Case Study 2 - Medical Grade Rubber Compound

A company developed a medical grade elastomeric compound to be used in a sterile device. This was a new formula that was developed to provide the required polymeric properties to aide in its intended use. The commercial launch of the new product was planned within a short period of time.

Upon auditing the facility it immediately became apparent that a number of technical issues were present when auditor asked to see the production area used to manufacture the initial parts. A batch record was requested to review the initial batches produced at the facility.

The following observations were made concerning the audit:

1. Production equipment was not used due to cleaning issue with the new rubber compound.
2. No batch record with the formula was available.
3. An audit of the production facility showed that the initial batches were compounded in an R&D facility using non commercial equipment.
4. No testing procedures or data were available for the initial batches manufactured.
5. The exact formula and process conditions were not recorded.
6. The commercial equipment had not been purchased nor had any work been initiated to qualify such equipment.
7. No production plan was developed to support a new product launch within the next 6 months.
8. The initial batches were made with uncontrolled compounded rubber compound.
9. Product specifications were not developed.
10. Cleaning procedures were not developed.

QbD offered the following suggestions:

1. Repeat the initial compounded batches using a documented formula and a batch record.
2. Develop the specifications and test methods for the compounded rubber.
3. Evaluate commercial scale equipment for compounding.
4. Develop preliminary specifications.
5. Produce parts made from the commercial compounding process.
6. Initiate stability testing on the parts manufactured.

Final Outcome of QbD recommendations:

1. A consistent process was developed that meet required specifications.
2. A commercial process was developed.

These audits are normally conducted for compliance regulation but as a result of some observations technical issues are noted and further investigation is performed. QbD principles aligned together with compliance yields design and product performance with expected quality requirements.