

Writing it down - Keeping good records! Part 1

Instructor's notes

Slide 1

Welcome to the class.

This session will focus on a specific aspect of Good Manufacturing Practice (GMP).

The aspect we will discuss today is good documentation and record keeping.

This is important because at our company, we put patients first.

Our company is committed to patients' health every day through the dedication of us all.

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GMP was first developed in 1962 as a result of congressional legislation.

This law requires the Food and Drug Administration (the FDA) to be proactive in working with the pharmaceutical industry to ensure that the pharmaceutical products available to the public be safe, pure, and effective.

FDA is a Federal Agency, part of the Department of Health and Human Services.

The basis for the development of GMP is the Federal Food, Drug, and Cosmetic Act passed by Congress in 1938. The 1962 law was an Amendment to the Federal Food, Drug, and Cosmetic Act.

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It may seem that there is a lot of paperwork in our company. We may even sometimes think that GMP really means Great Mounds of Paper.

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Well, think of it this way. If you started your own company manufacturing some widget, and you were successful to the point of hiring a few people to make these things while you go out and sell them, would you think about creating some written procedures for them to use and follow?

You probably would, to make sure that the product is made the same way each time. We call that consistency. And that's what our customers expect of us.

Our paperwork helps us produce consistent products.

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At our company, we consider our paperwork to be a product. It has equal importance to the actual product.

Our requirements for the paperwork is that it is complete, it is clear, and it is accurate.

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Our products cannot be shipped without the paperwork being reviewed and approved.

It's our Quality Control department that has the responsibility to review and approve our records.

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Our paperwork can only be approved if it is 100% accurate.

Our QC Department has the responsibility to check our records because our customers expect us to have records that are 100% accurate.

Our customers don't want us to guess – they want us to be sure all of the time.

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You wouldn't want your doctor to guess, would you?

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You want your doctor to be sure. You want your doctor to make good decisions using good data, and accurate lab results.

What would you do if you went to your doctor for an annual physical and your doctor told you the following. “We’re kind of busy here right now, so instead of sending you down to the lab where they would take a blood sample and run a test for cholesterol levels, I’m just going to guess at what your cholesterol level might be. I’m pretty good at this, been at it for 25 years now.”

Most of you would probably get a new doctor. We don’t want our doctor to guess. Since our products are used by patients under a doctor’s care, our patients don’t want us guessing either.

Our customers, the patients, trust us to be sure of what we do and record accurate values, numbers, and information all the time. Even when we’re busy.

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The FDA represents our customers. As consumers, we don’t have the time or the expertise to run around the country (or even the world) checking out the companies that manufacture the drug products we use.

We depend on the FDA to do that for us. The FDA works for the American consumer, ensuring that the drug products available are safe, pure, and effective. GMP’s are regulations that the FDA developed to provide the pharmaceutical industry some “guidelines” in the proper manufacturing of drug products.

The FDA also works for American industry by reviewing and approving new drug products before they can be sold.

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Why is so much paperwork required?

There are three main reasons.

- 1.To make sure we know exactly what we did, and when we did it.
- 2.To be able to correct mistakes when they happen.
- 3.To be able to PREVENT mistakes from happening in the future.

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What's the price of product failure in our industry?

Answers may include death, reduction in the quality of life, or grieving families due to the loss of a loved one.

Because the cost of failure is so high in our business, we must maintain paperwork which provides a permanent record of what we did.

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Here are three Tips on Keeping Good Records.

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Tip #1 is to always use a pen with permanent ink when writing on any of our records here at our company.

(You may want to talk about a preferred color, or type of pen that is commonly used in your department.)

We never use pencil to record anything on our records.

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Ask the group – “What's this number?”

You should hear 29, 27, 24, or maybe even 2%.

Now suppose that you are reviewing the manufacturing records for a batch of product waiting to be shipped. There are 18 pallets of product already shrink-wrapped waiting to be loaded on a truck.

And let's suppose that this value is a test result or some reading from a gauge. The specification is that 27 to 29 is acceptable.

So if the value is a 27 or a 29, then we're in good shape. It meets our spec.

But what if it's a 24? What then?

Do we scrap the lot? Can we take some samples and test for this again? If so, where do we get the samples?

Yes – break down the 18 pallets and obtain a representative sample. We might rush these samples into the lab, and ask for the test to be

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repeated – NOW! This puts additional pressure on the people working in the lab, further increasing the probability of contamination, mix-ups, and errors.

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Scrapping a batch of product costs us a lot of money.

Re-sampling and testing is called rework. It also costs a lot of money, and causes delays in our schedules.

A few seconds of composing yourself to make sure you write everything clearly can save hours of additional work.

Values that are not written clearly is often a big problem with our documentation.

Just ask the folks who have the responsibility to review these records.

Some of us write more clearly than others. Some of us have a tendency to write sloppy only when we're in a hurry. Some of us were born that way – and writing clearly for us requires some extra effort.

Make sure you take the time and the care to record data clearly.

Don't forget that our customers are counting on us.

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Yes – sloppy writing is 100% preventable.

And relaxing a bit by taking deep breaths helps reduce stress, something we all could probably benefit from.

Think of it as part of our company's fitness program – keeping ourselves healthier and in better shape – both physically and mentally.

Tip #2 is to Clearly Record our Data.

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Tip #3 defines the proper method for making corrections.

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If we do make an entry error, or a calculation error, the proper method for making the correction is to draw a single straight through the wrong item.

Then clearly record the correct item.

Record your initials and the date close to the correction.

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We never use correction fluid like White-Out®.

We never erase.

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When writing explanations for changes or deviations, enter enough details so that the document can be understood in the future.

You may not even be around when this document comes into question, so it must be able to be understood by someone with knowledge of the process at any time in the future.

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Proper documentation and record-keeping are essential to the success of our company.

Our management counts on us to keep good records.

The FDA counts on us to keep good records.

And, most importantly, our customers count on us to keep good records.

Answers to GMP Retention Quiz – Writing It Down Part 1

1. T
2. F
3. C
4. T
5. F
6. C
7. F
8. A
9. T
10. B