



IS YOUR BIGGEST BUSINESS RISK COMPLACENCY?

by Martin Lush

THE COMPLACENCY TEST:

Any of the following sound familiar?

- Recently passed a successful regulatory audit... and breathed a huge sigh of relief?
- Does your senior management think a successful regulatory audit is the "end game"?
- Are you drowning in key performance indicators that tell your leadership what they want to hear rather than the painful truth?
- Repeat deviations still an issue?
- Struggling to complete deviation investigations within 48 hours?
- Do you reward people for driving down deviation incidents?
- Has firefighting become such a habit you don't even notice it any longer?
- Ever read another company's 483s and thought they sounded familiar?
- Does your leadership spend more time in meetings than on the shop floor?
- Is your company severely risk averse?
- Suffering from initiative overload, when nothing gets done properly?
- Frustrated by poor communication and the time wasted on internal politics?
- Do you see training as a cost, not an investment?
- Does your company take the attitude "If it isn't broke, don't fix it"?
- Do you think what worked yesterday will be good enough today?
- Does your quality management look the same as it did five years ago?

Too many yes answers should ring a few alarm bells. You may be at risk from the silent killer at many organizations...COMPLACENCY. Just ask BlackBerry (everyone used to have one), Nokia (previous market leaders) and Kodak. The list is endless and includes a few big names in pharma too.

Companies who took their eye off the ball and saw their market share, legacy and reputation destroyed by consent decrees, warning letters and importation alert bans. In short, they all became complacent.

Jim Collins' books 'Good to Great' and 'Great by Choice' should be required reading for everyone. These books are a highly forensic (and readable) analyses of how companies achieve sustainable growth in difficult times. Here are two tremendous one-liners from Jim Collins:

- > "Good is the enemy of great."
- > "Companies that succeed work very hard at becoming productively paranoid."

HOW TO BECOME "PRODUCTIVELY PARANOID"

At NSF, we work in partnership with our clients to help them become productively paranoid:

- > Our global client base, strong industry networks and links with regulatory agencies and governing bodies allow us to keep our finger on the regulatory heartbeat and industry pulse for pharma and medical devices
- > Our regulatory experts can tell you what's coming and how to prepare
- > Most of our team members have over 30 years' hands-on industry experience. We know what works and what doesn't, and we have walked in your shoes



- > We have a reputation for challenging the status quo based on sound science, pragmatism and a genuine desire to help clients move from good to great. In an ever changing world we don't think "good" is good enough any longer
- > We focus on changing people, not just improving systems. Without changing the way people think, you can't change anything

HINTS FOR PRODUCTIVE PARANOIA: WHAT YOU MUST DO

HERE'S WHAT YOU MUST DO TO OVERCOME COMPLACENCY.

Measure what matters most: Less is more

We believe the more you measure, the less you know. Make your KPIs focused and meaningful, more leading than lagging, and make sure they drive the right behavior.

Provide visible supervision and leadership: The best form of performance management is vigilant supervision

We believe leadership at every level should spend more time where they add greatest value – on the shop floor "walking the talk." Only then will they get a sense of the challenges their teams face on a daily basis. How else can you see where improvement is needed?

Break the firefighting habit: Develop an unrelenting passion for continuous improvement

We believe deviations provide a fantastic opportunity for improvement and that people should be rewarded for raising them. We think incidents should be treated as a priority, triaged (risk ranked) and investigated in hours, not days, by educated (certified) problem solvers.

Give power to the people: Engage your entire workforce...they are just waiting to be switched on

We believe most companies only utilize 10% of the intellectual capability of their workforce. The skills and competencies of operators and junior staff usually remain untapped. When we help our clients move from "good to great," we help to improve their core competencies so they are equipped to complete root cause investigations and internal self-inspections and to drive continuous improvement.

Conduct internal audits and self-inspections: Your catalyst for productive paranoia

We believe a risk-based internal audit and self-inspection program is key to identifying your strengths and weaknesses needed to drive continuous improvement and manage risk. To have confidence in your audits, you must have confidence in your auditors by providing them with the skills and knowledge to do a tough job well. Don't let the first time you know of a problem be when your EMA or FDA inspector identifies it for you. The key is self-identification. Anything less and the control of the business moves from you to someone else. Don't let complacency allow control to slip away.

Benchmark: Learn from the best

We believe as soon as you think that "good is good enough," you are in trouble. You have to constantly challenge, question and improve... but not reinvent the wheel. We have worked very closely with best-in-class companies in pharma, automobiles and the retail sector. If you want to learn about what works and simple solutions to complex problems, our Quality System Benchmarking workshop will help.

Educate for the future: Don't train for the past

We are amazed how many companies stick with compliance-based training that tells people what to do without explaining why. At NSF, we believe in helping to educate our clients for the future, not training them for the past. Our clients tell us that our methods have changed behaviors in the work place, not just checked the compliance training box. If you want an educated workforce capable of doing more with less, our 'From Training to Education' workshop will transform your approach.

Focus on doing the basics to PhD level: Stop doing the rest

We believe your success is determined by what you stop doing. We help our clients focus on what really matters by helping them develop excellence in their products and processes, risk-based decision making, problem solving, error reduction and auditing.



In Summary: To Survive You Must Excel at Becoming Productively Paranoid!

- > Complacency is silent. History tells us it can be deadly
- > As soon as you stop challenging, questioning and improving, your days are numbered. Whether you call it arrogance or insularity, both can be equally damaging. Just ask BlackBerry, Nokia and Kodak
- > Create a culture of productive paranoia... and fast
- > NSF is obsessed by helping you prepare for the future, not the past
- > If you want to protect your business from the danger of complacency, please email us at pharmamail@nsf.org – we can help:
 - Our independently certified **Pharmaceutical Auditor education program** provides your auditors with the skills they need
 - **Benchmarking.** If you want to know how you compare with the best in class, we can help
 - **We help you do the basics to PhD level.** Our education programs on GMP, manufacturing processes, deviation and CAPA, and risk-based decision making are all designed to improve workplace behaviors and engage the 90% of your people waiting to be switched on
 - Our **free regulatory updates do just that.** Keeping you informed of what is coming as well as offer practical, no nonsense guidance on interpretation and implementation

For more information contact Martin Lush, Global Vice President at martinlush@nsf.org or John Johnson, Vice President, NSF Pharma Biotech at johnjohnson@nsf.org. Martin can also provide you with a pharmaceutical overview of Collins' Good to Great and Great by Choice free of charge.

ABOUT THE AUTHOR



Martin Lush has over 30 years' experience in the pharmaceutical and healthcare industry. He has held senior management positions in QA, manufacturing, QC and supply chain auditing and has conducted audits and education programs for many hundreds of companies in over 25 countries.

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Cite as: NSF International. June 2017. Is Your Biggest Business Risk Complacency? NSF: York, UK.

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LPH-459-0617