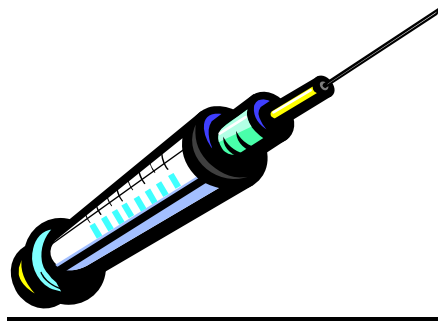


Pharmaceutical Production Operator Curriculum



By

Brian Anderson
John Tyler CC, Chester

Dr. John Ritz
OTED 785/885

Curriculum Foundations:

Definition of Training Courses for a Pharmaceutical Production Operator:

The Food and Drug Administration (FDA) regulates all pharmaceutical companies under the guidelines of The Food Drug and Cosmetic Act. The FDA is responsible for providing these companies with manufacturing guidelines, complaint investigation teams, and biannual audits of sites to ensure compliance. Each production site is expected to conform to all rules and regulations regarding basic Good Manufacturing Practices (cGMP's) and job task competencies. In addition to all FDA regulations, production workers are expected to follow all Occupational Safety and Health Administration (OSHA) and corporate safety regulations, as well as all Corporate Code of Conduct rules.

The Pharmaceutical Production Operator courses are designed to provide all training, practice, and skill checks necessary for production operators to perform their jobs within all regulations and guidelines. The first part of the course is designed to provide a basic understanding of cGMP's, how they are used, and why they are in place. The next section is designed to explain all applicable safety rules, what procedures to follow in case of an emergency, and why these rules are in place. The next section deals with interpersonal skills, such as how to work in a team, problem solving, and effective communication skills. The final area deals with specific job responsibilities, machinery operation, preventative maintenance, and task competencies.

Rationale for the Pharmaceutical Production Operator Training Course:

The curriculum for this course was developed in response to FDA audits, customer complaints, and internal corporate audits of production facilities. Other contributing factors were departmental investigation reports, Quality Assurance Department observations, and concerns and issues raised by department operators during monthly production meetings.

The information was gathered from all of these sources, and plant management analyzed it. The areas were then divided into four units, which were, Basic cGMP's, Safety and OSHA Regulations, Interpersonal Skills, and Task Competencies. The first three units of the curriculum were designed to be used to train any employee in the production area, while the last units can be personalized to individual employees areas of responsibility.

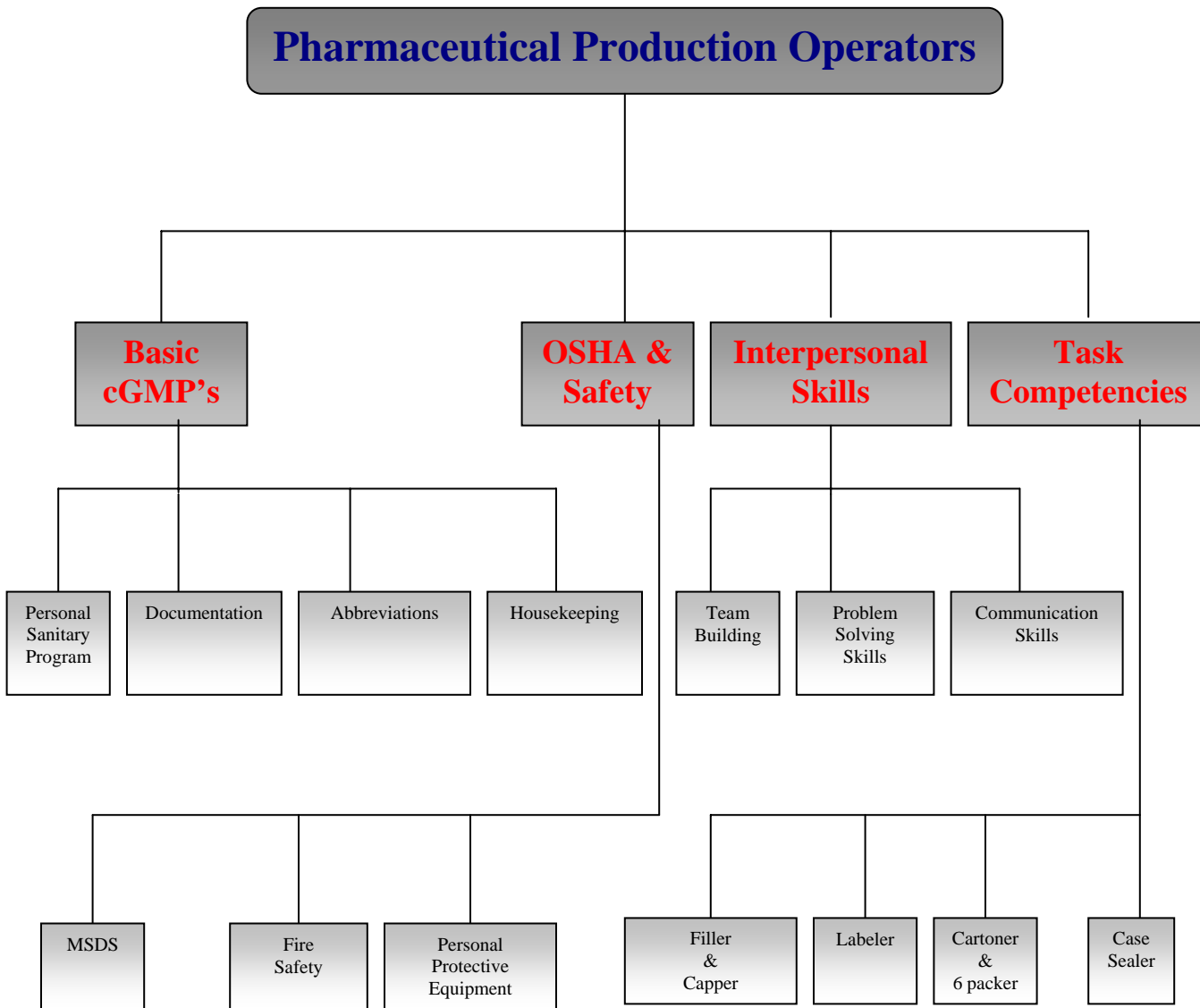
Course participants will be company employees who have had all of the proper human resource forms completed and have successfully passed a company physical, drug-screening test, and a reference and background check.

Content Source for the Pharmaceutical Production Operator Training Course:

The content source for this course is taken from currently acceptable practices from the FDA regulations. Other content sources will be the currently accepted guidelines from OSHA, the currently acceptable corporate human resource guidelines, and the current production techniques used in the pharmaceutical industry.

Topics within this field will be units into four units. These units will be, current good manufacturing practices, OSHA and safety regulations, interpersonal skills, and task competencies.

Content Structure for the Pharmaceutical Production Operator Training Course:



Aim for the Pharmaceutical Production Operator Training Course:

It is the aim of this course to provide all pharmaceutical production operators with the necessary training and information they need to produce a quality product, in a safe environment, in an efficient manner, and that conforms to government regulations.

Goals for the Pharmaceutical Production Operator Training Course:

At the end of this course all employees will be able to:

- Explain the regulations regarding the personal sanitary program and uniform policies.

- Explain the rules regarding proper documentation principles.
- Demonstrate proper housekeeping skills, and identify possible contamination situations.
- Identify acceptable forms of abbreviations used in the pharmaceutical industry.
- Show where the Material Safety Data Sheets are located and how to use them.
- Locate the facilities fire exits.
- List all of the required personal protective devices.
- Demonstrate good teamwork, problem solving, and communication skills.
- Perform all required job tasks for their assigned workstations.

Curriculum Content:

Scope and Sequence:

<u>Unit Number and Topic</u>	<u>Hours</u>
<u>Unit 1 Basic cGMP's</u> <ul style="list-style-type: none"> • Personal Sanitary Program • Documentation • Abbreviations • Housekeeping 	6
<u>Unit 2 OSHA & Safety</u> <ul style="list-style-type: none"> • Material Safety Data Sheets • Fire Safety • Personal Protective Equipment 	4
<u>Unit 3 Interpersonal Skills</u> <ul style="list-style-type: none"> • Team Building • Problem Solving Skills • Communication Skills 	6
<u>Unit 4 Task Competencies</u> <ul style="list-style-type: none"> • Filler & Capper • Labeler • Cartoner & 6 Packer • Case Sealer 	8
<u>Total Hours:</u>	24

Unit #1:

Basic cGMP Courses for Pharmaceutical Packaging Operators.

Time: 6 hours.

Unit Goals:

1. Employees will be able to describe the companies' procedures regarding cGMP (current good manufacturing practices).
2. Employees will be able to explain these procedures and how the FDA (Food and Drug Administration) regulates them.
3. Employees will practice the knowledge and skills learned and apply them in an actual production environment.
4. Employees will outline what areas of the facility the FDA regulations will apply.

Rationale for the Unit:

The Food, Drug, and Cosmetic Act, as well as the Public Health Service Act, regulate all pharmaceutical companies. The industry has adopted a set of guidelines to ensure compliance to these regulations, which are called the cGMP's. The cGMP's help employees by providing them with procedures such as, personal sanitary and uniform policies. Also included with these guides are procedures governing the proper use of abbreviations, documentation, general housekeeping, and contamination.

Additionally, these guidelines are continually revised to respond to FDA site audits, as well as customer complaints. The cGMP guidelines provide a fundamental base of knowledge for employees to build upon, and to be able to perform their jobs effectively, to answer FDA questions, to provide a quality product, and to ultimately manufacture pharmaceutical products within the guidelines of the United States Government.

Objectives for the Unit:

1. Explain the companies' regulations regarding the personal sanitary program, including uniform policies.
2. Explain the companies' rules regarding proper documentation principles.
3. Demonstrate proper housekeeping skills, including identifying possible contamination situations.
4. Identify acceptable forms of abbreviations used in the pharmaceutical industry.

Possible Unit Activities:

1. Test employees' knowledge of the Personal Sanitary and Uniform Policy as it relates to the production area, and how it relates to FDA compliance.
2. Provide employees with several forms of documentation errors and ask them to correct them using the rules and principles they have learned.
3. Take employees to a production area, and ask them to identify different housekeeping problems. Also, ask them to identify different areas of contamination, the causes, and the solutions for the problems.
4. Ask the employees to look at several documents containing abbreviations, and ask them to identify, which are incorrect, and what the correct forms would be.

References:

1. The companies' cGMP handbook.
2. The Food, Drug, and Cosmetic Act.
3. The Public Health Service Act.
4. The companies Standard Operating Procedures (SOP's).
5. International System of Units (SI).
6. United States Pharmacopoeia (USP).

Unit #2:

OSHA & Safety Courses for Pharmaceutical Packaging Operators.

Time: 4 hours.

Unit Goals:

1. Describe the site emergency procedures including chemical spills and emergency evacuation procedures.
2. Discuss the proper use of personal protective equipment, where it is required to be worn, and when it should be worn.

Rationale for the Unit:

The Occupational Safety and Health Administration (OSHA) have issued laws, rules, and regulations for all business industries to ensure a safe work environment for all employees. OSHA along with the companies Environmental Health & Safety department is responsible for the implementation, maintenance, and enforcement of these rules. Included in these rules are the use of the Material Safety Data Sheets (MSDS), the sites emergency evacuation procedures, and the use of the personal protective equipment.

These rules will be communicated and enforced by the plant management. These rules may be revised at anytime due to an accident investigation, an OSHA inspection, or an Environmental Health & Safety department audit.

Objectives for the Unit:

1. Identify the facilities Material Safety Data Sheets including how to use them.
2. Explain the facilities emergency evacuation procedures including the buildings' fire exits.
3. Identify all required personal protective equipment including demonstrating how to use it.

Possible Unit Activities:

1. Test employees' knowledge of the Material Safety Data sheets including where they are kept and how they are used.
2. Have the employees explain the buildings emergency evacuation procedures. Have the employee locate the buildings fire exits including the proper meeting area outside the building.
3. Ask the employee to identify the proper personal protective equipment to be worn including in what parts of the building it is required and at what times it is to be worn.

References:

1. The sites Material Safety Data Sheets.
2. The building emergency evacuation procedure.
3. Blueprint diagram of the building, which lists all exits.
4. The OSHA, and corporations policies regarding the used of personal protective equipment in the workplace.
5. Collins, Larry
Physical Hazards of the Workplace / Larry R. Collins. Thomas D Schneid.
Boca Raton, Fla. : Lewis Publishers, c2001.

Unit #3:

Interpersonal Skills for Pharmaceutical Packaging Operators.

Time: 6 hours.

Unit Goals:

1. Describe how good teamwork and good workgroup interaction skills are helpful in a production environment.
2. Discuss good problem solving skills and the advantages of using them in a production environment.
3. Compare different types of communication skills, such as good oral communication and effective listening skills.

Rationale for the Unit:

A business will not succeed in the marketplace today unless the workforce functions effectively as a team. A production line must work as one unit in order to produce a quality product, in a safe environment, and at a competitive price. Employees must learn certain interpersonal skills as well as technical knowledge in order to achieve all the business objectives.

These skills will help the employees' function together as an effective work team. These skills will also enable them to identify the causes of problems in the production process and to solve the problems as a group. The employees will refine their communication and listening skills and they will interact more effectively with each other while accomplishing these goals.

Objectives for the Unit:

1. Employees should be able to explain the advantages of good communication in a well functioning workgroup.
2. Explain the problem solving process including the different styles of source identification including desired outcome results.
3. Demonstrate good communication skills including good listening skills.

Possible Unit Activities:

1. Have employees participate in team building exercises and explain the advantages of a well functioning workgroup.
2. Have employees demonstrate the ability to solve problems by using root cause analysis and deductive reasoning.

3. Require participants to work on communication exercises including demonstrations of good listening skills.

References:

1. Parker, Glenn M.
Team Players and Teamwork: The New Competitive Business Strategy.
1st Ed.
San Francisco: Jossey-Bass Publishers, c1990
2. Nadler, Gerald.
Creative Solution Finding: The Finding of Full-Spectrum Creativity Over Conventional Thinking.
Rocklin, CA: Prima Pub. c1995
3. Sherriton, Jacalyn Carol.
Corporate Culture, Team Culture: Removing the Hidden Barriers to Team Success.
New York: Amacom, c1997.
4. Goodman, Paul S.
Designing Effective Work Groups.
San Francisco: Jossey-Bass, 1986

Unit #4:

Task Competencies for Pharmaceutical Packaging Operators.

Time: 8 hours.

Unit Goals:

1. Discuss the proper operation of the equipment and machinery used in the packaging of pharmaceutical products.
2. Outline the proper maintenance schedule and troubleshooting guides to be used on the equipment and machinery used in the packaging of pharmaceutical products.

Rationale for the Unit:

According to FDA complaint reports 57% of all customer complaints and product recalls for the year ending 2000 are due to operator error during the packaging process. In the interest of product quality, and the maintenance of the corporations capital investments all packaging operators must be familiar with the operation of the packaging equipment and machinery. By providing hands on training as well as

assessments for task competencies, the employees will become familiar and comfortable with the operation of their assigned equipment and machinery.

Objectives for the Unit:

1. Demonstrate the proper operation and maintenance of a pharmaceutical packaging filler & capper unit.
2. Demonstrate the proper operation and maintenance of a pharmaceutical packaging labeler.
3. Demonstrate the proper operation and maintenance of a pharmaceutical packaging cartoner & 6 packer.
4. Demonstrate the proper operation and maintenance of a pharmaceutical packaging case sealer.

Possible Unit Activities:

1. Employee will startup, operate, and shutdown their assigned piece of equipment or machinery.
2. Employee will locate the proper maintenance schedule of their assigned piece of equipment or machinery and will perform each maintenance task.
3. Employee will troubleshoot and repair simulated problems associated with their assigned piece of equipment or machinery.

References:

1. Omega Design Corporation.
Operation and Maintenance Manual.
<http://www.OmegaDesign.com>
2. Harland Machine Systems.
Saturn Labeler Machine Manual.
3. Industria Macchine Automatiche.
Manual for IMA F670 Filler.

Evaluations and Validation Surveys:

Student Evaluations for the Pharmaceutical Training Course:

Upon completion of each unit every employee will be required to complete either a written examination or complete a task oriented skill checklist. Units one and two will have a written examination, while units three and four will have a task-based demonstration. The written examinations for units one and two will consist of ten multiple-choice or true/false questions. Unit three will have a group exercise with ten objectives that will need to be achieved. Unit four will have a checklist of twenty basic skill competencies that will need to be demonstrated. All four examinations will be graded on a pass/fail basis. A score of eighty percent must be achieved in order to pass the examination. If a passing score is not achieved, the employee must retake the training session and pass the corresponding examination at a later date.

Sample Exam for Unit 1:

Circle the correct answer for each of the following questions. You must answer at least eight questions correctly.

1. Employees must wear a company provided uniform:
 - A. **At all times while working in the production areas.**
 - B. Only when working in areas with open product containers.
 - C. Only Monday through Fridays 9am to 5pm.
 - D. Only if the weather is nice outside.

2. Employees are permitted to wear jewelry and fake finger nails if:
 - A. They are working in areas with sealed products.
 - B. They have permission from their supervisor.
 - C. **Employees are not permitted to wear jewelry or fake finger nails at all.**
 - D. Only if they have a big date that night.

3. Employees must wash their hands:
 - A. **When they return to their work area after leaving the production area.**
 - B. Only if they leave the building for lunch.
 - C. Only if their supervisor tells them they have to.
 - D. Employees do not have to wash their hands if they don't want to.

4. The proper way to document an error is to:
 - A. **Draw a single line through it, initial it, and date it.**
 - B. Erase it and rewrite it.
 - C. Use whiteout.
 - D. Obliterate it and write the correct information next to it.

5. All documentation entries must be written in:
- A. Pen or pencil.
 - B. Any color pen.
 - C. A ballpoint pen with either blue or black ink.**
 - D. A purple crayon.
6. Ditto or tick marks are acceptable when writing multiple entries:
- A. True.
 - B. False.**
7. You may use abbreviations on documents only if:
- A. The abbreviation is listed in the abbreviation SOP as being approved for use.**
 - B. There is limited space to write in.
 - C. You have a lot of writing to do.
 - D. You have to hurry because it is almost time to go home.
8. The abbreviation MFD stands for:
- A. Manufacturing department.
 - B. Manufactured date.**
 - C. Mighty fine day.
 - D. None of the above.
9. All packing equipment can be cleaned with:
- A. Hot water only.
 - B. Any cleaning agent you want to use.
 - C. Bleach.
 - D. Only cleaning agents that are listed as approved for use in the production departments.**
10. Full line cleaning must be performed:
- A. Once a month.
 - B. When there is no production to be run.
 - C. The day before an FDA inspection.
 - D. Between each product run.**

Sample Exam for Unit 4:

The employee is to be observed performing the tasks listed on the Operator Skill Check. Ensure that the employee performs all required tasks completely and accurately. Make sure that all steps are performed in the proper sequence, and that all safety and cGMP regulations are adhered to during the skill check.

The employee should be able to perform a minimum of sixteen out of the twenty required skills listed on the Operator Skill Check. If the employee cannot perform a step, or has difficulty with a step please make a note of the deficiency in the comments section. The instructor may ask the employee to explain the step that they are performing at any time during the check to ensure the employee has a basic understanding why the step is being performed. At no time may the instructor answer any questions during the skill check.

Operator Skill Check

Task or Machine Fault	Desired Action	<u>Completed</u>
Turn the Bottle Cleaner On	• Did the operator know where the power switch was?	
	• Did the operator know where the start button was? (See attachment 1)	
Loading Bottles	• Did the operator load the bottles into the machine properly?	
Stop the Bottle Cleaner	• Did the operator know where the stop button was? (See attachment 1)	
	• Did the operator know how to turn the power off to the machine?	
Machine Will Not Start	• Did the operator check the power switch?	
	• Did the operator check the start button?	
	• Did the operator check the fault-reset button? (See attachment 2)	
	• Did the operator check the power fuse?	
	• Did the operator check to see that all guard doors were closed?	
	• Did the operator check all interlock switches?	
Clear Stop Fault on the OIT Screen	• Did the operator check to see if the machine was in pause mode?	
	• Did the operator check to see if there were bottles in the machine?	
	• Did the operator check to see if there was a bottle jam in the drop chute?	
	• Did the operator check for a turret overload?	
Bottles Are Falling Over	• Did the operator check for the proper speed between the turret drive and the discharge conveyor?	
Bottles Are Not Properly Oriented	• Did the operator check for proper adjustment of the container-sensing sensor?	
	• Did the operator check for proper sensitivity of the pocket actuator air cylinder?	
Low Output of Bottles	• Did the operator check for the proper machine speed setting?	
Bottles Jamming in Bottle Cleaner	• Did the operator check for the proper location of the bottle guide plate?	

Comments:

ATTACHMENT 1

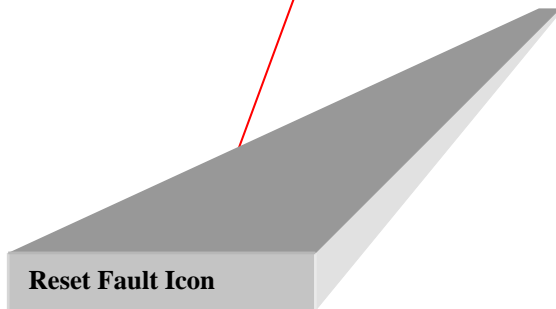
Start Screen



**Press to Start Auto Run
Icon (Becomes Press to
Stop Icon)**

ATTACHMENT 2

Fault Screen



Course Evaluation:

In order to effectively evaluate the course content and to improve future training courses, each student will be asked to fill out a course evaluation sheet.

Course Evaluation

Please rate the training course you just attended. The instructor, and the training department will use this information to make any necessary changes to the information that was presented, or how the information was delivered.

Please place a check mark in the corresponding box below:

Question	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Instructor stated the course objectives clearly.					
The learning activities supported the goals of the course.					
The information learned in this course can be applied to my daily work assignments.					
Any written materials or videos used supported the goals of the class.					
The instructor seemed prepared for the class.					
The instructor seemed to be knowledgeable of the subject matter.					
The instructor encouraged class participation.					

If I could change one thing about this course I would:

Validation of the Pharmaceutical Operator Training Course:

In order to validate the outlined curriculum for the Pharmaceutical Operator Training Course the production, environmental health & safety, and human resource management must approve it. The first person to review it would be Harry Gill the Liquid Business Unit department head. Mr. Gill would review the course content for technical correctness, and to ensure that the curriculum's scope and sequence is congruent. The next person to review it would be Dave Fore the director of the Environmental Health & Safety Department. Mr. Fore would ensure that all OSHA and corporate safety policies are covered and that the information has the correct breadth and depth. The final review would come from Sean Powell the director of the Human Resource Department. Mr. Powell would audit the curriculum evaluations for fairness and accuracy.

To: Sean Powell PBHR
Dave Fore EH&S
Harry Gill PBMF

From: Brian Anderson PBMF

Subject: Curriculum for the
Production Operator
Training Course

Date: November 10, 2001

Attached you will find a copy of the curriculum that was discussed at Liquid Business Units monthly operation meeting in October. The course was developed to meet the current departmental needs and provide an increase in content structure for our current training program.

Please review the information carefully. A survey sheet has been attached for you to list any comments, questions, or concerns. Please have the survey completed and mailed back to me by December 3, 2001.

Once again thank you for your assistance with this project and I am looking forward to your feedback.

Sincerely,

Brian Anderson

CC. Mike Berg, Managing Director, Richmond Operations

Survey for the Pharmaceutical Operator Training Course

- 1. Does the rationale justify the need for the curriculum and each of the four units?**

- 2. Is the content source taken from the appropriate sources, does the content structure have significance, will it be used, is it of interest, and will it promote human development?**

- 3. Is the aim of the curriculum on target with the current business needs and are the goals appropriate for the specified job titles?**

- 4. Does the curriculum content contain the proper scope and sequence?**

- 5. Are the goals and objectives of each unit attainable?**

- 6. Are the activities for each unit appropriate?**

- 7. Do the evaluations and skill checks accurately measure the knowledge learned?**

8. What changes if any would you like to see in this curriculum?

9. Are there additional areas that you would suggest that a company curriculum be developed?