Measure | Understand | Control

PAT Implementation Manager

Proven and Available Today...
synTQ Version 4

Optimal industrial automation

PAT is the future of Pharmaceutical Manufacturing and the tools to implement it are available NOW with synTQ Version 4

synTQ v4.0

Process Analytical Technology (PAT) is rapidly becoming the cornerstone of pharmaceutical manufacturing. It has already been proven to provide significant benefits in product quality and production time whilst delivering dramatic Returns On Investment. synTQ has been designed to facilitate the rapid implementation of PAT on your plant by enabling the seamless integration of disparate third party instrumentation, control systems and analysis packages within a secure and compliant real time environment. From initial R&D investigations, process model building and control model development to fully validated enterprise wide manufacturing, synTQ makes compliant PAT deployment possible.

Version 4 Highlights

- **synTQ Web Clients**
- **Enhanced Graphics**
- **synTQ EM (Enterprise Master)**
- **Centralisation of all plant data**
- **Easy sharing of Models between multiple synTQ FM and Lite machines**

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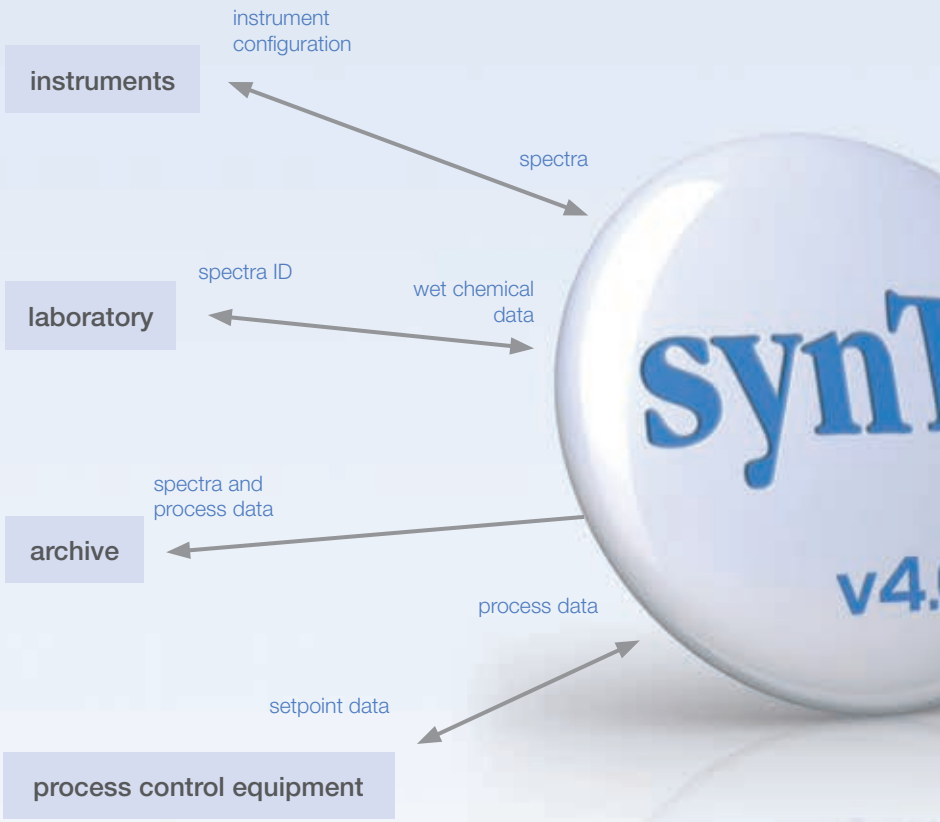
PAT

PAT is a very rare technology in that it can simultaneously lower manufacturing costs, improve product quality and dramatically reduce the time to market for new compounds. In addition, the advent of continuous manufacturing and real time release as enabled by PAT will significantly cut 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. The team at Optimal have had 25 years of worldwide experience in Pharmaceutical Manufacturing and have created synTQ specifically to ease these challenges and facilitate the efficient, timely and compliant implementation of PAT systems from R&D through to full manufacturing.



Instrumentation Management

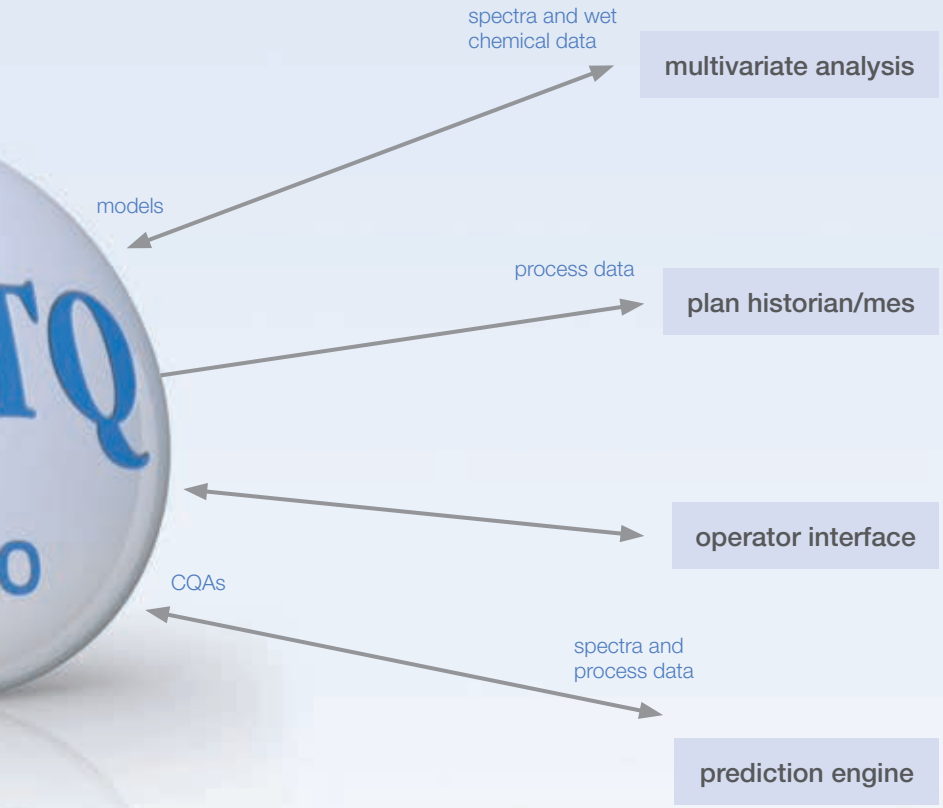
The use of complex instrumentation (NIR, Raman, Particle sizing etc.) offers the potential to reveal in real time those vital product variables in your process. To access this information however, the correct configuration and calibration status of the instruments is vital as without these being robustly 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 utilises industry standard databases such as MSSQL Server and Oracle as it's data repository. 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 most popular 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.



Scalability

synTQ is a scalable PAT Implementation 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 created 'Orchestration' facility. This facility 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.

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 controlled changes introduced 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 of Version 4 facilitates the continual enhancement of Process Understanding.

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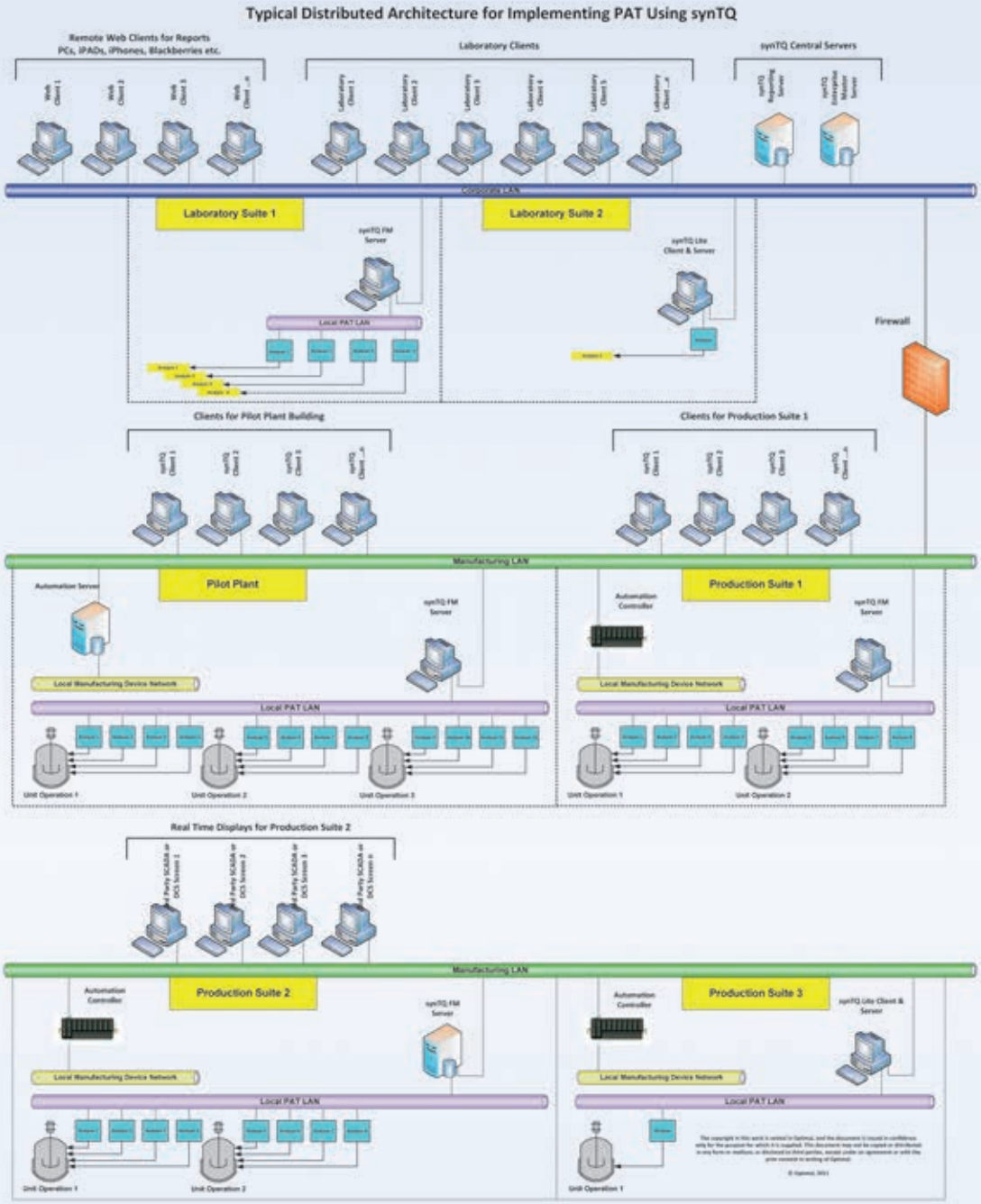

PAT Consultancy & Training

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 thus 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. To increase our supply and support capability we have entered into a strategic alliance agreement with Emerson Process Management, one of the world's leading automation vendors. This allows us to provide a local supply, implementation and support capability in all the major manufacturing centres across the world.

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Global supply and support by
Emerson Process Management

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