

## END SYSTEM LIMITED - FULFILLING YOUR SPECIALIST NEEDS

Besides ensuring the safety and well being of patients, in order for pharmaceutical manufacturers to market products in the US and continental Europe it is necessary for them to meet the strict requirements of the US Food and Drug Administration (FDA) and their European equivalent, the Medicines and Healthcare Regulatory Agency (MHRA). These requirements are addressed by following the process of validation.

Validation has formally been defined as “the process of establishing documented evidence which proves a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality characteristics”. Although making direct reference to product manufacture, the definition lends itself in principle to any item of equipment or service which by its nature or function has the potential to impact upon product quality.

***“Take the worry out of handover”***



End Systems has a team of experienced Validation Engineers available to meet the requirements of the Food and Drug Administration and the Medicines and Healthcare Products Regulatory Agency.

This validation service is offered to the following:-

- Clean Room Environments
- Process Equipment
- Process Services

We have an in depth knowledge of current best practice and computer validation to current GAMP\*\* standards.

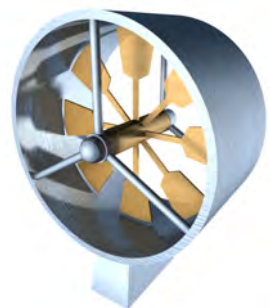
End Systems carryout the preparation, processing and execution of Validation Master Plans, Validation Plans, Functional Specifications, Installation Qualifications and Operational Qualification. These can be tailored to suit your project requirements.

We also carryout supplementary project support services to compliment our activities such as Work Package Co-ordination and Project Data Manual Preparation including the preparation of pressure vessel/relief registration packages.

\*\* Good Automated Manufacturing Practice.

End Systems Limited, the only choice For:

- Commissioning Management
- Commissioning & Testing
- Validation
- Technical Documentation
- CAD Services
- Building Leakage Testing
- Water Treatment



For More Information:

Telephone: 01942 673229

Email: [enquiries@endsystems.co.uk](mailto:enquiries@endsystems.co.uk)

Internet: [www.endsystems.co.uk](http://www.endsystems.co.uk)