

synTQ


Real-Time PAT Knowledge Manager

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

Measure | Understand | Control | Improve

Optimal
Industrial Technologies





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

“Process Analytical Technology (PAT) is now mature, proven, and a key emergent technology. PAT enables process industries to make a step change in reducing the cost and time of development and manufacturing, together with significantly 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 more than half of leading global drug manufacturers. synTQ has been implemented on processes ranging from R&D, laboratory, and small-scale production through to full-scale process manufacture – to achieve huge benefits from effective implementations of PAT.

synTQ provides universal hardware and software system integration via real-time univariate and multivariate data recording, management, knowledge generation and Multivariate Statistical Process Control (MSPC).

Why is there an exponential adoption of PAT with synTQ?

When properly applied, PAT provides significant gains in the time and cost of the research, development and manufacturing of products, whilst also delivering improvements to quality and the consistency of quality – with proven results.

The technology has now matured, with an increasing number of successful, online deployments 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 critical need for 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 tightly controlled. All raw, meta and derived data should then 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 a PAT specialist will need to be able to create these in a simple, controlled, and audited way, without resorting to code.

You will certainly need to make quality predictions. You may need to execute data fusion in real time or wish to control the process using quality-centric MSPC. It is highly likely that you will need to display univariate and multivariate data in various ways to suit the specific user and to generate the desired knowledge.

Being the most mature product in the marketplace, with over two decades of development behind it, synTQ is the product of choice to deliver these PAT-enabling features – and many more.

Achieve Lower Cost and Shorter Production Times Whilst Improving Product Quality

Process Analytical Technology

PAT is a rare technique that can reduce both the cost and time of product development, as well as applying the same benefits to full-scale manufacturing. It will, simultaneously, improve the product quality and consistency of quality.

The improvements can be significant – for example a ~3-fold increase in productivity for a biotechnology process has been reported. There has also been a ~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 holistic, fully automated Quality Assurance and Real-Time Release Testing, where no post-process inspection was necessary.

There are also further potential 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, and HPLC – offers the potential to reveal in real time those Critical Quality Attributes of your product.

By using synTQ, these will be configured and run in real time, either in-line, on-line or at-line. To ensure total data integrity, it is vital that the configuration and calibration or referencing status of each instrument is correct. If this information has not been robustly controlled and recorded, the data gathered from the process will be uncontrolled.

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.

synTQ can be tailored to the instrument and MVA package that you require. We have an extensive and ever-expanding portfolio of instrument adapters, that enable bidirectional communication with specific instruments. Contact us to discuss your needs – if the adapter that you require is unavailable, our team will endeavour to create it for you (often free of charge!).

Data Storage, Data Integrity, Cyber Security & Reporting

Data is at the heart of PAT, and the integrity of its handling and storage is vital. A large PAT infrastructure requires a vast architecture of communication, which requires optimum cyber security at every level.

synTQ has been developed using the very latest technology, including on-the-wire encryption and cyber secure gateways, to guarantee the security of data exchanges. Using synTQ will enable you to meet the requirements of ERES regulations, such as 21 CFR Part 11, with minimum configuration effort.

synTQ has been built using industry-standard databases and operating systems, enabling it to interface to a broad range of reporting tools suitable for your application. This data can then be accessed via the secure synTQ RS (Reporting Services) Server.

Multivariate Statistical Process Control

Whilst a PAT system could consist solely of monitoring, the full benefits of 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 a control module within synTQ or into your preferred third-party control system.

If used within synTQ, this may be a user-created algorithm, or you may choose to save time and use a 'self-teaching' algorithm such as the synTQ ACDC function (Advanced Computation for Dynamic Control). Typically, synTQ will execute the complex functions and instruct setpoint changes to your preferred PLC or DCS, leaving that system to execute the on-plant control. This type of control is very different to a traditional, closed-loop method as it is based on the real-time quality predictions, not merely on empirically based recipe setpoints.

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 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 versions of synTQ are vendor neutral. synTQ can connect to any device that has a communications interface and a known protocol. You have the flexibility to create a “best of breed” solution, using instrumentation or MVA packages from the vendor of your choice. The multi-vendor connection capability of synTQ lets you take full advantage of the latest or optimum MVA, instrumentation and control technologies, as it enables you to easily add new instruments to your systems as they evolve.

Analysis & Real-Time Prediction

Process model building with synTQ becomes a simple, quick and accurate process. synTQ communicates with Multivariate Analysis (MVA) packages to enable the easy association and export of automatically acquired and laboratory analysis data. 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 one or multiple instruments, along with any univariate data, to the MVA prediction engine, which will have been pre-loaded with the correct MVA model. Each then calculates the required CQAs of your product, which synTQ stores in the database, available for any other required action.

Dynamic Flow Modelling for Continuous Processes

PAT, and synTQ specifically, enables you to make the change from a batch process to a continuous one, which has the potential to provide financial savings and an improvement in quality. Many successful continuous production lines using synTQ have proven the realisation of these significant benefits, which are impossible to achieve without real-time quality assurance and associated control.

Material tracking and tracing is a critical element of this process, and the necessary technology to enable this is highly complex – an entirely different system to that of discreet tracking, as challenges such as forward and back mixing of materials must be considered. Suffice to say that we have a solution – synTQ DFM – Dynamic Flow Modeller. This provides a configuration package that enables you to precisely model your exact line, which may then be run in real time. Meanwhile, it interactively connects to PLCs, DCSs and synTQ to give you optimised predictions of material movement.

Continuous Improvement

A major change that a PAT-enabled process supports is Continuous Improvement. Processes that were once set in stone will now be constantly monitored, introducing necessary changes to improve process capability. synTQ facilitates the implementation of these changes in a straightforward, controlled and robust way, with specific functionality available to assist with and automate continuous improvement. As soon as you have a new prediction model available, synTQ is able to easily verify its performance before it is used in the process.

PAT Consultancy & Training

We know that embarking on a PAT implementation in any process industry can be a complex, daunting task. Working with Optimal gives you access to the technology that will enable PAT, along with a wealth of knowledge to complement the capabilities of your in-house team. We offer a wide range of specialised consultancy services, including PAT training, to ensure that you have the skills and resources that you need to move forward with your implementation.

Configuration & Installation

We offer a full configuration, installation, commissioning and validation service, alongside our software suite.

As well as being the developers of synTQ, the Optimal Group have been designing and installing bespoke automation systems relating to the pharmaceutical, chemical and food industries for over 30 years. 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, Optimal have been providing support for critical manufacturing systems all around the world. Our product support service, synTQ Assured, provides with 24/7/365 support.

synTQ application support can be supplied either directly from Optimal or from one of our approved, specialist synTQ partners.

Global Supply

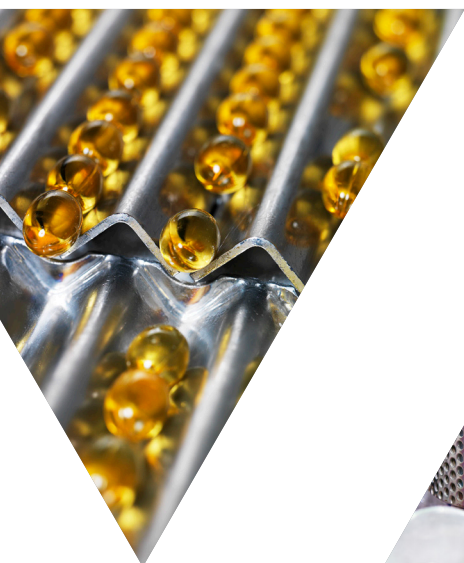
synTQ can be purchased directly from the manufacturer, Optimal, or via a global, growing network of approved synTQ Partners. Each partner has a specialisation in the implementation of PAT – typically from an instrument, MVA, consultancy or integration/application viewpoint. Please visit our website or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

Access and Availability

synTQ Assured Support is available to all end-user customers operating a licensed and registered instance of synTQ. All direct support is supplied in English as standard. Other languages are available on request.

Return on Investment

- ▶ 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 have 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





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

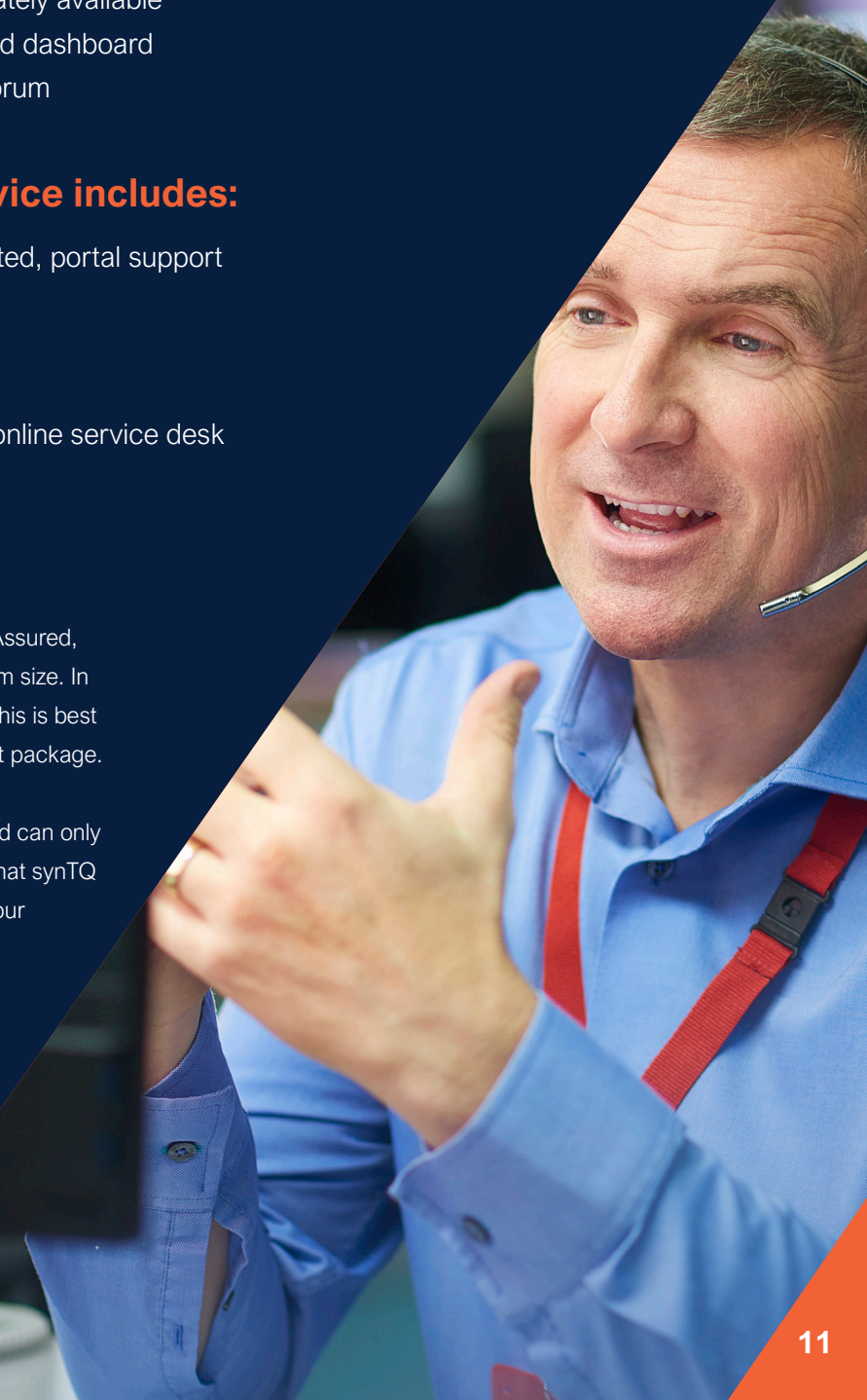
synTQ Assured support service includes:

- 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.

-  EXPERT TECHNICAL PHONE SUPPORT
-  REMOTE SYSTEM DIAGNOSTICS
-  ONLINE SERVICE INFORMATION
-  DEDICATED CUSTOMISED SYNTQ ASSURED ON-LINE SERVICE DESK
-  DOWNLOADABLE SOFTWARE UPDATES
-  MY SYNTQ PORTAL KNOWLEDGE BASE
-  SYNTQ FORUM





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