

Quality Assurance and Quality Control (Lecture 7)

What is Quality

- The ability to do the same thing the same way, over and over again
- Customer buys today is same as what they bought last week or will buy next week
- The product meets customer's expectations 100% of the time

From where quality programs begin

- Marketing has defined the customer expectations.
- Product development has created a product that meets those expectations.
- Engineering has designed a process to make the desired product.
- Now, all QA must do is design a control system which verifies that everything is working as designed.

Quality Relationships



Quality Assurance (QA)

- QA is a set of activities for ensuring quality in the processes by which products are developed.
- QA aims to prevent defects with a focus on the process used to make the product. It is a proactive quality process.
- The goal of QA is to improve development and test processes so that defects do not arise when the product is being developed.
- Establish a good quality management system and the assessment of its adequacy. Periodic conformance audits of the operations of the system.

- Prevention of quality problems through planned and systematic activities including documentation.
- Everyone on the team involved in developing the product is responsible for quality assurance.
- Verification is an example of QA.
- Statistical Tools and Techniques can be applied in both QA and QC. When they are applied to processes (process inputs & operational parameters), they are called Statistical Process Control (SPC) and it becomes the part of QA.
- QA is a managerial tool.
- Covers everything from raw materials and GMP verification till finished-product release.
- HACCP and GMP is part of QA.

Quality Control

- QC is a set of activities for ensuring quality in products. The activities focus on identifying defects in the actual products produced.
- QC aims to identify (and correct) defects in the finished product. Quality control, therefore, is a reactive process.
- The goal of QC is to identify defects after a product is developed and before it's released.
- Finding and eliminating sources of quality problems through tools and equipment so that customer's requirements are continually met.
- The activities or techniques used to achieve and maintain the product quality, process and service.
- Quality control is usually the responsibility of a specific team that tests the product for defects.
- Validation/Software Testing is an example of QC.
- When statistical tools and techniques are applied to finished products (process outputs), they are called as Statistical Quality Control (SQC) and comes under QC.
- QC is a corrective tool.
- Actual manufacturing process.

Installation of QA Plan

a. Organization of department

- Make use of supervisors

b. Amount and quality of training that affects finished product quality

- Every line employee should be trained
- Verify job is being done correctly

c. Automation of process changes, types and quantities of analyses needed

- Speed of testing
- What level of accuracy is necessary
- Maintenance and calibration of lab equipment
- Training of technicians
- Verification of accuracy and variation of technicians

QA Operation

- Reviewing the daily lab and production reports is a part of the QA responsibilities. This is to determine that the procedures are being followed and the tests are being made. QA can spot trends by conducting consistent record reviews. If record reviews don't stay current, no one will get timely feedback before a real problem crops up.
- If certain tests take several days to complete, the department must create a record review, and a well-coordinated release procedure must be developed so that the product is not shipped prior to the completion of all the tests.
- Electronic, as well as actual, inventory-control procedures are necessary, and fall under the supervision of QA.

The question is easier to answer with food-safety issues than with quality deviations.

- With food safety, if you don't know or there is doubt, you do not ship anything.
- However, with quality deviations, the manager must ask how bad the out-of-specification condition is.
 - ✓ Previous customer complaints about a problem can be reported along with the test data.
 - ✓ One recommendation might entail a quality review committee established by upper management that will make these decisions based on the data furnished by QA.

- ✓ This should occur at a management level that understands the total ramifications of a decision to ship or not ship the product. Usually, these are the people that established and approved the original product specifications.
- Production and purchasing should get feedback regarding raw-material and finished-product compliance, both the good, as well as the bad.
- These departments need advance notice of any negative trends that have been detected before they become out-of-specification problems.
- Recommendations on how to improve the process are always helpful, especially if someone has been observing the causes and effects of the various process inputs on the final product.
- Companies must avoid overly restrictive specifications that are not directly linked to product safety, government regulations or product quality, since these only raise the cost of the operation.
- QA is the voice of the customer in the plant.
- Establish the expectation that the products that are to be made will meet the specifications of the customer.
- Go to the people on the line and explain what the customer expects from the products.
- Get out of the office and ask the people what is going on.