

Case Study: InfoPlus.21 Speed Boost

Sometimes a problem is purely technical and only needs a technical solution.

A number of pharmaceutical manufacturers use AspenTech's InfoPlus.21 (IP21) system to archive data about production runs. To satisfy regulatory requirements for record-keeping about drug batches, IP21 can be set in 21 CFR Part 11 mode to ensure that data cannot be modified after it is stored in the proprietary database.

The Situation

A particular pharmaceutical company which we will call 'Med Makers' wanted to apply for a license to sell a new drug. Unfortunately, the drug is unusually complex to make. For evidence supporting the license, Med Makers needed to acquire data into IP21 at a rate orders of magnitude higher than it or its two favourite systems integrators had ever been able to accomplish.

Previous efforts outstripped IP21's input bandwidth when acquiring data from a 14 position tablet press running at high speed. A systems integrator dealt with the problem by using a high speed PLC as a buffer between the tablet press and IP1. The new drug would require acquisition of more data values per tablet and the tablet press had 70 positions. Tens of thousands more tablets would come from the press per hour.

The Solution

Conceptually, the solution was simple. IP21 normally takes in each data element individually. Havenshire saw that in the version of IP21 to be used for the project, most of what would be needed to accomplish block data transfer was available. Block data transfer can achieve much higher throughput rates than transfer of individual data elements. It was not a completely ready-to-use feature, but with work it could be cobbled together.

Implementation was not quite so simple. Havenshire embedded in the systems integrator selected by Med Makers and led the project.

Due to a deadline for submission of the license application, the project timeline was tight. The solution for this project could not involve addition of compiled software on the IP21. Any such additional software would have to go through validation procedures to satisfy regulators, making it impossible to meet the completion deadline. Havenshire designed and led the development of a mechanism using a bespoke record structure built with standard IP21 tools and a bespoke SQL script. The script was exempt from extra validation procedures that compiled software would have needed.

Vendors responsible for the tablet press and other production equipment modified their software to transmit data in blocks instead of one item at a time. Due to language differences, one vendor had some difficulty understanding. Havenshire made a 'movie' of the designed data movement which conquered the language barrier.

Med Makers' ambitious deadline was met by delivering in about 60% of the calendar time they originally estimated to be necessary.

The intermediate PLC was eliminated.

In the course of this project, Havenshire also mentored an engineer within the systems integrator to raise their in-house skill level with IP21. Havenshire made the integrator capable of doing follow-on projects on their own.