MALCOM ASSOCIATES
OPTIMIZING DOCUMENTATION AND QUALITY SYSTEMS







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84 %

Warning letters issued with observations for missing and/or inadequate documentation*

60 %

Products on hold due to documentation and/or procedural errors**

100 %

Percent of companies whose RFT metrics are actually lower than reported**

*FDA Warning Letters 2011 - 2015 YTD
**Malcom Associates internal client statistics

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What Malcom clients are saying:

"I liked the approach and methodology, involving the SMEs from the Operations and QA areas working together to improve our Records and redesign of the information flow. The redesigned Records will support our GMP enhancement initiative, increase our work capacity, and improve right first time for us."

Operations Director

"I like the new format, it makes it easier for both the users and myself (as a reviewer), to notice where entries are required and where entries are missing, as well as easier to notice whether or not the result recorded is in compliance with the specification."

Quality Operations, Batch Record Review

www.malcom-us.com

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- How We Help
- Prepare for EBR
- Get Started

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About Us

For over 25 years, our clients have utilized Malcom's experienced professionals and solutions for preventive measures, remediation, pre-approval inspections, in response to audit observations and to improve overall quality and work flow efficiencies.

Malcom Associates is known as the *proven expert* in the area of batch record simplification, process improvement, and redesign solutions for the Life Sciences industry.

We provide a solid cost effective solution to;

- **reduce human errors**
- **improve work flows**
- **improve regulatory compliance**
- **reduce redundancies**
- **reduce non-conformances**
- **reduce time and costs implementing EBR**
- **utilizing and implementing industry *"best practices"***
- **reduce number of document revisions**
- **eliminate risk**
- **improve overall data integrity**

We develop a realistic, understandable battle plan to tackle and resolve the issues on-time and on-budget.

This is our reputation in the industry and why clients continue to engage with Malcom Associates.

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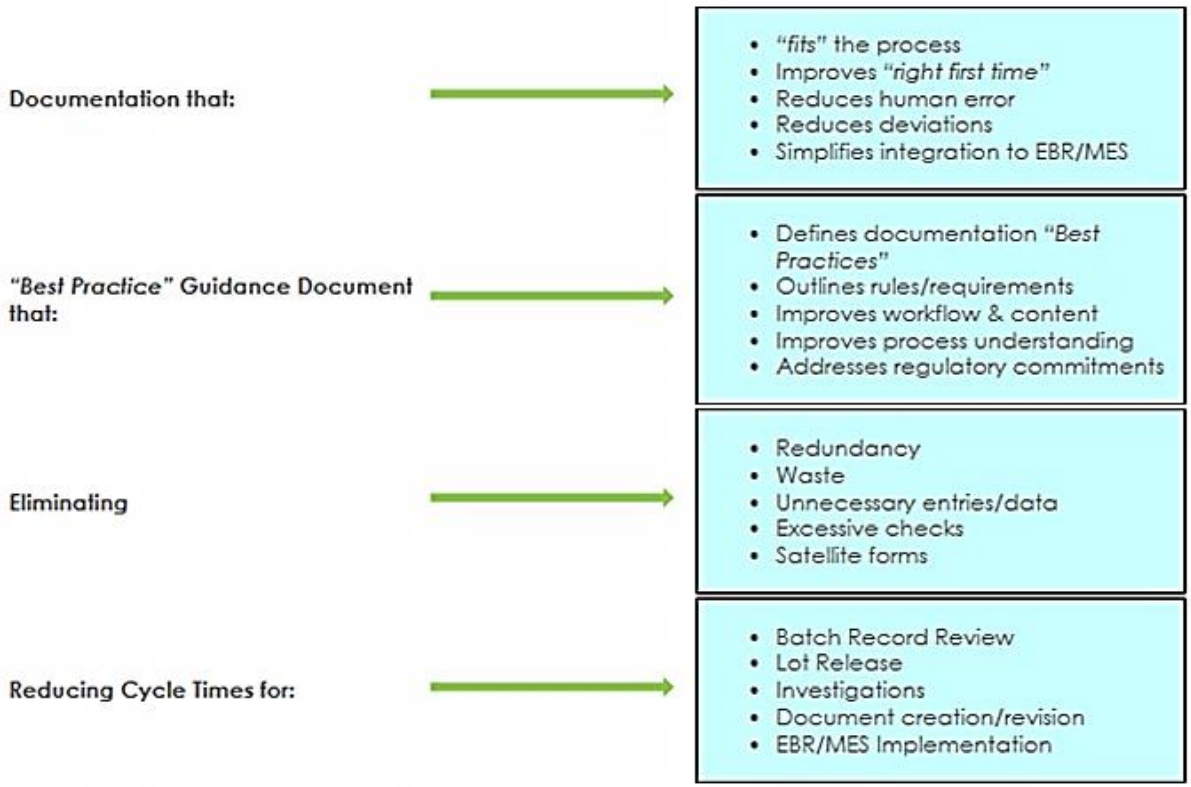
What We Do

Assess, Develop, Test, Implement = Results

Malcom has developed a proven approach, methodology, industry documentation and work flow *"best practices".* We assess, develop, test, and IMPLEMENT our solutions with achievable, measurable, and tangible results, on-time and on-budget.

Malcom professionals don't sit in an office all day. We spend time where the process happens and where the documentation is executed. This is how we gain first-hand knowledge to quickly address your business needs and interact with our clients on all levels to improve their current systems.



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How we help

Our clients are continually faced with resource, workload and time constraints, and *lack of a proven approach* and methodology to attack the documentation, work flow, and quality system problems resulting in non-conformances.

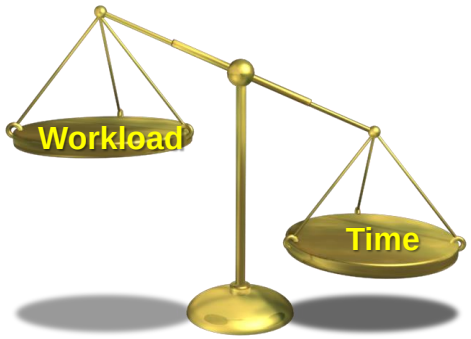
The ***"band aid"*** approach is often taken as the corrective action with documentation, procedural, and process non-conformances, and doesn't effectively address or prevent the incident from happening again.

The reality - corrective modifications become an accumulation of unnecessary content, added steps, and documentation.

The result - Management and supervision continually spend more time and resources on investigations then they do on the manufacturing and releasing of product. The system eventually becomes overloaded with document revisions, repetitive retraining, and unnecessary costs.

Malcom Associates redesign solutions assess and identify compliance gaps, unnecessary or redundant data requirements, and steps to improve the overall work flow and work process.

We guide the client through our process to ensure quality issues are resolved and that the documentation, procedures, manual or automated work flow ***"fits"*** the process.



The impact Malcom's program approach:

Percentage of Reductions	
Pages	20 - 35%
Entries	30 - 60%
Documentation / procedural errors	50 - 70%
Review cycle time	40 - 60%
Product release cycle time	30 - 50%
Manufacturing cycle time	10 - 15%
Time spent on investigations	20 - 30%

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EBR

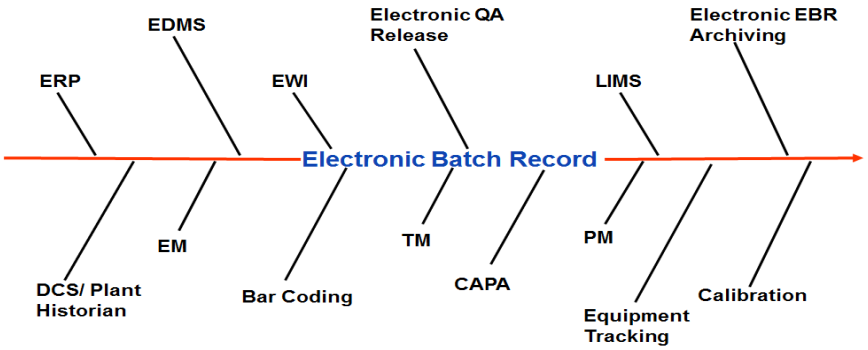
EBR/MES benefits will not be fully realized until you *'lean the existing Batch Record documentation FIRST.'*

- Lean the Batch Record documentation for easier migration to EBR/MES
- Eliminate redundant information and identify what data to integrate to EBR/MES
- Develop strategy for interface and implementation of electronic systems
- Validate or invalidate user and functional requirement specifications
- Revise and create SOPs to support and comply with system functionality and interfaces

By leaning the documentation and work flow first, additional questions will be identified as well as answered to determine …..

"Are you ready for EBR?"

Impact Assessment of System Touch Points, Data Transfers, Reporting, Etc.



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Get Started

How Do We Get Started?

We conduct a Value Assessment to identify opportunities, potential "compliance gaps", and the justification for the recommended path forward.

Examples of what we Assess:

- **Compliance and industry "*best practice*" gaps and the recommended fix**
- **Opportunities to reduce human errors, such as, instructions that are incomplete, inadequate or not clearly stated**
- **Unnecessary and/or redundant instructions and operator entries**
- **Inconsistency in how instructions, parameters and specifications are stated within the Batch Record or other documentation/ systems**
- **Operator recorded data, where no specification/ parameter is stated for comparison or is incorrect**
- **Sequence of steps in the Batch Records or work flow do not accurately follow the process, increase cycle times or are not streamlined to meet business demands.**
- **Readiness for automated/electronic environment and system integration**
- **Risk management process and Quality System redundancies**

Check out our results: Malcom Case Studies

For more information:
info@malcom-us.com *or* www.malcom-us.com

What our clients are saying:

"Malcom Associates took proprietary interest from day one. Their experience, depth of knowledge, and determination to get it right has resulted in documentation that is compliant, easy to understand, and most importantly, approved by our sharpest critics….the people closest to the process! Job well done."

Manager Manufacturing Documentation & Training