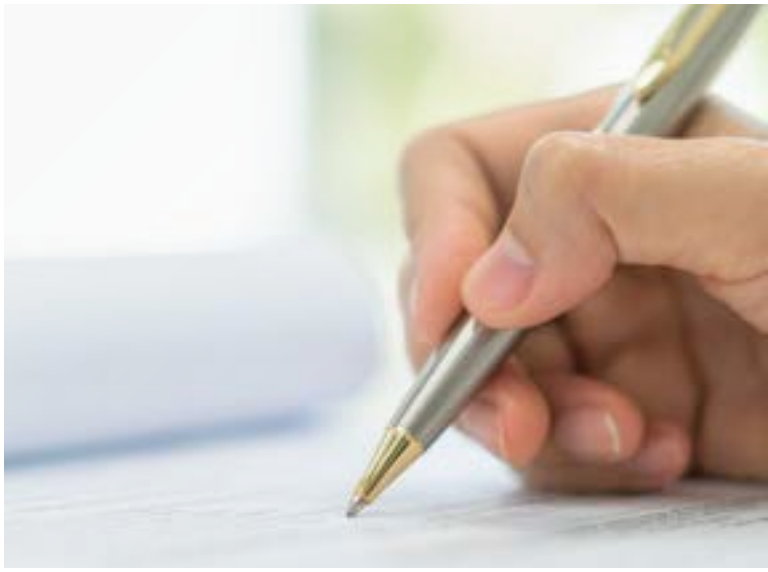
YOUR FREE PQS HEALTH CHECK: DO YOU WANT MORE OF THE SAME OR SOMETHING DIFFERENT?

IF YOU WANT TO IMPROVE YOU HAVE TO DO SOMETHING DIFFERENT.

by Martin Lush

Over the last few years the pharma industry has faced many challenges, many of which are set to continue:

- Continuing increase of Warning Letters, Consent Decrees, Field Alerts and Recalls
- Increasing price regulation as governments attempt to balance healthcare budgets
- Supply chains of bewildering complexity… and associated risk
- The unrelenting drive to cut costs
- Problems with data integrity as some companies ignore their moral compass (thankfully, only a very small minority, but we are all at risk of being painted with the same brush)
- Increasing levels of counterfeits and falsified medicines as criminals attempt to cash in, no matter what the consequences
- The erosion of expertise as those with the knowledge of what works and what doesn't leave, taking with them thousands of combined years of knowledge and wisdom
- More regulations to understand, interpret and embed, only with fewer or less experienced staff to implement them
- The need to reengineer quality systems built for a bygone era
- Regulators struggling with their own challenges and smaller budgets as they try their best to protect us all from unsafe medicines and poor GMP standards



Here at NSF, we're actually very optimistic about the future. Although the challenges in this unpredictable world may be significant, we think the future offers unparalleled opportunities for those who are well prepared. For tips on managing in an unpredictable environment, you need go no further than Roald Amundsen, the Norwegian Antarctic explorer:

> *"Victory awaits those who have everything in order. Luck people call it. Defeat is certain for those who have neglected to take the necessary precautions in time. They call it bad luck."*

We agree. In an unpredictable world, one thing can be guaranteed… that nothing can be guaranteed. We are privileged to work with some of the best companies in the world. We have found that best-in-class organizations and Amundsen have a few things in common:

- They invest heavily in skills and competencies. They educate, not train

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- They demonstrate excellent leadership and teamwork. One team, one purpose, guided by a moral compass that keeps everyone on track, no matter what
- When mistakes are made, they learn from them, not repeat them
- They focus on doing the basics (core competencies) very well and keep things simple. They don't try to do everything and work hard to drive out complexity and ambiguity
- Although they know what they are good at, they also know where they must improve
- They implement improvements with precision and discipline. In these organizations, actions speak louder than words

Your free pharmaceutical quality system "health check" (on the next few pages) is your opportunity to get everything in order. To be prepared for success, all you have to do is:

- Complete this really simple health check questionnaire. It will take only 10-15 minutes, but covers each key element of your quality management system
- Publicize it widely. Take it to your next team meeting. Leave copies in your coffee room. Circulate it on your intranet. Put it on your notice board. Ask as many people to complete it as possible. In our experience, you and your colleagues already know your strengths and weaknesses; you just didn't have an opportunity to share them. Until now that is!
- **Just answer each question with a yes or no**
- **Any nos should act as a catalyst for action!**

So, circulate the questionnaire widely, discuss openly, mark yourself honestly and act diligently. If you need any more guidance, help or support, please give us a call. That's what we're here for.

FROM THE AUTHOR

Many thanks to my colleagues at NSF for collating this health check: Stewart Green, Paul Cummings, Peter Savin and Bruce Davis. With over 140 years' combined experience, they know a healthy pharmaceutical quality system when they see one.

YOUR PQS HEALTH CHECK: FOCUS ON DOING THE BASICS WELL

POLICIES AND PROCEDURES:

Do they make your life easier and add value?

	Yes	No
Are all your SOPs written by the user, for the user?	☐	☐
Are they available at the workplace?	☐	☐
Do your policies describe the WHY (overview), and your SOPs the HOW (detail)?	☐	☐
Do you make use of pictures, schematics and diagrams to provide clarity?	☐	☐
Is the level of detail appropriate for the user?	☐	☐
Do you adopt the "less is more" approach for design/content?	☐	☐
Do you test key procedures before implementing them?	☐	☐
Do you review, amend and improve key procedures after 6 months' use?	☐	☐

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EDUCATION:

Do you focus on changing behaviors, not just checking the compliance box?

		Yes	No
>	Do you focus on education (changing behavior) not training (no lasting change)?	☐	☐
>	Is education seen as a profit center with a protected (ring-fenced) budget?	☐	☐
>	Do you have a 3-5 year education strategy?	☐	☐
>	When things get tough, do you increase your education budget?	☐	☐
>	Are your education programs designed to satisfy all learning styles?	☐	☐
>	Does most of your education take place in the workplace, outside the classroom?	☐	☐
>	Do you avoid "death by PowerPoint"?	☐	☐
>	Do you focus on providing the underpinning knowledge (the WHY)?	☐	☐
>	Is your GMP refresher education new, exciting and different each year?	☐	☐

QUALITY RISK MANAGEMENT:

Is QRM integrated, value-adding and part of your company DNA?

		Yes	No
>	Do you apply QRM more for prevention and improvement activities rather than firefighting, crisis management and when things go wrong?	☐	☐
>	Do you accept that there is no such thing as zero risk?	☐	☐
>	Does everyone have a clear understanding of your company's risk threshold?	☐	☐
>	Are the principles and practices of QRM understood at all levels from the CEO to the shop floor?	☐	☐
>	Do you use QRM throughout the product lifecycle? For example:	☐	☐
	• In focusing your validation activities?	☐	☐
	• In escalation of quality incidents?	☐	☐
	• To optimize your auditing resources?	☐	☐
	• To help in approving rejecting planned changes?	☐	☐
	• In deciding what to put into/leave out of your dossier/license application?	☐	☐
	• To risk-rank deviations and customer complaints?	☐	☐
	• To optimize environmental monitoring?	☐	☐
	• To provide a framework for risk-based decision making?	☐	☐
	• In simplifying SOPs and batch records?	☐	☐
>	Is there excellent understanding of your 'science', products and process throughout your organization… without which QRM is impossible?	☐	☐
>	Do you NEVER use QRM to justify what you know to be sub-standard?	☐	☐

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DEVIATION AND CAPA:

Are "mistakes" catalysts for improvement? Considered good, not bad?

		Yes	No
>	Do you have an open and blame-free culture where people are encouraged to raise deviations?	☐	☐
>	Are incident reports raised immediately, without delay?	☐	☐
>	Do you objectively risk-rank incidents within hours to prioritize resources to perform investigations?	☐	☐
>	Do you start investigations within one working day, maximum?	☐	☐
>	Do you investigate proportionate to risk, rather than treating every incident the same?	☐	☐
>	Are investigations done where the incident happened, not from behind a desk? Always?	☐	☐
>	Are investigations done by people with expert knowledge of products and processes, not just by QA?	☐	☐
>	Do your CAPAs focus on preventing recurrence rather than dealing with superficial symptoms?	☐	☐
>	Do you implement CAPAs ASAP, rather than apply the ridiculous, unfounded "30-day rule"?	☐	☐
>	Do you believe that human error is the "consequence", rarely the "cause" of deviations?	☐	☐
>	Do you trend repeat incidents?	☐	☐
>	Do you share incidents and CAPAs throughout your organization to drive continuous improvement?	☐	☐
>	Do you install a scheduled effectiveness check on each CAPA to evaluate how successful it has been to prevent recurrence of the deviation?	☐	☐

QUALITY METRICS AND KPIS:

Do they drive the right behavior toward improvement, not punishment?

		Yes	No
>	Do you have more "leading" (process related) metrics than "lagging" (output focused)?	☐	☐
>	Do your metrics drive the right behavior?	☐	☐
>	Do you use the "less is more" approach, focusing on the 20% of metrics that provide 80% of benefit?	☐	☐
>	Are your metrics "owned" by the users? Are most driven bottom up, not top down?	☐	☐
>	Is data shared with users and stakeholders to drive continuous improvement?	☐	☐

INTERNAL AUDITS AND SELF-INSPECTIONS:

Are you really inspecting?

		Yes	No
>	Is your program risk-based?	☐	☐
>	Do you have a fast and effective escalation process for critical observations and trends?	☐	☐
>	Are your auditors fully certified, up to date, educated pharmaceutical auditors from across all disciplines, not just QA?	☐	☐
>	Are inspections used to add value, not just for the sake of "compliance"?	☐	☐
	• To help prevent problems waiting to happen?	☐	☐
	• To share best practice across functions and sites?	☐	☐
	• To drive out complexity, not create it?	☐	☐
>	Do you trend audit findings to assess the big picture?	☐	☐
>	Does your audit and self-inspection program ensure you are inspection-ready at all times?	☐	☐

CHANGE CONTROL:

Does your system manage risk, prioritize resources and drive improvement?

		Yes	No
>	Has your change control system been designed with the active participation of all stakeholders, not just QA/regulatory affairs?	☐	☐
>	Is your system simple and understood by all?	☐	☐
>	Is change control considered vital for business improvement and risk management, not just for compliance?	☐	☐
>	Does your system allow a change request to be reviewed and approved in hours, not days, weeks or months?	☐	☐
>	Do you use a risk-based impact assessment form to help approve or reject changes?	☐	☐
>	Does your system reject 30-40% of change requests to help focus on priorities?	☐	☐
>	Do you follow up on every approved change to ensure it worked?	☐	☐

VALIDATION:

Do you REALLY understand your processes or just check the compliance box?

		Yes	No
>	Do you really understand process variability or just check the validation box?	☐	☐
>	Does everyone understand your process critical control points?	☐	☐
>	Does everyone really understand your key product attributes; those that impact patient safety?	☐	☐
>	Do your metrics confirm a process in control? Zero reworks/reprocessing and 100% right first time?	☐	☐

DATA INTEGRITY:

Is it considered to be your life blood, or just assumed?

		Yes	No
>	Does everyone realize that poor data integrity = NO regulatory trust?	☐	☐
>	Do you have all your data? Is it backed up and archived?	☐	☐
>	Do you routinely review and check for data integrity?	☐	☐
>	Do you routinely challenge all transactions (the audit trail)?	☐	☐
>	Have you validated your data handling systems?	☐	☐

YOUR QUALITY CULTURE:

What do people do when no-one is looking?

		Yes	No
>	Is QA totally integrated on the shop floor?	☐	☐
>	Do first-line managers/supervisors spend more time on the shop floor than in meetings?	☐	☐
>	Does everyone have personal quality performance objectives? Everyone?	☐	☐
>	Do your leaders walk the talk and demonstrate the right quality behaviors?	☐	☐
>	Do people talk about quality, not just output and financial returns?	☐	☐
>	Do you develop, reward and retain expertise rather than allow it to leave the organization whenever something better comes along?	☐	☐
>	Do you treat your suppliers as extensions of your production line?	☐	☐
>	Do you select your suppliers based on quality, not price?	☐	☐
>	Does everyone feel connected to the patient, not the share price?	☐	☐

NEXT STEPS: SCORING

Write down the areas where you scored "No":

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	Yes	No
> Are these areas featured in this year's Goals and Action Plan?	☐	☐

Write down who can help you address these areas of concern. What do you need to tackle these concerns?

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. Your Free PQS Health Check. NSF: York, UK.

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