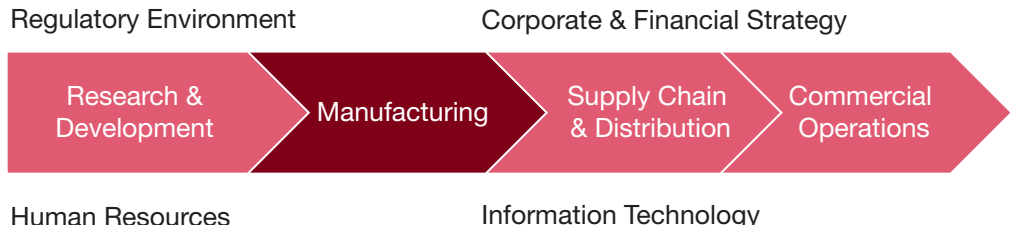


Process Analytical Technologies (PAT) and Quality by Design (QbD)



Benefits

The implementation of the PAT guidance is an important decision, which, if done well, can bring significant benefits:

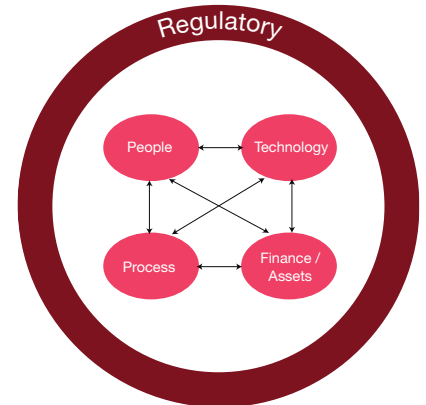
- Consistent product quality
 - Patient safety
- Reduced risk of recalls
- Real-time release
- Cost Reduction
- Reduced inventories
- Less waste
- Higher yields
- Increased process understanding resulting in more efficient production processes
- Faster process development, upscaling and tech transfer
- Regulatory flexibility, relief and easier regulatory approach
- Improved clinical outcome quality
- Easy Technology Transfer

Process Analytical Technology (PAT) is a system for designing, analysing, and controlling manufacturing through timely measurement of critical quality and performance attributes of raw materials, in-process materials and processes with the goal of ensuring final product quality.

The Quality by Design (QbD) framework concerns designing and developing processes that can consistently ensure a predefined quality, resulting in real-time release of products.

How PwC can help you?

PwC has developed a fully-integrated approach covering all the relevant domains: Technology, People, Processes and Finance, and has framed it into the regulatory context. It starts by defining the Business Case for PAT/QbD, then assessing the business impact, developing the PAT/QbD strategy and regulatory approach and finally developing the implementation roadmap and support.



QbD services

QbD is a new approach for R&D and can be a means to drastic time-to-market cutback, faster process knowledge and speeding up the development process. PwC can help with:

Training & Awareness on the benefits, approach and change by QbD

Development of a QbD Strategy, including technology solution design, regulatory and manufacturing strategy and personal & skills requirements

Financial Business Case development

PAT services

PAT tools in Manufacturing can optimise the supply chain and achieve cost reduction in Manufacturing and enable Real-Time product release. PwC can help with:

Assessments of "AS-IS" and "TO-BE"

Business Case development and calculation of Return on Investment

Contacts

Ingrid Maes

Director
ingrid.maes@pwc.be
+32 (0) 3 259 3305

Nico De Backer

Principal Advisor
nico.de.backer@pwc.be
+32 (0) 9 268 8395

www.pwc.com/pharma

This publication has been prepared for general guidance on matters of interest only, and does not constitute professional advice. You should not act upon the information contained in this publication without obtaining specific professional advice. No representation or warranty (express or implied) is given as to the accuracy or completeness of the information contained in this publication, and, to the extent permitted by law, PricewaterhouseCoopers does not accept or assume any liability, responsibility or duty of care for any consequences of you or anyone else acting, or refraining to act, in reliance on the information contained in this publication or for any decision based on it.

© 2011 PwC. All rights reserved. Not for further distribution without the permission of PwC. "PwC" refers to the network of member firms of PricewaterhouseCoopers International Limited (PwCIL), or, as the context requires, individual member firms of the PwC network. Each member firm is a separate legal entity and does not act as agent of PwCIL or any other member firm. PwCIL does not provide any services to clients. PwCIL is not responsible or liable for the acts or omissions of any of its member firms nor can it control the exercise of their professional judgment or bind them in any way. No member firm is responsible or liable for the acts or omissions of any other member firm nor can it control the exercise of another member firm's professional judgment or bind another member firm or PwCIL in any way.

Pilot project selection and definition of Key Performance Indicators (KPI)

Change Management Process

Tailor-made trainings

Change Control and Validation support in line with the objectives of the cGMPs for the 21st century and the new guidance on Process Validation

Proven experience

Client issue

The pharma injectables manufacturing sites were based on islands, with no integration. PAT/QbD had been evaluated with other new technologies to improve manufacturing cycle time and reduce manufacturing costs. Today's competitive situation called for a review of the current manufacturing sites and definition of a modernisation strategy, to prepare the company for the future.

PwC solution

We deployed a team with specific expertise in Manufacturing and Quality to look for improvement opportunities and prepare an investment roadmap. The team made an evaluation of the business impact of the suggested improvement scenarios. For this comparison, major KPIs were evaluated as well as the technical feasibility of the suggested solutions.

A final scenario with the biggest cost reduction has been selected, providing insight into the future by acknowledging that the world is increasingly 'safety' focused bringing proven and robust methods, tools and techniques to help accelerate the manufacturing process, also focusing on long-term change.

Benefits

This project was aligned with the overall strategic direction of the company and also considered the present and future product portfolio.

The suggested roadmap gave the manufacturing and quality operations a leaner and more agile organisation with a greater market-demand focus.

The benefits include:

- *Reduction of 25% in FTE's per batch*
- *Reduction of 13% in costs of quality*
- *Reduction of 5% in waste*
- *Reduction of 30% in inventory costs*

Besides a reduction in the cycle time the company also achieved predictable cycle times, to allow for better planning and lower inventory costs and safety stocks.

Global Pharmaceutical and Life Sciences Industry Group

The Global Pharmaceutical and Life Sciences Industry Group at PwC is dedicated to delivering effective solutions to the complex business challenges facing pharmaceutical and life sciences companies. A global leader in serving the pharmaceutical and life sciences industry PwC has extensive experience working with companies on industry-specific strategic, operational, and financial issues. Our expertise includes assurance, tax and advisory services, as well as specialised capabilities in regulatory compliance, risk management, performance improvement and transaction support. In helping our clients, we draw on the full knowledge and skills of PwC's professionals. More than 161,000 people in 154 countries connect their thinking, experience and solutions to build public trust and enhance value for clients and their stakeholders.