



**Training Proposal for:
Grifols Biologicals Inc.**

Agreement Number: ET17-0105

Panel Meeting of: June 24, 2016

ETP Regional Office: North Hollywood

Analyst: L. Vuong

PROJECT PROFILE

Contract Attributes:	Retrainee Priority Rate	Industry Sector(s):	Manufacturing Biotechnology/Life Sciences Priority Industry: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Counties Served:	Los Angeles	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: 1,800	U.S.: 11,000	Worldwide: 14,700
Turnover Rate:	6%		
Managers/Supervisors: (% of total trainees)	13%		

FUNDING DETAIL

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

In-Kind Contribution:	100% of Total ETP Funding Required	\$644,256
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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, Cont. Imp., Mfg. Skills	800	8-200	0-21	\$270	\$16.50
				Weighted Avg: 15			

Minimum Wage by County: \$16.48 per hour for Los Angeles 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

Wage Range by Occupation

Occupation Titles	Wage Range	Estimated # of Trainees
Manufacturing/Production Staff		450
Quality Control Staff		200
Administrative Staff		50
Supervisor/Manager I		50
Supervisor/Manager II		50

INTRODUCTION

Founded in 1940 Grifols Biologicals Inc. (GBI) (www.grifols.com) is wholly owned by Grifols S.A. in Spain. The Company develops and produces therapies and products in three healthcare divisions: bioscience therapies made from human plasma; hospital products and pharmacy IV solutions; and diagnostic tools for laboratory professionals. Grifols products and services serve healthcare professionals and patients in 90 countries worldwide. The Company has two manufacturing facilities in Los Angeles and Clayton, NC. All training will take place at the Los Angeles facility.

In 2003, GBI began manufacturing plasma-based biological products. Once plasma is collected and thoroughly tested, it is fractionated to obtain the individual plasma proteins used in therapeutic medicines. The proteins are then individually purified and subjected to a series of viral inactivation and viral removal steps before being measured into unit doses and packaged. The final product produced is plasma-based biological products.

The industry and business is experiencing growth. Since 2013, GBI has expanded its manufacturing activities by 52%, resulting in a need to hire additional Manufacturing and Support Staff. An expansion in the Albumin and Immunoglobulin (proteins that circulate throughout blood to help the body maintain fluid balance and function as antibodies) processing areas has resulted in the need for additional staff to support production increases and new

shifts. As a result, there is a need to train staff to ensure quality products, meet customer demand and make operations more efficient.

PROJECT DETAILS

To ensure a reliable, consistent source of protein therapies worldwide and in keeping with customer demand, GBI has established an all-inclusive system that begins with the collection of source plasma continues through the fractionation and purification processes to the finished product. Known as vertical integration, this system enables GBI to oversee every aspect of safety and quality throughout the process. Staff training is necessary on the regulations and requirements within the pharmaceutical industry, as well as the individual business needs for each department and job function. All employees will undergo refresher training in good manufacturing practices, equipment operation procedures, and job specific requirements. In addition, training on process improvement will be conducted.

Training Plan

ETP funds will help the Company deliver formalized training to upgrade worker skills, improve efficiency and quality production. Training will provide employees with the necessary skills to increase skill level of manufacturing operations, improve performance and equipment operations, and minimize errors and scrap. The Company hopes to increase efficiency in operations to reduce time from manufacturing to final release for commercial sales. Target timelines have been established for each product, and the achievement of these target goals will be supported by training.

Training will be delivered via Class/Lab, Videoconference and Computer-Based Training (CBT) as outline below:

Business Skills (30%): This training will be offered to all occupations to enhance communication skills, project planning and execution, time management, writing and leadership skills.

Continuous Improvement (20%): This training will be offered to all occupations to enhance understanding of production processes, process control and data, increase product knowledge, develop training and coaching skills, the ability to be more efficient and to be able to identify process improvement opportunities.

Manufacturing Skills (50%): This training will be offered to Supervisors/Managers, Manufacturing/Production and Quality Control Staff. Training will focus on good manufacturing practices and documentation, safety, equipment operations, supply chain, contamination prevention, cleaning and overall production operations and processes to ensure safe and effective products.

Computer-Based Training (CBT)

CBT has recently become an important part of the Company's training practices. This self-paced delivery method will allow workers to participate in training when it best suits their job schedule. CBT is typically used to supplement/complement planned instructor-led learning in an effort to ensure a solid understanding of the concepts presented. However, a small number of trainees in manufacturing, production and quality control may receive all of their ETP training via CBT. The Curriculum includes up to 21 hours of CBT in Manufacturing Skills to supplement class/lab training.

Commitment to Training

GBI has a current annual training budget of approximately \$900,000. Training includes new employee orientation training, good manufacturing practices, health & safety, harassment avoidance and job-specific skills. Training is delivered via class/lab, CBT and on-the-job training; and all training is both job specific and Company-wide. ETP funding will allow GBI to provide well-designed, goal-oriented company-wide training to sustain growth and remain competitive. The Company will also be able to implement changes throughout the organization to meet its goals. Once the ETP training program has concluded, GBI is committed to continuing the quality and frequency of employee training and development activities.

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

➤ Training Infrastructure

Training will be delivered on-site by in-house staff and outside training vendors if needed. GBI has designated a Centralized Training Department (one Performance Development Manager, one Supervisor, two Training Specialists and two Administrative Support Staff) responsible for all administrative responsibilities, including enrollment, recording, tracking and scheduling training, securing rosters, verify training and retention completion, invoicing and ensure compliance with all ETP requirements.

RECOMMENDATION

Staff recommends approval of this proposal.

DEVELOPMENT SERVICES

N/A

ADMINISTRATIVE SERVICES

N/A

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
- Business Writing
- Productivity
- Communication Skills
- Supervising and Managing Skills
- Leadership

CONTINUOUS IMPROVEMENT

- Statistics
- Trainer Development
- Coaching

MANUFACTURING SKILLS

- Process Overview
- Product and Process Knowledge
- Equipment Operations Training
- Good Manufacturing Practices
- Good Documentation Practices
- Manufacturing Documentation
- Aseptic Processing Area Training
- Contamination Prevention
- Manufacturing Area and Equipment Cleaning Training
- Weighing Training
- pH Training (potential hydrogen measurement)
- Fractionation Training
- Immunoglobulin Training
- Environmental Monitoring Training
- Albumin Training
- Coagulation Training
- Hazardous Materials
- Lockout/Tagout
- Forklift Training
- Quality Assurance Training
- Quality Control Training
- Production Support Training
- Supply Chain
- In Process and Final Product Testing Training

CBT Hours

0-21

MANUFACTURING SKILLS

- Aseptic Operator Training – Gloving (120 min)
- Cleanroom Terminology (60 min)
- Cleanroom Behavior (60 min)
- Good Documentation (60 min)
- Intro to Microbiology (60 min)

- Bloodborne Pathogens (30 min)
- Adverse Drug Events (30 min)
- Good Manufacturing Practices (60 min)
- Production Process Guide - IGIV (60 min)
- Production Process Guide – Albumin (60 min)
- Production Operations (60 min)
- Production Equipment (60 min)
- Production Cleaning (60 min)
- Product Testing (60 min)
- Fractionation Training (60 min)
- Albumin Training (60 min)
- Immunoglobulin Training (60 min)
- Coagulation Training (60 min)
- Product Testing Training (60 min)
- Quality Control Training (60 min)
- Environmental Monitoring Training (60 min)

Safety Training cannot exceed 10% of total training hours per-trainee

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