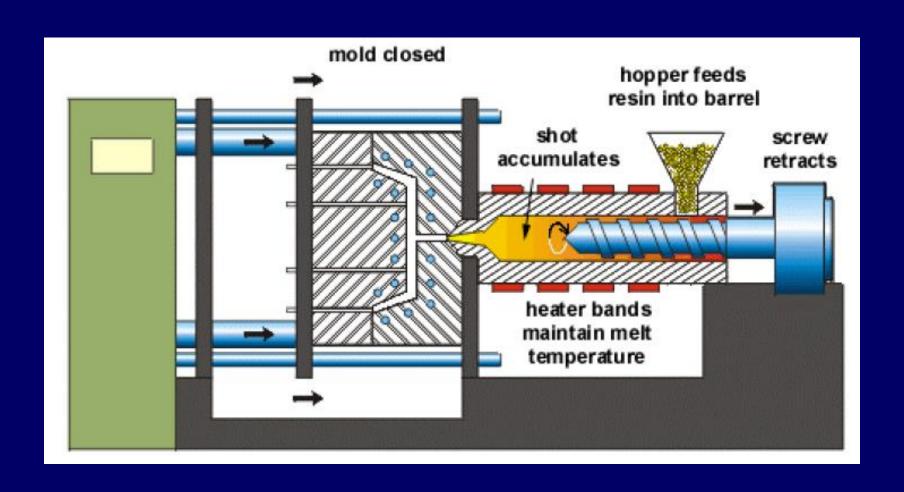
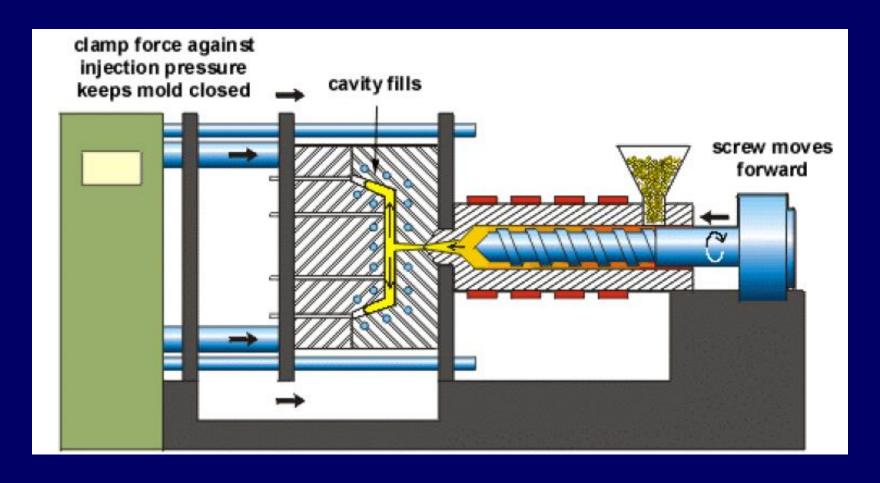
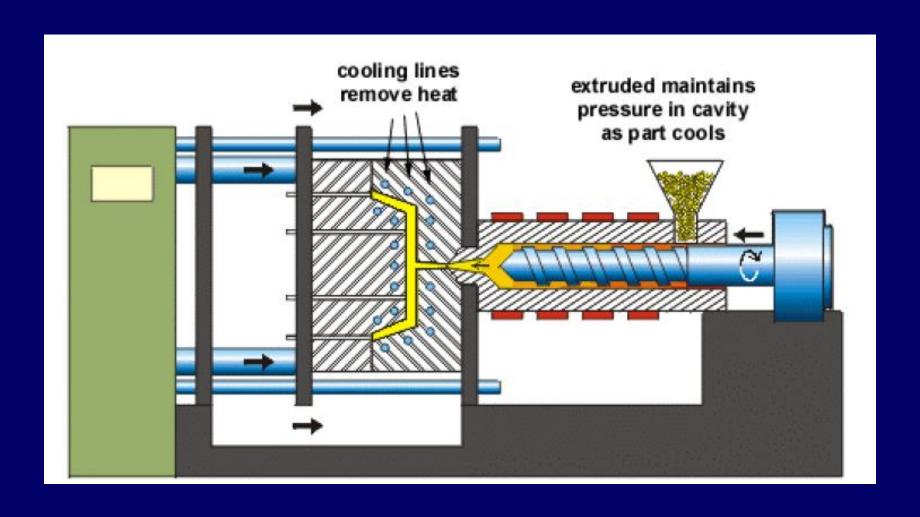
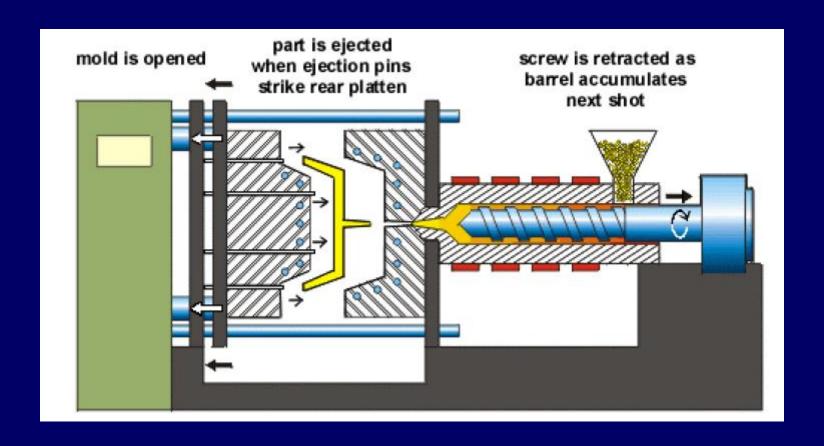


# New Hire Orientation









# On The Job



# Job duties and Assignments

- Each employee will receive a copy of their job description.
- Your supervisor will review with each employee
  - Duties
  - Assignments
  - Expectations
  - Requirements of Job

# Expectations & Standards

- Integrity, respect, ethics and morals
- Always Keep a Clean Work Space and take a personal responsibility to assist others in doing the same plant wide! (IT IS YOUR JOB!)
- Do not waste Supplies
- Be willing to assume unexpected tasks
- Be open and willing to accept change and always be support to others in times of change
- Follow Company Policies and Procedures

# Job Relationships

- Has responsibilities to Quality Inspectors and Production Technicians
- At times may be assigned as a Trainee to a "Buddy"
- At times may be assigned as a mentor to a "Buddy"

## Job Requirements and Functions

- Must be able to work assigned shift hours and mandatory overtime as required to meet all company deadlines.
- Must be able to meet all current and future gowning and dress requirements throughout entire scheduled shift and or overtime
- Must be able to read and write in English at a level required to understand and follow written job instructions and able to write at a level required to complete any and all required production reporting.



# Time Clock

- > Employee entrance
- > All hourly employees are required to accurately account for time worked
- ➤ No more than 7 minutes before or after your shift
- ➤ If you work overtime it must be approved by you Supervisor
- ➤ Lost Badges and Missed Punches Report to your Supervisor



# **Tobacco Use Policy**

- ► No Tobacco Use in the building
- Designated area outside employee entrance only
  - ► Make certain to dispose of in proper container

No tobacco anywhere on the plant floor



# Parking

- Must park in marked spots
- ➤ Please take care to only use one space
- ➤ Visitor, Handicap & Carpool are for those purposes only
- Carpool spots are for approved carpools only.

MedPlast



# Lockers

- Lockers are Company Property
  - Company reserves the right to search or consent to search your assigned locker.
- > Company not responsible for stolen items
- > Do not store valuables or money in them
- ➤ Locks will be provided to you. No personal locks may be used.

## Meal and Rest Breaks

- 8-Hour Shifts
  - One 30-Minute Paid Rest Breaks
  - One 30-Minute Unpaid Meal Break
    - Generally 4 hours into the shift.
  - All Breaks will be taken at the direction of the Shift Lead or Supervisor.



## Time and Attendance Policy

Time Off, to be considered approved, must be submitted and approved by your supervisor, 2 Weeks in advance and then submitted to HR.

Unexcused Absences, Leaving Early, Arriving Late, Losing Your Badge, Missing a Punch will accrue an occurrence at the following rate:

1/2 Occurrence – Leaving Early, Arriving Late, Losing Your Badge, Missing a Punch

1 Occurrence – Absence with less than 48 hours notice

3.5 Occurrence – No Call / No Show

Each employee may only collect less than 8 occurrences or they will be terminated. At 5 occurrences, you will be verbally counseled, at 6 occurrences, you will receive written counseling, at 7 occurrences, you will be suspended for 3 days without pay and issued a final warning letter.

Excessive Absenteeism in your initial 90 period may result in disciplinary action up to and including termination.



MedPlast Tempe Plant Permanent Employees: You must call the MedPlast Tempe Plant at (480) 553-6414 as soon as possible to notify them of your reason for being absent, sick or late, if late then the estimate time of your arrival. If no one answers, please leave a message with your reason for calling in absent, sick or late and the estimated time of your arrival.



### PAID TIME OFF (PTO)

- 1. You can use immediately.
- 2. If your employment ends before the end of the year and you have taken more hours than you have had time to accrue, the hours will be recouped by MedPlast.
- 3. PTO Balances will be printed on your paycheck stubs.



MedPlast's policy is that all employees will maintain a neat and well groomed appearance at all times. Hats, Caps, Head Coverings etc.. are not allowed in any engineering, production or maintenance area of the plant.

Each employee may bring a capped bottle of water with them to the production floor. At no time are food items are allowed on the production floor, clean rooms or warehouse. This includes chewing gum and smokeless tobacco.

All hairnets, beard nets, gloves and shoe coverings are to be disposed of properly when exiting a clean room, or at the end of your shift. Smocks are to be hung up or put away in the designated areas.

If you have a need for a reasonable accommodation such as a medical necessity, please see human resources at your first availability.



### Schedule and Working Hours

1. a. First Shift	0700-1530 or 7:00am – 3:30pm
b. Second Shift	1500-2330 or 3:00pm – 11:30pm
c. Third Shift	2300-0730 or 11:00pm – 7:30am

- 2. Scheduled Days will be determined by your Supervisor.
  - a. The "Work Week" begins with Sunday and ends with Saturday.
- b. There will be times where Overtime is scheduled and Mandatory.
- 3. Hourly Employees must clock in when arriving and clock out when leaving the premises during the course of your work day. (arriving for work, lunch, leaving work)
  - a. Time clock is located in the employee break room
  - b. Any issues with the time clock is to be reported immediately to your supervisor.



### Bathrooms

Located outside of break room off production floor Keep them neat and tidy Report Problems Immediately

### **Break Room**

Storage for Coats and Hats

Vending Machines

Refrigerators

Tables and Chairs

Keep neat and tidy

Dispose of rubbish in proper containers

Report Problems Immediately



### Benefits Offered

Medical

Dental

Vision

401K

FSA

Miscellaneous



# Prevention of Sexual Harassment Training for New Employees



## Dealing with Workplace Harassment

- Workplace harassment is unacceptable conduct and will not be tolerated at any level within MedPlast. You have responsibility for maintaining high standards of honesty, integrity, and conduct as employees.
- Any employee who believes he or she was a victim of harassment, including sexual harassment, should report the allegation to his/her supervisor, or contact Human Resources for assistance.

## Sexual Harassment



- Unwelcome
- Can be physical, verbal or nonverbal
- Severe and pervasive
- Unreasonably interferes with an individual's work performance

- Creates a hostile work environment
- Focus is on impact of the behavior, not the intent



### Types of Sexual Harassment

Quid Pro Quo: Making the submission to unwelcome sexual advances or submission to other verbal or physical conduct of a sexual nature a term or condition, implicitly, of an individual's employment. Basing employment decisions affecting the individual on his or her submission to or rejection of such conduct.

Hostile Environment: Making unwelcome sexual advances or other verbal or physical conduct of a sexual nature with the purpose of, or that creates the effect of, unreasonably interfering with an individual's work performance or creating an intimidating, hostile or offensive working environment.



## Prevention of Harassment

- Recognize your obligation to create and preserve a work environment free from sexual harassment
- Report the allegation
- Take immediate action to investigate the allegations
- Seek resolutions and document action(s) taken
- Even if you feel the complaint is groundless treat it seriously
- Contact Human Resources for assistance



## Creating a Positive Work Environment

If your attitudes and decisions are shaped by facts based on performance and behavior, you will create a work environment free of discrimination where people are treated with respect based on what they do - not on what they were born into. You will have created the kind of place where everyone would like to work.





## Coming together is a beginning.

Keeping together is progress.

Working together is success.

- Henry Ford

Recognize People. Engage People. Treat People like Equals



# MEDPLAST HOURLY PERFORMANCE BOARDS (WHITEBOARDS)



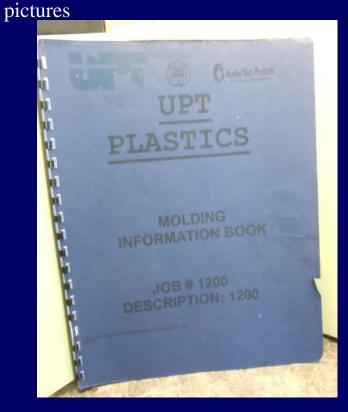
# Terminology

- Press # Number Assigned to Each Press
- Hourly Goal (Good/Bad) Parts Number located on the Work Order and Entered By Shift Supervisor or Lead.
- Actual # of Bad Parts The number of parts found to be bad per the specifications in the Part Specification Packet (Blue Book) per hour.
- Actual # of Good Parts The number of good parts that meet the specifications in the Part Specification Packet (Blue Book) per hour.

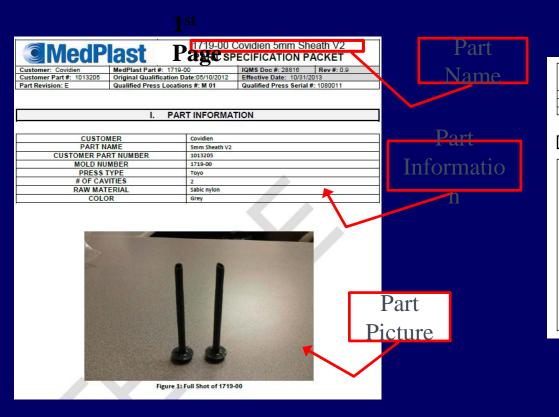
### PART SPECIFICATION PACKETS (BLUE BOOKS) -

Contains all part information, including operator instructions, packaging instructions and defect





### PART SPECIFICATION PACKET (BLUE BOOK) INFORMATION



### **Operator Instructions**

1719-00 Covidien 5mm Sheath V2 PART SPECIFICATION PACKET			
Customer: Covidien	MedPlast Part #: 1719-00	IQMS Doc #: 28816	Rev #: 0.9
Customer Part #: 1013205	Original Qualification Date:05/10/2012	Effective Date: 10/31/2013	
Part Revision: E	Qualified Press Locations #: M 01	Qualified Press Serial #: 1080011	

### OPERATOR INSTRUCTIONS

- 1. Mold runs automatic
- 2. Hairnet and gloves are required at all times in the work cell
- 3. Prepare packaging as described in packaging instructions below
- 4. Once parts are off loaded from the conveyor, remove parts from the tray
- 5. Ensure two (2) shots are molded in each shot
  - a. If two (2) parts are not being molded in each shot, notify a technician
- VISUALLY INSPECT THE PART FOR DEFECTS (FLASH, SHORTS, SPLAY, BURN, SINK, ETC.).by comparing to sign-in shots approved by QA – See part pictures
  - a. Components shall be free of molding defects short fills, sinks, voids, blisters, burns, drag marks.
  - b. Parts to be free of damage cracks, stress marks, malformed
  - c. Flash or mismatch not to exceed .010"
- 7. Place unacceptable parts in the red bin
- 8. Record all scrap on the scrap shift sheet
- 9. Place acceptable parts in the box
- 10. Do not remove parts from work cell until approved by QA
- 11. Notify Supervisor or QA if questions arise

What to do at the press

### PART SPECIFICATION PACKET (BLUE BOOK) INFORMATION





### IV. PACKAGING INSTRUCTIONS

# Type of Packaging Packaging Name/Size Part Number 2 Bags Polybag/ 1.5 Mil Bag-015 Box Box/ 13x13x13 CTN-001-KF Twist tie Twist tie

#### Packaging Procedure

**Packaging Materials** 

- 1. Place one (1) polybag in box, and wrap around inner sides of box
- 2. Place second bag in box
- Bulk pack parts. A maximum of 900 parts per box
   Once bag is filled, close inner bag using twist tie
- 5. Apply operator label to inner bag
- Do not seal box until QA inspection is complete

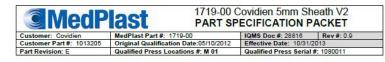






Figure 4: Double Bag with operator label

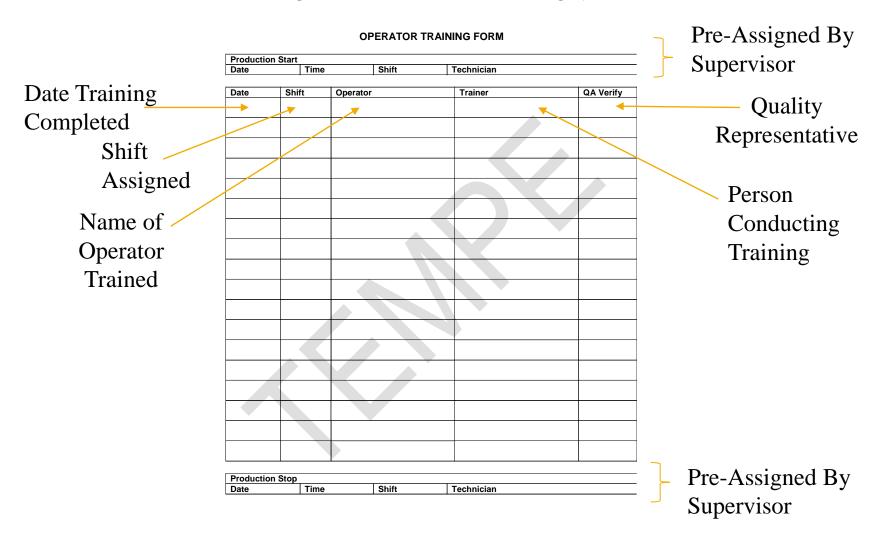
### Defect Pictures



### V. PART PICTURES

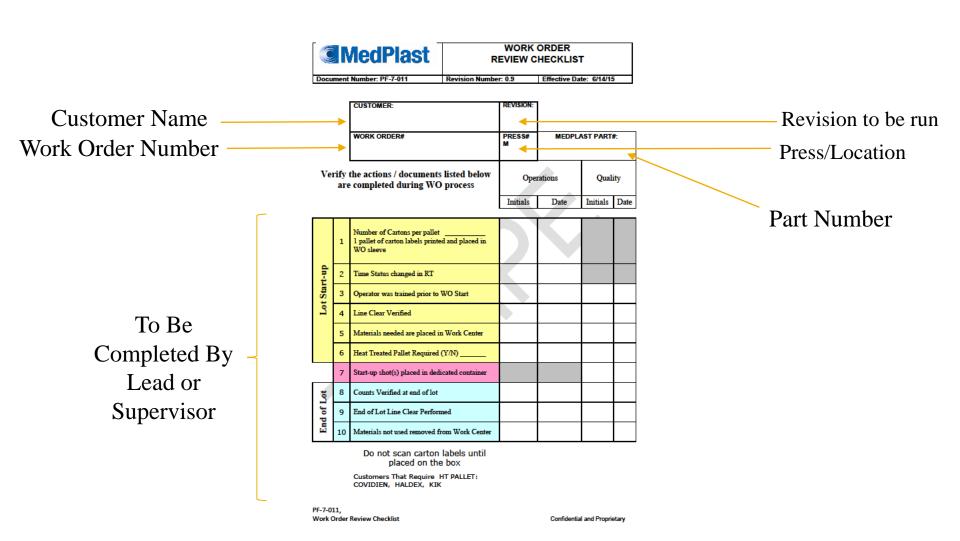


### MEDPLAST TEMPE OPERATOR WORK ORDER FAMILIARIZATION



### MEDPLAST TEMPE OPERATOR WORK ORDER FAMILIARIZATION

Work Order #	MEDPLAST TEMPE   Date: 2/24/2014 12:50:41PM   Page: 1	Work Order
Location/Press # Part #	Standard Information	Packaging/ Support
	Rel Date         Rel Qty         Order No.         PO No.         Customer         AKA Item No         Parent Item           3'5'2014         4,492.00         3135-04         950161         KIK ELRHART-WEST FLANT         183443ZZ           3'12/2014         161,500.00         5193-04         951915         KIK ELRHART-WEST FLANT         183443ZZ           Process Printed Out and Approved By:           Line Clearance:         MFG Sign-In:           Q.A. Sign-In:         MFG Final W.O. Approval:	Material Needed



### MEDPLAST TEMPE OPERATOR WORK ORDER FAMILIARIZATION

### Good Manufacturing Practice

**GMP** 



cGMP

### GMP – What is it?

"Good Manufacturing Practices"



**Principles of GMP** 



### What is GMP?

# Good Manufacturing Practice

### Introduction

 Here at MedPlast/Tempe, we manufacture plastic parts and about 95% of these parts are used in the medical industry. Therefore, it is very important for us to handle all parts with proper care.

 It is impossible to cover all circumstances so keep in mind our goal of keeping our parts free of contaminations, free of damage & to avoid customer returns.

### Course Objectives

- The importance of using "Written Procedures"
- The importance of Documentation
- Understanding the importance of PPE & "Workplace/Personal Cleanliness"
- Understanding our Food & Drink Policy on the Production Floor
- Handling Parts Properly
- The importance of Line Clearance
- Questions
- Test your knowledge

# Why Is GMP Training Important?

- Regulatory agencies are legally entitled to conduct unannounced inspections if they believe there are suitable grounds to warrant an inspection.
- These regulatory agencies include the U.S. FDA and California FDB.
- GMP Training helps MedPlast comply with industry and government good manufacturing practices, specifications, and regulations.

#### GMP -



Principle #1 - Writing step by step procedures that provide a roadmap for controlled and consistent performance

DO WHAT WE SAY!

Principle #2- Carefully follow written procedures to prevent contaminations, mix-ups, and errors

RECORD WHAT
WE DID!

Principle #3 - Prompt and accurate documentation of work for compliance and traceability

Principle #4 - Proving systems do what they are designed to do by validating work

**ENGINEERING!** 

Principle #5 - Integrating productivity, product quality, and employee safety into the design and construction of facilities and equipment

**FACILITIES** 

Principle #6 - Properly maintaining facilities and equipment

Principle #7 - Clearly defining and developing job competence

Management Team & HR Department

Principle #8 - Protecting products against contamination by making cleanliness a daily habit

**EVERYONE!!** 

Principle #9 - Building quality into products by systematically controlling components and product related processes: such as manufacturing, packaging, labeling, testing, distribution, and marketing

QC
ENGINEERING &
PRODUCTION

Principle #10 - Conducting planned and periodic audits

**Internal Audit Team** 

### Why Does MedPlast Need to Practice GMP?

- About 95% of the parts we manufacture are used in the medical industry.
- It is very important that we handle all parts with proper care.
- Our goal is to keep our parts free of contaminations, free of damage & to avoid customer returns/complaints.

### Requirements

- FDB = Food & Drug Branch (State)
- FDA = Food & Drug Administration (Federal)
- GMP is required by both FDB & FDA
- Summarize:
  - Must use and follow work instructions
  - Parts must be checked for quality and meet specifications
  - Any complaints must be addressed

### The Importance of "Written Procedures"

- Good "Written Procedures" are key in GMP
- Just knowing the procedures is not enough, applying them is a must if they are to be effective
- If there are no work instructions, don't assume...ASK... your lead or supervisor
- Always review the written procedures, even if you think you are familiar with the procedures, the job or procedure might have changed.

#### Written Procedures

#### Instructions may include:

- Visual Inspections Instructions
  - Specific defects to reject
- Packaging Instructions
  - How parts are packaged
  - Information included on label
  - Where the label is to be placed
- Quantity of parts per container
  - Weighed, Counted

PPE is <u>VERY IMPORTANT</u> & is supplied by the company

A hairnet must be worn at <u>all</u> times while out on the production floor. Beard covers should be worn when applicable.

All hair should be tucked in to the hairnet (including bangs). There are mirrors in the restrooms to make sure this is done.



### Properly Applying your PPE

If a beard cover is necessary, ensure all facial hair is completely covered including mustaches, side burns & facial stubble.

TEAMWORK

Ensure bangs & hair in the back are completely covered.



Properly Applying your PPE

Use mirrors that are supplied to ensure that all hair is completely covered before entering the production floor.





### Proper PPE Off The Floor

- Do not store your hairnets in your pockets or anywhere else on your person. Always dispose of your hairnet in the garbage once you take it off your head, or before going for your break or lunch period.
- It is ok to keep the same hairnet to conduct business in the office area as long as you keep it on your head.

Hairnets & Beard Covers can be found at all major entryways into the Production floor.



Gloves can be found right outside the Supervisors office on the Production Floor.



You should wear gloves at all times while handling parts.

Gloves should be in good condition with no holes.

When touching anything other than parts, always, wipe gloves with alcohol.



Safety Glasses can be obtained by the shift supervisor at the shift supervisor's office on the Production Floor.

Note: Please do not get your safety glasses from the Front Desk as these glasses are stocked for visitors & customers.



- Safety Glasses are to be worn at all times while on the production floor. Prescription glasses are acceptable.
- ■Ensure your glasses are in good condition and cleaned regularly. Dirty or smudged glasses can result in not being able to identify rejects properly.



### Personal Hygiene

 Keeping yourself clean is equally as important. You must bathe regularly, this keeps any excess dirt or oil on your person from transferring onto the parts.

 It is important to keep your hands & your work area clean.

### Workplace & Personal Cleanliness

#### Before you start work:

Start with wiping down your workstation and bins with alcohol wipes before you start the job.



#### When using the restroom:

Do not take your hairnets or gloves into the restrooms, dispose of these before leaving the production floor. <u>NEVER</u> take parts into the restroom.



### Workplace & Personal Cleanliness

### When adjusting or moving your chair:

Wipe your gloves with the alcohol wipes every time you touch something other than the part.





### Workplace & Personal Cleanliness

Always wash your hands with soap & water when returning from your break & lunch, and after visiting the restroom.



#### Work Station Cleanliness

There are alcohol wipes at each workstation for your convenience. If they are missing, please inform the supervisor or lead. They will make sure wipes are supplied for you.



#### Work Station Cleanliness

### Alcohol Wipe Containers:

Make sure the containers of alcohol wipes are sealed to keep the wipes from drying out.





### Food & Drinks

- Food and drinks other than a capped bottle of water are <u>never</u> allowed on the production floor. This includes maintenance, shipping / receiving & tooling departments.
- No gum & candy in your mouth while on the production floor (this includes cough drops).
- Violators will be disciplined up to and including termination.





### Handling Parts

- If a part were to fall on the floor, that part is now considered contaminated and is not to be picked up or touched by the machine operator.
- It is <u>not</u> acceptable to pick up a part and wipe it with alcohol and package it.
- Notify the nearest lead or supervisor to make sure that parts are picked up and disposed of in the reject pile.



#### Line Clearance

 One of the most important aspects of GMP is Line Clearance.

- Before starting a new job, always remove items from the previous jobs, such as:
  - Parts
  - Work Instructions
  - Labels

## Why Is Line Clearance Important?

- Because old & new parts can be mixed and this can cause rejects.
- Because old labels can accidentally be put on boxes of new jobs and this can cause rejects.
- Because old instructions left behind can be confused with the instructions for the new job and this can cause rejects.

### Line Clearance



What's wrong with this picture?

### Line Clearance



Example of Good Line Clearance

# Who's Responsibility Is Line Clearance?

Do not blame other people from other shifts. Line clearance is <u>each of our responsibility</u>.

If we fail at line clearance, we lose business and money. We can't afford this.



Insects in Packaging



**Correct Reject Label** 

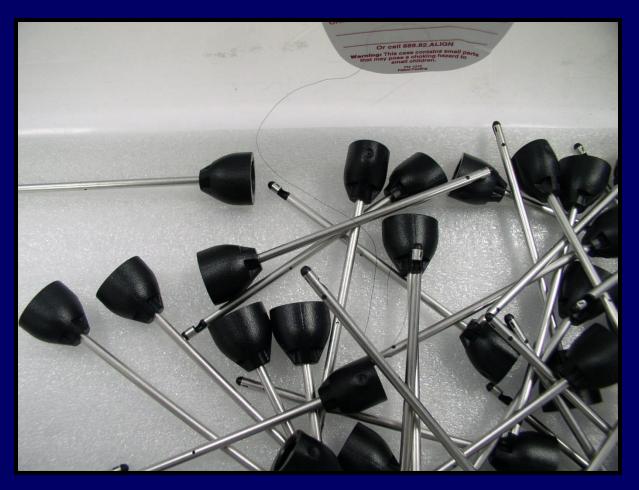
Half a Label / Wrong Reject Label



Lint on Part



Box of Bags on Floor



Human Hair = UNACCEPTABLE GMP

Incorrect Labeling = UNACCEPTABLE GMP

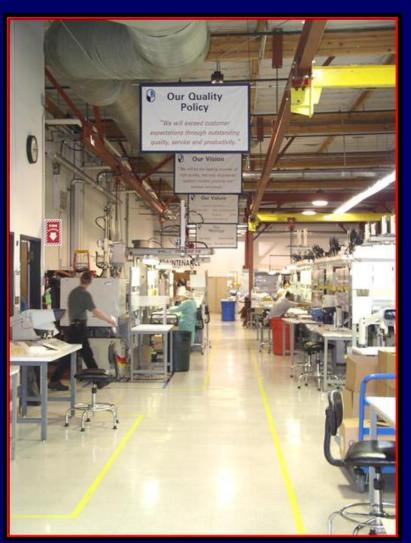




Label says, Deployment Knob, parts inside are Vent Caps. Label says, Vent Cap, parts inside are Deployment Knobs.

## Good Manufacturing Practice

- Make GMP a HABIT
- Practicing GMP is a key to our success
- •GMP is NEVER ENDING !!!





If no further questions, let's get started on the quiz.





- No talking & keep your eyes on your paper.
- If you should have any questions, please raise your hand.
- There will be 10 questions, you will need to get 80% correct in order to pass the quiz (8 correct answers).
- I will read the questions, you will have 2 or 3 options for the correct answer. There will only be one correct answer for each question. Pick the correct answer and write the letter on the corresponding number on your answer sheet.
- Any questions before we get started?



# 1 \_\_\_\_\_

# 2 \_\_\_\_\_

# 3 \_\_\_\_\_

# 4 \_\_\_\_\_

# 5 \_\_\_\_\_

# 6

#7

#8

#9

# 10

What does GMP stand for?

- A) Good Manufacturing Practice
- B) Good Material Process
- C) Good Material Price

It is acceptable to keep your same hairnet while in the restroom as long as you keep it on your head.

- A) True
- B) False

If there are no work instructions at your workstation, you should:

- A) Sit at your workstation till someone notices you have no instructions
- B) Copy the instructions from the machine next to you
- C) Ask your lead or supervisor

It is acceptable to continue to wear the same hairnet while conducting business in the office, as long as you don't take it off your head.

- A) True
- B) False

If you make a mistake on the P-Chart or any controlled document you should:

- A) Use white out before correcting the mistake
- B) Ignore it, & hope no one catches it
- C) Single line through mistake, correct, initial & date

It is acceptable to pick up a part off the floor and package it <u>as long as you</u> wipe it down with alcohol?

- A) True
- B) False

If you lose or misplace your safety glasses, you can get another pair from:

- A) The Human Resources Dept.
- B) The Front Desk
- C) The Supervisors Office

It is acceptable to keep your hairnet in your pocket as long as your pocket is free of lint and other items.

- A) True
- B) False

Food or drink is never allowed on the production floor, but cough drops are the exception.

- A) True
- B) False

Leaving old parts, work instructions & labels from a previous job at a workstation is called:

- A) A safety hazard
- B) Workplace Harassment
- C) Bad line clearance

#### How did you do?

$$#1 = A$$

$$#2 = B$$

$$#3 = C$$

$$#4 = A$$

$$#5 = C$$

$$\#6 = B$$

$$#7 = C$$

$$\#8 = B$$

$$#9 = B$$

$$#10 = C$$



