




# Real Time PAT Knowledge Manager

Global leader for integrated Process Analytical Technology solutions, from the laboratory to manufacturing.

**Measure | Understand | Control | Improve**





Achieve the huge cost and time saving benefits of automated, quality centric PAT based knowledge management and real time control via synTQ.

“There is no doubt that Process Analytical Technology (PAT) is now mature, proven and the key emergent technology that is allowing process industries to make a step change in the cost and time of development through to manufacture together with improved quality and consistency of quality.”

**Martin Gadsby**, Director of Optimal Industrial Technologies

Image courtesy of Gericke

## Join the revolution

The synTQ PAT Knowledge Management and Quality Centric Control Software Suite has now been adopted by over half the top ten global drug producers, plus many other leading manufacturers in the life sciences and other process industries to effectively implement PAT.

synTQ provides universal hardware and software system integration via effective real-time univariate and multivariate data recording, management, knowledge generation and MSPC from the laboratory and small scale manufacture, through to full-scale production.

### Why is there an exponential adoption of PAT with synTQ?

When properly applied, PAT is a key emergent technology that has been proven to be capable of providing very significant gains in terms of time and cost for the research, development and manufacturing of products whilst also delivering gains in quality and the consistency of quality.

The technology has now matured, with an increasing number of case studies becoming available that demonstrate the staggering gains that have been made by implementing PAT with synTQ. Integrated PAT is not possible without using a product such as synTQ, therefore there is an increasing swell of companies of all sizes and industry sector adopting the technology.

### Why choose to use synTQ?

When first embarking on a PAT project, the need for synTQ may not be immediately apparent. However, as the potential complexities of a PAT project become revealed, then so too is the criticality of synTQ in a process. A robust and quality compliant PAT process requires all instruments, process models and control models to be configured and loaded at runtime, for this event to be rigorously recorded and then all raw, meta and derived data to be gathered in real time and stored with total data integrity. PAT Methods (or Orchestrations as we call them), may be simple or may be very complex, and your scientist will need to be able to create these in a simple yet controlled and audited way without resorting to code. You may need to execute data fusion in real time, you will certainly need to make quality predictions, you may wish to control the process using quality centric MSPC, and you will need to display univariate and multivariate data in many ways to suit the specific user and enable them to generate the desired knowledge. Being the most mature product in the marketplace with nearly 2 decades of development behind it, synTQ is the product of choice to deliver all these PAT enabling features – plus many more.



# Achieve Lower Cost and Shorter Production Times Whilst Improving Product Quality.

## Process Analytical Technology

PAT is a very rare technique as it can simultaneously reduce the cost and time of product development though to full scale manufacture, whilst also improving the product quality and consistency of quality. And the improvements can be significant – for example a ~3 fold increase in productivity for a biotechnology process has been reported, plus the ~500 fold decrease in manufacturing time for some small molecule pharmaceutical products. In this latter case synTQ enabled the production to be transformed from a batch process to a continuous process with fully automated Quality Assurance and Real time Release Testing. There are also the potential further gains in relation to the reduction of Work in Progress, the effect of increasing patent life (as products come to market sooner), energy usage, production footprint and a reduction in the necessary manufacturing infrastructure. The list goes on!

## Instrumentation Management & CQA Prediction

The use of complex instrumentation such as NIR, Raman, UV Vis, Particle Size, Mass Spec, UPLC, HPLC etc. offer the potential to reveal in real time those Critical Quality Attributes of your product. By using synTQ, these can be configured and run in real time either in-line, on-line or at-line. However to ensure total data integrity, the correct configuration and calibration/referencing status of each instrument is vital, as without these being robustly controlled and recorded, then all your gathered data will be invalidated. synTQ controls one or multiple instruments, executes data fusion if required, and passes the data into your prediction model(s) for CQA prediction. synTQ then stores all data automatically. With synTQ you are normally free to choose whatever instrument and MVA package you need – we have a large and ever-expanding portfolio of 'adaptors', and if we don't have the right one for you then we will normally write it for you free of charge! All data associated with the instruments that may be used by your synTQ system can be maintained in the Instrument Store, together with any commonly used configurations which are stored as templates.

## Data Storage, Data Integrity, Cyber Security & Reporting

Furthermore, a large PAT infrastructure will invariably require multiple communication connections – often between different corporate LANs. This infrastructure must be possible whilst providing the maximum possible Cyber Security. All synTQ data communications have been developed using the very latest technology and include encryption on the wire to ensure robust data exchanges. Furthermore, Cyber Secure gateways have been developed to provide the maximum possible protection against Cyber Attack. synTQ was designed from day one to ensure that all the requirements of ERES regulations such as 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.



## Multivariate Statistical Process 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. 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 Lean** - For small scale, cost effective systems that need to be fully configurable.

**synTQ RT Lean** - a system similar to synTQ FM Lean, but suited for production environments where it can be run 'headless' and configuration is not required.

**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 and secure collaboration 'portal' for all PAT data.

## 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.

## 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 process data together with laboratory analysis data. The resulting process models are imported and stored within the synTQ Model Store. When running in real time, synTQ passes the acquired data from one or multiple instruments along with any univariate data to the MVA prediction engine(s) which synTQ will have pre-loaded with the correct MVA model. Each then calculates the required Critical Quality Attributes of your product and synTQ automatically stores them in the database and also makes them available for any other required action.

## Continuous Improvement

One of the major changes which will need to be embraced with a PAT enabled process is that of continuous improvement. Processes which were once fixed forever should 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, with functions available in the latest versions of synTQ specifically to assist with Continuous Improvement.

## PAT Consultancy & Training

PAT is a major change for any process industry, and embarking on a PAT implementation can be a very daunting task. The deployment of PAT demands the application of multiple skill sets, which are not always fully available within a single organisation. By working with a company such as Optimal, you will not only have access to the technology that will enable PAT, but also a wealth of knowledge and most likely the skill sets that you may require to add to your in-house team. In addition, Optimal can offer a wide range of specialised consultancy services including PAT training to fill any knowledge gaps that you may have.

## Configuration & Installation

As well as being the developers of synTQ, within the 'Optimal Group' we have been designing and installing bespoke automation systems relating to the pharmaceutical, chemical and food industries for over 32 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.

## Global Supply

synTQ can be purchased directly from the manufacturer, Optimal else via a global, growing network of approved synTQ Application, Consultant, OEM or Instrument Partners. Each partner has a specialisation in the implementation of PAT – typically from an instrument, MVA, consultancy or integration/application viewpoint. Please check out our website or contact us for the Partner closest to you!

## Access and availability

synTQ Assured Support is available to all end user customers operating a live licensed and registered instance of synTQ.

All direct support is supplied in English as standard, other languages are available on request.





## Return on Investment

It remains very difficult for us to obtain return on investment data that can be shared openly, however some key facts are as follows:

- ▶ The tripling of fed batch titre has been reported by one company
- ▶ The adoption of continuous manufacturing and the reduction of manufacturing time to up to 500 fold has been achieved by several companies
- ▶ A solid financial and quality return on investment is proved by companies rolling the technology out through their business operation







EXPERT TECHNICAL  
PHONE SUPPORT



REMOTE SYSTEM  
DIAGNOSTICS



ONLINE SERVICE  
INFORMATION



DEDICATED  
CUSTOMIZED SYNTQ  
ASSURED ON-LINE  
SERVICE DESK



DOWNLOADABLE  
SOFTWARE UPDATES



MY SYNTQ PORTAL  
KNOWLEDGE BASE



SYNTQ FORUM



# **synTQ** **Assured**

Global Product Support

## **synTQ Assured benefits:**

- Expert support when you need it, 24/7/365
- Optimise reliability and performance
- Minimize maintenance costs
- Achieve and maintain peak productivity
- Have the latest synTQ software immediately available
- View your issues via your synTQ Assured dashboard
- Collaborate with peers via the synTQ Forum

## **synTQ Assured support service includes:**

- Expert technical phone, email and ticketed, portal support
- Issue tracking
- Remote system diagnostics
- Online service information and FAQs
- Dedicated customized synTQ Assured online service desk
- Downloadable software updates
- My synTQ Portal knowledge base

All of these features are provided as part of synTQ Assured, which is charged for annually and is based on system size. In addition, application support can be provided, and this is best added to the product support to form a total support package.

synTQ product support in the form of synTQ Assured can only be provided by Optimal, however it is worth noting that synTQ application support can often also be provided by your local synTQ Partner.





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