Real-Time PAT Knowledge Manager

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

Measure | Understand | Control | Improve





"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,

Image courtesy of Gericke

together with significantly improved quality and

Martin Gadsby, Director of Optimal Industrial Technologies

consistency of quality."

Join the revolution

The synTQ PAT Knowledge Management and Quality-Centric Control Software Suite has now been adopted by a wide range of leading manufacturers – 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 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 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 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 over two decades of development behind it, synTQ is the product of choice to deliver all these PAT-enabling features – and 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, as well as apply 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 fermentation process has been reported, plus the ~500-fold decrease in manufacturing time for a manufacturer using PAT to switch from batch to continuous manufacturing. In this latter case, synTQ enabled the production to be transformed by using holistic, fully automated Quality Assurance and Real-Time Release Testing, where no post-process inspection was necessary. 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, a reduction in the necessary manufacturing infrastructure and greater flexibility in raw material sourcing. 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 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, all your gathered data 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. With synTQ you are normally free to choose whatever instrument and MVA package you need – we have a large and ever-expanding portfolio of 'adapters', 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 Electronic Records and Electronic Signatures (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 access a broad range of reporting tools suitable for your application. The portal to the data is via the 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.

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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.

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

One of the major changes that should be embraced with a PAT-enabled process is continuous improvement. Processes which were once fixed forever should now be constantly monitored and, when appropriate, changes should be 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 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

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 many process industries for over 34 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, or 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 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 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







synTQ Assured benefits:

- Expert support when you need it, 24/7/365
- Optimise reliability and performance
- Minimise 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, customised 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 annually and is based on system size. In addition, application support can be provided, which 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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