



ARE YOU FACING A COMPLEXITY CRISIS?

by Martin Lush

I spend a lot of time in bland hotels and rarely remember any of them... except one. This particular hotel will, forever, remain etched on my mind because of the complexity of its toilets. Now, most toilets are simple and straightforward with all the usual features in usual places. Not this one. This model came with a three-page instruction manual describing various power jets, temperature and "vibration" settings. I immediately did a risk assessment. Severity of harm? High. Probability of harm occurring? Off the scale. My conclusion? Ignore the gizmos and go for the manual override.

The experience reminded me of the challenges facing us all every day, unnecessary over-complexity.

Over the last 30 years my colleagues and I have seen levels of complexity in the pharma industry increase dramatically. It's getting close to a crisis point. Although some complexity is triggered by events we can't influence (regulations, globalization and the like), most is created by choice.

OVER-COMPLEXITY: THE COSTS

I was with a client recently following a tough GMP inspection. Their long and expensive Form 483 from FDA included all the usual "failure to follow SOPs," "repeat deviations," "multiple documentation errors", "data integrity issues" and lots more. Following the company's internal review, the site director provided me with a list of root causes and their even bigger, more expensive list of Corrective and Preventive Actions (CAPAs). He asked me what I thought, so I told him:

"These CAPAs will only make the situation worse because you've missed the single biggest cause of each and every regulatory criticism – OVER-COMPLEXITY."



OVER-COMPLEXITY: ROOT CAUSES

Your Self-Assessment Questionnaire

I firmly believe over-complexity is a silent killer for many companies. Most people know (and complain) about it but do little to minimize the dangers and risks.

Remember, complexity increases over time to such an extent that people just get used to it. Successful simplification only happens if you provide the reassurance that it will benefit those involved. If you do not, your attempts to simplify will be sabotaged.

Whenever we help companies following a tough inspection, we are interested in one thing: making sure they bounce back stronger by fixing the underlying cause, which is usually complexity.

YOUR TASK:

Over the last 30 years we've identified the symptoms of over-complexity that lead to regulatory action.

- > Discuss the eight symptoms listed on the next page with your colleagues over a cup of coffee
- > Answer each with a yes or no
- > Any yes's means you have a level of over-complexity that could prove risky



DON'T WORRY

- > This edition of the Journal provides simple rules and guidelines to reduce risk by removing its cause – COMPLEXITY

Symptom 1:

Risk Aversion and a Focus on Risk Assessment, Not Risk Management

Yes
/ No

Are you risk-averse? Do you focus on reactive risk assessment rather than proactive risk management where data and common sense rule?

Remember: Risk aversion drives a “more is better” mindset; more checks and measures, more detail in SOPs, more environmental monitoring, more everything. This is not surprising; most people are wired to want more. More is safety. More is less risk. But the opposite is true. Risk aversion drives the “pursuit of more” which increases risk.

Symptom 2:

Poor Knowledge of Products and Processes

Yes
/ No

Is there a lack of detailed knowledge of your products and processes across your organization? Unless there is deep understanding of every product's key quality attributes and process critical control points, attempts to simplify are dangerous.

Remember: Simplification is about understanding what's essential and what's not. Simplification is about focusing on the former and ruthlessly eliminating the latter. To simplify you must be brutal; you have to keep the essential and jettison the rest. This can't be done without in-depth knowledge.

Symptom 3:

Organizational Bureaucracy and Complex Hierarchy

Yes
/ No

Complex organizations are always at risk. Hierarchy and bureaucracy distracts and demotivates.

Remember: If you have any of the following you could be in trouble.

- > Very busy but ineffective people
- > A closed, blame culture
- > Interdepartmental conflicts
- > Lots of KPIs and measures
- > Slow and ponderous decision making
- > Poor morale and engagement
- > Drawn-out sign-off and approval processes
- > Lots of activity but not much change

Symptom 4:

Corporate Rules

Yes
/ No

Do your corporate colleagues issue rules and guidelines without user consultation and engagement?

Remember: Although well-intentioned, rules and guidance written without user involvement will always add complexity and risk.

Symptom 5:

Unworkable SOPs and Documentation

Yes
/ No

Most SOPs are so complicated they are impossible to understand and follow. Symptoms 1 to 4 lead to an epidemic of over-explaining in the mistaken belief that more information means greater clarity.

Remember: The opposite is true. More information leads to confusion and fuzziness. The **simplicity paradox** holds true. *“The less you tell educated people, the more they know.”*

Symptom 6:

The Firefighting Habit

Yes
/ No

Do you struggle with large numbers of repeat deviations or human error incidents? Do many of your CAPAs recommend retraining, extra checks or more detailed instructions?

Remember: If you are addicted to firefighting and obsessed with the quick fix, the complexity created will turn the embers into infernos.

Symptom 7:

Poor Change Management System – Initiative Overload

Yes
/ No

Does your change control system approve every change request? If it does, it's creating complexity.

Remember: Your change control system is where “brutal thinking” is practiced. It's where changes that add complexity are rejected and those that simplify are applauded and approved.

Symptom 8:

Bad Consultants

Yes
/ No

Ever experienced consultants and third parties who just add “stuff” without understanding your needs? Do they use a one-size-fits-all approach?

Remember: Good consultants leave you more resilient and efficient. Good consultants simplify, bad consultants complicate and confuse. Time for some brutal thinking followed by action! Get rid of the bad, keep the good.



SOLUTIONS: MOVING FROM COMPLEX TO SIMPLE

If you want to simplify, remember:

- > **Simplification is hard work.** It must be actively pursued. Making things complicated is the easy way out and symptomatic of lazy thinking and a wasteful organization
 - > Simplification requires **TOTAL dedication to clarity, honesty, discipline and intelligence**
 - > **Less IS more**
 - > **Be brutal.** Simplification is about understanding what's essential and what's not, focusing on the former and ruthlessly eliminating the latter
 - > **Excel at saying NO!** Simplification is about focusing on the essentials. Focusing is about saying no, no, no...
- > **You don't have a choice!** Simplify or suffer

Remember, complexity leads to:

- > More time needed when you have less available
- > More cost you can no longer afford
- > More energy wasted
- > Greater risk
- > Demotivation and disengagement

And finally, make sense and simplification your mantra. Simplicity is an exact medium between too little and too much. That's your goal.

SOME SIMPLIFICATION RULES

Throughout this Journal we describe how we've helped clients simplify:

- > SOPs
- > Batch manufacturing records
- > Deviation and CAPA systems
- > New product introductions
- > Vendor assurance

If you would like more information on how these were achieved and the processes we used, drop us a line at pharmamail@nsf.org

When simplifying, here are some common steps to consider:

STEP ONE: GET THE BASICS IN PLACE FIRST

- > Make sure you **have an open and transparent culture.** Simplicity only thrives in an open culture
- > Make sure everyone understands your products and processes. **Only the knowledgeable can simplify safely**
- > Make sure you **excel at risk management,** not emotive risk assessment. Be data driven, proportionate and sensible. Only those with a mature and intelligent approach to risk can simplify
- > **Design in simplicity from the start.** It's cheaper! Always involve the users and key stakeholders from the start

STEP TWO: USE SMALL GROUPS OF SMART PEOPLE AND MOVE FAST

Simplicity's best friends are small groups of users. Spectators are not welcome. In simplification the "law of small" applies: *"The quality of work increases in direct proportion to user involvement."*

User input is critical. Leadership must provide the resources and commit to implement what the users decide will work. Avoid involving those who created the complexity in the first place.

Adopt a **smart timeline.** The easiest way to make things complicated is to give people too much time. To achieve simple solutions three ingredients are required:

- > A good plan
- > Good people
- > Not quite enough time



STEP THREE: IDENTIFY THE CORE PURPOSE

Identify the core purpose of the system, procedure or process you are trying to simplify.

STEP FOUR: PROCESS MAP REALITY

Get the users to process map (visualize) what they actually do.

STEP FIVE: REMOVE THE NON-ESSENTIALS

Time for some brutal thinking; remove anything that doesn't contribute to the core purpose.

STEP SIX: PROTECT WHAT YOU'VE SIMPLIFIED

Having worked so hard to simplify, protect what you've created. Removing complexity is like creating a vacuum. It's unnatural. Unless you prevent people from putting the complexity back in, they will do just that!

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.

SIMPLIFICATION: FREE RESOURCES

At NSF we believe levels of complexity have reached crisis levels in many companies. In addition to the information contained in this Journal, please visit the NSF Pharma Biotech Consulting resources library (www.nsf.org/info/pblibrary) for free simplification resources.

For more information, contact pharmamail@nsf.org or visit www.nsfpharmabiotech.org

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