7.5.2 Validation of processes

Process validation demonstrates the ability of the processes to achieve planned results.

* Define what controls are required (e.g. time, temperature, pressure)
* Define the level of training and competence required
* Approve equipment
* Use detailed work instructions
* Periodically re-validating the process

Validate production and services by:

* Proving that special processes have achieved planned outputs
* Proving that process owners are capable of achieving planned results
* Proving that process equipment is capable of achieving planned results
* Maintaining records

Your organisation should define arrangements for validation that include the following:

* Qualification of processes
* Qualification of equipment and personnel
* Use of defined methodologies and procedures
* Requirements for records
* Revalidation

### Should I document our production and service validation process?

It is not a mandatory requirement to document your service and production validation processes. However, you should always look to adequately define and control any operational processes that directly impact upon product quality. Therefore, the implementation of a service and production validation procedure will be appropriate to most businesses where such activities are undertaken.

### How's best to document the process?

Develop and implement a procedure that defines:

* The criteria for review and approval of processes
* The level of approval for appropriate equipment
* The level of competence required for staff to validate the process
* Any particular methods and procedures that may be required

### Measuring production and service validation effectiveness

The effectiveness of the production and service validation may be evaluated by reviewing all elements of process and by looking for evidence that all activities are planned and conducted under controlled conditions.