COMPLIANCE INSIGHT, INC

Infusing GxP Into Your Organization's DNA

GMP Dosing

Write It Down

Leader's Guide

General Guidelines

- Discuss and confirm with department management the availability of workers
- Plan appropriate space for event
- Reserve the room/area with appropriate time before and after the training session to allow for seating and Q&A sessions
- Determine the appropriate number of attendees that best suits your teaching style. Remember that too many may not generate the best environment for learning.
- Have a sufficient number of chairs
- Send out reminders via email and/or posted signage – remind management of the event as well
- Have sign-in sheets
- Confirm room environmental controls can be adjusted or plan accordingly
- Pre-set appropriate tools – projector, laptop, easels, markers, pens for notes, extra paper, printouts, etc.
- Candy is sometimes appropriate – typically, it is best to avoid chewing gum which can be carried back into the operations room
- It may be appropriate to request that phones be turned off or put on vibration mode
- Lastly, always plan for the unexpected. The unanticipated audit or company issue that will necessitate a change in plans.

Note:

If you send out the training materials via email, confirm the delivery of the material to all parties.

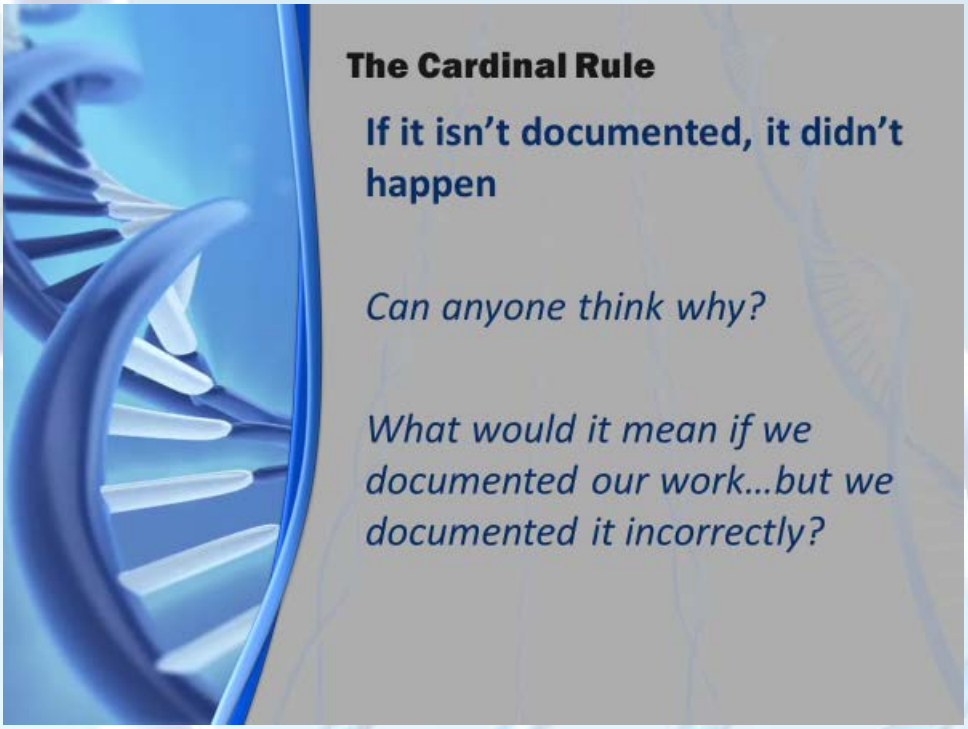
Slide 1:

- Confirm everyone has signed in for the training
- Provide general announcements: e.g. – turn off cell phones, bathroom locations, etc.
- Provide attendees with Participant Worksheet and Reinforcement Guide

Slide 2:

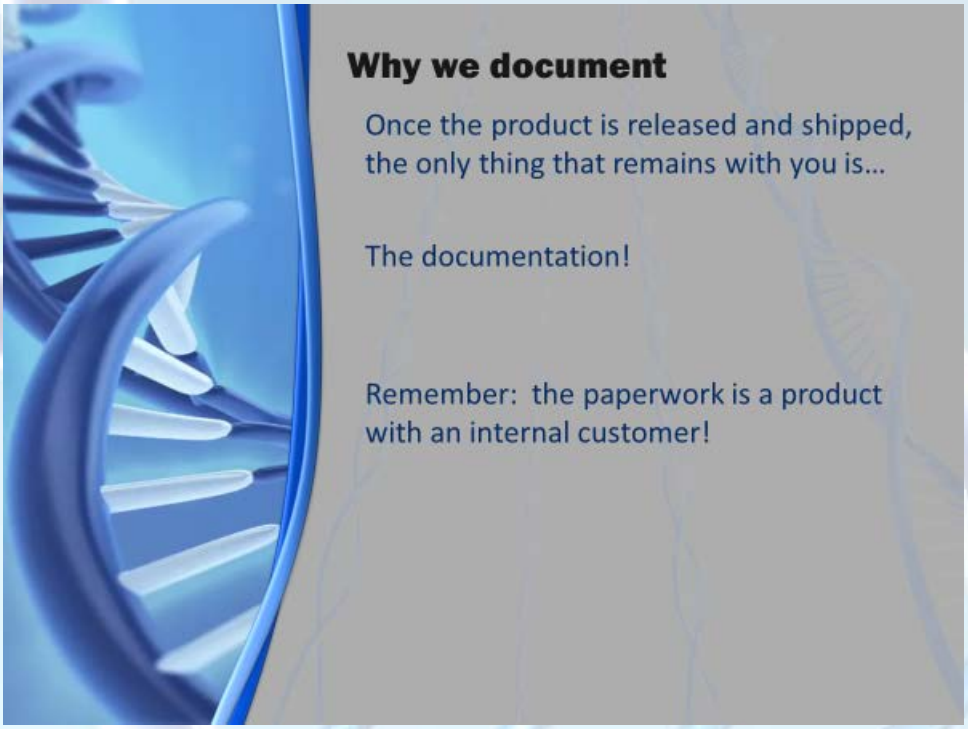
- Review
- If there are any questions – dependent upon the training, questions can be asked during the session or wait until the end

Slide 3:



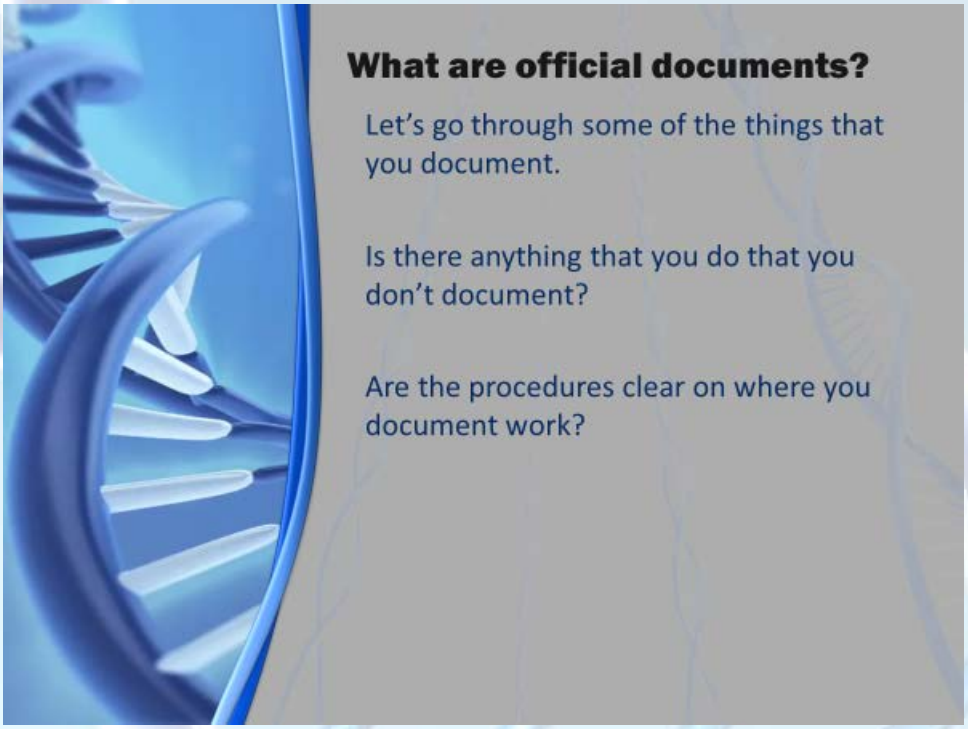
- Can anyone think why?
  - Probe and facilitate responses
  - Best answer: although the inspector may want to believe that you performed the task, without documentation – there is no proof. The FDA and our company require proof of actions to demonstrate compliance.
    - Leader Note: You can modify this answer pursuant to your own unique context and culture.
- Documenting incorrectly?
  - Again, probe and facilitate responses
  - Best answer: It means the entry you wrote on the document is the entry that an inspector will take. If it was 2:00pm and you incorrectly wrote 12:00pm, then it will be questioned as to how that value could be real. Also, it causes the inspector to question the accuracy of the other entries.

Slide 4:



- Discuss the concept that the workers are generating a "product" for an internal customer. And really…it is for external customers and regulatory agencies as well.
- Ask who is the attendees customers – dependent upon the department, they have different internal customers.

Slide 5:

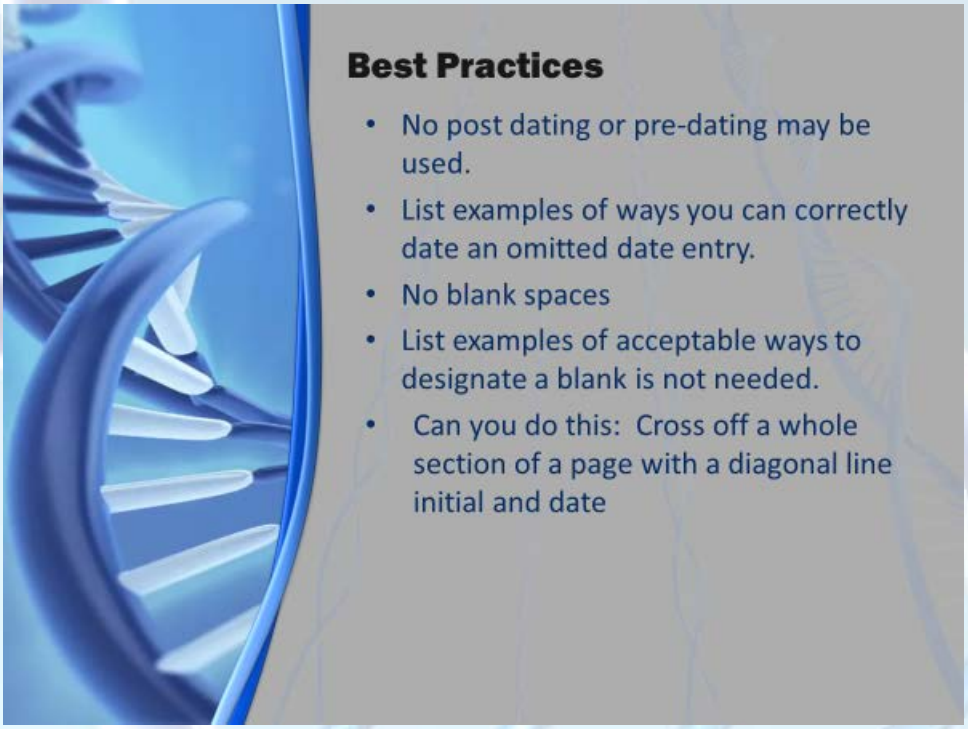


- Probe the attendees as to what they document. You can ask them to write down the items on an easel or whiteboard. You can also write them down as each person provides a response.
- Probe as to anything that they do which is not documented. If a GMP activity is not documented, make note of it and ask the QA department.
- Ask the attendees if the procedures, batch records, forms, etc. are clear on how and where to document.
- Probe the attendees based upon their answers and discussions.

Slide 6:

Leader's Note: The best practices slides can be enhanced pursuant to your own SOP and context. It is best to provide actual examples of documents to demonstrate how to perform entries. As necessary, focus on examples where documentation errors frequently occur.

Slide 7:



- Discuss each point. Ask the attendees why these are important practices.
- Example of ways you can correctly date an omitted date entry:

Performed on _____ documented on _____ "then initial and date"

Leader's Note: Modify the example as necessary to address any specific concerns or issues at your site.

- Example of way to designate a blank section is not needed:

NA or "-" (if indicated as such in your SOP)

- Can you cross off a whole page?
  - Yes.

Slide 8:

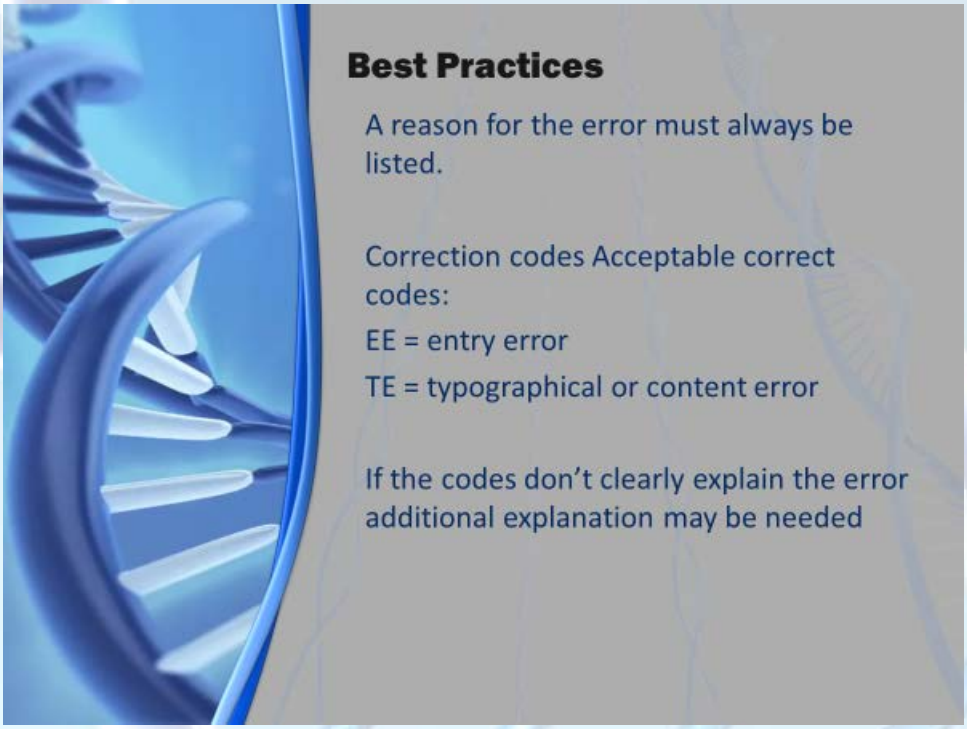
- Ask attendees for answer.
  - Correction to entry error: single line cross-out, initial and date

Leader's Note: Enhance answer as to your specific procedural requirements. Many firms have error codes used to indicated why the error happened. We'll focus on this point in the next slide. For example,

① indicates transposition of numbers

- Unacceptable ways to correct an entry error – seek input from attendees. Potential ideas to discuss are listed below:
  - Whiteout
  - Obliterate
  - Write-over (making a 7 into a 9)
  - Get new page and re-write

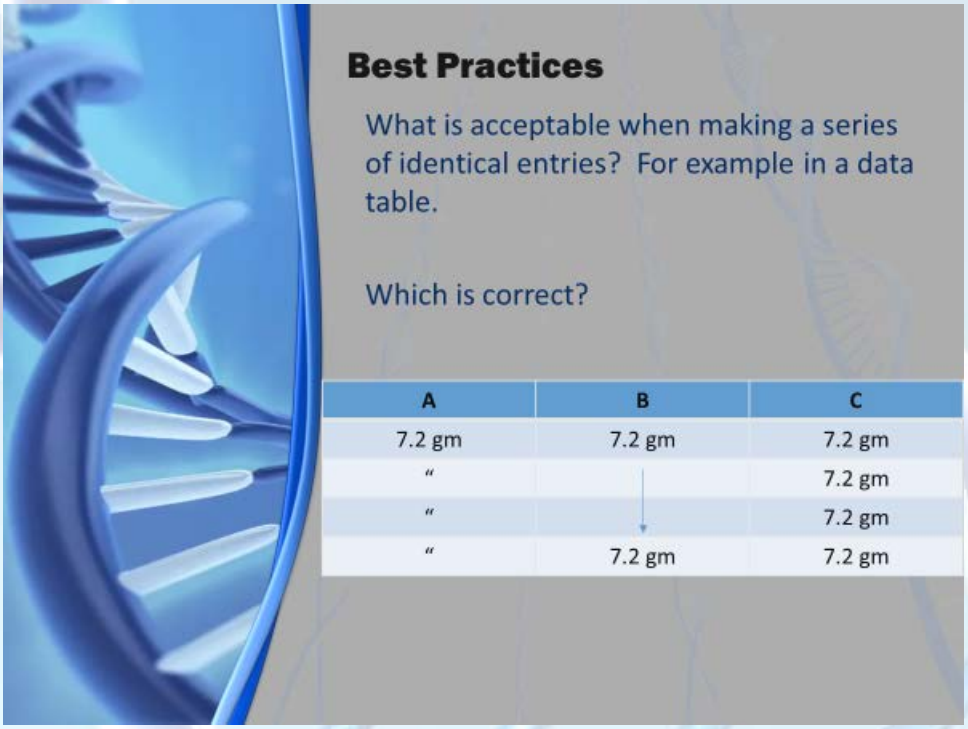
Slide 9:



Leader's Note: This slide should be updated pursuant to your unique procedure. It is suggested that you discuss the various error codes and how people can use them when making an error.

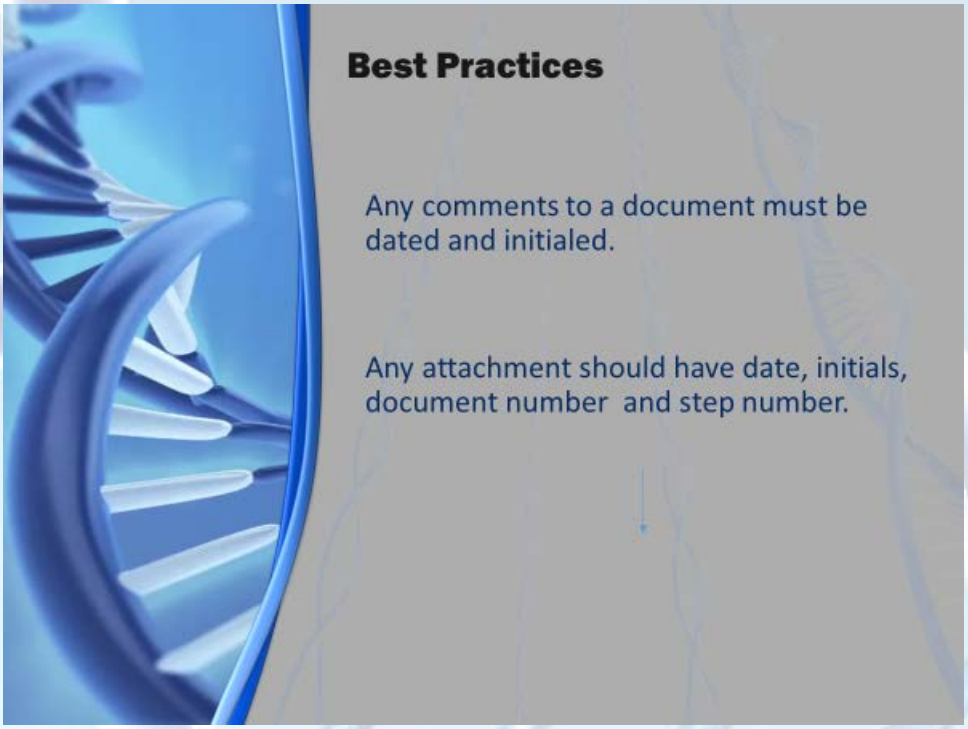
- Discuss when an error correction can result in more questions. For example, you make the same mistake on numerous documents.

Slide 10:



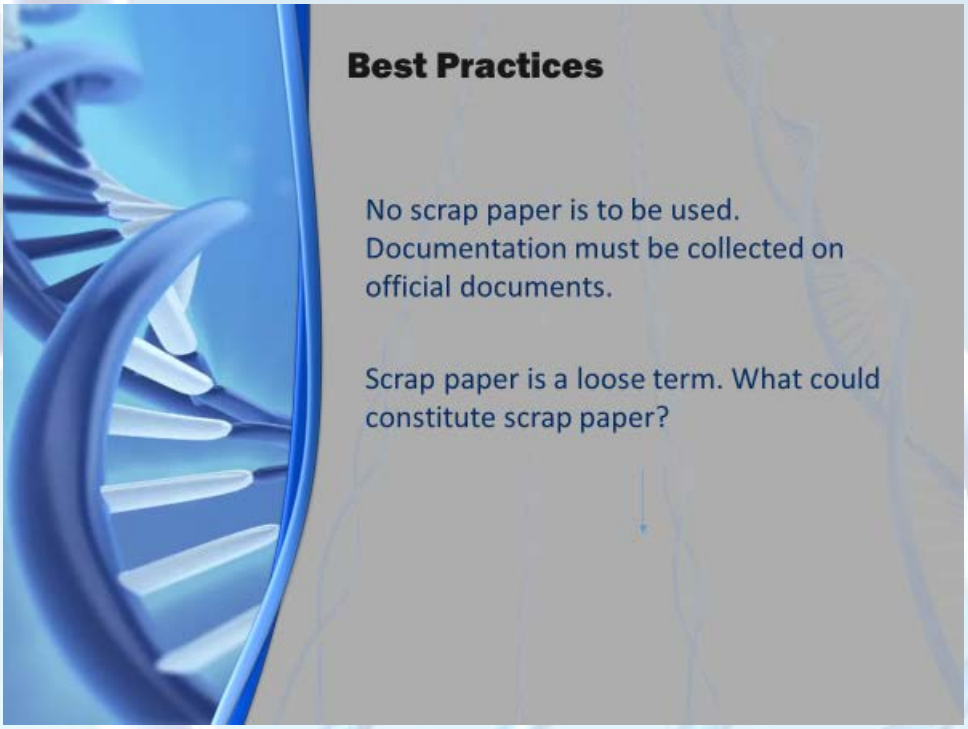
- Ask which process is correct.
- Discuss why
  - Common practice with firms – the "c" in cGMP
  - FDA wants to see the actual test value as it is too easy just to draw a line or ditto mark and forget that the value was actually different.

Slide 11:



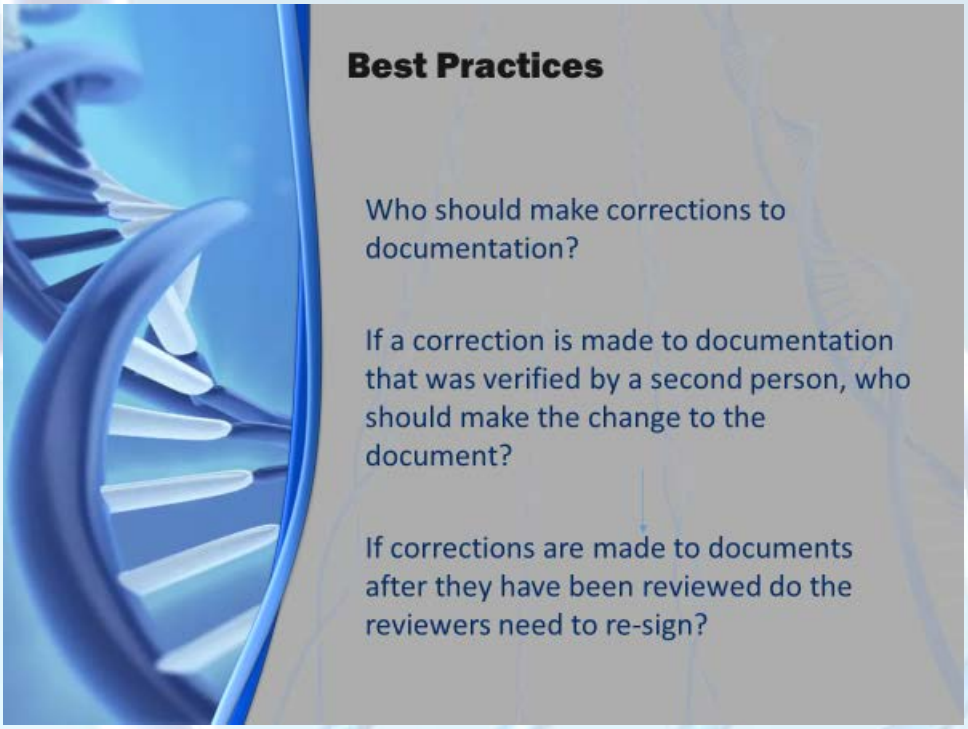
- If you add a comment, you must initial and date it.
  - But here is the issue: If you write down something that is not correct, it is still there. No matter if you cross it out, it is still viewable for an inspector.
  - Before you write down a long statement on something, discuss it with the appropriate people first – supervisors, QA, etc.
  - Remember – once it is written down, you cannot undo it. You can cross it out and put in a correction but the wording is there forever!

Slide 12:



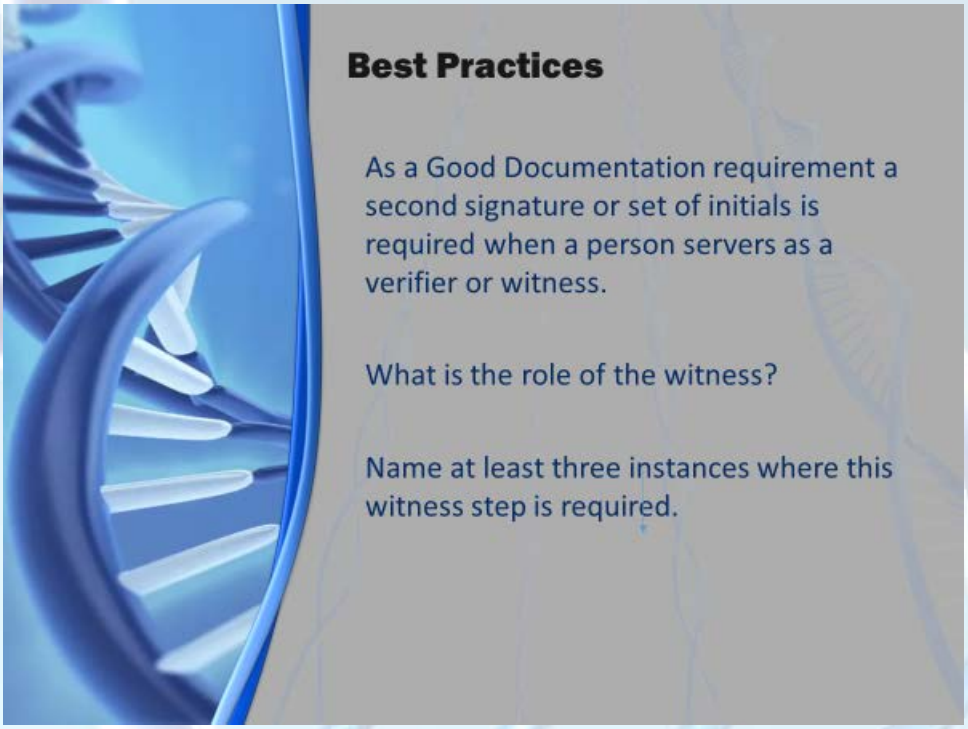
- Seek input from the attendees
  - Blank sheets of paper
  - Post-It notes
  - Card board boxes
  - The FDA has observed people writing observations on gloves and then transcribing that data to a document
- Why is this an issue?
  - The FDA requires the data to be original. Performing calculations on a scrap sheet of paper and then transcribing to the official document is not original.
- Does anyone have an issue with getting data and then writing it on a document?
  - Seek input and discuss any issues.

Slide 13:



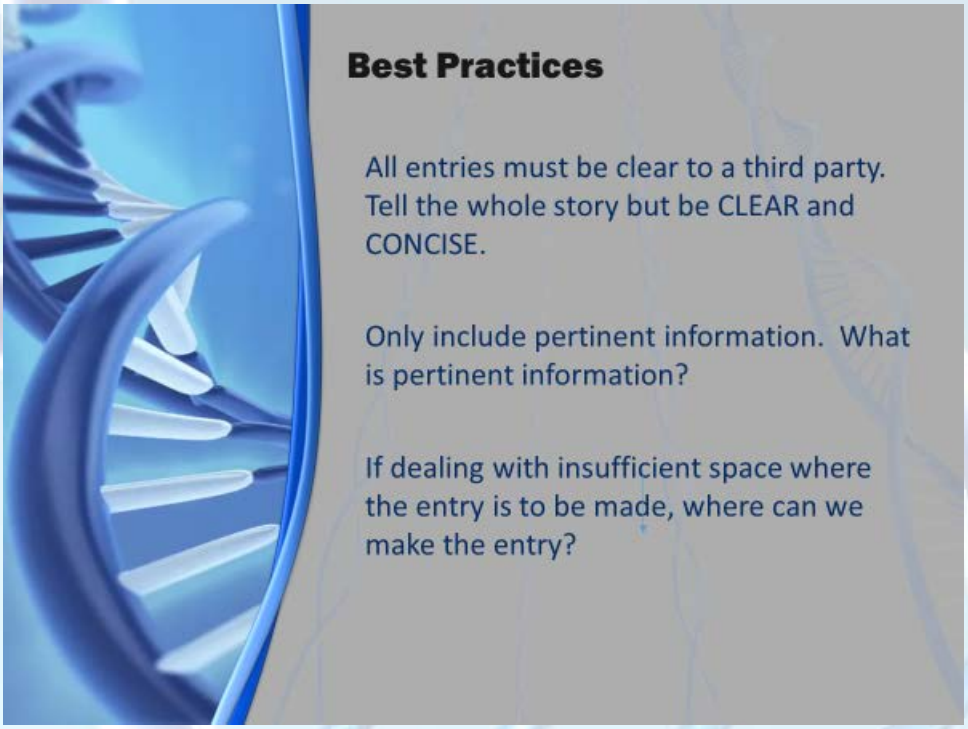
- Who should make corrections – ask for input from the attendees
  - The original person that made the entry
  - What if that person is not there? Now what?
    - Leader's Note: You should address this point in your procedure. Indicate the recommended actions per the SOP.
- If verified by a second person, who makes the change to documentation?
  - This question is taking into consideration that the second person found the error.
  - The original person that made the entry should do the correction.
- If changes made after review, do the reviewers need to re-sign?
  - Yes. Why?
    - When changes are made, they are dated. In this scenario, the reviewers signature and date would be before the correction date.

Slide 14:



- What is the role of the witness or verifier? – seek discussion from the attendees
  - To confirm that a step was actually taken
  - To confirm the accuracy of the function
  - To prevent an error from happening
- Instances where witness/verification is required – seek discussion
  - Raw material weights
  - Charging of the material into the batch
  - Calculations
  - Settings
  - Cleaning
- Does everything need to have a second person verification?
  - No – you can use a printout from the scale/balance to serve as the second person verification.

Slide 15:



- Discuss clear and concise – what does it mean?
  - Remember, the FDA inspector will read your documentation. If it is clear to you but may mean something else to them, then it is a problem.
    - Leader's Note: add any examples you have
    - "The test finally worked" – really, it has never worked before?
    - "Found issue with product" – what issue? Where? What did you do?
    - "Had to halt operation" – why? What did you do?
- Discuss what is pertinent
  - The approach is "Who, What, When, Where…" Related to the quality of the operation.
  - Poor wording "The material was clear but I hate the typical smell".
- For insufficient space – ask for input from attendees
  - Cross reference the spot with a note. For example, put a "*" and then a "*" at the bottom of the page to continue the documentation

- **Slide 15:**

- Close out each session with a question and answer section
- If you cannot answer a question, write it down and get the answer
  - Don't ask them to find the answer or it will probably not be done
  - After you get the answer, send it out to everyone in attendance
- Include any pertinent closing remarks
  - Message from the president
  - Company goals
  - Recent issues or good news