



RETRAINEE - JOB CREATION

Training Proposal for:

Edwards Lifesciences LLC

Agreement Number: ET16-0306

Panel Meeting of: January 22, 2016

ETP Regional Office: San Diego

Analyst: J. Davey

PROJECT PROFILE

Contract Attributes:	Job Creation Initiative Retrainee Priority Rate	Industry Sector(s):	Healthcare Biotechnology/Life Sciences Priority Industry: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Counties Served:	Orange	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: 3,356	U.S.: 4,173	Worldwide: 9,875
<u>Turnover Rate:</u>	8%		
<u>Managers/Supervisors:</u> (% of total trainees)	12%		

FUNDING DETAIL

Program Costs	-	(Substantial Contribution)	=	(High Earner Reduction)	=	Total ETP Funding
\$688,000		\$216,000 50%		\$0		\$472,000

In-Kind Contribution:	100% of Total ETP Funding Required	\$503,000
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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	Business Skills, Computer Skills, Cont. Imp., HazMat, Mgmt. Skills, Mfg. Skills	400	8-200	0	*\$540	\$16.51
				Weighted Avg: 60			
2	Job Creation Initiative Retrainee Priority Rate	Business Skills, Computer Skills, Cont. Imp., HazMat, Mgmt. Skills, Mfg. Skills	160	8-200	0	\$1,600	\$16.02
				Weighted Avg: 80			

*Reflects Substantial Contribution

Minimum Wage by County: Job Number 1: \$16.51 per hour for Orange County; Job Number 2 (Job Creation): \$13.76 per hour for Orange 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

Up to \$0.49 per hour may be added to meet Post-Retention Wage in Job Number 1.

Wage Range by Occupation		
Occupation Titles	Wage Range	Estimated # of Trainees
Job Number 1		
Clinical Marketing Specialist		20
Clinical Sales Specialist		40
Engineer 1		50
Engineer 2		60
Manager 1		10
Manager 2		10
Production Staff		50
Professional Administrative Staff		20
Quality Specialist		70
Regulatory Specialist		10
Supervisor		15
Technician		45

Job Number 2		
Clinical Marketing Specialist		3
Clinical Sales Specialist		5
Engineer		15
Manager 1		8
Manager 2		8
Production Staff		58
Quality Specialist		50
Supervisor		8
Technician		5

INTRODUCTION

Founded in 1958 and headquartered in Irvine, Edwards Lifesciences LLC (Edwards) (www.edwards.com) develops, manufactures and markets medical devices and technologies used in the treatment of advanced cardiovascular disease and hemodynamic monitoring. The Company's product line is sold in over 100 countries. It includes tissue replacement heart valves, valve repair products, hemodynamic monitoring devices, and other critical care technologies that facilitate cardiac surgery procedures through small incisions. In California, Edwards has one facility or "campus" located in Irvine.

Prior ETP Projects

This is the fifth proposal between Edwards and ETP within the last five years. The second project focused on training for newly hired production employees in skills needed to support the expansion of the Company's heart valve production line. The 75 employees in Job Creation (Job 2) were temporary workers. Edwards earned payment for all 75 trainees who were hired into full-time permanent positions in time for retention. The average "conversion period" was 180 days from their start date at Edwards.

This new proposal will include Production Staff (Job Creation) and build on the training delivered to Engineers in the previous contract. It will also include a variety of occupations. Edwards is also establishing functional technical competencies and career pathways for Quality, Engineering and Manufacturing Staff. Once completed, specific training for each occupation career-path will define training to allow employees to create an individualized career path within Edwards.

PROJECT DETAILS

To remain at the forefront of heart valve technology, Edwards must continually invest in the training and development of its Engineers and other staff responsible for the research, development and marketing of its products. Because the Company's products require scientific expertise and regulatory oversight, continuous training is critical in maintaining and advancing these unique products.

The training proposed is being driven by the following initiatives: 1) the purchase and implementation of a companywide enterprise strategy, Product Lifestyle Management (PLM) Software, and the recent upgrade to its Oracle ERP system; 2) the launch of the Edwards Global Technical Training Program, an industry driven curriculum to give employees the business acumen

to successfully transition into and move up the career ladder in biotechnology careers. Graduates from this program will gain knowledge about the highly regulated life science business environment and the reality of work in multi-disciplinary project teams to meet business goals; and 3) Edwards also have several new cardiac surgery and heart valve therapy technologies in development. ETP funding will allow the company to be able to provide training to its workforce on a timely, cost-effective basis.

Retrainee – Job Creation

To support the development of these new technologies, Edwards needs to expand its workforce. The Company has added additional training topics and clean rooms; converted warehouse space for offices; leased additional office space in Irvine with room for 200 additional employees; and constructed a new, multi-level parking structure. The Company will hire 160 new employees during the term of this contract.

Training for newly hired employees is reimbursed at a higher rate and trainees are subject to a lower post-retention wage. These trainees must be hired within the three-month period prior to Panel approval or during the term of the contract. The Company also represents that these trainees will be hired into “net new jobs” as a condition of contract. As a feature of this program, the Substantial Contribution requirement will be waived for Job Number 2.

Temporary-to-Permanent Hiring

As part of its business growth, Edwards expects to expand its permanent workforce by 160 employees within the term of the ETP Agreement. All 160 trainees in Job Creation (Job Number 2) will be trained under Panel guidelines for “temporary-to-permanent” employment. As discussed earlier, in its most recent Agreement (ET14-0208), Edwards earned payment for all 75 Job Creation trainees under this same program. [Note: An earlier project solely for newly hired trainees (ET11-0267) did not fare as well. See footnote under the Prior Projects table.] Edwards will retain these employees through a temporary agency, with the intention of hiring them into full-time permanent positions after training. These 160 temp-to-perm trainees will all be hired into net new jobs.

These trainees must be determined eligible to participate in ETP-funded training before the start of training, while on payroll with the temporary agency. However, the retention and post-retention wage requirements cannot be satisfied until after they have been hired by Edwards. Until then, Edwards will not receive progress payments. The Company reports the following regarding their current temp-to-perm hiring practices:

- Tem-to-perm occupation are primarily Production and Professional Administrative Staff;
- After working at Edwards for 180 days (six months) as temporary workers, the Company will assess their readiness to convert to full-time employment; once they are certified in at least one skill area, they are hired as full-time employees of Edwards;
- The temp agency operates on-site at the Irvine campus as a staffing office for Edwards’ staffing needs; however, there is no exclusive relationship;
- Some retrainees (Job Number 1) may be hired under the temp-to-perm program.

Training Plan

The proposed training will focus on training and development for research, development, and marketing of Edwards' products. Although there may be similar courses to the previous Agreement, incumbent employees will not receive duplicate courses.

Computer Skills (20%): All occupations will receive training in the Company's new PLM System, an enterprise strategy that allows organizations to work as a single team to design, produce, support and retire products. Training will be required across all functional areas and will interface globally with other quality systems. Training will also include the latest upgrades of the Company's Oracle ERP system as it relates to their individual job function. Engineering Staff and Technicians will receive training in Auto-Cad software, control charts, Matlab and Validation software. Advanced MS Office Suite will be provided to Administrative Support Staff and select Managers/Supervisors.

Continuous Improvement (25%): Engineering, Quality Staff and Technicians will receive training in advanced Lean Manufacturing topics critical to reducing waste and streamlining processes: design of experiments, test method validation, ISO internal auditing and other skills. Good clinical and good manufacturing processes, innovation, quality concepts and other skills will provide leaders and their teams with the skills to achieve high levels of product quality, strengthen skills in work process flow, and increase efficiency of the workplace. Some of the topics to be delivered include mistake proofing, root cause analysis, risk management, process improvement, geometric dimensioning and tolerancing, and preventive maintenance and calibration.

Business Skills (15%): Training will be provided to Engineering Staff, Technicians, Clinical Marketing/Sales Specialists and select Managers/Supervisors. Topics include technical writing, project management, advanced product knowledge and market validation, and marketing and product promotion skills. Engineering Staff and Technicians will also receive training in the Edwards' Global Technical Training Program, a comprehensive program designed to give employees the skills sets to advance within the organization.

Certified Safety Training (10%)

Hazardous Materials (HAZMAT). This training may be a series of courses, specific to industry sectors involved in the transport of hazardous materials. The coursework varies in length depending on the industry and the occupational title. It is generally a minimum of 24 hours with an 8-hour annual refresher, and may be delivered by classroom or CBT. In this proposal, Production Staff and Quality Staff will receive training in chemical hygiene/safety for laboratories, waste management, and hazard communication.

Management Skills (10%): Training is designed for Managers/Supervisors to improve leadership skills. Leadership skills topics, coaching techniques, and health care economics will ensure that the Company's management team has the acumen to implement goals in a Lean environment. A newly designed three-day course entitled "Leading at Edwards" will also be delivered to this audience.

Manufacturing Skills (20%): Training is designed for to production operation workers. The training is necessary for production workers that don't have the skills necessary to sew heart valves to strict specifications. This position takes months of practice to ensure a very high quality product.

Substantial Contribution

Edwards is a repeat contractor with payment earned in excess of \$250,000 within the last five years. Edwards was required to provide a Substantial Contribution of 30% for its most recent ETP

Agreement. (See Prior Project Table.) Accordingly, reimbursement for trainees in Job Number 1 will be reduced by 50% to reflect the Company's Substantial Contribution to the cost of training.

Commitment to Training

The Company reports that its 2014 training budget was \$2,000,000 for OSHA and FDA mandated safety, and regulatory training; anti-harassment and violence in the workplace prevention training; new-hire orientation training; rudimentary job skills training; basic desktop training in Microsoft Office; and executive development programs. The Company also continues to provide technical and laboratory training that supports the development of new products and improve business processes. The resources provided by ETP will increase Edwards' training budget and allow the company to deliver supplemental and more in-depth training courses.

Training Infrastructure

Edwards' training department will work directly with California Manufacturing and Technology Association (CMTA) to administer the ETP-funded contract. All training will be delivered at the Edwards campus in Irvine. Edwards will use the SABA® Learning System in keeping with ETP guidelines.

RECOMMENDATION

Staff recommends approval of this proposal.

DEVELOPMENT SERVICES

CMTA in Sacramento assisted with development of this proposal for a flat fee of \$13,000.

ADMINISTRATIVE SERVICES

CMTA will also perform administrative services for a fee not to exceed 13% of payment earned.

TRAINING VENDORS

To Be Determined

PRIOR PROJECTS

The following table summarizes performance by Edwards under ETP Agreements that were completed within the last five years:

Agreement No.	Location (City)	Term	Approved Amount	Payment Earned \$ %
ET14-0208	Irvine	10/28/13 – 10/27/15	\$495,000	\$409,907 (83%)
ET12-0211	Irvine	12/31/11-12/30/13	\$349,713	\$349,713 (100%)
ET11-0267* (Job Creation only)	Irvine	6/01/11-5/31/13	\$299,880	\$82,017 (27%)
ET09-0503	Irvine	5/04/09-5/03/11	\$489,048	\$489,048 (100%)

***ET11-0267-** Under this Job Creation only project, Edwards proposed to train 85 temp-to-perm employees who would ultimately be hired as permanent workers during the term of the agreement. Because the Panel meeting was postponed, the start of training was delayed by a month. This resulted in some employees completing their training prior to the start of the ETP eligibility, consequently narrowing the “window period” for trainee eligibility. In addition, Edwards had over-estimated the projected number of new employees. This factor could not be balanced against training for their incumbent workforce because, at the time of this Agreement, the Job Creation pilot did not extend to standard retrainees.

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

8-200

Trainees may receive any of the following:

BUSINESS SKILLS

- Technical Writing
- Project Management
- Marketing
- Technical Presentations
- Advanced Product Knowledge
- Customer Communications
- Global Technical Training Program

COMPUTER SKILLS

- Product Lifecycle Management Software, Ignite
- Enterprise Resource Planning Software (Oracle)
- Control Charts
- Minitab/Matlab Software Tools
- Non Normal Data Analysis Systems
- Advanced Desktop Applications
- CAD Design – Pro E
- CREO I, II, III CAD – Pro Engineer
- Solidworks
- Advanced Software Validation
- Configuration Management II

CONTINUOUS IMPROVEMENT

- Starr Technical Training Program
- APICS Certification
- Innovation
- Product Definition
- Good Clinical Practices
- Lean Manufacturing
- Problem-Solving/Troubleshooting Skills
- Production Operations
- Process Improvements
- Teambuilding
- Quality Concepts
- Project Management
- Mini Tab
- Statistical Process Control
- Process Validation
- Risk Management
- Mistake Proofing
- Root Cause Analysis
- Geometric Dimensioning and Tolerance
- Preventive Maintenance & Calibration

- Test Method Validation
- Design Control
- Design of Experiments
- Technical Information Mapping
- Regulatory Inspection Procedures
- Good Laboratory Practices
- ISO Internal Auditing
- Audit Readiness
- Global Model Master
- ROHS – Product Surveillance

HAZARDOUS MATERIALS

- Chemical Hygiene/Safety for Laboratories
- Waste Management
- Hazard Communication
- Hazardous Waste and Biowaste for Laboratories
- Storm Water Discharges

MANUFACTURING SKILLS

- BioDesign
- Edwards Research Center Wet Labs
- Heart Valve Clinical
- Production and Equipment Operations
- Manufacturing Biological & Non-Biological Products
- Cross-Training on Production Operations
- Manufacturing Assembly Standards & Procedures

MANAGEMENT SKILLS (Managers/Supervisors Only)

- Change Management
- Leadership Skills for Managers
- Business Strategies
- Global Negotiations
- Operations & Supply Chain Management
- Finance for Non-Financial Managers
- Critical Thinking for Managers
- Innovation & Product Development
- Healthcare Economics
- Marketing in a Global Economy
- Leading at Edwards
- Situational Leadership II
- Performance Management & Coaching
- Talent Management and Competency Skill Assessment

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