



RETRAINEE - JOB CREATION

**Critical Proposal for
Cepheid**

Agreement Number: ET16-0148

Panel Meeting of: August 28, 2015

ETP Regional Office: San Francisco Bay Area

Analyst: A. Nastari

PROJECT PROFILE

Contract Attributes:	Retrainee Priority Rate Job Creation Initiative Critical Proposal	Industry Sector(s):	Manufacturing Biotechnology/Life Sciences Priority Industry: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Counties Served:	San Joaquin, Santa Clara	Repeat Contractor:	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Union(s):	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		
Number of Employees in:	CA: 900	U.S.: 1,100	Worldwide: 1,560
<u>Turnover Rate:</u>	10%		
<u>Managers/Supervisors:</u> (% of total trainees)	3%		

FUNDING DETAIL

Program Costs	-	(Substantial Contribution)	(High Earner Reduction)	=	Total ETP Funding
\$569,640		\$0	\$0		\$569,640

In-Kind Contribution:	100% of Total ETP Funding Required	\$633,647
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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, Manufacturing Skills, PL-Manufacturing	403	8 - 200	0	\$1,080	\$15.70
				Weighted Avg: 60			
2	Retrainee Priority Rate Job Creation	Continuous Improvement, Business Skills, Computer Skills, Manufacturing Skills, PL-Manufacturing	84	8 - 200	0	\$1,600	\$15.07
				Weighted Avg: 80			

Minimum Wage by County: San Joaquin - \$15.07; Santa Clara - \$16.44

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

Up to \$4.63 per hour may be used to meet the Post-Retention Wage.

Wage Range by Occupation

Occupation Titles	Wage Range	Estimated # of Trainees
Job 1		
Engineers		4
Leads		9
Production Workers		360
Supervisors		16
Technicians		14
Job 2		
Engineers		3
Leads		1
Production Workers		75
Supervisors		2
Technicians		3

CRITICAL PROPOSAL

This proposal has been designated as a “Critical Proposal” by the Governor’s Office of Business and Economic Development (GO-Biz) as they are expanding facilities in California. In this proposal, Cepheid seeks ETP funding to train 403 currently employed and 84 new employees.

INTRODUCTION

Cepheid, www.cepheid.com, founded in 1998 and based in Sunnyvale, is a molecular diagnostics company that develops, manufactures and markets integrated testing systems for the clinical and non-clinical market. Cepheid’s testing systems enable rapid, sophisticated molecular testing for organisms and genetic-based diseases by automating otherwise complex manual laboratory procedures.

Cepheid operates two California facilities: Sunnyvale is where assembly of systems, production of reagents, and tests for use on GeneXpert and SmartCycler system are conducted. Lodi, established in 2012 is where the assembly of its disposable molecular testing/reaction tubes and cartridges occurs. This proposal addresses training needs at both facilities.

Cepheid’s testing systems were used after the 2001 anthrax attacks which produced rapid, accurate bio-detection field units based on DNA analysis. Since those attacks, the United States Postal Service has used Cepheid’s instruments and technology to screen U.S. mail for possible Anthrax contamination. Federal agencies also use Cepheid machines to detect the spreading of anthrax contamination and to identify its possible sources. Today, Cepheid’s GeneXpert system is designed for a broad range of user types from reference laboratories and hospital central laboratories to satellite testing locations including emergency departments and intensive care units within hospitals, as well as physician offices and other alternate site laboratories.

Cepheid expects that due to its ability to deliver accurate and rapid results, ease of use, flexibility and scalability, its GeneXpert system will continue to significantly expand its presence in the clinical market. Cepheid continually invests in its plant and equipment, but needs to maintain a well-trained and highly skilled manufacturing workforce to meet expected demands.

PROJECT DETAILS

Company Growth

Cepheid’s growth objective for its California facilities is to develop essential clinical diagnostic products for its GeneXpert system. Cepheid invested over \$95 million in research and development in 2014 confirming its commitment to California and its business strategy. Cepheid focuses its efforts on four main areas:

- Evaluate product development efforts to design, improve and produce specific tests; expand product offering to customers
- Chemistry research to develop innovative testing methods
- System engineering to extend capabilities
- Target discovery research for development of future analyses.

This is Cepheid’s first ETP project. Cepheid proposes to train 403 currently employed, front-line workers and 84 newly-hired, front-line manufacturing workers at its Sunnyvale and Lodi facilities.

Retrainee - Job Creation

In support of job creation, the Panel is offering 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.

Cepheid has committed to hiring 84 new employees. 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.

To address its California business growth objectives, Cepheid will add 84 additional positions in existing occupations over the next two years. In 2013, Cepheid hired 140 full-time workers and 205 in 2014. Therefore, the proposed hiring of 84 new workers is within the Company’s realistic hiring goals.

Cepheid projects to hire approximately 54 workers at its Sunnyvale facility and 30 workers for its Lodi facility. Both facilities can accommodate the additions; however, it is in the process of expanding the Lodi facility. That expansion will be completed in the fall of 2016.

Training Plan

To successfully meet its goals, Cepheid must have an experienced, well trained, workforce that can understand and follow specific quality protocols and manufacturing procedures. Cepheid is requesting the Panel’s assistance to provide 8-200 Class/Lab, CBT, and Productive Lab (PL) training hours in the following areas:

Business Skills (5%): Engineers and Supervisors will receive training in technical writing, project management, marketing, communication, finance, and preparing effective oral and written presentations to customers. Workers must effectively communicate FDA regulations, the complexity of Cepheid’s products and business transactions, and essential accuracy when placing product orders. Engineers and Supervisors who meet with customers and suppliers will receive training in presentation skills, product knowledge, project management, and related professional development skills.

Computer Skills (5%): Cepheid has been implementing a state-of-the art Manufacturing Execution System (MES) that will scale with the project growth of the Company. The MES manages and monitors work-in-process on the factory floor. It keeps track of all manufacturing information in real time, receiving up-to-the minute data from robots, machine monitors and employee status. Engineers, Technicians, Leads, Supervisors, and Production Workers will receive training in technical skills development, functional skills, and specific MES Software skills.

Engineers, Technicians, Leads, and Supervisors will complete training in desktop applications, such as advanced levels of computer assisted design (CAD) software, advanced desktop applications, and in-house productivity applications used for inventory, account management, and manufacturing control.

All basic desktop training such as Microsoft Word, Excel, and PowerPoint will be delivered at Cepheid’s own expense.

Continuous Improvement (10%): All occupations will receive training in Quality, Leadership, Process Analysis, Problem Solving and Statistical Process Control skills to ensure process ownership carries through to the end user. Training will also include “Lean” processes for improvement in productivity and quality by identifying and eliminating waste from the value stream. All trainees will receive training in cost reduction, effective team member skills, and the

use of tools to identify root causes of problems. Leads and Supervisors may also receive Six Sigma courses.

Manufacturing Skills (20%): Cepheid's facilities and manufacturing processes are designed to comply with the quality standard set by the International Organization for Standardization and the FDA's Quality System Regulations. In its manufacturing facilities, Production Operators assemble systems and produce reagents and tests for use on in the GeneXpert systems. Cepheid's customized automated assembly lines have expandable capacities, essential for the assembly of its disposable reaction tubes and cartridges.

Production Operators, as well as Engineers, Technicians, Leads, and Supervisors require cross-functional production skills on manufacturing equipment operation and assembly techniques. Cepheid's manufacturing processes are complex, requiring a high degree of accurate measuring processes, clean-room equipment operations, and specialized handling and assembly of testing systems. Training in Manufacturing skills will be taught by highly skilled, internal production supervisors, chemists, scientists, technicians, production trainers, production associates and/or engineers. The instructors will oversee an employee's use of Cepheid's proprietary biotech equipment.

Productive Laboratory

Trainees may produce goods for profit as part of the Productive Laboratory (PL) training, in the courses identified under the Curriculum. The instructor must be dedicated to training delivery during all hours of training, and special attendance rosters will be used to assist in monitoring.

PL-Manufacturing Skills (66%)

Cepheid will train Supervisors and front-line Production Workers, Technicians, Engineers and Leads in PL-Manufacturing skills. These trainees are directly impacted by new and/or improved manufacturing processes. The proposed PL cross-training and new skills will consist of several production lines/procedures used throughout the manufacturing facility both within the clean room manufacturing and in a non-clean room manufacturing area. PL Manufacturing Skills will be specific to Cepheid's biotech machines, equipment, tools, and techniques to produce FDA regulated products. This is critical because the manufacture of Cepheid's products is a highly complex process due in part to strict regulatory requirements imposed by the FDA and other foreign regulatory agencies where products are sold. To be successful, the Company must have an experienced, well-trained manufacturing workforce across all occupations that can understand and follow specific quality protocols and manufacturing procedures, while working efficiently, and adhering to the high work standards required by the biotech industry.

Due to the critical nature of Cepheid's processes, it is essential that most processes are delivered at a 1:1 Trainer-to-Trainee ratio in a Productive Lab environment so that specialized and experienced trainers are able to independently focus on a trainee's skills, ensuring precautions measures are followed. Rather than create live classroom training sessions for each process, PL Manufacturing is the most logical alternative to deliver the substantial quantity of critical manufacturing skills to front-line manufacturing workers including supervisors. All PL training will occur on the factory floor and will be conducted by internal qualified trainers. During ETP-funded training, the trainer's time will be solely dedicated to the delivery of PL. Less than 10% of the total PL delivered may have a ratio of 1:3, and only when new hires are learning a workstation and/or aggressive cross training is required to meet customer requirements.

Cepheid projects each employee will receive PL-Manufacturing Skills, including newly hired workers in Job 2. Each tainee will receive an average of 42 PL hours, not to exceed 60.

Cepheid informs ETP staff that productive lab competency procedures are available for ETP's review upon request.

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. Many production trainees will become certified in welding and injection molding for plastics. As trainees progress through the proposed Manufacturing Skills curriculum, each individual will attain documented certification of competency for each significant manufacturing tool and/or procedure they learn.

Commitment to Training

ETP funds will not displace Cepheid's existing financial commitment to training. The company's statewide training expenditures in California for non-ETP related training is in excess of \$1,000,000. The proposed ETP-funded training is different in content and format from 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.

Cepheid currently funds all training in OSHA and FDA-mandated safety regulations; sexual harassment prevention; rudimentary job skills; basic desktop training in Microsoft Word, Excel, and PowerPoint; and executive development programs. Cepheid will continue to fund such training and all training hours delivered over 200 hours will be at its own expense. The resources provided by ETP will supplement Cepheid's training budget by helping the Company to further its efforts to deliver more and better quality training. Safety training is, and will continue to be, provided in accordance with all pertinent requirements under state and federal law.

Training Infrastructure

Beginning in January 2014, Cepheid's management team invested in centralizing and formalizing its workforce training efforts. The Company analyzed its training needs and updated its internal training tracking procedures. Cepheid's internal training department will work directly with Herrera & Company to administer the training ETP training contract. The Company expects to start training within 7 days after Panel approval.

High Unemployment Area

Trainees in Job Numbers 1 and 2 may work in Lodi, a High Unemployment Area (HUA), a region with unemployment exceeding the state average by at least 8.1%. The Company's location in San Joaquin County qualifies for HUA status under these standards.

➤ Wage Modification

For these trainees, the Panel may modify the ETP Minimum Wage by up to 25% if post-retention wages exceed the start-of-training wages. However, Cepheid is not asking for a wage modification.

RECOMMENDATION

Staff recommends approval of this proposal.

DEVELOPMENT SERVICES

Cepheid retained Herrera & Company in Stockton, to assist with development of this proposal for a flat fee of \$8,750.

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

To Be Determined

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

8 – 200

Trainees may receive any of the following:

BUSINESS SKILLS

- Project Management
- Presentation Skills
- Influencing Others
- Product Knowledge and Market Validation
- Finance and Accounting Skills
- Marketing Promotion and Position

COMPUTER SKILLS

- Management Execution Software (MES) Systems
- Materials and Logistics Software Development
- Database and Technology
- Desktop Applications (not including Microsoft Office basics)
- Project Management Software
- Internal Corporate Systems and Communications

CONTINUOUS IMPROVEMENT SKILLS

- Lean Manufacturing
- Six Sigma
- Process Modeling and Analysis
- Good Laboratory Practices
- Problem Solving
- Statistical Process Control
- Blueprint Reading
- GxP Compliance Training
- Quality fundamentals/core skills
- Leadership / Coaching Skills
 - Facilitating Groups
 - Efficiency Workflow
 - Facilitation Skills and Mentorship
 - Strategic Sales Negotiation Techniques

MANUFACTURING SKILLS

- Production and Equipment Operations
- Manufacturing Process Cross Training
- Machine Operations, Calibration, and Maintenance
- Mold Setter Skills
- Hydraulic Pneumatic Operations
- Basic Electrical, Welding, and HVAC
- Routsis On-Line Training
- Tools Training: Drill Press, Lathes, Milling, Grinders
- Computer Numerical Controls Machines (CNC)

Productive Lab Hours

0-60

MANUFACTURING SKILLS (1:3 RATIO)

- Clean-room Environment
 - Production and Equipment Operations
 - Manufacturing Process Cross Training
 - Machine Operations, Calibration, and Maintenance
 - Mold Setter Skills
 - Hydraulic Pneumatic Operations
- Basic Electrical, Welding, and HVAC
- Routsis On-Line Training
- Tools Training: Drill Press, Lathes, Milling, Grinders
- Computer Numerical Controls Machines (CNC)

* Cotractor will provide ETP with a comprehensive list of productive lab course titles including codes that correspond to the PL topics listed above.

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