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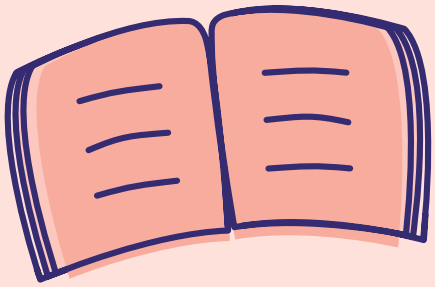

4 scary life science quality management stories

100% real
100% anonymized
100% scary

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Our mission at Qualio is to help life science companies embed robust digitized quality to get their critical products to market at rapid speed, and keep them there.

And because the Qualio+ team combines over a century of collective quality and regulatory experience from within the life science industry, including auditing, we've witnessed what can happen when the wrong quality management decisions are made, when the wrong tools are used, and when visibility of the quality landscape is incomplete.

We've jotted down some of the most enlightening quality management stories we can think of.

Some involve companies we used to work at. Others are high-profile cases we've heard on the grapevine. All have a moral and a clear warning of the stakes involved in our critical work as quality professionals.

We've anonymized key details and told everything else exactly as it happened.

Kelly Stanton
Director of Quality, Qualio

1. The design ‘tweak’

The situation

Andy worked for a medical device organization producing Class III catheters used in emergency surgery. An apparently trivial design change involving the coating of the needle end was signed off by the quality director as a way of simplifying and standardizing the manufacturing process.

The problem

Within weeks of the change, device faults – and subsequent patient deaths – began to be reported from hospitals in the United Kingdom.

But curiously, nothing was reported for identical devices in the United States and, when device samples were received back from British hospitals, Andy could not find a single fault or defect.

Critically, the company had no digital records of the device’s design controls and design history. Stacks and boxes of paper records were scattered across multiple archives and storage sites, both on-site and in third-party contracted storage areas.

As reported faults and deaths continued to snowball, Andy had the unenviable and highly stressful task of finding the problem as quickly as humanly possible. That meant sourcing and gathering reams of paper records and scouring them on workdays, evenings and weekends for an entire month for the solution.

What had happened?

The quality director's design change, pushed through without careful consideration or FMEA, was eventually identified as the culprit. The change in coating would cause the end of the catheter to become blocked, preventing usage.

The blockage would then dissolve by the time the defective device reached Andy. And the American surgical procedure of washing the catheters with saline as they were placed onto the sterile tray meant the problem didn't manifest at all in the US.

This caused a highly puzzling and confusing situation where no apparent fault could be easily detected.

Impact

- Multiple device failures and UK patient deaths
- Multimillion-dollar product recall
- Intricate series of overlapping factors coupled with scattered design control records made fault detection highly difficult
- Highly stressful 80-hour work weeks for an entire month as Andy scrambled to find the problem
- Quality director moved on

Conclusions

- Even ‘trivial’ medical device design updates require complete collaborative testing and analysis before marketization
- Paper-based records take up physical space which eventually necessitates scattering across off-site archives – this becomes a major blocker to defect investigations like this one
- Digitize your design control records wherever possible

> *You need to treat your design control records in the same way you would treat your financial records in anticipation of the IRS coming.*
>
> *How quickly can you put your hands on the information you need to see when something goes wrong? If I’d had digital design control records, my job would’ve been so much easier.*
>
> *My kid still remembers eating McDonalds in my office on a Saturday morning as I pored over stacks of paper for the problem.*
>
> **— Andy**

2. No warning letter? No problem!

The situation

Jenny worked for a pharmaceutical and biotech giant. They were supplied with sterilizing alcohol wipes by a third-party supplier based in the United States. The wipes were used during surgeries to sterilize incisions.

The problem

The alcohol wipe manufacturer was an approved supplier of Jenny's company. But they weren't doing things right. FDA audits resulted in the issuing of multiple Form 483s, mainly because of contamination risks.

Crucially, though, they didn't receive a formal warning letter.

Their customers, including Jenny's company, therefore continued to work with them, and didn't even conduct on-site audits. The manufacturer was only infrequently audited remotely.

The situation came to a head after the death of a 2-year boy during an operation.

What had happened?

The alcohol wipes were contaminated with bacillus cereus, causing fatal meningitis in the boy during his surgery.

Any audit of the manufacturer would have revealed dirty, contaminated pipes, bare-hand packing of 'sterile' product, understaffing, unsuitable plant equipment, and staff who couldn't speak English - and therefore couldn't follow the documented SOPs in the QMS.

But because they'd never been formally warned by the FDA, their customers' supplier management systems hadn't caught onto the massive risk that had been introduced into their supply chains.

Impact

- Death of a young boy and serious injury of another
- Complete financial collapse of alcohol wipe manufacturer
- Liability passed onto their customers
- Owner convicted on felony charges

Conclusions

- Both the manufacturer and Jenny's company were at fault
- The alcohol wipes could cause serious potential patient harm, so the manufacturer should've been treated as a higher-risk supplier and audited accordingly
- Never rely on regulatory warning letters as the only trigger for on-site supplier audits
- Build a robust and organized supplier management system that automatically enforces risk-based activities like audit types and frequencies

3. Paper, paper everywhere

The situation

Tim worked for a Class I medical device company that assembled and distributed first aid kits.

Drugs and devices were purchased from different suppliers along with their package inserts, then bundled together by Tim's company before being passed onto customers.

The problem

The entire operation ran on paper. Tim's company ran a paper-based QMS, and paper inserts from the supplied drugs were collected and added into the kits.

Tim's company decided to streamline the inserts into a single combined page that would fit more easily into the kit boxes, and began working with a local printing company to do so.

Since the company distributed around 80 drugs, this involved a huge amount of manual paper work. In a paper-based QMS, the only way to control the kit inserts was to write part numbers on the outside.

Before long, it became clear that outdated and inaccurate inserts had made their way into the first aid kits and been distributed to customers for emergency use. Multiple batches of kits had also been manufactured incorrectly and diverged from the manufacturing SOPs.

What had happened?

The paper-based QMS run by Tim's company worked fine when an unchanging set of drug inserts could be received, combined and reprinted.

But as the drug manufacturers made their own product updates, based on requirements changes, internal CAPAs, complaints or recalls, Tim's company simply couldn't keep up with the resulting changes in insert content.

Although the company was formally notified of these changes, Tim's colleagues on the manufacturing floor were storing stacks of inserts in multiple locations and, without robust document control, inevitably began to pull old inserts for placement in the kits.

At the same time, SOPs governing how the kits were to be assembled were stored in a single physical binder. Because all 20 employees needed to follow them simultaneously, they began to create local copies for easy access and reference from their stations. These local copies could not be easily recalled and replaced as the SOPs were revised.

Kit contents, including product dosages, began to diverge from their documented inserts and multiple recalls ensued.

Impact

- Incorrect dosage of emergency first aid drugs in the kits
- Multiple national kit recalls
- 20+ discovered instances of defective change control processes
- Unstandardized manufacturing processes triggered by multiple circulating SOP versions

Conclusions

- A paper-based document management system coupled with intensive paper management became unworkable
- Manufacturing room 'habit' of storing and pulling inserts from familiar locations and following local SOPs wasn't checked with robust and simultaneous version control
- Paper worked fine in a static, repeatable process, but couldn't keep up with change
- The perceived cost savings of a paper-based QMS were rapidly undone by the recalls

> *It was a nightmare. The company didn't want to control the documents electronically and print them out as needed because it would've 'cost too much money'.*
>
> *But the time and effort we put into chasing this down, constantly keeping up with changes, going through CAPAs, outweighed all that.*
>
> *We had so many situations come up as a result of paper and poor document control.*
>
> **— Tim**

4. Not keeping abreast post-market

The situation

Kate worked for a multibillion-dollar American-Irish company that manufactured breast implants.

The organization had multiple international manufacturing sites, including one in France.

The problem

A global recall was issued for the company's textured breast implants after a spike in cancer cases related to implant scar tissue. 16 French women died.

The company's French site had its ISO 13485 accreditation revoked and was banned from manufacturing any future product. The product itself was banned entirely in France, triggering a domino effect in other territories like Canada and the Netherlands.

What had happened?

During the ongoing investigation, it was found that the organization's post-market surveillance activities had been consistently weak. Long-term safety studies had failed to involve the required minimum of participants, and adequate amounts of safety data hadn't been collected.

Complaint response, defect response, adverse event reporting and testing protocols were all suboptimal and failed to keep pace with the volume of product distribution.

After the complete shutdown of the company's French operation, the American FDA requested that all breast implant manufacturers submit quarterly trending analyses of adverse events.

Impact

- 16 deaths
- Complete national market collapse
- Multimillion-dollar recall
- Reputational damage

Conclusions

- Focus on marketization came at the expense of robust post-market activity for a high-risk Class III device
- Standardized and controlled quality event management could've prevented colossal financial and reputational damage, not to mention the loss of ISO 13485 certification

Other bad memories from the Qualio+ team

> *I've seen old versions of work instructions left in manufacturing cleanrooms, which gave me chills.*

> *I worked for a company that acquired a smaller company, and we discovered that all the operators had been 'grandfathered' into their roles. There was no training documentation for them, they had just 'learned on the job'!*

> *Our auditor saw some manufacturing instructions on the floor and wrote the info down. When we got back to the audit room, he asked for that procedure from us.*
>
> *He checked the version on the floor against the one we handed him and, sure enough, the manufacturing supervisor hadn't updated the copy on the floor. Adding insult to injury, the revision had been released for over a month and no-one had caught it.*

> *We had an auditor go through the trash cans in our lab and find the results of an assay for a batch being tested on a Post-it Note. We couldn't prove why or when that data was recorded.*

At a lab that I audited, they did not have a training record for employees that created processes such as test methods because they were considered Subject Matter Experts.

We had our training requirements on sheets of paper stapled together, that we were meant to have signed by managers/trainees when training on certain topics was completed.

Each person was meant to keep their own copy. They always went missing and could not be located during audits.

The problem with paper-based documents is when you update a version, you have to go to all the sources of storage and remove/destroy the old versions.

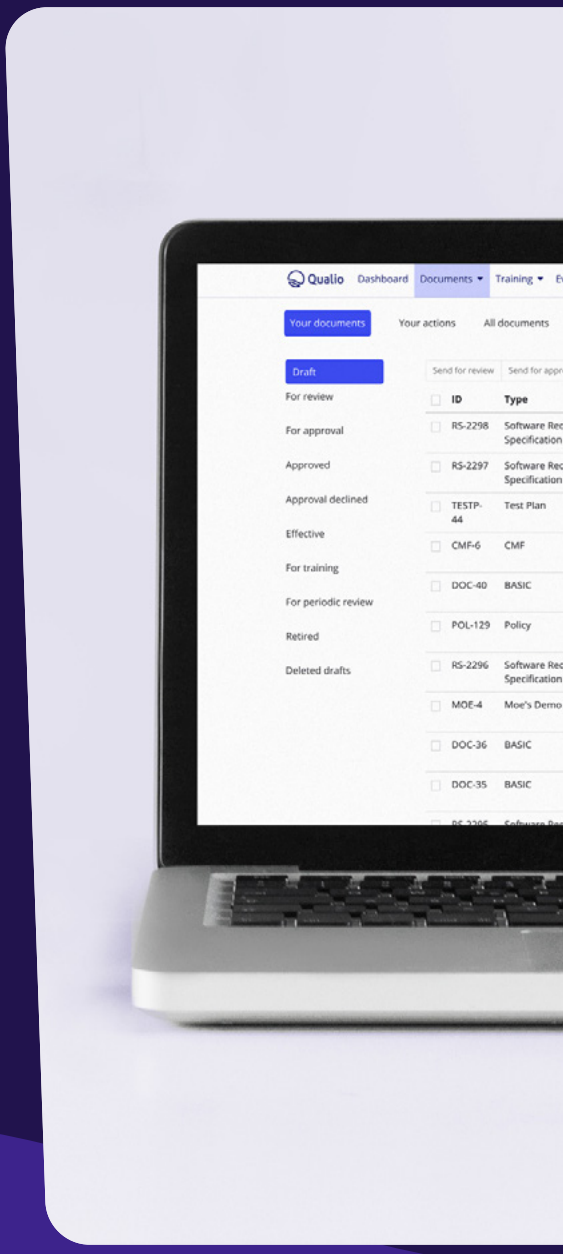
Paper documents go wandering and, sure enough, an old one will always turn up right in the middle of an audit!

Qualio

Don't make the same mistakes

See how our electronic quality management system crushes quality errors and infuses lasting compliance

Request a demo today



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