# A case study of a data historian migration project for Wyeth Bio Pharmaceuticals

## *Company Background*

Based out of Madison, New Jersey, Wyeth is a global leader in the over $213 billion per year pharmaceutical industry. Wyeth's bio pharmaceuticals division is a leader in the rapidly developing field of recombinant protein biopharmaceuticals. The Andover, MA campus of Wyeth BioPharma is one of the largest biopharmaceutical operations in the United States with 7 manufacturing sites, 21 bioreactors and 1,800 employees.

## *Data Collection and Storage Challenge*

Wyeth recognized several years ago the need to manage the immense amount of data being generated by its facility with a data historian. They had standardized on Automsoft's RAPID® Historian for both their GMP ("Good Manufacturing Practice", regulated by the FDA under 21 CFR Part 11) and non-GMP parts of their facility. However, the immense amount of data being generated and their desire to further increase the manufacturing capabilities of the site necessitated that they migrate to a more powerful and flexible data historian. Wyeth chose GE's Proficy® Historian for its scalability, ease-of-use and world-class performance for their new data historian. However, migrating from RAPID to the Proficy Historian presented Wyeth with several challenges:

- FDA Regulations: 21 CFR 11
  The GMP portion of the system is tightly regulated by the federal regulations known as "21 CFR 11". In particular, 21 CFR 11 requires that Wyeth certify that all 80+ GB of the legacy data in RAPID is successfully migrated to the Proficy Historian. The immense size of the data appeared daunting and potentially would prevent Wyeth from migrating without an enormous cost in system validation.

- Trending and Data Analysis Interface
  The trending tool used by the engineers and scientists was customized for use with the RAPID system. A common complaint was that it was slow and limited their ability to do the data analysis they required, but at the same time any new system would have a similar "look and feel" so that it would not require retraining.

- iFIX® SCADA/HMI Graphics Updates
  The utility-side of the Andover campus was the largest historian system with an equally complex SCADA/HMI with over 2,200 iFIX graphic displays. The vast majority of these displays had embedded code that would open a trend display from the RAPID historian. Any new system would not only need to replace the trend display, but it would need to address the fact that 2,200+ pictures would need to be examined and have their code modified: a potentially enormous effort requiring possibly several weeks or months to implement.

- Time and Budget Constraints
  As with any project, Wyeth had strict budget constraints and any proposed upgrade would need to be implemented quickly and at a minimal cost.  The project scope was immense:
  Phase 1: ADF Facility (GMP) with 80+ GB of data
  Phase 2: Campus facilities, Utility Management System ("UMS") (non-GMP) had over 120GB of data in RAPID and 2,200+ iFIX pictures

## *The Solution*

Wyeth looked towards Newton, MA-based firm, EVSystems Data Solutions, LLC to solve their problem.  Partnering with AutomaTech, Inc., EVSystems guided Wyeth through a successful facilities upgrade at minimal cost and in a short amount of time.   Each of the client's challenges was met with a unique and efficient solution:

- FDA Regulations: 21 CFR 11
  EVSystems developed a powerful migration tool that would automatically generate a report for every 50,000 records migrated verifying and cross-referencing the data from RAPID to the GE Proficy Historian.  In addition, to facilitate post-migration audits, the migration reports included a unique "hash" (a unique alpha numeric sequence) for every set of 50,000 records migrated from each data point.  The hash key, while unique, is readily reproducible using standard algorithms available in the public domain so that at any point in the future an auditor could verify the data was migrated correctly by calculating a hash key independently and verifying that they match.
  Result:  Wyeth QA and validation department was able to certify the migration as 21 CFR 11 compliant with a fraction of the effort anticipated.

- Trending and Data Analysis Interface
  EVSystems developed a powerful, flexible and easy-to-use trending interface for the Proficy Historian.  While sharing a similar look and feel to the previous trending tool, the new interface brought several new enhancements including "golden batch analysis", ad-hoc query capabilities, print & print preview, data export, and much more.  Most importantly, the new interface using the GE Historian was blindingly fast.  The old trend display typically took a few minutes to load (a source of constant frustration).  The new trend would load in under 5 seconds.  When it was later discovered that some of the operator HMI screens were running on older computers and the screen load time was 30 seconds, EVSystems further optimized the code so that even on the slowest computers load time was no more than 3 to 5 seconds (to the delight of plant operators).

- iFIX® SCADA/HMI Graphics Updates
  The 2,200+ iFIX screens presented a unique problem.  It simply was not feasible to open every picture and manually inspect and modify the code that opened the older trend display.  Even a "search & replace" operation would be time-prohibitive and small differences in the internal code (how the old trend display was called) practically guaranteed that things would be missed and there would be errors.  To tackle this

problem EVSystems wrote a utility that inspected the VBA code within every iFIX picture and automatically modified any code that called upon the old trend display. Instead of taking weeks or even months, all 2,200+ pictures were inspected and updated in a matter of hours.

- Time and Budget Constraints
  The combination of all of the tools above enabled EVSystems to implement the data migration and system configuration changes in a fraction of the time that Wyeth had anticipated. For example, the UMS system had all 120+GB of data migrated automatically with the multi-threaded migration tool in a matter of only a couple of weeks (and it would have been faster if the data extracted out of RAPID could have been faster).

## *Final Outcome*

Over a period of just a few weeks EVSystems was able to convert the outdated data historian system of this growing facility to one that will enable them to grow their business continually. Wyeth BioPharma was spared the extra costs and limitations associated with their old data management system and were able to migrate to the powerful GE Proficy Historian to enable their facility to grow and support further operations. Most importantly, they were able to do so cost-effectively while ensuring full 21 CFR 11/GMP compliance as well as minimal downtime.

EVSystems Data Solutions, LLC was able to help Wyeth BioPharma to meet their goals efficiently and expeditiously. Contact us today to see how we might be able to help you in your unique data management system upgrade.