



# WHAT CAN WE LEARN FROM QUALITY MANAGEMENT SYSTEMS IN OTHER INDUSTRIES?

by John Johnson

Why is it that we often view the pharmaceutical quality system as somehow distinct and separate from the approaches taken in other manufacturing industries? What are we missing by not studying the architecture and content of quality systems in, for example, the nuclear, “fast-moving consumer goods”, and automotive industries? Would we be able to take an insight from a world-class company, even if it wasn’t a firm identifiable with pharma manufacturing?

The question which got me thinking about this was:

***“If there was one book that influenced your perspective on how to design and monitor a quality management system, what was it?”***

As part of my professional development as a QP and Quality Leader, gaining insights from some of the most influential thinkers in quality management has been critical in helping me to determine the proportions and performance required of a local pharma quality system. Of course, the classic reads from Joseph Juran and James Collins are part of the staple diet; but what stood out for me was Jeffrey Liker’s book, “The Toyota Way: 14 Management Principles from the World’s Greatest Manufacturer.” I had the honor of spending time with Liker in 1998 during a tour of the UK and what impressed me most was how the key learnings were:

- > Easily transferable to the pharma industry
- > Based on reducing the risk of quality defaults and as a consequence on reducing cost and scrap product
- > Illustrated with real-life shop floor case studies that showed how the key principles could be applied in practice

The principles are grouped under the key headings of:

- > Maintaining a quality philosophy
- > Using process thinking to resolve issues
- > Adding value to the organization by developing people and partners
- > Creating a learning organization by understanding the root causes of key issues through relentless challenge and reflection

When I reflect on the key concerns of the regulatory bodies, distilled from intimate knowledge of FDA warning letters and MHRA referrals to the Inspection Action Group, the recurring themes are:

- > Failing to install a pharma quality system that is shown to be insightful, easily interpreted, noticeably in place, sustainable and proportionate; and by consequence the quality culture or mindset will be misplaced or under-performing
- > Failing to install processes that are risk based, scientifically derived, logical and clearly defined
- > Failing to invest the time and effort in professional development within the company and with suppliers, and failing to grow leaders and subject matter experts so that no organization relies on a single individual
- > Failing to understand the most probable root cause of GMP deviations and misinterpreting the consequences of failure; such that expensive, unreliable and misplaced CAPAs are then applied in error, which is later evidenced by recurring failures as the CAPA is shown to be ineffective.



Theme	Toyota's Management Principle	Your Pharma Quality System	Score: High 9 Medium 3 Low 1
Develop a long-term philosophy	<b>1</b> Base your management on long-term philosophy, even if in conflict with short-term financial goals	Quality policy, vision/mission/values, mid-/long-term objectives in growing a long-term, sustainable business	
The right process will produce the right results	<b>2</b> Create process flow to ensure problems are detectable	Management review, key metrics, use of insightful product quality reviews, real-time trending, root cause analysis techniques	
	<b>3</b> Use "pull" systems to prevent overproduction	Sales and operational planning process, inventory management, amount of material as "work-in progress"	
	<b>4</b> Level out the workload; work like the tortoise not the hare	Understanding resource planning, contingency planning, successor management, development of standard processes, sharing the strain across teams	
	<b>5</b> Build a culture of stopping to fix problems once and for all	GMP deviation process, root cause analysis, CAPA effectiveness checks, knowledge management	
	<b>6</b> Standardized tasks drive continuous improvement	Accuracy, readability, logic and accessibility of SOPs, use of process flow charts, service level agreements and performance measures	
	<b>7</b> Use visual control so that no problems are hidden	Daily huddles, workplace performance indicators, management of critical process parameters, risk management and prioritization of key resources	
	<b>8</b> Use only reliable and thoroughly tested services and technology	Vendor assurance, lifecycle approach to qualification and validation studies that ensures predictable performance, focus on calibration and planned maintenance	
	Add value to the organization by developing its people and its partners	<b>9</b> Grow leaders who thoroughly understand the work and who can teach others the same skills	Continuing professional development, 'Train the Trainer', management skills, long term investment in staff through thorough selection, onboarding and ongoing development
<b>10</b> Develop exceptional people and teams who embrace the quality principle		Reward and recognition, objective setting and appraisal through qualitative and quantitative measurement, mentoring, employee engagement	
<b>11</b> Respect your extended network and engage them in the quest for quality		Vendor and contractor relationships, technical agreements, complaint/issue resolution, building relationships not just financial transactions	
Continuously solving issues using root cause analysis	<b>12</b> Go and see for yourself ("Gemba" meaning "real place")	Use of Ishikawa, 5 whys, is/is not, HACCP/HAZOP, issues seen as opportunities for deepening understanding of the products & processes, shop floor not office-based solutions	
	<b>13</b> Make decisions slowly and thoroughly by consensus, then implement rapidly	Change control committee, management review and deviation investigation is thorough and multidisciplinary but very rapid (<5 days)	
	<b>14</b> Become a learning organization	Spend your training budget wisely, always seeking a return on investment, broadening and deepening expertise ahead of crises	

**Grand Total**



It is depressingly common that the four issues described here often contribute significantly to the onset of serious regulatory action; leading to cost, drug shortages, lost reputation and lost revenue.

So my simple advice is, get a copy of The Toyota Way and judge for yourself how well your company performs against the 14 management principles within it (see box alongside):

So, once you have added up your scores from the table:

- If you scored less than 84, breathe hard and think through what you need to do to improve your organization's quality culture.
- If you scored less than 50, I am guessing that you already feel pretty uncomfortable and need some urgent help!

## ABOUT THE AUTHOR



John Johnson is passionate about helping organizations foresee and overcome the barriers to sustainable long-term growth. He brings 28 years' experience across a range of companies in the pharmaceutical and healthcare industry. He has worked in small, medium and large pharma biotech companies across the product lifecycle for a wide range of dosage forms, holding senior operational and corporate-level experience in operations and quality assurance and leading multinational companies in many strategic projects.

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