



QUALITY MANAGEMENT BEST PRACTICES MANAGING QUALITY THE 'TOYOTA WAY'!

BACKGROUND

Many pharma companies have now woken up to the fact that their Quality Systems are both ineffective and unaffordable. Not a pleasant situation to be in! For those of you searching for answers why not look outside the pharmaceutical industry? In fact if you're looking for industry 'best practice' for Quality Systems you need to look no further than Toyota.

'What can Toyota teach the Pharmaceutical industry?' I hear you say... well actually an awful lot! Toyota's philosophy and approach to quality management is generally regarded as world class, sustainable and **proven to work**. Crucially, their success is not down to a set of 'lean' tools or techniques, but an underpinning philosophy that focuses on only doing those activities that add value to internal and external customers. There is, however, a twist to the Toyota success story that serves as a painful reminder to all...more on this later.

But is it fair to draw comparisons between a manufacturer of cars and an industry making medicines? Although differences clearly exist, there are some striking similarities:

- > Both industry sectors are heavily regulated. Although automobiles have no FDA or EMA equivalent, Toyota would argue that their activities are regulated by the most important and influential stakeholder of all... its customers. Like many other consumer industries, satisfy the customer and you stay in business. Upset them and you lose them for ever
- > The consumers of both demand high quality, affordable products
- > Both need to eliminate waste and non value adding activities to stay in business
- > Both have complex processes and products. The assembly of a 'Lexus' is probably more



complicated than most pharmaceutical manufacturing processes

- > Both face the challenges of very complex supply chains

So there you have it, manufacturing cars and medicines is actually quite similar! What is different is Toyota's approach to 'Quality Management.' For decades they have made cars more efficiently and with a lower defect rate than any other manufacturer. So how have they achieved this success?

THE 'TOYOTA PRODUCTION SYSTEM'

Although the key principles of Toyota's Production System can be conveniently summarised it is vital to remember it represents a way of thinking, not just a set of tools and techniques. For those of you looking for a quick fix you may as well stop reading now. There isn't one. It's taken Toyota 60 years to create what they have and they still haven't finished!

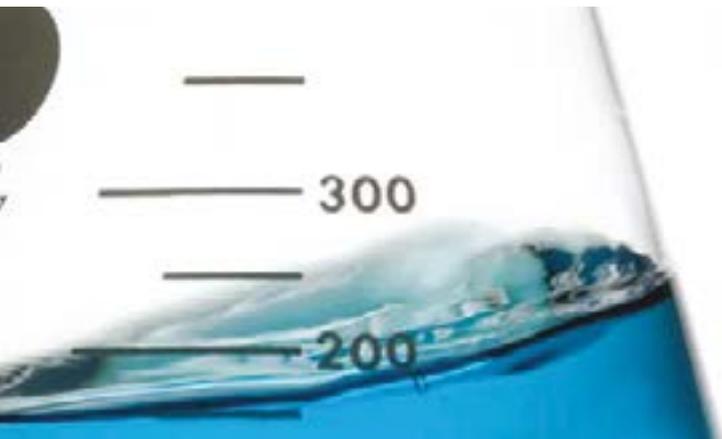
So, what is the 'Toyota Way'? Their success has been achieved by:

1. **Adopting a Long Term Philosophy and Sense of Purpose:** Thinking beyond just making a profit
2. **Investment in People:** 'We build people before we build cars'



3. **Focusing on the Production Line:** 'Keep the main thing the main thing'
4. **Being a 'Learning Organisation':** Continuously solving problems to learn
5. **Focusing on the Process, not output:** 'The right process will generate the right results'
6. **Standardising when ever possible**
7. **The War on Waste:** The heart of the Toyota Production System
8. **Supplier and Third Party Relationships:** The extended family
9. **Performance Measurement:** Less IS more!

THE 'TOYOTA WAY'!



So, how does your company compare with the following?

1. ADOPT A LONG TERM PHILOSOPHY: IT'S NOT JUST ABOUT MAKING A PROFIT

Until most recently, Toyota was different from most companies. Decisions are not driven entirely by satisfying short term profit and loss forecasts. They actually think beyond the desire to satisfy the accountants. Toyota plan and act with the long term in mind, not the quarterly results.

- > They have strong commitment to serve and benefit society in general, not just shareholders
- > Toyota's mission and guiding principles is not a poster on the wall, they're practiced each and every day. They represent Toyota's 'moral compass' for routine and strategic decision making

- > Toyota has very little secrets. They even train their competitors in how to implement their 'Toyota Production System' so that other communities can benefit. They love to share best practice
- > The beliefs and values of Kiichiro Toyoda still drive the Toyota organisation. Successive leadership teams have worked hard to ensure these are passed onto the next generation. They work hard to protect and maintain the Toyota legacy
- > There is a constancy of purpose no matter how tough the environment. Their focus is to add value to customers, employees and society, not just shareholders
- > There is a very strong sense of purpose. 'Protect the legacy' even at the cost of short term profits. Day to day decisions are driven by the company's long term strategy. There is no short term thinking

2. INVESTMENT IN PEOPLE: 'WE BUILD PEOPLE BEFORE WE BUILD CARS'

Every company says its products are only as good as its people. Toyota actually means it. They invest considerable effort in recruiting and keeping the very best. The recruitment of an assembly line worker can take up to 14 months before they are offered a full time contract. When asked:

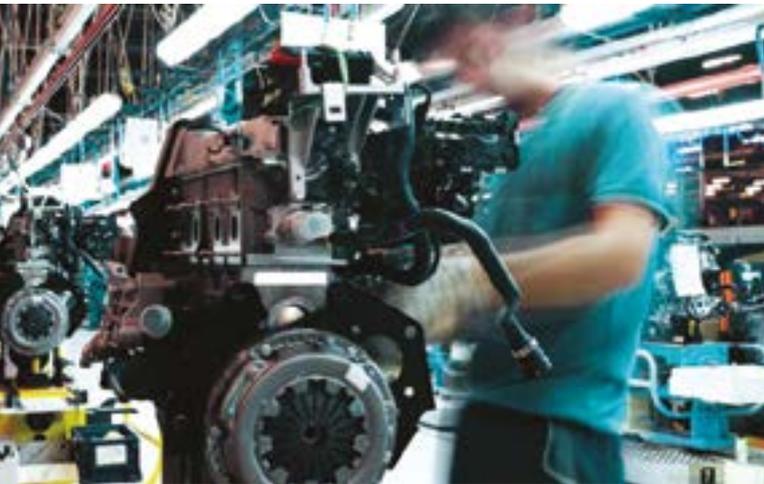
"How can you afford this kind of recruitment process," Toyota's response is swift

"How can YOU afford not to?"

- > Once they have recruited the best, people tend to stay. On average their staff turnover is less than 3%. Compare this with the 10-12%+ experienced by many pharmaceutical companies
- > They make a commitment to all of their employees 'Your job is safe'. Even in the midst of the deepest financial crisis to hit the automobile industry in decades, Toyota has not made any full time employees redundant. Efficiencies and lean initiatives are used to create job opportunities, not make redundancies



- > Contractors and full timers are treated as equal in pay and privileges
- > Toyota reward team performance, not that of the individual. Promotion can take time. Slow promotion and rewards for team work is the norm
- > Toyota sees ongoing education as vital. They have even built their own University to ensure a steady flow of high quality engineers! They regard education as an investment, not a cost
- > Managers are seen as mentors and coaches, teachers not dictators
- > Toyota generally promote from within. They grow leaders rather than purchasing them



3. FOCUS ON THE PRODUCTION LINE: KEEP THE MAIN THING THE MAIN THING

Everyone focuses on servicing the production line. Every other activity is seen as 'non value added'. They achieve this by having:

- > An 'upside down' management structure. Team leaders and managers support those at the sharp end, not the other way around. Assembly line operators are at the top of the pyramid, not the bottom
- > There is a genuine belief that only assembly operators and engineers add value. Everyone else must justify their reason for being!
- > Everyone must serve their apprenticeship and develop deep understanding of the process.

Even those in HR have 'time served' on the assembly line

- > Managers and team leaders spend up to 80% of their time on the production line solving problems and adding value – not in meetings or 'emailing'
- > Leaders manage from where the work is done, not from their office

4. A GENUINE LEARNING ORGANISATION: 'SOLVING PROBLEMS IS KEY TO OUR SUCCESS'

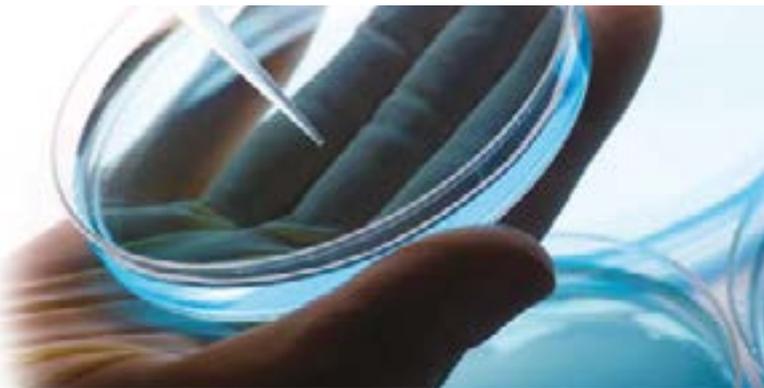
- > Toyota intentionally runs very, very lean. There are no buffer stocks to fall back on. Running lean means that problems can **have** a dramatic impact on production output. Problems have to be fixed, and fixed quickly
- > The pervading attitude is that problems and process deviations are **really** good news, providing you learn from them. It's accepted that 'real time' solving problems at source saves time and money later on downstream
- > Toyota famously adopts the 'andon' approach to problem solving. Deviations are acted upon within minutes and always solved at the site of the incident, never from behind a desk. Deviations are brought to the surface quickly and solved within hours. How does this compare with your '30 day' limit for deviations?
- > Deviations are triaged (prioritised) and solved by teams of trained problem solvers, usually those at the sharp end using a standardised approach to problem solving and decision making. Recurrent problems are rare.
- > Suggestion schemes are used to generate new ideas and ways of working with over 90% of suggestions implemented. Payments are weighted towards the small incremental improvements not the big ones.



5. ONLY FOCUS ON THE MANUFACTURING PROCESS AND NOTHING ELSE

Toyota's attitude is 'get the process right and the results (output) will follow'. Most of their performance measures relate to the assembly process, not how many units are actually manufactured or rejected.

- > They rarely use any new or unproven technology. They let others suffer the cost and disruption of 'being the first'. Those at the sharp end are also involved in process design and the implementation of new technology. In fact they usually have the last say!
- > Technology is only used when it can add value and keep things simple. Toyota's attitude is that people do the work, computers only move the information. If technology distracts or confuses the user, it is simply not used



6. STANDARDISATION IS THE NAME OF THE GAME

- > Standardisation is considered as vital in order to stabilise any process. Just like the pharmaceutical industry, Toyota has SOPs to ensure processes are standardised to help guarantee a consistent output
- > Standardisation is about finding out the scientifically best way of doing a task, proving that it works and then 'freezing' it. Although people are expected to 'follow the rules' SOPs are not allowed to stifle innovation and further improvement. Users are encouraged to share best practice, 'hints and tips' and improve SOPs further. SOPs are constantly reviewed and improved, not every 2-3 years!

- > The level of procedural compliance is very high for one simple reason – user involvement. SOPs are developed from the bottom up not from the top down. Management have very little input. Users are seen as the document owner. They write, design, refine and implement all new SOPs. Not surprisingly compliance is not a problem because they usually work!

7. THE WAR ON WASTE: IT NEVER STOPS

Anything that adds no value is removed from the system.

- > Toyota has created a continuous process flow for everything, removing non value adding activities from the system such as:
 - Over production
 - Waiting
 - Unnecessary movement of anything, including people
 - Over processing
 - Excess inventory
 - Defects
 - Unused employee creativity
- > Toyota also considers complex organisations and bureaucracy to be wasteful:
 - Rules and procedures are seen as 'enabling' and open to challenge, change and improvement. There is no such thing as 'blind compliance', following the rules for the sake of it
 - There is a 'bottom up' hierarchy. Corporate functions are small and very efficient

8. SUPPLIER AND THIRD PARTY RELATIONSHIPS

- > Suppliers seen as an extended member of the family, an extension of the production line if you like
- > Toyota typically dual source most, but not all, components



- > Although Toyota depends heavily on suppliers they retain their core competencies to maintain self reliance and protect their intellectual property. They want to learn from suppliers but never transfer and lose core knowledge. Toyota wants to know what's in the 'black box' and never lose internal capability
- > Toyota views any new supplier cautiously and starts with small orders first until trust and creditability have been established. This process can take up to 10 years for key suppliers.
- > Toyota's purchasing department includes quality experts who play a key role in the selection process. They never select on price alone and concentrate on building a long term 'win:win' relationship based on 'fair and honourable business relationships'
- > Although they set very aggressive targets for service and quality, Toyota then provides the help and support needed to achieve these. Toyota actually helps suppliers improve their own business

9. PERFORMANCE MEASURES: LESS IS MORE!

- > Less is more. Toyota measures only what is important and avoids the 'death by measure' approach adopted by many
- > They only select measures that drive the right behaviour. For example, assembly line workers are rewarded for raising deviations. After all, you learn more from your mistakes than from your successes. Contrast this approach with that taken by many pharma companies, namely to encourage people to reduce deviation numbers! This measure drives completely the wrong behaviour

THE TWIST TO THE TALE!

What Toyota has achieved can be replicated elsewhere; it **just** takes leadership and commitment! There is, however, a twist to this tale. For 50 years Toyota has led the market place with its performance, customer service and attitude to quality...until recently! In the last two years they have recorded annual losses. The company has also suffered embarrassing recalls in the USA. So what has gone wrong and, more importantly, what can we learn from Toyota's recent experience? Independent observers put Toyota's recent troubles down to:

- > Senior managers focusing on the financial results and forgetting the basic principles that made the company great. Yes, the 'financials' are important but focus on them at your peril
- > The emergence of 'lean fatigue' and failing to keep focused on lean practices. The war on waste never stops
- > Failing to really fix problems with its customary patience and discipline, accepting compromises and 'workarounds' instead

After years of success Toyota assumed that 'quality' was a given and something that could be achieved without paying attention to the 'how'. The company's top executives made the mistake of pursuing finance driven growth and pricing at the cost of sacrificing the principles that had made Toyota thrive. They took their eye off the ball.

For many pharmaceutical companies the facts remain unchanged. Quality Systems have to become more efficient and effective to stay in business. Although this transformation isn't going to be easy, let's learn from the best rather than reinvent the wheel.

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