



Process Management International

# Accelerating Approvals for Pharmaceutical Manufacture

## Context

Multinational company whose products require approval from regulatory agencies before a licence can be achieved and product released to customers.

## Challenge

This approval process had been a bottleneck for the organisation, with delays of up to many weeks, leading to the need for high inventory levels and associated high costs.

## PMI's Contribution

We supported the improvement team leader, trained several specialist staff to Green Belt and Black Belt level, and conducted custom process management workshops with relevant managers.

## Lessons

People appreciated that the separate job of gaining approval is a process in itself, subject to many of the same characteristics as the core manufacturing process.

They saw the value of understanding the whole system of gaining approval, including the understanding of the regulator as customer. Once they recognised the opportunities, they were able to identify delays and rework that were previously hidden and address their causes.

**“** *I would think it probably took several months out of the process. That was very vital time to us. It's been a platform on which we've built. We're continually working in this area and I think that the groundwork that we laid with PMI has really been the foundation for a lot (more) of what we've done.* **”**

CEO

## Wider Applicability

Many organisations are required to certify their key processes, ranging from aerospace manufacture for safety, to schools for examinations. Such certification processes are often seen as poor relations to the main business of the organisation, but their poor operation can lead to waste, delays and direct and indirect costs.

## Further Reading

A podcast of the full interview is available to download. Visit [www.pmi.co.uk](http://www.pmi.co.uk) for more details.