

OPC: Closing the Data Gap Between Pharmaceuticals and CMOs

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Executive Summary

Intense competition in the Pharmaceutical industry is driving Pharmaceutical companies to find ever more efficient production strategies to maximize yield and quality while minimizing waste and capital investments. Outsourcing production to Contract Manufacturing Organizations (CMOs) is increasingly popular and with it, the need to share production data between CMOs and their sponsors - this paper examines how OPC simplifies such data sharing.

THE PHARMA/CMO RELATIONSHIP



Just as real-world relationships require more work than their happily-ever-after movie counterparts portray – ensuring Contract Manufacturing Organizations (CMOs) and their Pharmaceutical company sponsors can enjoy the full benefits of working together takes a lot more than just signing of an agreement and sharing of recipes. Production of pharmaceutical products requires precise execution of recipes in carefully controlled environments all of which must be meticulously monitored and documented to meet quality standards, public safety regulations, and assist in an ongoing effort to maximize yields while minimizing waste. Given the interdependency of these two organizations – a fundamental hurdle CMOs and their clients must overcome is: how to effectively share data with each other. In particular, what format the data needs to be in so systems on both sides can work with it, how to overcome connectivity barriers, and how to keep sensitive data confidential. This paper examines common data sharing challenges Pharmaceuticals and CMOs face and outlines strategies that keep data sharing simple and effective.

As a first step, it is prudent to ask why a Pharmaceutical company would bother with outsourcing in the first place.

The simple answer is: cost. Pharmaceutical companies typically opt to enter into agreements with CMOs when the Pharmaceutical companies need additional production capacity to meet their production targets or require the use of specialized infrastructure they do not have. There is also a growing segment of virtual pharma and biotech manufacturers that rely exclusively on CMOs for commercial production of their products. So, the decision to outsource manufacturing depends on how well the in-house manufacturing return on investment stacks up against outsourcing.

With the motivation behind contract manufacturing established, the next question is why the exchange of production data is so important. Here again, the answer is simple: profitability and compliance. First, given the cost and complexity of producing today's pharmaceutical products, especially the biopharmaceuticals – it is imperative for both Pharma and the CMOs to have well-defined manufacturing and acceptance criteria, data measurements to document compliance to those specifications, and an agreed to method of maintaining such records to ensure data integrity is preserved. Given that recipes and processes may need to be adjusted to improve overall yield and quality – key measurements and results need to be shared between the two companies. While recipes and production methods change on an ongoing basis, the best-practices behind them remain relatively consistent. Guidelines, such as the Good Automated Manufacturing Practice (GAMP) have been adopted throughout the Pharma industry and drive the need for data exchange by treating record keeping as a key activity.

Given the inherent impact drugs can have on public safety –stringent government regulations have been defined and legislated to ensure every step in the drug development and production lifecycle is

sufficiently documented to prove due process was followed and that the end product consistently delivers the potency and quality the formulation calls for. It is interesting to note that despite efforts to accurately define what data is required, the topic is complex and the rate of technological change fast enough to lead to some confusion on what data needs to be captured for companies to remain compliant. For this reason – it is common to err on the side of caution – and capture as much data as is feasible.



What are the challenges of sharing such data between Pharma clients and their CMOs? There are a few key issues. First, seeing how CMOs typically deal with multiple Pharma clients who are often competitors – it is imperative for a CMO to only provide access to data that each client should be privy to since, such production information is highly proprietary. To complicate matters, the data infrastructure at each CMO's facilities rarely if ever matches that used by its Pharma clients and the companies may be spread throughout the world. Given the complexity of such infrastructures, flexibility in accepting complex data from other sources is not inherent in the design. This makes exchanging data complicated from a technical perspective. In addition, given the dynamic and constantly evolving nature of drug production and process refinement – access to such data needs to be timely (on-demand) so adjustments can be made, monitored and evaluated in a timely manner.

The complexity of successfully exchanging the right data, at the right time, with the right people – let's look at the criteria an ideal system would look like and then work backward to real-world implementation options.

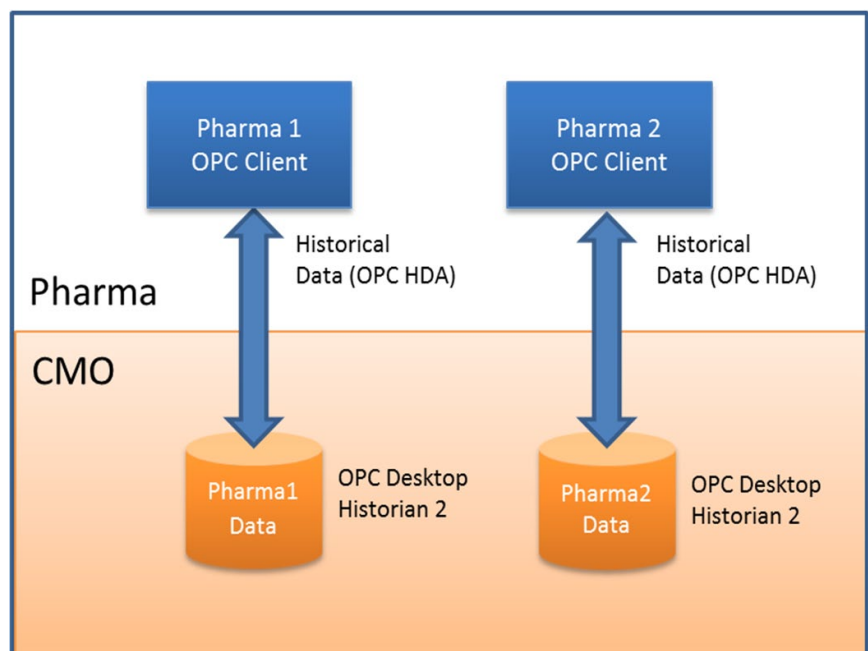
While preventing data loss and preserving data confidentiality are paramount – keeping the implementation of such a solution on budget is also important. This not only refers to the actual infrastructure component costs but extends to the time and effort spent trying to allow the organizations to communicate with each other. Second, captured data should be sent regularly and automatically from the CMO to its Pharma clients – ensuring Pharma personnel at every level of that organization have the data they need at their fingertips. This is especially important for reducing the turn-around time between the time changes are implemented, samples collected, and test results returned. Finally, such data sharing capabilities – regardless of how each company organizes data in its database – should be bi-directional and easy to setup and maintain because the setup of such data sharing arrangements can be frequent. After all, a Pharma company may be a CMO client on one hand while acting as a CMO to one or more other Pharma companies on the other hand.

With these requirements in mind, what follow are two possible architectures that would meet such criteria. Which one is chosen depends on what the two companies prefer however both leverage the power of the world's most popular open standard aptly called OPen Connectivity or OPC for short. In a nut-shell, OPC technology is the 'glue' that makes it possible to share real-time, archived, and alarm data between different systems, regardless of the vendor they come from or the native protocols they use.

ARCHITECTURE ONE: DATA ON DEMAND

In this architecture, a CMO stores all data associated with a given Pharma client's product on a dedicated, OPC enabled historian. This provides the Pharma client with exclusive access to all of its production data while ensuring data confidentiality is preserved since no other client is granted access. Two key OPC components are needed to make such a solution feasible. First, a low cost, OPC enabled historian like the MatrikonOPC Desktop Historian is used to make the historian-per-client solution financially feasible while providing clients with solid functionality.

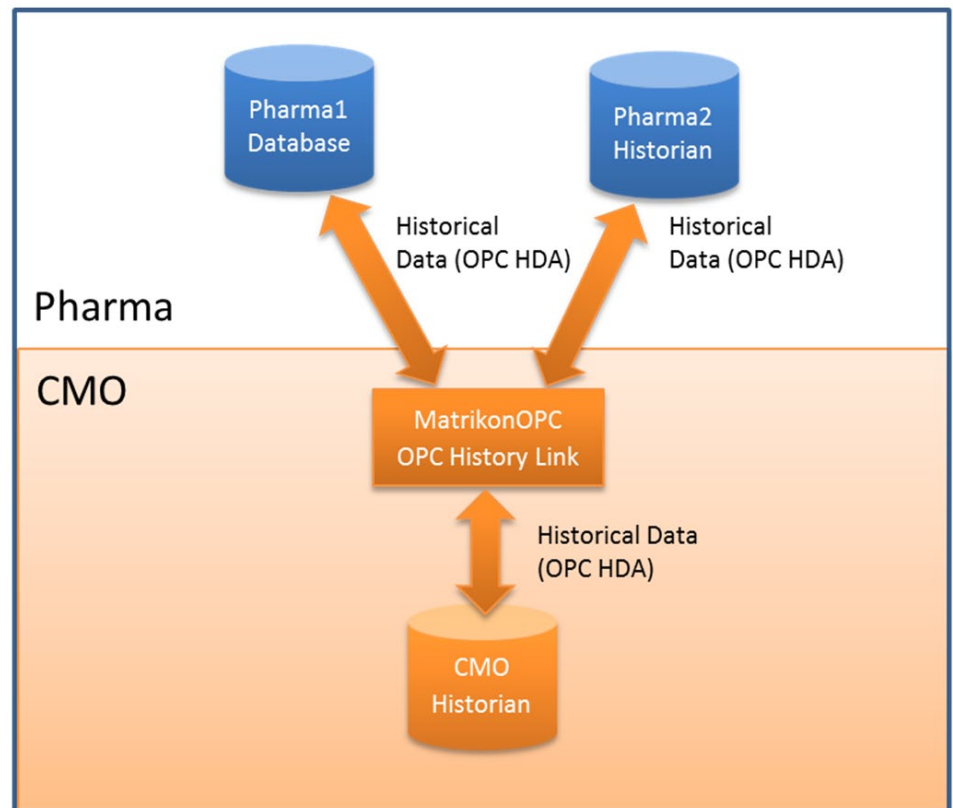
The CMO uses OPC to read in real time data into the Desktop Historian on one side while providing historical data access (via OPC HDA) to the Pharma client on the other. The second standard OPC component needed in this solution is OPC Tunneller HDA. OPC tunneling is used to facilitate OPC connectivity between the CMO and the Pharma client regardless of the complexity of the network(s) they use to connect with each other. Just as corporate users log into their business networks from airports and remote locations using Virtual Private Network (VPN) connections – OPC data can be securely accessed using OPC Tunneling technology from MatrikonOPC. LikeVPNs, OPC Tunneller runs in the background meaning users on both sides can take advantage of its secure connectivity features without even knowing that they are using it – an advantage considering that a simple solution lends itself well to creating an easily repeatable workflow.



ARCHITECTURE TWO: AUTOMATIC UPDATES

In this scenario, the CMO simply uses a single historian or database of choice (like OSI PI, IP.21, Oracle, etc.) and automatically “pushes” data updates to each Pharma client’s data archive. Here again, two OPC components are needed: a standard history transfer component called OPC History Link and OPC Tunneller HDA.

History Link provides guaranteed historical data delivery by periodically transferring user selected amounts of data from the CMO’s archive to each Pharma client’s destination archive. Designed to work in the most challenging environments, History Link works even if the network connection is repeatedly lost during the synchronization process. OPC History Link is a powerful data synchronization and migration tool with many advanced features however, its default settings make it ready to use with minimal effort. Here again, just like OPC Tunneller, OPC History Link also works in the background.



With each Pharma client’s data stored in the same historian on the CMO side – segregation of the data is accomplished by having an administrator on the CMO side map appropriate data from the CMO archive to each particular Pharma client’s OPC HDA enabled client. Once such mapping is complete – data is transferred without any additional configuration.

LEVERAGING DATA - BEYOND DATA ACQUISITION

To gain competitive advantage through operational excellence, improved process performance, predictability, and scalability - CMOs must properly leverage the information hidden in the raw manufacturing data they generate and capture for their sponsors. Industry leaders employ powerful Enterprise Manufacturing Process Intelligence (EMI) tools like Aegis Analytical's Discoverant CM™ for Contract Manufacturing to do this. Software platforms like Discoverant CM go beyond business intelligence, to enable process intelligence which provides a deeper understanding of each process and product through cross network, on-demand access, contextualization, analysis, and reporting on various topics such as manufacturing, process development, and quality data.

"Transparency into product production is essential for our clients. CMOs face increased quality control scrutiny from their sponsors as well as regulatory agencies. When you have a virtual manufacturing network, secure applications that help you collaborate, distribute and understand data become critical to running your business."

Joe Rothman, Aegis Analytical

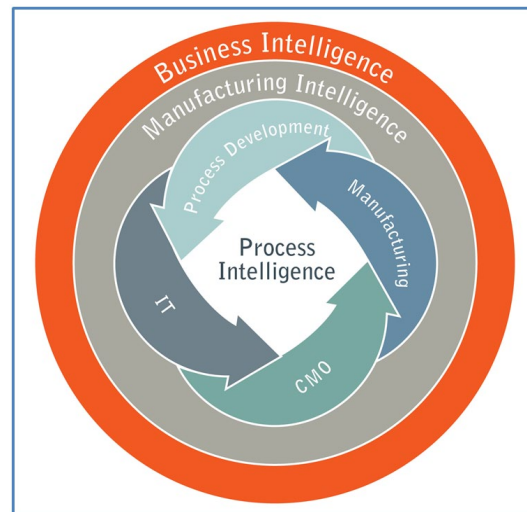


Diagram courtesy of Aegis Analytical Corp.

Pharmaceutical companies often employ relational databases to store their manufacturing data. While this works well for archiving and general reporting, some databases may not be well suited for the high data throughput needed when performing investigational analytics. In such cases, a simple, low cost solution is to use OPC History Link and MatrikonOPC Desktop Historian to overcome data retrieval performance issues. History Link automatically transfers data from a company's relational database into Desktop Historian which easily facilitates the data needs of an application like Discoverant. The advantage of such architecture is twofold. First, the company can continue using its existing IT infrastructure for all of its day-to-day tasks while second - the company gets maximum benefit from its EMI platform thanks to the high speed data transfer provided by OPC Desktop Historian.

CONCLUSION

Thanks to the flexibility, low cost, and ease of use OPC brings the table, Pharmaceutical companies often use it to ensure they quickly and reliably gain access to data they rely on for their competitive advantage. Whether such companies need to collect data from their CMOs, are looking to centralize data from multiple campus locations, or need to achieve high data throughput between powerful analysis tools like Discoverant and the company data archives – one answer is clear: using standards-based OPC components from MatrikonOPC truly pays off. Components like OPC Desktop Historian, OPC History Link, and OPC Tunneller HDA can greatly simplify data connectivity issues allowing companies to take advantage of their data while spending a lot less time on IT related issues.

OPC COMPONENTS DESCRIBED IN THIS PAPER

MATRIKONOPC HISTORY LINK

MatrikonOPC History Link is the only historical data transfer tool you will ever need. No longer will isolated islands of data plague your operation. A truly flexible and agile tool, MatrikonOPC History Link is for anyone who is currently collecting or storing historical data. This OPC compliant software is a quick and easy way to transfer historical data.

MATRIKONOPC DESKTOP HISTORIAN

For manufacturers who need to analyze process data, OPC Desktop Historian is an affordable, easy to install, configure and administer data archiving tool. Unlike enterprise process historians that are designed to manage the needs of the entire corporation, OPC Desktop Historian focuses on data collection, not data presentation or processing. OPC Desktop Historian is a lightweight solution for time-based data storage that can stand alone or become part of a total enterprise data historian solution. Also it is a powerful historian for the price of an OPC HDA driver!