CEMD 0920

Salt Lake Community College

Basic Manufacturing Skills Week 3

c3bc Community College Consortium for Bioscience Credentials

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Good Manufacturing Practices (cGMP) & Good Documentation Practices (GDP)

Four GDP essentials during the Manufacturing Process:

1) Standard Operating Procedure (SOP)
2) Bill of Materials (BOM)
3) Work Instruction Document (WID)
4) Batch Record

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- Controlled by document number and revision level
- Operator must be trained before performing

Two additional GDP essentials will be covered next week:

1) Device History Record
2) Device Master Record

Bill of Materials (BOM)

- BOM should include
  - BOM level
  - Part number
  - Part name
  - Phase
  - Description
  - Quantity
  - Unit of Measure
  - Procurement type
  - Reference designators
  - BOM notes

An accurate BOM supports efficient manufacturing processes.

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Bill of Materials (BOM) Cont.

- BOM should include
  - BOM level
  - Part number
- BOM Level: The place within the process of assembling a finished good a raw material (or subassembly) is consumed.
- Part number: Used as a locator to find the item in the database

- For example om the table to the right:
  - KIT 0001 contains: Can04, Box01 and Label014
  - Can04 contains: Part72, Part73
  - Box01 contains: Part90, Bag32
  - Bag32 contains: 30 of Part213, 15 of Part214

P/N KIT-0001 BOM		
Level 1	Level 2	Level 3
Label014 (1)		
Can04 (1)		
	Part72 (1)	
	Part73 (1)	
Box01 (1)		
	Part90 (1)	
	Bag32 (1)	
		Part213 (30)
		Part214 (15)

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Bill of Materials (BOM) Cont. 2

- BOM should include
  - Part Name: Name of part in question
  - Phase: The point of development for the part
    - Alpha (may have different versions)
    - Beta (pre-release)
    - Released (may have different versions) In production

P/N KIT-0001 BOM	Name: Reagent Kit A	Phase: Released
Level 1	Level 2	Level 3
Label014 (1)		
Can04 (1)		
	Part72 (1)	
	Part73 (1)	
Box01 (1)		
	Part90 (1)	
	Bag32 (1)	
		Part213 (30)
		Part214 (15)

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Bill of Materials (BOM) Cont. 3

- BOM should include
  - Description
  - Quantity
  - Unit of Measure
  - Procurement Type
- Description: A short description of the product
- Quantity: the amount of the part required
- Unit of measurement: The unit of measure that the quantity refers to
- Procurement type: Usually documented with code
  - Manufactured In-House
  - External Purchase
    - Off the Shelf
    - Made to Order
  - Can be made in house or purchased
  - This information is used to create efficiencies in manufacturing, planning and procurement activities.

P/N KIT-0001 BOM	Name: Reagent Kit A	Phase: Released	
Description: Kit containing essential consumables for ABC system			UOM: Each
Level 1	Level 2	Level 3	
Label014 (1)			Procurement: A
Can04 (1)			
	Part72 (1)		
	Part73 (1)		
Box01 (1)			
	Part90 (1)		
	Bag32 (1)		
		Part213 (30)	
		Part214 (15)	

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Bill of Materials (BOM) Cont. 4

- BOM should include
  - Referenced designators
  - BOM Notes
- Referenced designators: (RD) normally a text field that helps to specify what this component does and how to find this component. In most cases, used when more than one component with the same Part Number need to appear in BOMs.*
- BOM notes: Relevant notes to the BOM

* Do not confuse with the RD used on circuit diagrams or printed circuit boards. However, if the BOM is for a PCB, the RDs should be included.

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Bill of Materials (BOM) Cont. 5

4 key questions you must answer before creating a bill of materials

1. Will you document consumables in your BOM record?
   Many manufacturers second-guess the decision to include glue, wires, fasteners and other non-modeled parts like labels and boxes in their BOM record. But if the part does not make it into your BOM, it might not make it into your product. So take the time to document these parts.

2. How will you attach files to your BOM record?
   As you create your BOM, keep records of supporting documentation like CAD drawings, part datasheets and work instructions. It is best to also associate these files with their specific BOM level items.

3. Who is going to use the BOM record?
   It is important to include as many details as possible in your BOM. You may never interact face-to-face with some of the people utilizing your BOM, so it should convey all the information they might need throughout the product's lifecycle.

4. How will you reconcile your BOM record?
   Your BOM record may go through several iterations during the design phase, so you should have a way to distinguish between multiple BOM record versions. That way, when it is time for production, you can be sure each person who uses your BOM is consulting the correct version.

Human & Organizational Performance (HOP)

This quote sums up our responsibility as Leaders to do everything we can to ensure the safety of our employees.

"Every decision that we make will effect them in some way….good or bad.

- Why did the commercial nuclear industry adopted human performance:
  - 21 out of 26 fuel-damaging accidents caused by human performance, besides the accident at Three Mile Island in 1979.
  - 3 out of 4 significant events were triggered by human performance.
  - One mistake can cost a utility approx. $1M a day in replacement power costs.

On any given day in the US, around 90,000 people are admitted to an intensive care unit. Average stay is 4 days per patient; survival rate is 86%. Israeli study (1994): average patient required 178 individual actions (touches) per day, ranging from administering a drug to suctioning the lungs, and every of them posed risks. Doctors and nurses were observe to make an error in one percent of these actions (99% error free) amounting to approximately two errors a day with every patient. (Gawande, A. (2009), *The Checklist Manifesto*, pp.23-24)

- Course Goal: To exert control over something that is resistant to control – human fallibility, to minimize the frequency and severity of events and accidents.
- New way of thinking about safety, about human performance; state of the art approach to avoiding events triggered by human error.

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Work Instruction HOP demo

Study: if the speed limit is posted at 65, when there is very little traffic, good visibility, good road conditions, and not a cop in sight, how fast will you likely drive your car?

Saying failure was caused by human error is like saying a fall was caused by gravity…

They both are true but incomplete.

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To err is human …

To deviate is also human …

- We are outcome-based and value immediate and certain results
- We make decisions to achieve the results we desire
- As we try to do more with less, we drift away from expected behaviors

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The question we always have to answer…

"Why did the choice the employee made, MAKE SENSE to them at that time and under the existing circumstances?"

If you cannot answer this question, your investigation is not finished. Some events may not allow you to fully answer this question (e.g. fatality), but this is the goal.

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Drift

- How leaders IMAGINE work is being done
  - Work is always consistent
- How work IS being done
  - There is a lot of production variability (Drift)
- Question: “When does the organization normally discover drift?”
- What is the typical reaction?”

People are outcome-based and value immediate and certain results. They make decisions to achieve the desired results. As they try to do more with less, they drift away from expected behaviors. The workers know how to do the job, what the risks and pitfalls are and how to navigate through the multiple conflicting requirements to get successful results

Local Rationality

"It seemed like the right thing to do at the time?"

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Thoroughness vs Productivity

1. People routinely make a choice between being highly efficient (productive) and being thorough (safe or compliant), since it is rarely possible to be both at the same time.
2. If demands for productivity are high ("go" time), thoroughness may be reduced until productivity goals are met.
3. If demands for safety and compliance are high ("safety time" (following an accident perhaps) efficiency may be reduced until the safety goals are met.

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Drift and Accumulation

- Factors that drive “Drift”
- Mgt allows DRIFT –
- Example: UHP gives a speed buffer over the posted limit.
  - Chance of getting caught is low
  - Risk vs. Benefit – Relatively low risk if caught
  - Perception of risk – Driver doesn’t feel they will get hurt driving faster than the limit (so far!)

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Work Instruction (WI)

- The WI is one of the key document in any given manufacturing activity. (Can you list any others?)
- WI contains a detailed set of instructions that describe exactly how a manufacturing activity must be performed.
- Discussion: when is a WI too detailed? Not detailed enough?
- Challenge:
- - How should your work instruction refer to the components being assembled? By part no? Reference no? Assy no?
- - The impact of duplicating the BOM in the work instruction is that the WI may be required to change for every BOM change. Thoughts?

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Work Instruction (WI) - Requirements

- PURPOSE / SCOPE:
  - Short statement of the purpose / scope of the WI
- DEFINITIONS
  - A description of the meaning of terms specific to the WI
- REFERENCES
  - Documents that are referenced in the body of the procedure
- MATERIALS:
  - Some WI's may contain an itemized list of the product affected by the work instruction. Discussion?
- TOOLS and EQUIPMENT
  - List specific/special tools, equipment and materials required to perform the instruction. Torque tools, and limits? Discussion of torque and impact of decisions.

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Work Instruction (WI) – Requirements Cont.

Instructions

1. Identify Step-by-step Actions Required To Perform The Task:
2. Identify Special Working Conditions
3. Identify Requirements/Specifications Such As Pressure, Temperature, Voltage Settings, Etc.
4. Identify Accept/Reject Criteria
5. Identify Data Records And/Or Forms That Must Be Completed.
6. Include Aids That Will Help The User Such As Flow Diagrams, Checklists, Diagrams, Schematics, Tables, Etc.

– Quality Records

Identify The Necessary Quality Records To Provide The Objective Evidence That You Met The Assembly And Test Requirements.

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Work Instruction (WI) – Requirements Cont. 2

- Defect Awareness
  - Section where defects and impact of defect may be included.
- Discussion:
  - Use of photos? Level of detail in the document?
- WI as a training document compared to detailed work instruction compared to assembly guide?

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Batch Record

- The batch record is the manufacturing data for a specific product lot. The batch record must contain:

- A document number, title and revision
- Fields to record:
    - Date of manufacture
    - Part # / lot # information for both manufactured & consumed parts
    - Quantities consumed (if applicable)
    - User identification (signature and date)
    - Process specific measurements (temp, time, humidity, etc. all as a function of the product being made).

–The main purpose of the batch record is to have written proof of what occurred during the Manufacturing Process.

Part numbers/Lot numbers/Revisions-

- Part numbers
  - Used as a locator to find the item in the database
- Lot numbers
  - Segregate large batch into manageable quantity
  - Assigned to date-sensitive materials for production scheduling
- Revisions
  - Track changes to the item
  - Maintain traceability of part number
  - (not always tracked on BR, although the BR revision is)

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Manufacturing components

- Raw Materials:
  - must be received and checked for quality
  - must be tracked throughout its use in the Manufacturing Activity by using an ID code (usually a part number)
  - the ID code will appear on all BOM and work instruction documents. (Remember: will the BOM be included in WI?)
- Manufacturing Activity:
  - Governed by the WI
- Verification:
  - accomplished by comparing to a standard

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The Process of Manufacturing can happen in many different ways:

1. One person performs all of the tasks to produce the device at one sitting - home cooking.
2. Someone at another location can do part of the work to a large batch of parts and send them to a different location for final processing - restaurant cooking.
3. It can be written to divide the work into individual tasks that require the same amounts of time to accomplish, then assign a team of workers to perform the tasks simultaneously - automaker.

Line Clearance: Included in WI? Stand alone WI?

- Line clearance may include:
- The area must be clean. (Thoughts?)
- There must not be any traces of previous stage material. (Exceptions?)
- There must not be excess tools / equipment as they can affect smooth functioning. (Thoughts?)
- Inspect equipment for cleanliness, functionality, safety, PM, cal stickers, etc. (Thoughts?)
- Inform supervisor if any discrepancy is observed.
- FDA audits look for Line Clearance: Why?

Lab Activity : Lego building

- Raw Materials—BOM
- Manufacturing activities
- Work instruction (read, understand)
- Perform (follow instructions)
- Verification---compare to standards

Do it in three different ways:

first individual: all blocks are unsorted, both by color and size. Record how long it takes for each person to make two dogs (all three manufacturing simultaneously)

After: disassemble into one bag

second: team with mixed material: each person has one task (body, tail and legs, or head). How long does it take to make six dogs?

After: disassemble into sorted bags labeled 1) Body, 2) Tail & Legs, and 3) Head

last team with sorted stations: each person has one task (body, tail and legs, or head). How long does it take to make six dogs?

{From prior class: Record time for each building activity or total of product made in a given time.}

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Assignments

- Review your submissions, grades, and completion.

- Contact Paul Tinker if you want to re-submit a quiz or homework to improve your point total.

- Review concepts covered to determine if you need more time, instruction, or help to learn the concepts.

- Determine if the class (lecture, lab, homework, quiz, etc.) meets your needs and desires. Contact Paul Tinker if you feel some part of the class is not addressing your needs.