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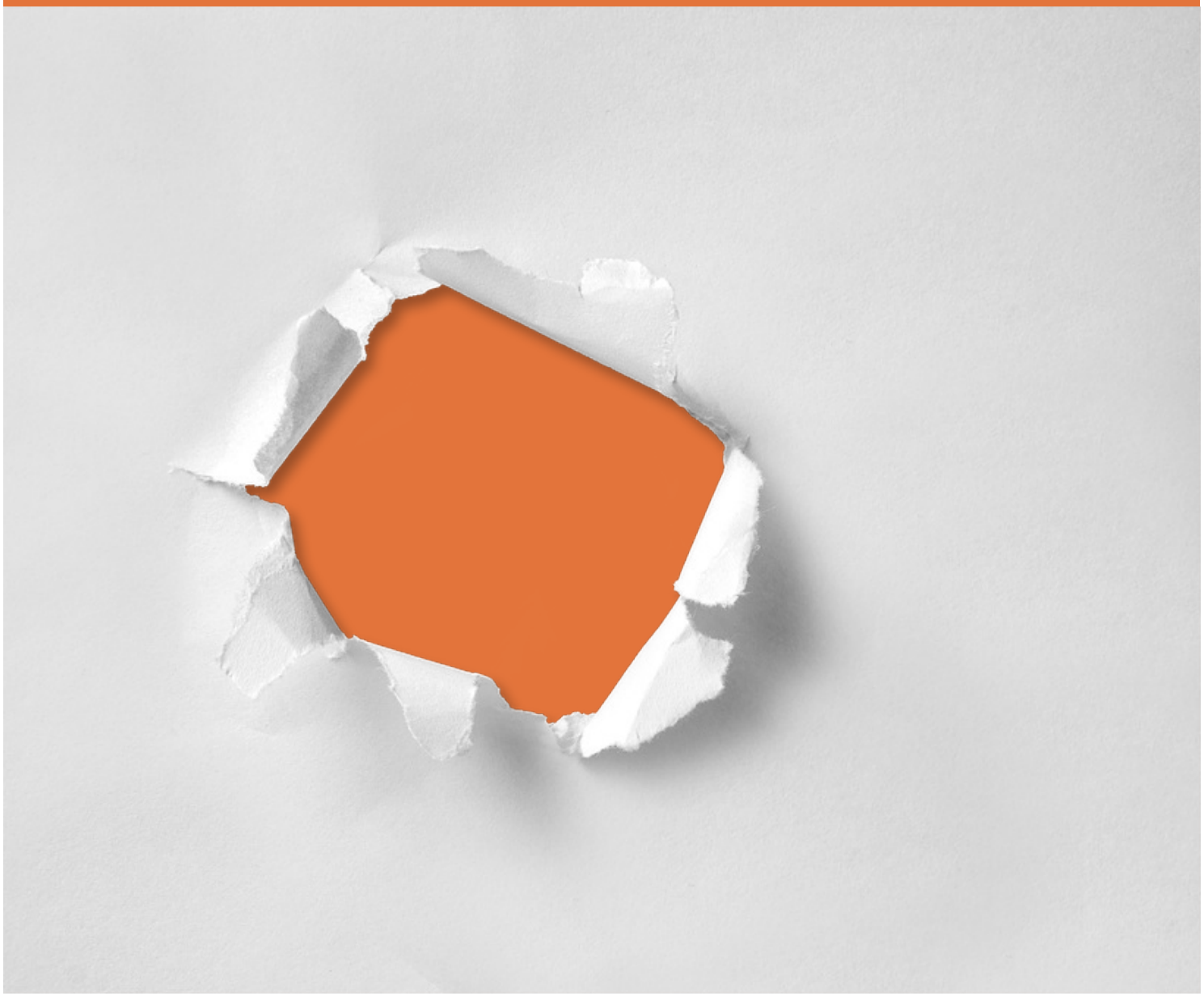
GENERIS

Understanding the Hidden Costs of Weak GMP Documentation and the Return on Investment for Strong GMP Documentation

A Q&A eBook with Bulletproof



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Why are industry leaders in the biomanufacturing industry missing hidden documentation costs within their organizations?

The fundamental reasons companies may not recognize hidden documentation costs are:

- Documentation is deemed a necessary part of the business that cannot be helped, so it is frequently overlooked or misunderstood.
- Manufacturers are comprised of technical people who generally prefer to focus on the technical aspects of their jobs; documentation is often an afterthought.
- Writers are assumed to be document processors, peripheral to technical teams, with minimal ability to influence documentation quality and content.
- Documentation-related responsibilities are spread across functions, with limited or no accountability, making it difficult to quantify costs.
- It is assumed anyone can write GMP documentation.

As companies advance and their portfolios expand, document volumes increase, lead times and labor hours grow, and the quality of the documentation drops. This leads to a cascade of issues with significant cost impacts, including:

- The need for additional writers and document control personnel.
- Constant document revision cycles.
- Increased demand on subject matter experts and approvers.
- Greater likelihood for documentation inconsistencies, contradictions, and complexity.
- Increased errors, rework, deviations, CAPAs, and batch disposition times.
- Failure to follow written procedures.
- Potential audit observations or worse.

How can organizations save documentation time and money in such a fast-paced industry?

They key to saving time and money is to view GMP documentation differently. Instead of seeing documentation as necessary overhead, it would be beneficial to view documentation the way an engineer might view a production skid: Something that can be designed with a focus on accuracy, scalability, simplicity, compliance, and elegance.

SCENARIO:

Company 123 has a new product going into a new facility. The company has two other products that are 5 and 9 years old and manufactured in older facility, with dated processes and historic challenges.

TYPICAL APPROACH:

Company 123 decides to create new master batch records and SOPs by adapting the "best, latest" older documents and agrees to address historic issues during the document review process and training. However, despite efforts to implement improvements and align to the new facility, the approach is not holistic. The resulting documents mirror the legacy documentation, perpetuating the old problems, ambiguities, and deviations. Additionally, incremental improvements have unintended consequences and the quality of the documentation is largely unchanged or worse.

BETTER APPROACH:

Company 123 seizes the opportunity to create new master batch records and associated SOPs. Instead of looking back, they look forward to define the desired state, leverage unit operations, incorporate automated processes, and distill product documentation from supporting documentation. Ultimately they create an integrated and systematic documentation body that enables successful GMP operations, is embraced by technicians and management, and provides flexibility and agility for future products.

OUTCOMES:

The *Typical Approach*, which may seem to require less time and effort at first, results in repeating the historic deviations, frequent revision cycles, familiar CAPAs, and unimproved batch release times.

The *Better Approach*, which may seem to require more time and effort initially, results in fewer errors, fewer deviations, fewer revision cycles, fewer CAPAs, and faster batch release, all of which will continue to improve. Additionally, the *Better Approach* enables all documentation (future and legacy) to be elevated to a higher standard.

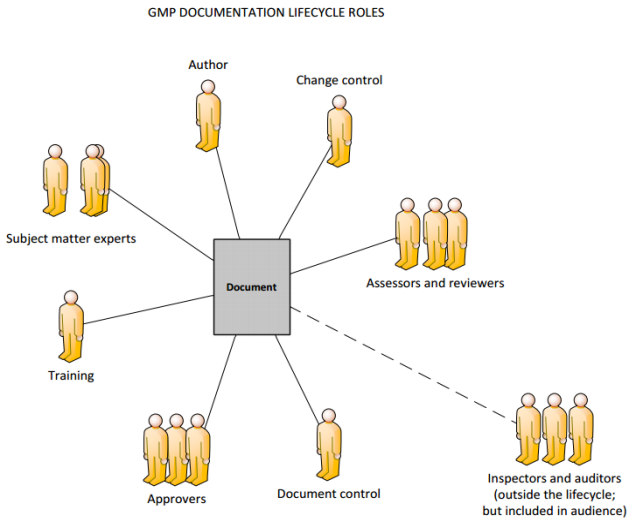
What may seem like the simplest, fastest approach could be the most expensive approach over time. Robust, well designed documentation reduces costs over time.

How can strong GMP documentation benefit an organization in the long-run?

From a financial perspective, strong GMP documentation can enable a company to better control and reduce their documentation-related costs.

CASE STUDY: Documentation Labor Costs

Recently, we determined the cost of one moderately complex document revision to be approximately $3120. We calculated the total hours for development, assessments, review and approval cycles, word-processing, document release activities, and read/understood training, multiplied by the average hourly rate of an FTE. (We assumed new documents and highly complex rewrites to be more costly.)



For a company with two commercial products there may be approximately 800 GMP-controlled documents across manufacturing, QC, facilities, and QA. Regulations require that GMP documents be reviewed at least every two years – commonly referred to as “periodic review”.

To baseline the cost for managing these 800 documents, let's assume the documents are revised once every two-years for periodic review at a total cost of $2,496,000 or $1,248,000 per year (800 x $3120 = $2,496,000 / 2).

At an active manufacturing site, GMP controlled documents are routinely revised before periodic review for various reasons including corrections and formatting, CAPAs, process improvements, and facility/engineering modifications. It is common for many complex or challenging documents to be revised multiple times in a year.

Assuming, conservatively, that 35% of the 800 documents required one revision, 20% required two revisions, and 5% required 3 revisions so that in total, 60% of the documents were revised at some point during the year. The cost per year for those documents is broken down in the table below:

Number of Documents	Number of Revisions	Cost per Revision	Overall Cost
240	1	$ 3,120	$ 748,800
160	2	$ 3,120	$ 998,400
40	3	$ 3,120	$ 374,400
180 (50% of 360 docs requiring periodic review)	1	$ 1,000 (assumed to be little/no change required)	$ 180,000
		TOTAL	$ **2,301,600**

• In a year, documentation cost increased $1,053,600 (from $1,248,000 to $2,301,600; 84%).

• Over 5 years, documentation cost could increase $5,000,000!

In summary, robust GMP documentation:

- Effectively leverages periodic review as an affordable way to maintain documents.
- Reduces fatigue associated with constant document changes and re-trainings.
- Mitigates risk for error.
- Can help save companies millions of dollars by reducing functional group operating budgets and reducing their cost of goods.

What are some misconceptions surrounding GMP documentation?

Misconception:

GMP documentation must be very detailed with lengthy explanations because manufacturing is complicated and technicians aren't very knowledgeable or experienced.

This is an unfortunate misconception because it leads to long, complex documents with superfluous information that alienates the reader. Documents can quickly become long and complex when writers provide multiple ways to perform a task, create extra content around unlikely scenarios, add detailed descriptions intended to prevent mistakes, and generally operate from fear when determining how much information to provide.

Long, complex documents cause readers to:

- Not find what they're looking for
- Get lost in the document
- Jump around because it's too long to read through
- Skip content and miss crucial instruction
- Deviate from the process unknowingly
- Avoid the document altogether
- Do it their own way

Misconception:

GMP documentation is easy to write and anyone can do it.

Well-written, concise, accurate technical documentation requires the ability to reconcile different factors:

• *Multiple Audiences:* A document has many audiences including the author, primary user (the person who executes the procedure), technical reviewers and subject matter experts (the people who develop the process), approvers (cross-functional management), and auditors (third party and inspectors). Writing a document that is technically accurate, robust, easy to follow, and compliant requires aligning the requirements and input from all audience members.

• *Excellent Writing Skills:* GMP documentation requires strong writing skills and application of voice, tone, consistency, precision, grammar, punctuation, and format. It also requires excellent ability to select and assemble words into clean, clear instruction that everyone can agree on.

• *GMP Documentation as a System:* Individual documents must be integrated with other documents and systems to support compliance and product quality. It is important to understand document hand-offs, dependencies, relationships, and references, as well as ensuring documents do not overlap or contradict one another.

• *Project Timelines:* Typically documents are part of a larger project such as a campaign or CAPA. Commonly, documents are left until the last minute and then rushed to meet the deadline. This results in sloppy, poorly written documents that are prone to errors.

Effective GMP writers are:

- Able to intelligently write about and discuss technical content, and advocate for optimal results.
- Strong interpersonally and comfortable working with different scientific/technical perspectives and personalities.
- Excellent partners with their colleagues in developing the strongest documentation possible, to challenge convention, and to facilitate the best outcome.
- Able to simplify complex instruction for clarity and repeatability.
- Passionate about documentation.

Misconception:

GMP documentation is boring and dry.

One of the most surprising things about GMP documentation is that, when well-designed and inclusively developed, it is wholeheartedly embraced, championed, and perpetuated by all levels of an organization. When staff understand what is expected of them and they are given the right tools, they will not only succeed, they will excel. GMP documentation has the power to help transform an organization into a quality-first culture that performs with a high level of autonomy and personal responsibility.

In your experience, when an organization has invested in proper documentation, what have the results been like?

The results have been tremendous!

- We've seen organizations move away from poor compliance and low morale toward a quality mindset with excitement for innovation.
- We've opened career paths for promising writers who love challenge and have a desire to help patients through strong GMP documentation.
- Our clients have demonstrated returns on investment for our projects by lowering documentation-based costs, reducing turnaround times, reducing documentation-based errors, and shortening regulatory filing times.
- Documentation comes off the critical path for the first time!
- Lastly, we've seen our projects serve as a springboard for further innovation and enhancements.

In a nutshell, our best results have been realized when GMP documentation is embraced as an opportunity and powerful mechanism to help companies advance new therapies for their patients.

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American Biomanufacturing Summit 2017

Join Bulletproof at Generis' American Biomanufacturing Summit taking place in San Diego, May 23-24th, 2017. Find out more about understanding the hidden costs of poor GMP documentation and the return on investment for strong GMP documentation on the website below!

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