DOCUMENTATION COMPLEXITY AT CRISIS POINT?

by Martin Lush

Do we focus too much on the paperwork, to the detriment of product and patients? Has documentation become so complex it's become a dangerous distraction and your biggest risk?

SETTING THE SCENE

Three years ago, I met with a site head responsible for 2,300 people manufacturing five lifesaving (critical care) medicines. The site was struggling. For every person there were five SOPs. They had more paper than people! Policies and SOPs had increased by over 1,000% in three years, but headcount had been reduced by 11%. That's right, less people – more paperwork.

SOP complexity had also increased, with SOPs averaging 34 pages. A quick assessment of readability showed 89% of SOPs were incomprehensible for the target audience. Let's pause for thought – almost nine out of ten SOPs could not be understood by the users. The site operated on shortcuts. People were forced to work around SOPs rather than follow them. They had written themselves into non-compliance. Errors and mistakes (due to procedural non-compliances) made up over 56% of deviations. Corrective actions added even more complexity to the complexity that caused the error in the first place.

When we sat down with their finance people the numbers looked bad. We calculated the cost per SOP to be approximately $12,000 and the site had to reduce costs by 32% in two years.

Don't worry, there's a happy ending! Now, three years after we worked with the client to reduce complexity, SOP numbers have reduced by 38%; deviations, errors and mistakes have fallen by 75%, and productivity is up. Cycle times have improved and they're making more product faster and rejecting far less. Right first time has improved from 67% to 98%. Staff morale has soared.

WHAT ABOUT YOU?
TAKE THE HIGHLIGHTER TEST

Documentation complexity has reached such levels it's impossible for most users to follow procedures and complete the task. They can't do both. But how do you know? Set up a **highlighter (honesty) test.**

In a room where users gather, place lots of copies of your most important SOP, plenty of highlighters and a sealed box. Leave a note asking people to highlight only what they do in practice – the instructions they actually follow – and then drop the pages into the box. Anonymity must be guaranteed.

We've done this exercise countless times to help companies simplify their SOPs. On average, 60-70% of SOP content is not followed. Just try it and see.

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DEEPER DIVE: DOCUMENTATION COMPLEXITY

For a broader perspective than the highlighter test, circulate this questionnaire to as many people as possible across your organization, particularly document users.

		YES	NO
1	Are your policy documents kept simple (no more than 3-4 pages) and issued only after consultation/input and adjustment from users?		
2	When new regulations arrive, do you consult with users before updating your policy guidance?		
3	Are users allowed to interpret policy (standards) locally to meet local/regional needs?		
4	Have you calculated cost per SOP and the total investment put into your documentation system?		
5	Are all SOPs written by the users for the users (not the regulator)?		
6	Do you routinely use the Gunning Fog or Flesch-Kincaid indexes to assess readability for users?		
7	Do your SOPs have more pictures/schematics than words?		
8	Do you test usability of SOPs in the workplace before implementation?		
9	Do you actively prevent CAPAs adding detail to SOPs following a mistake or error?		
10	Do you routinely conduct the highlighter test?		
11	When auditors/consultants/regulators/customers insist on more detail, do you challenge or push back?		
12	Do you make it difficult for people to write new SOPs or amend old ones?		
13	Do you focus on educating your people, rather than training them, by explaining the 'why' more than the 'how to do'?		
14	Have you banned the 'read and understand' approach to training?		
15	Are you investing in video/YouTube technology to replace words/paper?		
16	Is simplification your company's top priority and do leaders walk the talk?		
17	Do you use intelligent risk assessment to decide what goes into/stays out of documents rather than putting everything in 'just in case'?		
18	Do you routinely run simplification FedEx days? (If you've never heard of this, answer no and give us a call for more information). These are vital if you're committed to simplification.		

So, has your documentation become more important than your patient? If you answered yes to most questions, you're in good shape. Lots of no's? You could be in trouble.

WHAT YOU CAN DO: YOUR SIMPLIFICATION ROAD MAP

The site we mentioned was able to turn it around and stay in business because they followed these four *very hard* steps – our simplification road map. Adding complexity is easy and requires very little thinking. That's why we add complexity in the first place. Simplification is the opposite, it takes brains, blood sweat and tears.

STEP ONE: CREATE THE INTRINSIC MOTIVATION

Everyone, from the senior leadership team to the shop floor, must be totally committed. Simplification is not a project, but a way of life. Without a 'what's in it for me' people will just give up. We spent three to four days getting the entire site to understand that simplification = survival.

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STEP TWO:
EATING THE ELEPHANT ONE BITE AT A TIME

With thousands of SOPs, where do you start? By using Pareto's principle (or the 80/20 rule), which states that 80% of your risk is due to 20% of your SOPs, or there about. By talking to users and looking at quality metrics, we identified just over 800 high-risk SOPs. Over many months we then boiled this down to 202 using the highlighter test.

STEP THREE:
LET THE USERS LOSE – FEDEX DAYS

FedEx guarantees delivery in one day. We assigned each SOP to a smart, dedicated group of four to five users and asked them to deliver a drastically simpler version – by the end of the day. To prepare them, we trained each group in many of the tools and techniques in our simplification toolkit (below).

STEP FOUR:
STOP COMPLEXITY AT THE SOURCE

Preventing complexity is a lot easier than removing it. We focused on:

> Ensuring the change control system filtered out change requests that added complexity

> Redesigning the deviation and CAPA system so it focused on prevention, not correction

> Training people on how to conduct simplification audits

> Redesigning the SOP system to prevent complexity being added by co-authors and agreeing to KISS (keep it simple, stupid!) rules for SOP design, creation and content

Tip: You could also consider creating SOPs as videos. What do you do if you need to look up how to do something around the house? You go to YouTube. Other industries use video, so why don't we?

Your Simplification Toolkit all resources are available in our online resource library – **www.nsf.org/info/pblibrary**:

White Paper: Are You Facing a Complexity Crisis

Webinar: The Art and Science of Simplification – How to Win Your War on Complexity

White Paper: Changing Your Quality Culture and Improving GMP Behaviors: What Works and What Doesn't

White Paper: How to Use B = M.A.t.H

Video: How to Jumpstart Your Pharma Business by Simplifying Processes

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YOUR CALL TO ACTION:

> Start now!

> Do the highlighter test

> Circulate the questionnaire – are you at risk?

> Follow our simplification road map and start using our simplification toolkits

> Get in touch with us at **pharmamail@nsf.org** with questions

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

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