

# **Batch Execution Case Study**

**When Novotek Solutions implemented a Batch Execution system for one of the world's largest pharmaceutical companies, product-based solutions delivered an array of benefits.**



## Background

Novotek's client is a large multinational that manufactures an impressive range of medicines and consumer health products, from toothpaste to nicotine replacements. In 1995 they commissioned a mouthwash manufacturing suite in Berkshire, and few years later at the same site, work commenced on a second plant known as 'Mouthwash 2'. This plant, which still operates today, replaced the original to manufacture, blend and pack a higher volume of well-known mouthwash brands. Novotek has provided system support since its installation, and system engineers have an exceptionally detailed knowledge of the manufacturing process and systems which deliver production.

More recently, the client completed the R&D process for a new mouthwash product formula, and additional production capacity was required to prepare

for the product launch. Novotek engineers were called in again – this time to implement a new batch process control system for a third manufacturing plant, ensuring effective implementation and long-term supportability. Operating within the highly competitive pharmaceutical market, the client relies on continuous innovation for survival, so 'Mouthwash 3' presented the ideal opportunity to install the latest in advanced batch production software technology.


## Solution

While the existing Mouthwash 2 production facility provided a basic mechanical template for the new Mouthwash 3 plant, Novotek recommended the implementation of a Proficy Batch Execution software solution. This was to provide a significant upgrade in functionality when compared with the now legacy Mouthwash 2, equipping the manufacturing suite with a large

range of new software capabilities such as an ISA-88 compliant unit with phase based recipes and formulations, detailed visualisation and alarms, in addition to a full batch reporting system.

As a Premier Solutions Partner for GE, Novotek Solutions' engineers were able to effectively maximise the functionality of the product to suit their client's specific requirements, using its full set of tools, open architecture and intuitive user interface. During the project Novotek worked alongside the principal contractor and well-respected partner T-Musk Engineering, who provided the necessary process design, project management and mechanical/electrical installation.

When the site was reclassified to producing medical grade products instead of cosmetic, processes and projects came under greater scrutiny from the Computer Systems Validation (CSV) department.



**Our team work closely with your key stakeholders to understand the ambitions of your improvement's programme.**

**Looking beyond any individual project, we'll set your operation up to be fit for the future and ready for any upgrades.**

While the implementation of standards based systems using Commercially available Off The Shelf (COTS) products is always a significant advantage when working under the auspices of GAMP, Novotek were required to provide the additional assistance necessary during project validation and qualification stages required to gain 'production ready' approval.

Challenges around the skills gaps of production and engineering support staff were overcome by the provision of formal operation and maintenance training sessions run by Novotek engineers on site as well as the provision of an on-going technical support contract.

The Mouthwash 3 manufacturing plant provides mouthwash to a brand new and dedicated bottling line. The new bottling line is designed to run at 180 bottles per minute requiring Mouthwash 3 to turn round 6000L batches of concentrated product every two hours.



It also adheres more tightly with the ISA-88 Batch Control standards and the product's implementation of them, with the primary outcome of providing the site with a more robust and supportable system, which presents the absolute minimum customisation.

The new system provides a more comprehensive picture of batch operations when compared with its immediate neighbour, Mouthwash 2. This will help to drive continuous improvement initiatives, facilitate wider information sharing and electronic batch records. The client now has the potential to bring new products to market more quickly, with reusable recipe components, a common equipment model and process simulation capabilities.

*“Novotek has responded to our requirement to introduce a new product formula by providing what has proven to be flexible and robust batch control system. Plant operators are able to produce batches and blends easily, with faster access to system information. The level of batch and audit trail reporting available has helped improve accountability across departments, which in turn aids plant maintenance and drives performance improvements. Further product variants have been introduced with ease since the system went live”*

Project Manager





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