Self Inspection – GMP audit

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What is it?

- Review of one's own operations
- Identifies defects which may be:
  - Critical
  - Major
  - Minor
- Monitors implementation and compliance of a process
- Ensures corrective actions are put in place

What to consider

- All manufacturing processes should be defined and capable of manufacturing products for the intended use.
- Qualification and validation are performed.
- All necessary resources are provided.
- Instructions and procedures are written in clear and unambiguous language.
- Procedures are carried out correctly and personnel are trained to do so.
- Records are made during all the manufacturing processes.
- Records cover both manufacturing and distribution to show the complete history.
- The proper storage and distribution minimizes any risk to their quality and takes account of good distribution practices.
- A system is available to recall any batch of product from sale or supply.
- Complaints are examined, investigated and taken care of.

Why do it?

- Evaluate the operating processes and systems
- All aspects covered
- Prevent and overcome problems

Regulators expectation

- Planning and completion
- Written reports with all observations documents
- Actions to put things right documented and completed within the identified timescale