honeyman

Pharmaceutical Process Support

enquiries@honeyman.co.uk
www.honeyman.co.uk

Process, System and Equipment Upgrades...

Do You Have...?

Unsupported and Non-Compliant cGMP Processes Systems or Equipment?

That are Obsolete, Unreliable and Difficult to Operate?

Avoid the expensive and time-consuming process involved with replacing your processes, systems or equipment and join the growing number of pharmaceutical, biotech and medical device companies opting to upgrade their facilities for a fraction of the cost.

Applied to all types of cGMP equipment including; Autoclaves, Ovens, Steam and Pure Steam Generators, Steam Distribution Systems, Filling Machines, Purified Water Generation Systems, Purified Water/WFI Distribution Systems and WFI Stills, our upgrades minimise capital investment costs, reduce disruption to your processes and ensure continued confidence in compliance.

We can assess the current design and offer a risk based approach to delivering the compliance and reliability you need. Our experience in this area has delivered more efficient, cost-effective and improved timescales by targeting the critical control points within the process. Tools such as HACCP and FMEA are applied under the ICH Q9 and ASTM 2500 framework.

Our risk based approach means that we can offer an efficient and cost effective approach to the life cycle of design and engineering services for the upgrades we carry out including:

- Development of the URS
- Option Studies
- Criticality Assessments
- Design
- Project Management
- Equipment Procurement
- Equipment Qualification

- Control System Development and Software Validation
- Validation Documentation (DQ, IQ, OQ and PQ) and Invigilation
- Factory and Site Acceptance Tests (FAT/SAT)- Commissioning
- Service and Maintenance

Our bespoke service contracts all include a component criticality matrix to ensure that throughout the process, system or equipment lifecycle, capability and performance are fully optimised.

Why Upgrade?

Significantly Lower Cost:

Typically save 80% of overall project cost.

Project Timescales Cut:

Reduced from 15 months to just 3 months!

Production Outage Time Dramatically Reduced:

No need for major re-building work or the upheaval of removing redundant equipment.

Compliant to Latest Regulatory Requirements:

Full GAMP and retrospective equipment / systems validated to IQ, OQ and PQ.

Fully Supported:

Access to our full remit of pharmaceutical process support services including; process validation, servicing, maintenance and on-going technical support.

honeyman

Pharmaceutical Process Support

enquiries@honeyman.co.uk
www.honeyman.co.uk

Xenova BioManufacturing – Control System Upgrade...

The Client:
Xenova BioManufacturing is a contract manufacturing organisation providing biologics development and manufacturing to the biopharmaceutical industry.

Location:
Cambridge, U.K.

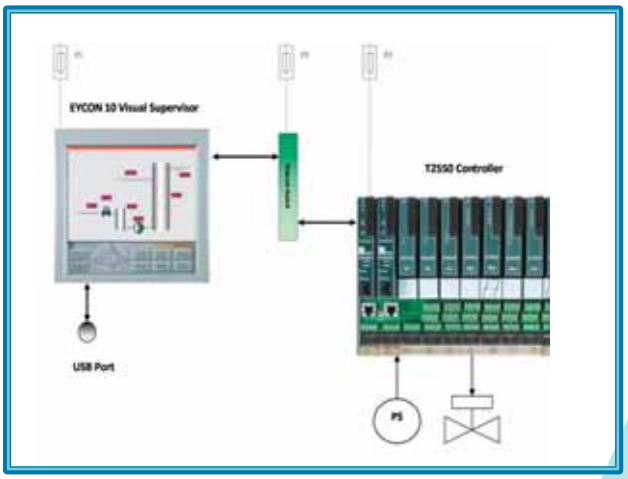
Project Scope:
Design, manufacture, test, install, commission, validate and project manage the upgrade of the control system for a Pure Steam Generator (PSG).

Project Duration:
6 weeks from commencement of system construction.

The Project:
Pure Steam Generator Control System Upgrade

Due to the existing PSG control system being old and unsupported, Honeyman were engaged to provide a modern, industry recognised and supported control system.

The control system upgrade comprised of a DCS solution (Eurotherm EYCON 10 Visual Supervisor with T2550 rack mounted controller). The existing Kemotron 1902 conductivity analyser was retained, as were all external field instruments.



The existing control system was fitted with an independent chart recorder to monitor historical data (feed water and pure steam conductivity). This outdated system was removed and replaced with electronic data storage, within the EYCON 10.

The Eurotherm EYCON 10 Visual Supervisor provides the operator with a graphical process interface, and is used to execute across-network control operations. Process mimics, historic trend displays, password controls and alarm and event logs fully inform the operator of system status ensuring compliance with 21 CFR Part 11. Touch screen features are provided for screen navigation and execution of operator commands.

Compared to replacing the entire PSG, the upgrade project not only incurred significant cost savings but also minimised production down-time. Since completion of the project, Honeyman have secured the service and maintenance contract for the pure steam generator and are also involved in steam quality testing exercises.

Registered Office:
Honeyman Group Limited, Harmire Enterprise Park, Harmire Road,
Barnard Castle, County Durham, DL12 8BN, U.K.
Registered in England & Wales 03308581

Telephone No: **+44 (0)1833 690101**
Fax No: **+44 (0)1833 690102**
Email & Website: **enquiries@honeyman.co.uk www.honeyman.co.uk**