

Measure | Understand | Control



Real Time PAT Knowledge Manager

Worldwide market leader for achieving regulatory compliant PAT based production.

synTQ^{v5} by **Optimal**
Industrial Automation

Achieve the huge cost saving benefits of PAT enabled manufacture via the most effective, easiest to use real-time PAT knowledge manager on the market...

Introducing - synTQ V5

Join the revolution...

The synTQ PAT Knowledge Management Software Suite has been quickly adopted by several of the top ten global drug producers to effectively implement PAT, providing universal hardware and software system integration via effective real-time data recording and data management from the development lab, through to full-scale production.

Why are the global majors standardising on synTQ?

Crucially for the bottom line, synTQ V5 allows very fast and efficient implementation of an operational PAT framework, adding hugely to the inherent benefits of fast, accurate model development and continuous high-speed production with fully compliant and integrated real-time measurement and control, automated quality assurance and report generation that can lead to true Real time Release.

What's new for synTQ V5

Developed and honed for over a decade by one of the industry's leading system integration specialists, synTQ V5 is founded on hard won practical implementation and operational knowledge.

New user interface graphics make for a contemporary look and feel adding speed and intuitive control for users, including the latest touch screen HMIs. This adds to a long list of additional user functions developed directly from internal and customer feedback.

The key to effective data management is speed and accuracy, the latest version has further enhanced the speed of real-time data handling with developments in system architecture as well as client multitasking, this further strengthening the existing state of synTQ being the fastest running product of its type in the marketplace.

The addition of a user dashboard further simplifies the already intuitive way of running synTQ and viewing the data and information. By using the new system framework it is simple to pin required views into your personal dashboard, thus providing you with exactly the information that you require, when you require it.



Image used courtesy of GEA

“There is no doubt that Process Analytical Technology (PAT) is the key emergent process technology that is allowing the pharmaceutical industry to make the step change from the stricture of slow, inefficient and cumbersome batch production techniques to fully integrated regulatory compliant continuous production techniques.”

Martin Gadsby, Director Optimal

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Achieve Lower Cost and Shorter Production Times Whilst Improving Product Quality

PAT

PAT can simultaneously reduce manufacturing costs, improve product quality and dramatically reduce the time to market for new compounds.

Continuous manufacturing and real time release, as enabled by PAT is slashing production cycle times.

Whilst much of the measurement technology surrounding PAT is well understood, its implementation at all manufacturing stages presents a number of challenges.

With 25 years of worldwide experience in Pharmaceutical Manufacturing, Optimal has spent the last decade developing and fine tuning synTQ specifically to meet these challenges and facilitate the efficient, timely and compliant implementation of PAT systems from R&D through to full manufacturing.

Instrumentation Management

The use of complex instrumentation (NIR, Raman, Particle sizing etc.) offers the potential to reveal in real time those Critical Quality Attributes of your product. To access this information however, the correct configuration and calibration/referencing status of the instruments is vital as without these being robustly controlled and recorded then all your gathered data will be invalidated. synTQ controls all possible attributes of your instrument as well as controlling the operation of the instruments and of course gathering and storing all of the output spectral data. synTQ has a large and ever expanding library of instrument adaptors enabling bidirectional communication with them, and if

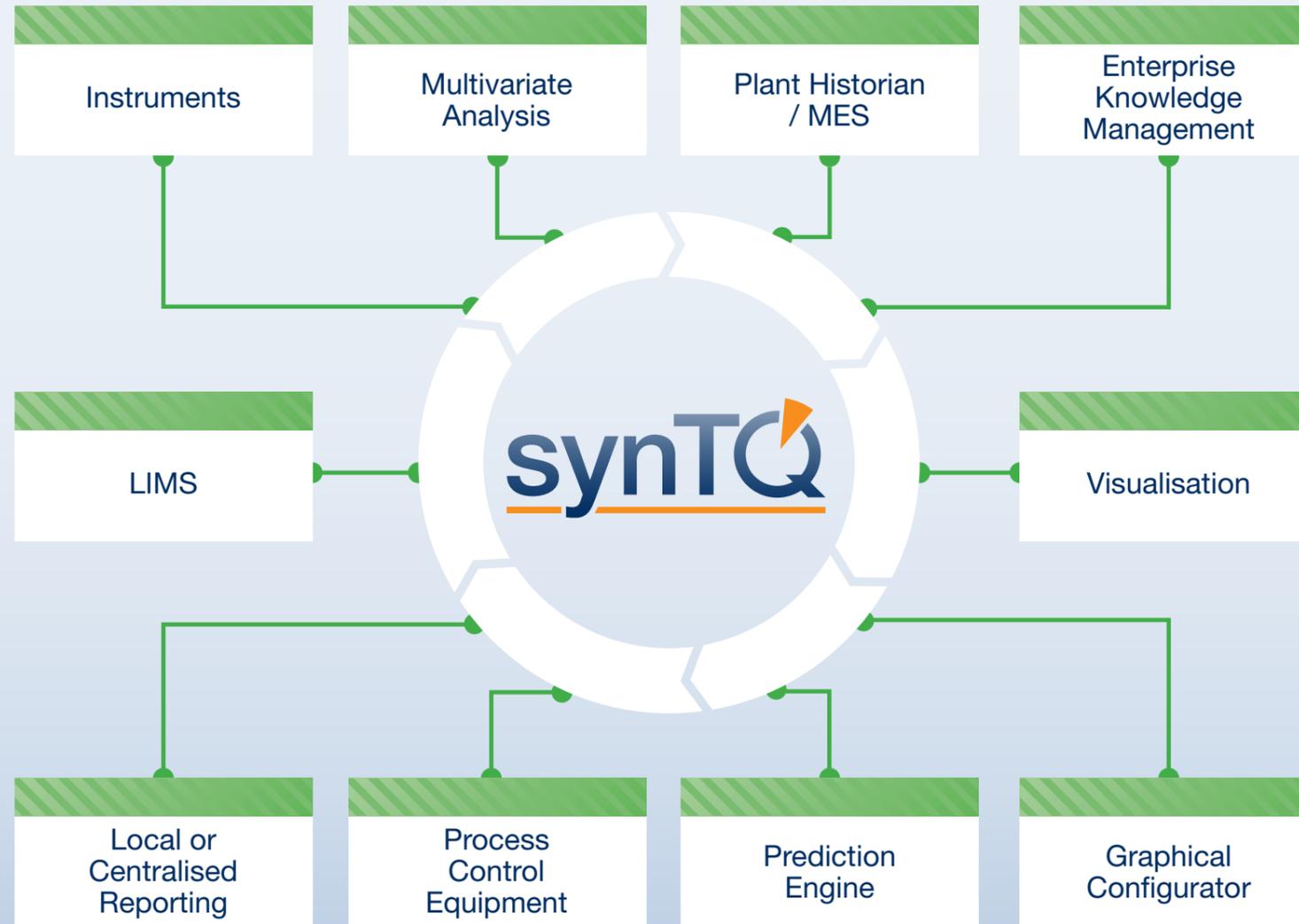
we don't happen to have an adaptor for your specific instrument then we will undertake to write one for you. Thus synTQ assures the complete integrity of all data associated with all of your instruments.

Data Storage & Reporting

PAT is highly data centric and as such the data produced must be handled and stored in a very secure manner. synTQ V5 has been developed using the very latest technology and utilises industry standard operating systems and databases. synTQ has been designed from day one to ensure that all the requirements of 21 CFR Part 11 can be fully satisfied with the minimum of configuration effort. The use of industry standard databases enables synTQ to use a broad range of reporting tools suitable for your application, and the portal to the data is via the synTQ RS Reporting Services server. All the data is available on this server to authorised personnel for reporting purposes, and if using the Windows Reporting Services package that comes with synTQ RS then the reports can be stored, printed or published over the web.

Analysis & Real Time Prediction

Process model building with synTQ becomes a simple, quick and accurate process. synTQ communicates with most of the commonly used Multivariate Analysis (MVA) packages enabling the easy association and export of automatically acquired and Laboratory analysis data. This export is carried out within the synTQ environment and as such is fully 21CFR Part 11 compliant. The resulting process models are kept within the synTQ environment and stored in the database. When running in real time synTQ passes the acquired data from multiple instruments along with any univariate data to the MVA prediction engine which will have been pre-loaded with the correct MVA model. This then calculates the required Critical Quality Attributes of your product and stores them in the database and makes them available for any other required action.



The internal control module can be either a synTQ module else one from a 3rd party. The external control system can be virtually any control system – typically your preferred PLC or DCS.

Scalability

synTQ is a scalable PAT Knowledge Manager that can be easily upgraded from one edition to another.

synTQ Lite

For cost effective single instrument, single unit operation applications.

synTQ FM

For Flexible Manufacturing & Orchestration development using multiple instruments & unit operations.

synTQ RS

For Reporting Services functions allowing the printing and web publishing of PAT reports.

synTQ EM

For Enterprise Management functions providing a central repository for all PAT data.

Control

The FDA's guidance document clearly states that PAT can only be fully realised with a robust control element. synTQ enables the implementation of this control element by using a sophisticated and graphically based PAT Method creation facility, known as 'Orchestrations'. This methodology allows the CQAs that have been generated by the real time prediction engine to be fed into either a control module within synTQ else output to your existing control system – typically over OPC.

Vendor Neutral Connectivity

All synTQ Editions are designed to be vendor neutral. Provided that the device requiring connection has a communications interface and a known protocol, synTQ can connect to it. You are not forced to use any specific vendor's control system, instrument or indeed Multivariate Analysis (MVA) package – you are free to select these, creating a "best of breed" solution. As your systems evolve, synTQ's multi-vendor connectivity capability allows you to easily add new instruments, control systems or indeed MVA packages with the minimum of fuss and validation, this allowing you to take full advantage of the latest and optimum technologies.

Continuous Improvement

One of the major changes which will need to be embraced following the advent of PAT is that of continuous improvement. Processes which were once 'set in stone' will now be constantly monitored, and when appropriate changes introduced in a controlled way to improve process capability. synTQ is designed to facilitate the implementation of these changes in a straightforward and robust way. Version control of all facets of data storage ensures that the historical development of a process can be fully traced from inception and the enhanced graphing facilitates the continual enhancement of Process Understanding.

PAT Consultancy & Training

PAT is a major change for the pharmaceutical industry, and embarking on a PAT implementation can be a very daunting task. The deployment of PAT demands the application of multiple skill sets, and if you don't yet have all the skills or resources to move forward with your implementation then Optimal can offer a wide range of specialised consultancy services including PAT training to fill the gaps.

Configuration & Installation

As well as being the developers of synTQ, we at Optimal have been designing and installing bespoke automation systems for pharmaceutical, chemical and food industry clients for over 25 years. We are therefore well placed to offer a full configuration, installation, commissioning and validation service. This can cover all aspects of a PAT system as well as the more traditional PLC/SCADA/DCS/ MES automation requirements.

Global Supply and Support

For many years, we at Optimal have been providing support for critical manufacturing systems all around the world, and to further enhance this we now provide a 24/7/365 product support service called synTQ Assured. If required, synTQ Assured application support can also be provided either directly from us or in collaboration with your local approved synTQ provider. From a supply perspective synTQ can be supplied either directly from us, from Emerson Process Management else via one of our continually expanding approved synTQ Partners.

synTQ Assured
Global Product Support





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