



# Industry Update



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### CONTACT:

Award Staffing  
8030 Old Cedar Avenue South  
Suite 110  
Bloomington, MN 55425  
Tel: (952)924-9000  
Fax: (952)929-1300  
Email: success@awardstaffing.com

## The Three “Rs” of Effective GMP Training: Right Employees, Right Training and Re-Training



**GMP TRAINING HANDBOOK**  
for  
**Award Employees working at YOUR COMPANY**

*Accompanies GMP Training Presentation*

If you work at a food, drug or medical device manufacturing company, then you probably know your GMPs (Good Manufacturing Practices) as well as you know your ABCs. GMPs are regulations set forth and monitored by the U.S. Food and Drug Administration (FDA) to ensure that food, drug, and medical devices are safe and uncontaminated when they reach consumers. All food, drug, and medical device manufacturers are subject to GMP regulations and FDA audits. For this reason, companies that manufacture food, drug and medical device products must have quality systems in place to ensure that they meet federal GMP regulations and to avoid the costly results of product contamination. Employees who understand the importance of and are trained in current Good Manufacturing Practices

are integral to achieving this result.

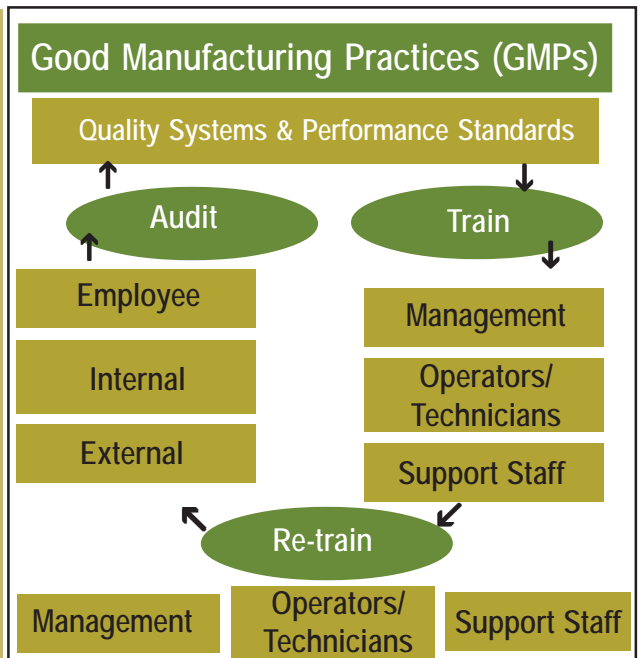
*(The Three “Rs” of GMP Training continued on page 2...)*

### In this month’s issue:

- The Three “Rs” of Effective GMP Training: Right Employees, Right Training and Re-Training
- Sample GMP Training Procedure & Record
- In the Break Room Double Feature: Award Staffing Cryptoquip & Sudoku

### GMP Training Processes Flow Chart

The chart at right displays the components of an effective Quality Systems and Good Manufacturing Practices (GMPs) cycle. If you’d like to learn more about GMPs and effective GMP training, read this month’s feature article inside this newsletter. If your company is subject to FDA-regulations and you need employees with experience working according to GMPs, call Award Staffing to learn more about our GMP training program. We have a large pool of available Award employees who are GMP trained to work on assignments at food, drug, and medical device manufac-



*(Chart source: <http://www.gmp1st.com/gmp.htm>. Google Image Search. 14 September 2007.)*

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(...The Three “Rs” of GMP Training continued from page 1)

Federal regulations for employee GMP training are very general so companies subject to GMP regulations are able to create training programs that are the most effective for their specific manufacturing facilities. While this gives food, drug, and medical device manufacturers the advantage of flexibility in creating their employee GMP training programs, it simultaneously creates the challenge of creating a training program that ensures employees are properly trained on all aspects of GMP regulations. In the face of this challenge, there are three “Rs” food, drug, and medical device manufacturers should keep in mind when creating employee GMP training programs. The three “Rs” are Right employees, Right training, and Re-training.

### **The First “R”: The Right Employees**

First, while important in all industries, it is especially important in FDA-regulated industries for hiring managers to select the right employees. The right employees for companies that are regulated by GMPs are those with the appropriate levels of education, experience, work ethic, and personal habits for the job they will be performing. All employees hired to design and/or modify food, drug or medical device products should have the education and training to do so in a way that ensures the quality and safety of those products for the end user. All employees hired should have a good work ethic and be dedicated to creating safe, quality products. Finally, employees should be screened for health, hygiene, and safety habits to ensure that they are not hired if they possess traits that may compromise the quality of the product they will be working with or the safety of their coworkers and consumers.

### **The Second “R”: The Right Training**

Once hiring managers choose the right employees, it is important that those employees receive the right training. It is not enough to merely ask employees to read a GMP training manual when they are finished with their shift. An effective GMP training program should be held in a designated training area where distractions are limited, and led by a company-qualified GMP trainer. The trainer should be equipped with training materials that deliver information through a variety of media, including: pamphlets, presentations, videos, cd-roms, tests, and questionnaires, to ensure that both audio and visual learners absorb the message. Additionally, the training session should be interactive; with trainers guiding trainees in practicing the appropriate procedures for clean room production. Trainers may want administer tests at the end of each training session to ensure that trainees clearly understand training components. Trainers should keep copies of these tests in employee files along with a GMP training log that outlines the training components they’ve completed and the date of completion. The FDA offers samples of employee training logs on their website at [www.fda.gov](http://www.fda.gov). An example of a training documentation sample from the FDA website is shown at right.

### **The Third “R”: Re-training**

Finally, once your company has hired the right employees and given them the right training, it is important to continually re-train employees on various aspects of GMPs and quality-control systems. Re-training serves the dual purpose of reinforcing initial GMP training and training employees on new processes and procedures that are developed as a result what the FDA terms “training indicators”. According to the FDA, training indicators are factors that indicate the need for new or updated training, including (but not limited to): verification failures due to basic problems, excessive design transfer problems or delays, excessive device defects, excessive process equipment or line down-time, improper labeling or packaging, employees ignoring environmental or control conditions, process or sterilization failures, customer complaints, and excessive or basic items on the FDA list of observations.

Ultimately, in the food, drug, and medical device industry, quality systems are designed to ensure that every product is manufactured in the same safe and sanitary way. However, when a quality system involves a human element, the system is subject to human error. The best way for food, drug, and medical device companies to protect themselves against losses caused by the human element in their quality systems is to follow the three “Rs” of hiring and training employees to work in their food, drug, or medical device manufacturing facility.



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\*\*\*SAMPLE PROCEDURE\*\*\*

C O M P A N Y L O G O Page 1 of 2

Title \_\_\_\_\_ SOP Number \_\_\_\_\_

Prepared by \_\_\_\_\_ Date Prepared \_\_\_\_\_

Approved by \_\_\_\_\_ Date Rev \_\_\_\_\_

ECN Note \_\_\_\_\_

**Policy** Employees shall be trained as needed to perform their assigned tasks and shall be made aware that we produce medical devices in accordance with various regulations and standards.

**Scope** The procedure applies to all employees.

**Hiring** The education, background, training, and experience of prospective employees shall be considered with respect to the requirements of the job to be filled.

**Responsibility** Managers are responsible for assuring that the employees assigned to them are trained or otherwise qualified for the assigned jobs. Before assigning an employee for the first time to a new job, managers shall check their training to verify that the employee has been trained or qualified for the new job.

**The QA department is responsible for training facilities, equipment, and supplies.**

**Training** All inexperienced employees shall be trained to perform their assigned jobs. On-the-job training shall be monitored closely by a supervisor. All employees shall be made aware of design and/or production defects, visible and invisible, in the device, labeling, and packaging that may occur from the improper performance of their jobs and defects that they should look for and detect. Our cleanliness (environmental control) and safety procedures shall be explained to all employees.

**Quality Assurance Employees** QA or product acceptance employees shall receive the training noted above and shall be made aware of errors and defects, visible and invisible, likely to be encountered as part of their quality assurance functions.

**Customer Complaints** Receptionists, managers, representatives, salespersons, and other employees likely to receive complaints and trained in complaint handling procedures applicable to their functions.

**Change Control** All employees are to be advised that they are to perform their jobs as instructed or as covered by standard operating procedures (SOPs). They are NOT allowed to change cleaning, compounding, processing, testing, packaging, labeling, or tasks covered by SOPs until the change is approved according to our change control SOP.

**Documentation** All classroom and on-the-job training shall be documented by the supervisor and trainer of the employee on the form as shown on sheet 2. A separate form for each employee with a record of their training shall be filed and shall be updated at the end of each training session.

\*\*\*Sample Record\*\*\*

EMPLOYEE TRAINING RECORD Page 2 of 2				
Employee Name:			Hire Date:	
Date	Employee Name	Present Job	Type of Training	Supervisor/Trainer Sign.

Source of Sample Procedure and Sample Report: <http://www.fda.gov/cdrh/qsr/05prsnl.html>

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## In the Break Room Double Feature: Award Staffing Cryptoquip & Sudoku

*Cryptoquip Clue: J equals L*

KEQ EQAZS SE VJFVKM

VPS RXPWJK SEFVOB SZW

BWRSXMS VHSWO VJJ ,

ZW ZVM HXJJXRAM SEE .

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	2		3			1		6
				5	2	4		
9			4			6	2	
			8		9			
	3	4			5			8
		3	5	1				
5		6			4		1	
	1	2				8		

*Stumped!? Call Award Staffing at (952)924-9000 for the solutions to this month's puzzles!*

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