subcontractor to assist them with project administration. The company and vendor parties have experience working with ETP in BIFI's prior ETP contracts. Both parties were involved in the prior projects approved by the Panel.

## **Impact/Outcome**

As trainees progress through the proposed curriculum, each will attain documented certification of competency for each significant manufacturing tool and/or procedure they learn. Trainees will receive certifications in: primary and secondary packaging equipment, electrophoresis equipment packaging, foto/phoresis DNA analysis, Pipette Carousel Stands, Structure Quality Control Biochemistry, Operation and Maintenance of VITEK 2, Glassware Wash Process, Swab Sampling, HVAC Sampling, Single Use Bioreactor, Tubing Welder, SciLog, Aseptic Aliquoting, Freezing of Microorganisms, Bioburden Testing, Endotoxin, Validation of Microbial Recovery, Buffer Preparation, Processing of Samples for Microbial Identification. These are internal certifications given to employees who complete the training plan and achieve competency. Employees with these certifications achieve critical biotech manufacturing skills that are highly transferable to other pharmacological employers. BIFI is ISO certified. A portion of the training is designed to maintain existing ISO276 certification. Additionally, BIFI's successful expansion into commercial contract manufacturing will allow them to serve a larger customer base, increase revenue, and make additional investments in California.

## **Substantial Contribution**

BIFI is a repeat contractor with payment earned in excess of \$250,000 at the Fremont facility within the past five years. Accordingly, reimbursement for trainees in Job Number 1 will be reduced by 15% to reflect the Company's maximum \$34,160 Substantial Contribution to the cost of training. Job Number 2 is not subject to a substantial contribution because Job Creation is exempt from Substantial Contribution requirements.

A task competency list is on file and supports the request for Manufacturing Skills to be delivered via PL.

BIFI estimates that 310 trainees (Production Staff and Engineers) will receive an average of 30 hours (max 60) hours of PL at a 1:1 trainer-to-trainee ratio. BIFI represents no more than 50% of the total training hours in the proposal will be PL-Manufacturing. The Company will utilize an experienced trainer to specify the scope of work; explain the process and needed equipment; and verify the trainee understands standards, specifications, and safe operation of equipment.

The trainer will observe the employee perform the tasks, provide feedback, assist with re-work if necessary, and ensure that the task has been performed correctly.

BIFI is expanding into commercial manufacturing in the pharmaceutical market. FDA, requirements necessitate processes have a highly controlled error-rate to maximize product quality. The formulation, mixing, preparation of active agents into final form, (liquid or lyophilized powder) and filling and sealing within final containers requires supervised training on bio-tech machinery. The training must be conducted in clean rooms. PL training is the best method due to the level of the detailed nature of the training. Tasks are best demonstrated using actual product fulfillment scenarios. The hands-on PL training compliments class-lab training and is additive to prerequisite reviews of processes.

### **RECOMMENDATION**

Staff recommends approval of this proposal.

### **PRIOR PROJECTS**

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

Agreement No.	Location (City)	Term	Approved Amount	Payment Earned \$ %
ET15-0142	Fremont	7/7/2014- 7/6/2016	\$249,388	*\$249,388 (100%)
ET12-0407	Fremont	6/30/2012- 6/29/2014	\$442,656	\$248,794 (56%)

ET15-0142: Fiscal closeout is still in process. The number of hours tracked represent potential earnings equivalent to 100% of the approved contract amount.

ET12-0407: Unfortunately, the start of training was initially delayed. As a first-time ETP contractor, BIFI struggled with ETP recordkeeping requirements. The Contractor eventually hired an experienced ETP subcontractor to help them with administration tasks and get the project on track. However, due to the initial delay in start of training and lack of sufficient recordkeeping, many of the trainees did not meet the minimum 24 hours of training requirement. Many of the training hours delivered were ineligible and earnings and performance suffered.

### **DEVELOPMENT SERVICES**

BIFI retained Herrera & Company of Stockton to assist with development services at no cost.

### **ADMINISTRATIVE SERVICES**

Herrera & Company will also perform administrative services in connection with this proposal for a fee not to exceed 13% of payment earned.

### **TRAINING VENDORS**

Training will be provided by in house trainers.

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

8-200

**BUSINESS SKILLS**

- ✚ Sales and Planning

**COMMERCIAL SKILLS**

- ✚ Clinical Practice
- ✚ Site Qualification for Trials
- ✚ Clinical Research
  - Trial Monitoring and Audits
  - Protocols for Preclinical Studies and Data
- ✚ Production of Gene Therapy Vectors
- ✚ Cell Growth and Productivity
- ✚ Bioreactors Practice and Theory
- ✚ Downstream Processing Steps
  - High yield, Potency and Purity
- ✚ Producing research drug products for clinical studies
- ✚ Good Manufacturing Practices (GMP)
- ✚ Regulatory Requirements Challenges
- ✚ Production of Research Drug Products
- ✚ New Manufacturing Technologies
- ✚ Drug Product Development Components
- ✚ Advanced Process Modeling and Analysis
- ✚ Advanced Laboratory Practices
- ✚ Advanced Compliance Training
- ✚ Advanced Cell Data Modeling and Architecture
- ✚ Advanced Programming Development Applications

**CONTINUOUS IMPROVEMENT SKILLS**

- ✚ Advanced Factory Automation Tools
- ✚ Instrument Modeling/Integration Software Development
- ✚ Quality Measurement Biosciences Practice and Theory
- ✚ Quality Fundamentals/Core Skills
- ✚ Leadership
- ✚ Optimizing Virus Vector Production
- ✚ Vector System Design
- ✚ Production Experiments and Designs
- ✚ Isolation and Characterization of Stable Cell Lines
- ✚ Developing Novel Assays to Assess Viral Vector Attributes
- ✚ Analytical Assays to Support Process Development
- ✚ Developing and Maintaining Laboratory Quality Control Systems
- ✚ Coordinating Internal and External Research Activities
- ✚ Integrated 3D (decide, desire, delight) Insights

**COMPUTER SKILLS**

- ✚ Shelving Assortment System
- ✚ Enterprise Resources Software
- ✚ Financial/Accounting Tools
- ✚ Government Management Tools

- + Human Capital Management Systems
- + Microsoft Office Tools (intermediate/advanced)
- + Project Road-Mapping
- + Systems, Applications, Products Integration Software (SAP)
- + SharePoint/Share

### **MANUFACTURING SKILLS**

- + Technical Design Tools
  - Schematic Drafting
  - Drawing
- + Product Data Management System
- + Product Lifecycle Management Tool
- + Clean room (bleach, chlorine, mercury, lead)
- + Cross training Production Equipment
- + Equipment Operation/SafeStart
- + Lean Manufacturing
- + Packaging/Shipping/Inventory Processes
- + Product Labeling Process & Controls
- + Product Transfer/Workflow
- + Production Floor Processes
- + Restricting of Hazardous Substances
- + Technical Qualifications and Certifications
- + Testing and Troubleshooting Cells

### **Productive Lab Hours**

8 - 60

### **MANUFACTURING SKILLS (1:1 RATIO)**

- + Cell Culture Activities
  - Cell-based In-vitro Potency Assays for Products
  - Cell Line Processes
- + Designing, Engineering, and Commissioning New Systems
- + Quality Control
  - Minimizing Deviations and Downtime
  - Conducting Equipment Qualification and Validation Studies
  - Change Control Policies Implementation
  - Testing Components for Functionality/Capacity
  - Maintaining Mechanical Systems
  - Conducting Safety Checks
  - Setting Up and Testing Equipment
  - Detect Residual impurities, Titration and Residual Impurity
  - Qualifying Equipment
  - Calibrating and Maintaining Equipment
  - ISO 276 Requirements
  - Production Equipment Inspection
  - Installing and Control of Automation Systems
- + Managing Calibration services
  - Instrument Procedures

- Temperature, Pressure, Level, Flow and Analytical Instruments
- ✚ Producing Products in Shake Flasks and Bench-scale Bioreactors
- ✚ Developing Process Sampling
- ✚ Interpreting Analytic Data
- ✚ Fill-finish Manufacturing Vessels
  - Homogenizer
  - Stirrers
- ✚ Equipment Operations
  - Microprocessor tablet disintegration
  - Tablet hardness, friability and melting point apparatus
  - Automatic Tablet Counting
  - Tablet Operations.
  - Filling and Sealing
  - Drying Machinery
  - Automatic Labeling, Gumming, and Stikering
  - High Speed Automatic Bottle Filling & Cap Sealing
  - Twin Head Volumetric Filling
  - Rotary Bottle Washing

Note: Reimbursement for retraining is capped at 200 total training hours per trainee, regardless of the method of delivery. PL is capped at 60 hours per-trainee.