



**Training Proposal for:**  
**Boehringer Ingelheim Fremont, Inc.**  
**Agreement Number: ET15-0142**

**Panel Meeting of:** June 27, 2014

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

**Analyst:** D. Woodside

**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: 400	U.S.: 400	Worldwide: 42,500
<u>Turnover Rate:</u>	8%		
<u>Managers/Supervisors:</u> (% of total trainees)	20%		

**FUNDING DETAIL**

Program Costs	-	(Substantial Contribution)	(High Earner Reduction)	=	Total ETP Funding
\$249,388		\$0	\$0		\$249,388

In-Kind Contribution:	100% of Total ETP Funding Required	\$279,887
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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	Advanced Technology, Business, Computer, Continuous Improvement, Manufacturing Skills, PL-Manufacturing Skills	214	8-200	0-100	\$792	\$16.25
				Weighted Avg: 44			
2	Retrainee Priority Job Creation Initiative	Advanced Technology, Business, Computer, Continuous Improvement, Manufacturing Skills, PL-Manufacturing Skills	47	8-200	0-100	\$1,700	\$16.25
				Weighted Avg: 85			

**ETP Minimum Wage by County:** \$16.25 for Alameda County for Retrainees; \$13.55 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

**Wage Range by Occupation**

Occupation Titles	Wage Range	Estimated # of Trainees
Manufacturing/Quality/Engineering Staff		151
Production Worker		47
Administrative Staff		42
Manager/Supervisor		21

**INTRODUCTION**

Boehringer Ingelheim Fremont, Inc. [www.boehringer-ingelheim.com](http://www.boehringer-ingelheim.com) (BIFI), the parent corporation is Boehringer Ingelheim, a family-owned, 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.

The Fremont facility 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 commercial use.

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 said products.

This is BFI second ETP Agreement within the previous five years. Because the Company will earn less than \$250,000 under its prior ETP Agreement, there is no Substantial Contribution for Job Number 1 trainees. Job Number 2 is exempt from Substantial Contribution as Retrainee-Job Creation.

### **Prior ETP Project**

This proposed training plan differs from BIFI's first ETP agreement. ETP funds assisted the Company to implement its first manufacturing skills training project to front-line Manufacturing Staff and Support Staff at the newly acquired Fremont facility. Manufacturing training courses provided base-line production and operations skills. Continuous improvement and business skills training courses were delivered to train non-manufacturing employees, including Engineers, to better serve multiple customers, produce multiple products, bring new products to market, and to realize improved cost savings. All training was delivered via classroom/laboratory methods.

Under this new proposal, BIFI will deliver more customized, advanced bio-tech manufacturing skills training using all three available ETP methodologies including class/lab, CBT, and Productive Lab. The proposed training plan is designed to expand trainee skills enabling them to adapt to changing business requirements; improve product quality; and gain transferable skills in advanced biotechnologies, pharmaceutical equipment, and processes. Training for frontline Manufacturing Staff under this proposal is different from previous ETP Agreements because it will focus primarily on new product manufacturing technologies and procedures.

Advanced Technology was not delivered in the previous agreement and will now be delivered to Engineering Staff conducting research and product development. These advanced courses will enable Engineers to develop and validate biopharmaceutical manufacturing processes which are inherently complex; require long development cycles, and extensive retraining of Manufacturing, Engineering, and Quality Staff.

Finally, BIFI states that it has recently invested a large amount of capital for new manufacturing tools/equipment to build out the Fremont facility. Thus, all PL and Manufacturing Skills courses will be for new equipment. None of the courses funded under previous ETP Agreements will be delivered to incumbent workers in Job Number 1 but may be delivered to the Job Creation trainees in Job Number 2.

## Retrainee - Job Creation

Under the Retrainee-Job Creation program, training for newly-hired employees will be reimbursed at a higher rate and trainees may be subject to a lower post-retention wage. BIFI is not requesting the lower wage rate for its newly-hired employees.

In its previous ETP Agreement, BIFI retained 40 Job Creation trainees. For this new proposal, the Company is committed to hiring and training at least 47 newly-hired employees in Fremont. To be eligible for reimbursement these trainees must be hired within the three-month period prior to Panel approval or during the term of the contract.

BIFI reports that the Company has continued to invest significant resources into the Fremont facility since it purchased the plant in April 2011. BIFI has plans to build-out an unused section of the Fremont facility to house aseptic fill and finish operations. As a result, construction of new filling, visual inspection, and secondary packaging lines will be ongoing from 2014 through 2016. These investments allow BIFI to expand its customer base and the number of drugs in clinical trials which continues to grow. Because of the investments and outlook for continued growth, BIFI will be adding new manufacturing jobs over the next two years.

## Training Plan

Training will consist of Classroom/Laboratory, Productive Lab, and Computer-Based Training (CBT) from among the following Types of Training:

**Advanced Technology** (10%) – BIFI is requesting the AT reimbursement rate of \$26 per hour for class/lab training to be delivered to Engineering and Quality Staff in BIFI's proprietary biotechnology, bio-analytical, and electronic measurement methods including: inorganic spectroscopy, organic spectroscopy, particle separations, advanced life science and biotechnology tools and techniques. The Company reports that this type of training 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 BIFI's newest product technologies. 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. Because of the sophisticated specifications in biotechnology, the complex processes, and high cost to deliver the training, Panel staff recommends that the Company receive the AT reimbursement rate for this training.

**Business Skills** (6%) – Training will be provided to Administrative Staff and Supervisor/Managers in technical writing; how to manage projects, marketing communications; finance; and preparing effective oral and written presentations to customers. FDA regulations, including the complexity of BIFI's products and business transactions, dictate that effective customer communications and order accuracy must be achieved.

**Computer Skills** (4%) - Training will be provided to all occupations in topics from desktop applications, such as advanced levels of computer assisted design (CAD) software, advanced desktop applications, and personal productivity software applications, the Company's in-house computer applications for inventory, account management, and manufacturing control.

**Continuous Improvement** (15%) - Training will be provided to all occupations in compliance and quality performance throughout the organization. Titled the "Quality Master Plan" the goal is to make significant improvements to quality systems, including areas of field action decision-making, corrective and preventative actions, management controls, process validations and complaint management systems. Front-line Manufacturing Staff will learn continuous

improvement techniques that will teach employees how to reduce costs, work in teams, lead teams, become more effective in their jobs, and find root causes of problems.

**Manufacturing Skills (15%)** – Training will be provided to Production Workers. Trainees will learn cross-functional production skills to use several different pieces of equipment and manufacturing assembly techniques. Manufacturing skills training will be taught by a combination of highly skilled internal production supervisors, chemists, scientists, technicians, production trainers, production associates and/or engineers. ETP-funded training will enable BIFI to manufacture drug products successfully with a commercially viable process and at a scale large enough to support new and expanding commercial markets.

### **Productive Lab (PL) Manufacturing Skills (50%)**

Productive Laboratory (PL) trainees may produce goods for profit as part of the training, in the courses identified under the Curriculum and with no more than 10 trainees per instructor. BIFI has agreed to conduct its PL Training with a 1:1 trainer-to-trainee ratio. The instructor will be dedicated to training delivery during all hours of training.

PL training under this proposal is capped at 80 hours per individual trainee. BIFI expects that up to 150 incumbent and newly hired frontline manufacturing workers at the Fremont plant will receive some PL training. All trainees who receive PL directly interface with new equipment and/or improved manufacturing processes in the clean room.

BIFI is proposing to deliver Productive Lab training to its front line manufacturing workforce in California to ensure that employees acquire the critical manufacturing skills needed to perform their jobs at a quality standard acceptable by the FDA. Rather than create live classroom training sessions for each new manufacturing process, production supervisors will use PL training to deliver this substantial quantity of critical manufacturing skills to front-line workers. The PL training method is more effective than classroom training because it is conducted on the manufacturing floor (clean room) using biotech tools/equipment and affords manufacturing workers with cross-training opportunities on various production lines products at each facility. The training for each individual will include:

- A written PL training plan with a unique course name is delivered during each PL session.
- Managers and Supervisors will ensure that PL hours tracked under BIFI's established record-keeping practices are accurate and meet ETP requirements as follows:
  - The current PL record-keeping system has been used for many years;
  - The information entered into BIFI's PL tracking system is continually audited by internal and external auditors;
  - Training personnel approve each PL tracking form for completeness/quality prior to impute into BIFI's LMS;
  - The FDA has accepted BIFI's record-keeping system as meeting FDA's rigorous audit standards for worker skills certification.

## **LMS**

BIFI will utilize a LMS to track training. The LMS has been reviewed and approved by ETP staff for documentation of all training.

In the previous ETP Agreement, reporting into ETP's on-line system was based solely on whether a copy of the training record was provided to the ETP administrative consultant. This process doubled the volume of paper, copying, and duplications and was both burdensome and ineffective. The new ETP Agreement will have a LMS which automates the tracking of manufacturing skills certification requirements of individual trainees that is not readily available from a paper-based system. FDA requires that a manufacturing worker be certified and trained on the use of all sophisticated biotech tools/machines in the clean room. Using the LMS to ensure that trainees complete the required manufacturing skills training will increase ETP performance.

## **Impact/Outcome**

The life sciences industry is the most regulated in the State and trainees who are knowledgeable in performing their job to the most current manufacturing operating procedures acceptable under FDA standards attain highly transferable skills.

As trainees progress through the proposed manufacturing skills curriculum, each individual will receive documented certifications of competency for each significant manufacturing tool and/or procedure they learn. Trainees will receive certifications in: 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 and others depending on work order conditions.

## **Commitment to Training**

BIFI states that ETP funds will not displace its existing financial commitment to training. Company representative's report that the Company's statewide training expenditures in California for non-ETP related training is in excess of \$400,000. 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.

BIFI currently funds all training in OSHA and FDA-mandated safety regulations; sexual harassment, basic job skills; desktop training in Microsoft Word, Excel, and PowerPoint; and executive development training programs. BIFI will continue to fund such training, and any training hours delivered beyond the 200 total hour cap and 85 hour PL cap for this project.

BIFI represents that safety training is, and will continue to be, provided in accordance with all pertinent requirements under state and federal law.

## **RECOMMENDATION**

Staff recommends approval of this proposal.

## **PRIOR PROJECTS**

The following table summarizes performance by BIFI under an active ETP Agreement:

Agreement No.	Approved Amount	Term	No. Trainees (Estimated)	No. Completed Training	No. Retained
ET12-0407	\$442,656	6/30/2012-6/29/2014	267	146	146

Training has ended under ET12-0407. 146 trainees completed training and retention, of which 40 were Job Creation trainees. A total of 13,021 training hours have been entered online resulting in potential earnings of \$242,414. If all retentions are verified, BIFI will earn 55% of the Agreement amount.

The Company reports that performance was less than expected because since this was the first time for BIFI to implement ETP funded training, there was a learning curve for internal training staff, who were challenged in meeting ETP reporting requirements. This further delayed the initial start of training. ETP. BIFI subsequently hired an experienced ETP consultant who brought the project current and helped BIFI to better capture/record eligible training hours.

Because of the delay in start-up, many employees received less than the 24 training hour per trainee minimum.

The new project has been "right-sized" to more closely mirror earnings in its most recent Agreement. The Company is committed to earning 100% of the funds under this project, and expects to return to the Panel for additional funding for incumbent and newly-hired workers.

## **DEVELOPMENT SERVICES**

Herrera & Company of Stockton provided development services at no cost to BIFI.

## **ADMINISTRATIVE SERVICES**

BIFI also retained Herrera & Company to perform administrative services in connection with this proposal for an amount not to exceed 13% of payment earned.

## **TRAINING VENDORS**

Training will be delivered primarily by in-house trainers. Any outside vendors will be identified during the term of the contract.

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

8-200

Trainees may receive any of the following:

**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

**BUSINESS SKILLS**

- + Technical presentations
- + Customer communications and awareness
- + 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

**CONTINUOUS IMPROVEMENT**

- + Quality Master Plan (QMP)
- + Process improvement training
- + Problem solving tools and techniques
- + Quality fundamentals/core skills
- + Leadership / Coaching Skills
- + Effective teams
- + Efficiency workflow
- + Facilitation skills and mentorship
- + Strategic sales negotiation techniques

**MANUFACTURING SKILLS\***

- + Production and equipment operations
- + Lean manufacturing
- + Process capability mapping
- + Manufacturing process cross training
- + Machine operations, calibration, and maintenance
- + FDA manufacturing procedures and protocols
- + Manufacturing assembly standards and procedures

\*Safety training is capped at 10% of a trainee's total training hours.  
This cap does not apply to HazMat.

**PL HOURS**

0-80

**PRODUCTIVE LAB TRAINING-MANUFACTURING SKILLS**

- ✦ Production and equipment operations
- ✦ Manufacturing process cross training
- ✦ Machine operations, calibration, and maintenance
- ✦ Calibration of pressure
- ✦ Calibration of gas flow
- ✦ Calibration of spectrometer
- ✦ Calibration of ph. Individual
- ✦ Calibration of liquid
- ✦ Mechanical seals inspection
- ✦ Repair/replace bearings
- ✦ Rotating machinery replacement
- ✦ Replace reverse osmosis procedures
- ✦ Mechanical pipe maintenance
- ✦ HVAC Technicians: operations and maintenance
- ✦ Maintenance of incubator
- ✦ Main Biological safety cabinets
- ✦ Conductivity meter, accumet AR20
- ✦ Stedim irradiated bags
- ✦ pH/conductivity meter
- ✦ Rapid lab analyzer
- ✦ CeDex cell counter
- ✦ Planova filter integrity tester
- ✦ Use of laminar flow hood
- ✦ Flexed for magnetic mixer
- ✦ Downstream autoclave item preparation
- ✦ Upstream autoclave item preparation
- ✦ Fixed tanks media
- ✦ Rosemount DO transmitter and DO Pro
- ✦ Bioreactor Assembly
- ✦ Bioreactor to bioreactor transfer
- ✦ Centrifuge maintenance
- ✦ Milistak pod holder
- ✦ Aseptic technique qualification
- ✦ Harvest tanks operations
- ✦ Media filter cart media transfer
- ✦ Fixed mettle pH transmitter
- ✦ Hach 2100 laboratory turbidmeter
- ✦ Media filter cart procedure
- ✦ Panitumumab bioreactor scale up
- ✦ Skid cleaning and prep
- ✦ Protein filtration operations
- ✦ Chromatography operations
- ✦ Dilution operations
- ✦ Manual cleaning and sanitization
- ✦ Batch compilation for cell culture
- ✦ Downstream purification
- ✦ Bio burden testing of in-process materials

**CBT HOURS**

0-100

**COMPUTER-BASED TRAINING (CBT)\*\*****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.)

**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.)

**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.)
- + Business Excellence: Class A (1 hr.)
- + Business Excellence: Six Sigma (1 hr.)
- + Business Excellence: Lean (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. Delivery of CBT topics is subject to prior ETP approval.

Note: Reimbursement for training is capped at 200 total training hours per trainee regardless of delivery method. CBT is capped at 50% of total training hours per trainee.