



Turnkey Purified Water Project



Gerard Laboratories

Location
Baldoyle, Dublin

Background

Gerard Laboratories based in Baldoyle, Dublin is a fully owned subsidiary of Merck KGaA of Germany, now one of the top ten generic pharmaceutical manufacturers worldwide.

Employing over 300 people the plant manufacturing tablets and capsules for the European market, supplying over 1,500 products.

Following a number of years of production expansion the site began to experience difficulties with their Purified Water system which had been installed in 1986. Various remedial measures were taken to keep the system operational. In mid 2004 a decision was made to completely replace the system and fit a new Purified water Generation, Storage & Distribution, and Control system.

Front End Design

Gerard Laboratories contracted Honeyman Ltd to undertake an initial study of the plants purified water requirements and produce a front end design of a state of the art system to replace the existing.

A location for a new plant room was identified in a warehouse adjacent to the production building and the route and user points of the distribution system identified. By late summer 2004 a URS and an outline plan for the new distribution system was in place.

At this stage parts of the old system were condemned and purified water was delivered by portage which was leading to real production losses and a serious effect on plant efficiency.

Competitive Tender

In August 2004 Gerard invited suppliers to tender for the supply of individual components.

The initial tender request broke the project up into three main packages

- Purified Water Pre Treatment and Generation
- Storage, Control and Distribution skid
- Mechanical installation of Purified Water Loop

The project as envisaged at this stage was particularly onerous as Gerard Laboratories required the new system to be installed and commissioned by the end of January 2005.

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Loop installation was critical as the plant would remain in production and some areas of the proposed route were not available for visual survey.

Following receipt of tenders from the various suppliers Gerard realized that the project had now become so critical that the risks of delays, and implementation by employing a number of suppliers put the planned 2005 production schedule in serious doubt.

It quickly became apparent that a Turn-key contract offered the best solution to the tight schedule required to meet the January deadline.

Three suppliers were invited to offer Turn-key proposals and in early September Puretech were awarded the contract.

Puretech were selected as they were the only supplier that offered the complete package from their own in house resources.

Other competitors relied on subcontractors to install the loop or the control system, whereas Puretech had the experience and capabilities to supply and install the complete package.

System Description

The system selected was designed to deliver 800l/hr of purified water conforming to the USP 27 standard.

Major components included, Profilers, Raw water Storage tank, Water Softening Plant, Activated Carbon back washable filters, Heat Sanitizable Genesys Purified system based on Reverse Osmosis/CEDI technology.

The Genesys Control system based on a Eurotherm T800 controller and HMI interface controls the operation of the entire system and is compliant to the 21 cfr part 11 standard.

Water is stored in a 5000l Stainless steel storage vessel polished internally to 0.5 @m RA, level control is based on radar technology.

Water is supplied to 18 user points over two floors via two 316l 0.5 @m RA distribution loops.

The storage and distribution system is heat sanitized via a 316L double plate and frame heat exchanger which raises the circulating water temperature to 80°C.

A similar in line trim heat exchanger maintains the circulating purified water temperature at 20°C during production.

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Project Execution

A Project team was quickly put in place under the sponsorship of Technical director Gary Littlewood.

Design Qualification tasks were managed by Design Manager Lynn Haines.

Pretreatment design and Genesys Purified Water designs were managed by Development Director John Parks.

Site Establishment, procurement and loop installation was managed by Senior Contract Manager Robert Cafferty.

In early October 2005 installation work on each of the two distribution loops commenced, over the next seven weeks over 400 meters of high purity pipework and 18 user points were put in place. As the plant continued to operate 24 hrs a day/7 days a week close liaison with plant management was vital.

Installation had to plan around production which always took priority and sections of the loop were installed at night and at the weekend.

In Parallel to loop installation the Construction of the Pretreatment, Genesys Purified Water and Storage and Control skids was undertaken at the Puretech facility in Redhill.

In December 2005, FAT was completed in Redhill and the Skids shipped to Dublin.

By Christmas 2005 the major components of the new system were in place and the team took a short but well earned rest.

In early January utility tie ins were established and the system was commissioned.

The IQ was executed and the system handed over to client in mid January 2005.

P/Q was undertaken by Honeyman Ltd and the system supplied water to production in early April 2005.

References

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