Creating the Process from Pilot to Launch and Beyond

With a serious health issue to be addressed, an entrepreneurial global manufacturer needed a reliable process in place to launch and maintain a high production level for the female condom that would empower women to take charge of their sexual health and contraception needs.

Background

Chartex International was a new enterprise, started by a Danish entrepreneur, who saw the opportunity to create female condoms for a global market. The business was based in London and the concept for the Femidom was bought in 1987, with a view to developing manufacturing processes capable of scaling up to meet global demand.

Their Issue

Having identified exactly what was required to produce these polyurethane Femidoms by hand, this process needed to be automated and multiplied. The main objective was to perfect the process, and people to meet the projected global demand for 55 million units per year.

The Story

Andy Dobson joined as Shift Manager at a time when the product was just entering volume manufacture.

As the Shift Manager he was responsible for all functions within the factory: Production, Packaging, Stores with a dotted line to Engineering.

During this hectic period Andy was instrumental in developing processes and machinery as well as recruiting and training people to efficiently run machines and inspect/pack product.

After an initial take off in production, it became clear that there were technical issues in several areas. A decision to develop a new design was taken.

The new design fundamentally changed the way the devices were manufactured and proved to be much more reliable.

The task then was to integrate the new machines into the existing processes, this involved taking half the original large machines away and replacing these with 8 individual smaller machines surrounding a base. During this time, Andy and the other Shift Manager worked on the other processes, developing staff and equipment for when the expected demand would come.

Issues such as factory layout and other equipment problems were worked on by Andy and a small team of Operators and Engineers. One solution developed for a flow-wrapping issue was subsequently adopted by the equipment manufacturer.

An area of necessary focus was the approval for this new medical product by the licensing authorities of various countries, particularly the US and UK markets.

The US authority (The Food and Drug Administration or FDA) set rigorous standards for product approval. As a start-up, there was no previous documentation to support an FDA application so this was created by Andy and the team in short order.

The result of the company's hard work was that FDA approval was granted 1st. time around within 12 months of starting the process.

Within 18 months of joining Chartex, capacity had exceeded 25 Million units/year. It was time to do something different. Andy then took the lead in Process improvement becoming a Production Engineer again and started by chasing the factory bottlenecks. By a programme of process review and standardisation the capacity of the factory was increased to 50 Million units/year.

Andy, recruited, coached, trained the workforce whilst driving output, whilst being part of a successful team scaling a new product.

"I didn't do this alone; I recruited the right people then nurtured them to give their best. It wasn't just about the technology."

*Andy Dobson, PaCkRaT Ltd.t/a **Lean 4 Business** Registered in England,*
Company no. 4676181 Vat. No. 122 6139 44
Tel: 0845 108 3949 Mob: 07850 776994 E: andy@lean4business.co.uk