

CGMP MEETING SERIES

<p>Good Documentation Practices 1-1</p>	<p>Why Document?</p> <p>It has been said that in the pharmaceutical industry, "If it isn't documented, it didn't happen"</p> <p>Therefore, in the pharmaceutical and medical device industry, we document to provide written proof that something happened.</p> <p>For this reason good documentation practices—commonly referred to as GDPs—are critical. Records and reports related to production events represent the only official, documented record of:</p> <ul style="list-style-type: none"> • processing a batch • producing a device • the final decision to release (or reject) a batch or product • the evidence for a corrective or preventive action (CAPA) • an investigation of manufacturing deviations, complaints or alleged product defects • meeting product and quality specifications generated from test results <p>Records and reports, along with procedures, "tell the story" of manufactured products and devices.</p> <p>In addition to regulatory requirements, it is also very important to maintain accurate records for business reasons. By maintaining clear, accurate and timely records you can take a critical look at various processes related to product manufacture with the intent of making quality, product or cost saving improvements.</p> <p>GDPs apply to everyone who documents activities related to cGMP or current Good Manufacturing Practices.</p> <p>Compliance with the Food and Drug Administration's GLP, or Good Laboratory Practices, regulations (21 CFR Part 58), as well as GMP regulations for drugs and medical devices (21 CFR Parts 211 and 820) requires the use of Good Documentation Practices.</p> <p>GDPs are enforced by regulatory agencies such as the FDA, TGA, EMEA, Health Canada or WHO.</p>
<p>Training Date:</p>	
<p>Training Time:</p>	
<p>Training Conducted By:</p>	
<p>Training Attendees:</p>	
	<p>Notes:</p>

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Good Documentation Practices 1-2		<h2 style="margin: 0;">What Are Good Documentation Practices?</h2> <p style="margin: 0;">Good Documentation Practices, commonly referred to as GDPs, are the guidelines that one follows in recording raw data entries in a legible, traceable and reproducible manner.</p> <p style="margin: 0;">A key to Good Documentation Practices is to consider these questions each time you record your raw data:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">1. Is it true?</td> <td style="width: 50%;">3. Is it timely?</td> </tr> <tr> <td>2. Is it accurate?</td> <td>4. Is it legible?</td> </tr> </table> <h3 style="margin: 0;">What types of documents require following Good Documentation Practices?</h3> <p style="margin: 0;">Some examples include:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> <ul style="list-style-type: none"> • Analytical Methods • Batch Records • Bills of Materials (BOMs) • Certificate of Analyses (CoA) • Certificate of Compliance (CoC) • Laboratory Notebooks • Logbooks • Policies • Protocols </td> <td style="width: 50%; vertical-align: top;"> <ul style="list-style-type: none"> • Quality records <ul style="list-style-type: none"> ○ non-conformances ○ CAPAs ○ internal inspection reports ○ change control • Standard Operating Procedures • Test Methods • Training Documentation • Validation Documents (IQs, OQs and PQs) • Work Instructions • Product and Sample Labels </td> </tr> </table> <h3 style="margin: 0;">Categories of Documents</h3> <ol style="list-style-type: none"> 1. Primary records such as those obtained from the master formula, manufacturing and packaging instructions. 2. Supporting procedures such as instructions on how to perform a manufacturing step or test methodology. 3. Subsidiary records which support the process as it is being carried out, such as environmental monitoring or preventive maintenance/calibration on process or lab equipment. 4. Quality control records include all lab testing results for the process or products and all investigative reports and records. <p style="margin: 0;">Notes:</p>	1. Is it true?	3. Is it timely?	2. Is it accurate?	4. Is it legible?	<ul style="list-style-type: none"> • Analytical Methods • Batch Records • Bills of Materials (BOMs) • Certificate of Analyses (CoA) • Certificate of Compliance (CoC) • Laboratory Notebooks • Logbooks • Policies • Protocols 	<ul style="list-style-type: none"> • Quality records <ul style="list-style-type: none"> ○ non-conformances ○ CAPAs ○ internal inspection reports ○ change control • Standard Operating Procedures • Test Methods • Training Documentation • Validation Documents (IQs, OQs and PQs) • Work Instructions • Product and Sample Labels
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Good Documentation
1-3

The Meaning of Signature

Generally speaking, when signing your name to a GMP document, you:

1. Confirm your unique identity.
2. State that you have the authorization to perform, verify, check, review or approve the activity associated with your name.
3. Recognize that your signature and initials cannot be taken back; once signed, you are personally, professionally and legally responsible for the action taken.

Training Date:

Training Time:

Training Conducted By:

Training Attendees:

Controlling Your Signature

It is imperative that you maintain strict control over the use of your signature and initials. Sign and initial only for yourself. Never allow someone else to sign or initial for you unless that person is authorized in writing to do so and according to procedure.

Signature Log or Signature Logbook

Everyone who signs controlled documentation must register their signature and initials. This allows identification of a person performing or supervising a specific GMP activity. This registration includes all temporary and contract employees.

The current Good Manufacturing Practices state: "Batch production and control records shall be prepared for each batch of drug product produced and shall include complete information relating to production and control of each batch. These records shall include: identification of the persons performing and directly supervising or checking each significant step in the operation." 21CFR211.188

We should always be able to see who is responsible for performing a specific operation or entering data. We cannot just use names because names are not unique—several people may have the same name. And, it is difficult to use signatures all of the time because they are often illegible. As a result, we use initials; and it is these signatures and initials that must be registered.

Remember, you must always sign or initial documents exactly as you have entered your signature and initials in the signature log book.

Note: Don't forget to update your signature and initials if your name changes.

Notes:

