CEMD 0920

Salt Lake Community College

Basic Manufacturing Skills Week 6

c3bc Community College Consortium for Bioscience Credentials

This product was funded by a grant awarded by the U.S. Department of Labor's Employment and Training Administration. This product was created by the grantee and does not necessarily reflect the official position of the U.S. Department of Labor. The Department of Labor makes no guarantees, warranties, or assurances of any kind, express or implied, with respect to such information, including any information on linked sites and including, but not limited to, accuracy of the information or its completeness, timeliness, usefulness, adequacy, continued availability, or ownership.

Modeling the effect of Training on the Manufacturing Activity

Salt Lake Community College

The Effect of Training

Simple heart with written instruction

- Origami Heart

Water balloon with video & written instruction

- Origami Water Balloon

Desk organizer with instructor demonstration

- Origami Square Base
- Origami Desk Organizer

Salt Lake Community College

Manufacturing Activity Discussion

- We completed 3 Manufacturing Activities:

1. Read, Analyze, and Do: origami product
   - How was the shape and quality?
2. Ready, Analyze, Watch, and Do:
   - How was the shape and quality?
3. Ready, Analyze, Watch, Follow, and Do:
   - how was the shape and quality?

What was the effect of Proper Training on the Manufacturing Activity?

Salt Lake Community College

The Process of Manufacturing Discussion-GMP review

- All training must be current!
- Perform Line Clearance before manufacturing.
- Under NO circumstance should the employee make any changes to the MP on his/her own, even if he/she knows exactly what is wrong and can fix it easily.
- Stop performing the activity if you observe that something is going wrong. You can inform the supervisor of all concerns.
- Perform final Line Clearance after the activity is complete.

It is Essential to Follow the MP Exactly!!!

Salt Lake Community College

It is Essential to Follow the SOP/WID (MP) Exactly

Example: the WID calls for 10,000 tubes to be cut to a certain length, and in-process inspection requires that the tubes be cut in groups of 100 then a random sample of 10 tubes be pulled from the group of 100 and measured using a ruler. The average length of the sample is calculated and recorded on the form included in the batch record. If the WID calls for this average to be written down prior to cutting the next group of 100 tubes but the operator cuts 500 tubes before stopping to measure them, then the entire group of 500 tubes is suspect and must be set aside. This is called a discrepancy, and must be written up in a Non-Compliance Report (NCR) (aka a Discrepancy Report (DR)). The Quality Control department must get involved and the tubes must undergo further analysis, usually at a significantly higher cost and time than intended, even though the tubes may all be within the correct specification for length.

It is Essential to Follow the SOP/WID (MP) Exactly Cont.

An example of this is an operator who was gluing foam sides to a movie reel. The adhesive felt too stiff so the operator added some thinner to the adhesive to make it easier to spread onto the foam. This appeared to solve the problem and the operator did not tell anyone what he had done. All seemed well until several months later when a film company called the company to complain that their reels were causing films to tear as they fed off the reel. It turned out that the thinned adhesive wicked through the foam and soaked into the film, gluing the film together and causing it to tear. Since these films were the master copies of several hundred blockbuster movies, many multi- millions of dollars were at risk. The reel manufacturing company had to set up a large and expensive special group to painstakingly un-reel the film of each movie to every spot where it was stuck together (several locations per revolution) and carefully swab the adhesive off with a mild solvent. This cost the company several million dollars in extra labor and incalculable cost in goodwill within the market.

DR/NCR & CAPA

Discrepancy Report / Non-Compliance Report:

- This is a document that is prepared to describe a problem that is encountered during the manufacturing activity, who discovered it, the affected parts, and when the problem was first noticed. (CFR 21, Ch. I, Sub. H, Part 820.90)

Corrective Action, Preventative Action:

- This is a document that is prepared to describe a problem that is encountered during the manufacturing activity, who discovered it, the affected parts, and when the problem was first noticed. (CFR 21, Ch. I, Sub. H, Part 820.100)

Discrepancies
Products that don't meet the specification are discrepant / non-compliant

- A Non-Compliance Report (NCR) / Discrepancy Report (DR) is filled out
  - Description of the problem
  - All document numbers that are affected
  - Number of parts involved
  - Date/time the problem was first noticed
- Notice that the operator must not try to solve the problem
- A Material Reject Board (MRB) team may include the operator
- Solutions must be tested and approved prior to implementation

Assembly Skills – Past the Introduction Level

Manual dexterity

ESD avoidance

Technical writing

- In-process inspection

Clean room habits

Salt Lake Community College

Medical Device Assembly – Past the Basics

Three aspects:

Process

- Components
- Process documents
- In-process inspection (next week)

Verification/Validation

- Control process to control product

Packaging/sterilization

- Package testing
- Sterilization validation

Salt Lake Community College

Verification & Validation

Verification

- ensures the product is designed to deliver all functionality to the customer; it typically involves reviews and meetings to evaluate documents, plans, code, requirements and specifications; this can be done with checklists, issues lists, walkthroughs and inspection meetings. You CAN learn to do verification, with little or no outside help.

Validation

- ensures that functionality, as defined in requirements, is the intended behavior of the product; validation typically involves actual testing and takes place after verifications are completed.

Verification & Validation Cont.

Verification (did you build it well, to print, to spec?) takes place before Validation (did you build what the customer wanted?

Why is this? How do you know what the customer wants?

- Verification evaluates what you assembled or built against its design requirements. The inputs of verification are BOMS, drawings, technical specs, inspection results, DMR documents, etc. The output of verification is a set of documents, plans, specifications, and requirement documents.

- Validation evaluates the product against the need that the product was designed to satisfy. The input of validation is testing the actual product against the original “need”. The output of validation is an actual product that meets the customers needs.

Verification & Validation Cont. 1

Validation: Are we building the right system?

Verification: Are we building the system right?

- Unified Modeling Language (UML) a general-purpose modeling language in the field of software engineering, which is designed to provide a standard way to visualize the design of a system.
- accepted by the International Organization for Standardization (ISO) as an approved ISO standard.

Past the Basics

Packaging and /sterilization (CFR 21, Ch. I, Sub. H, Part 801.150 & CFR 21, Ch. I, Sub. H, Part 820.130)

Procedures developed according to the User Requirement Specification (USR).
Must go through documented development and implementation:

DQ – Design Qualification

IQ – Installation Qualification

OQ – Operational Qualification

PQ – Performance Qualification

DQ, IQ, OQ, PQ

DQ – Design Qualification

IQ – Installation Qualification

OQ – Operational Qualification

PQ – Performance Qualification

DQ, IQ, OQ, PQ Cont.

DQ – Design Qualification

IQ – Installation Qualification

OQ – Operational Qualification

PQ – Performance Qualification

Note: 21 CFR Part 820 and ISO 13485:2003 have explicit elements requiring the manufacturer to perform tasks associated with IQ's, OQ's and PQ's, but these terms are not defined and the actual abbreviations don't even appear.

- 21 CFR Part 820.75 “Process Validation”
- It is an expectation that manufacturers will validate their production processes. For IVD manufacturers, production processes typically requiring validation include sterilization, cleaning, mixing, storage and labeling.

DQ, IQ, OQ, PQ Cont. 2

What about IQ/OQ/PQ in your plant?

Can you think why manufacturing equipment would or would not be subject to the same requirements as IQ/OQ/PQ at the customers site?

See compendium.

FDA Warning Letter assignment

- Homework: Read your choice of warning letter and write a short synopsis addressing:
- The type of device in question
- Whether or not some kind of problem with documentation was noted in the warning letter
- What did the company do to provoke the warning letter from FDA
- The part of Title 21, Chapter 1, Subpart H, Section 820 that the company has failed to satisfy.

Salt Lake Community College

Gage Repeatability & Reproducibility (time allowing)

- Gage R&R is an analysis technique to assess your measurement systems using an analysis of variance (ANOVA).
- The analysis is applicable to all types of measuring instruments, test methods, and other measurement systems.

Gage R&R (If we have time)

- Several factors affect a measurement system:

•Measuring instruments and the mounting blocks, supports, fixtures, load cells (etc.): The machine's ease of use, sloppiness among mating parts, and fixtures contribute variation to the measurement system. When making electrical measurements, electrical noise and cabling may contribute to system variation.

•

Gage R&R (If we have time) Cont.

- Operators (people): the ability of a person to follow the written / verbal instructions.
- Test methods: how the devices are set up, the test fixtures, how the data is recorded, etc.
- Specifications: the measurement is reported against a specification or a reference value. The tolerance does not affect the measurement, but is an important factor in evaluating the viability of the measurement system.

Gage R&R (If we have time) Cont. 2

•Parts being measured: some parts are better suited to one type of measurement system than another. For example, a specific measurement system measure steel block dimensions well but may not measure injection molded plastic pieces well.

Gage R&R (If we have time) Cont. 3

- Repeatability: The variation in measurements taken by a single person/instrument on the same item under the same conditions.
- Reproducibility: the variation when different operators, instruments, or laboratories measure the same specimen

Gage R&R (If we have time) Cont. 4

- Gage R&R assesses the precision of a measurement system.
- To determine if a measurement system is acceptable you will determine the ratio of the measurement system precision to the total tolerance available to the part or process.
- If the ratio is low (~10%), the amount of product variation due to the measurement system is small.
- If the ratio is >~25% the measurement system is "eating up" allowable tolerance from the process or part variation and you may choose not to use it.

Gage R&R (If we have time) Cont. 5

- The calculations for the analysis are significant.
- After collecting the variable measurements (multiple operators performing repeat measurements on a series of product or process), the analysis is best performed by a computer program that automatically performs the calculations.