

Good Documentation Practices

1.0 PURPOSE

This procedure provides the requirements of Good Documentation Practices (GDP) to ensure quality-related documentation, including records used throughout Abbott Cardiovascular and Neuromodulation are complete, consistent and accurate.

2.0 REFERENCES

2.1 Applicable Documents

Number	Title
N/A	N/A

2.2 External References

Number	Title
21 CFR Part 11	Electronic Records; Electronic Signatures

3.0 RESPONSIBILITIES

Function or Title	Responsibility
Employee	All Abbott CN employees must comply with the requirements stated in this procedure as applicable to their job responsibilities.

4.0 DEFINITIONS

Term	Definition
Data Integrity	The completeness, consistency, and accuracy of data. Complete, consistent, and accurate data should be attributable, legible, contemporaneously recorded, original or a true copy, and accurate (ALCOA).

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5.0 FLOWCHART

N/A

6.0 REQUIREMENTS

6.1 Data / Information Entries

6.1.1 General

When entries are made in records, they:

- Must be made in spaces provided for such entries, or if space is limited, entries must be defined in procedures
- Must be made during or directly after performing the activities; back or forward dating is prohibited, and
- Must identify the person making the entry.

6.1.2 Employee Identification

Employee identification shall be uniquely identifiable to the individual. This may be accomplished with a Signature Record or on the record itself. The following formats are examples:

- First initial, full last name (e.g., J. Adams)
- First and last name (e.g., John Adams)
- Employee number
- Employee login username
- Stamp number (with associated stamp controls)
- Employee initials (e.g., CMJ, PW)

6.1.3 Decimal Numbers

If a value is between zero (0) and one (1), it shall be recorded with a zero (0) placed before the decimal point. Example: 0.76 rather than .76

This is the preferred format for data generated by an electronic or software system

6.1.4 Units of Measure

Where a specification exists, a result shall be expressed or reported in the same unit of measure before making an acceptance decision.

6.1.5 Blank Fields

When a field or space does not require any data, or is “Not Applicable,” the abbreviation “N/A” or “NA” shall be entered, either handwritten, typed or stamped, in or near that space along with employee identification, the date, and an explanation for not using these field(s) if not obvious (i.e., a work instruction or the completed record itself makes it clear). See Appendix A for examples.

6.1.6 Same or Repetitive Entries

Ditto marks (“”) or arrows to indicate the same or repeated entries shall not be used.

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6.1.7 Omitted Information/Data

If an entry was omitted and the activity performed at a later time, the entry shall clearly indicate:

- the date the activity was performed
- the identification of who performed it
- the date the activity was recorded on the record, and
- the reason for the delay in recording.

6.1.8 Acronyms, Abbreviations, Jargon

Definitions of acronyms, abbreviations or jargon shall be explained the first time they are used in a record or document.

6.1.9 Margins

Data/information entries shall not be made in the margins to ensure all information is legible and clear if the record is copied or scanned.

6.1.10 Use of Off-Record Notes

Temporary notes, such as sticky notes or scrap paper, shall not be attached to records or used to record quality data/information.

6.1.11 Thermal Printouts

All printouts made on thermal paper shall be copied, indicated as "Copy", signed and dated before attaching to a record.

6.1.12 Data Transcription

When data/information are transcribed or copied, then:

- Original data must be attached or appropriately documented and referenced
- Transcribed data should be verified by a second person, and
- The reason for the transcription must be documented, signed and dated.

6.2 Signatures and Dates

6.2.1 Handwritten Signatures

A person's handwritten signature minimally consists of:

- First name
- Full last name, and
- Date.

Signatures are incomplete without the date entered by the person signing the document. A signature may be considered complete if it is entered on a correctly dated document (e.g., a typed memo that includes the date where the signatory is signing for the content and therefore confirming the date.)

Handwritten signatures and entries of information must be made in indelible, non-erasable ink that allows for clear copying/rendering.

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Initials and date may be used in place of signatures throughout a single document or record provided the:

- Initials are traceable back to the author and
- Initials are not used to indicate approval.

Handwritten signatures and initials shall be uniquely identifiable to the originator/author. This could be accomplished by a signature card, log, or form kept on file

Where a stamp or seal is considered a legal signature, these may be used.

6.2.2 Date Format

Handwritten dates shall include the day, month, and year. The month is required to be written using letters unless local instructions, forms or templates makes the date unambiguous. Examples:

- 29MAY18
- 29MAY2018
- May 29, 2018

6.2.3 Time Format

- Time shall be recorded in 24-hour format (00:00 – 23:59) or denoting am or pm if using 12-hour format. Examples: 15:00 **or** 03:00 pm
- A period of time shall be recorded in hours and/or minutes. Example: 1 hr. 36 min (or 1:36 hrs.) (or 96 min)

6.2.4 Electronic Signatures

Written procedures must be established and maintained for the administration and control of electronic signatures. A verifiable method for assigning, verifying, certifying or sanctioning an individual's electronic signature must be established.

When an electronic signature and associated record meet the requirements of applicable regulations, then the electronic signature is considered a legal equivalent to a handwritten signature. An electronic signature must:

- Be unique to one individual and
- Not be used by or reassigned to anyone else.

Automated execution of a system login or an electronic signature is not allowed.

6.2.5 Digital Signatures

Written procedures must be established and maintained for the administration and control of digital signatures.

Digital signatures may be used as an acceptable signature method. A document's digital signature provides assurance that the message cannot be tampered with, and the data cannot be changed, added, or deleted without the sender's knowledge.

A digital certificate must be obtained to use a digital signature. Secured digital certificates associated with digital signatures must be maintained.

Third-party certificate authorities can be used to obtain certificates for general use. If an outsourced certificate is used, it is recommended to use certificates with three years validity.

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6.2.6 Signatures for Others

Signatures for original data entries must be made by the originator, although, someone may “sign for” a person when authorized by that person. Delegation authorization is not required for organizational superiors or as procedurally defined. Such delegated authorization should:

- Be documented, and
- Contain the period or conditions for which the delegation is authorized.

One function may not sign for another unless such circumstances are defined by written procedures. Other functions may not sign for the Quality function.

6.3 Approvals

6.3.1 Written Approvals or Reviews

- Approvers shall include their signature and date.
- When a record review is required, the review shall be performed by a person who did not complete the original entries. The reviewer shall ensure that entries are clear, complete, legible and meet documentation requirements.

6.3.2 Electronic Approvals

Approvals may be transmitted via electronic means such as fax, scanned files, or e-mail.

6.3.2.1 Fax Approvals

When a written approval is received by fax, the handwritten version is not required to be retained. The fax copy may be considered the original and retained as the approval documentation.

6.3.2.2 Scanned Approvals

When a scanned document is used to document approval, the document is signed and dated by the author/approver and scanned to render an un-editable electronic file. The scanned file may be considered the original and retained as the approval documentation.

6.3.2.3 E-mail Approvals

When e-mail is used to document approval, correspondence is signed and dated by the author/approver, rendered into an un-editable electronic file, attached to the e-mail and sent. The un-editable electronic file may be considered the original and retained as the approval documentation. An e-mail itself may not be used for approvals.

6.4 Corrections

6.4.1 Document / Record Error Correction

When correcting original data/information on documentation, the individual who made the original entry should make the corrections:

- If the originator is not available, another individual may change/correct a record if the change can be substantiated by documented objective evidence.

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- When objective evidence is not available, then the change must be processed as a nonconformance.

6.4.1.1 Written Corrections

Corrections must:

- Be signed and dated
- Not obscure the original record and data, and
- Include a reason for the correction written as close as possible to the correction.

To complete the correction:

- Draw a single line through the entire entry being corrected, and
- Sign and date.
- The following are prohibited: use of correction fluid/tape, blot out, erasing, using multiple cross-outs, overwriting, or obscuring the original data/information.

6.4.1.2 Electronic Corrections

Electronic corrections must have a secure, computer generated audit trail to independently record the:

- Date
- Time
- Action taken
- Reason, and
- Person making the change.

6.5 Forgery and Falsification

6.5.1 Forgery

Employees shall sign for their own work. Forgery is not acceptable and may result in disciplinary action.

6.5.2 Falsification

Falsifying data/information on documents or records is not acceptable and may result in disciplinary action. Examples of falsification of data include, but are not limited to, the following:

- Entering data results when inspection, measurement, or testing has not been performed
- Entering data results which are not reflective of the actual data
- Signing for work or a process step that has not been performed
- Entering a date / time other than the actual date / time a task was completed
- Forging another employee's identification or signature
- Using another employee's username and password
- Destroying or discarding original data without supporting documentation or management approval.

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APPENDIX A: BLANK FIELDS: EXAMPLES FOR ENTERING NA

Case	Example																																					
Multiple fields example	<p>For tables or multiple blank spaces that are not applicable, include a single “/” line through the space.</p> <table border="1" data-bbox="302 466 1253 669"> <tr> <td>SILVER BRAZING PASTE STL-1205 S-657</td> <td></td> <td>ML</td> <td>1.300</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>SPOOLED WIRE 34 GAUGE CLEAR COPPER</td> <td></td> <td>EA</td> <td>13</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>ELECTRODE RING .095X.003X.040</td> <td></td> <td>EA</td> <td>16</td> <td></td> <td></td> <td></td> <td></td> </tr> </table> <p style="text-align: right; margin-right: 100px;">NA 18 Jul 16 1915239</p>	SILVER BRAZING PASTE STL-1205 S-657		ML	1.300					SPOOLED WIRE 34 GAUGE CLEAR COPPER		EA	13					ELECTRODE RING .095X.003X.040		EA	16																	
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Single field example	<p>Example 1</p> <table border="1" data-bbox="553 747 946 928"> <thead> <tr> <th>Operation Description</th> <th>UoM</th> <th>Qty Accept</th> <th>Qty Reject</th> </tr> </thead> <tbody> <tr> <td>Two Piece Tray Assembly Package in Tray</td> <td>EA</td> <td>N/A CD 01MAY17</td> <td>N/A CD 01MAY17</td> </tr> </tbody> </table> <p style="text-align: center;">OR</p> <table border="1" data-bbox="1052 739 1227 928"> <thead> <tr> <th>Qty Accept</th> <th>Qty Reject</th> </tr> </thead> <tbody> <tr> <td colspan="2" style="text-align: center;">/</td> </tr> </tbody> </table> <p>Example 2: When multiple N/A's are entered on a form by the same employee it is acceptable to annotate the employee identification and date on the form.</p> <table border="1" data-bbox="589 1037 1195 1257"> <thead> <tr> <th>UoM</th> <th>Cantidad Aceptada</th> <th>Cantidad Rechazada</th> <th>Disp.</th> </tr> </thead> <tbody> <tr> <td>EA</td> <td>N/A ①</td> <td>N/A ①</td> <td>N/A ①</td> </tr> </tbody> </table> <p>① MF 30014959 07 Jun 17</p> <p>Example 3: For line items, on shop floor paperwork for example, the column for employee identification and date pertains to all the written entries for that line. Additional ID /Date is not required for the N/A.</p> <table border="1" data-bbox="435 1394 1344 1530"> <tr> <td>Final Visual Inspection</td> <td>IP 620594</td> <td>AS</td> <td>N/A</td> <td>N/A</td> <td>MGS 07 Jul 17 30033238</td> <td>1</td> </tr> <tr> <td>Stent Packaging</td> <td>MP 650751</td> <td>P</td> <td>N/A</td> <td>NA</td> <td>MGS 07 Jul 17 30033238</td> <td>1</td> </tr> </table> <p>Example 4: Areas on forms, including grayed sections, with N/A pre-printed do not require an employee ID/Date in that field.</p> <table border="1" data-bbox="602 1682 1182 1745"> <tr> <td>Repair Inspection</td> <td>See attached Tally Sheet</td> <td>N/A</td> </tr> </table>	Operation Description	UoM	Qty Accept	Qty Reject	Two Piece Tray Assembly Package in Tray	EA	N/A CD 01MAY17	N/A CD 01MAY17	Qty Accept	Qty Reject	/		UoM	Cantidad Aceptada	Cantidad Rechazada	Disp.	EA	N/A ①	N/A ①	N/A ①	Final Visual Inspection	IP 620594	AS	N/A	N/A	MGS 07 Jul 17 30033238	1	Stent Packaging	MP 650751	P	N/A	NA	MGS 07 Jul 17 30033238	1	Repair Inspection	See attached Tally Sheet	N/A
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Case	Example									
	<p>Example 5: When a pre-printed line does not create two separate cells (because the line is incomplete), N/A is not required in a cell which has information documented.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;">SLEEVE, 278/425 BLU/DK GRY 8.5</td> <td style="width: 5%;">H</td> <td style="width: 5%;">224</td> <td style="width: 5%;">EA</td> <td style="width: 10%; text-align: center;">5825073</td> <td style="width: 10%; text-align: center;">205</td> <td style="width: 10%; text-align: center;">30023718</td> <td style="width: 10%; text-align: center;">30029814</td> <td style="width: 10%; text-align: center;">20MAR17</td> </tr> </table> <p>Example: N/A not required in spaces below 5825073, 205, etc.</p>	SLEEVE, 278/425 BLU/DK GRY 8.5	H	224	EA	5825073	205	30023718	30029814	20MAR17
SLEEVE, 278/425 BLU/DK GRY 8.5	H	224	EA	5825073	205	30023718	30029814	20MAR17		

APPENDIX B: CORRECTION EXAMPLE FOR MULTIPLE ERRORS BY SAME PERSON

Case	Example																											
Legible correction	<p>It is acceptable if multiple errors made by the same person on the same date and contained in one cell or table to be annotated and corrected.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Start Up Inspection</th> <th style="text-align: center;">Pass</th> <th style="text-align: center;">Fail</th> </tr> </thead> <tbody> <tr> <td>Visual</td> <td style="text-align: center;">① 9 8</td> <td style="text-align: center;">① 0 1</td> </tr> <tr> <td>Hub ID</td> <td style="text-align: center;">① 9 8</td> <td style="text-align: center;">0</td> </tr> <tr> <td>Tubing ID</td> <td style="text-align: center;">① 9 8</td> <td style="text-align: center;">0</td> </tr> <tr> <td>Side-Port ID</td> <td style="text-align: center;">① 9 8</td> <td style="text-align: center;">0</td> </tr> <tr> <td>Slit Wall</td> <td style="text-align: center;">① 9 8</td> <td style="text-align: center;">0</td> </tr> <tr> <td>Hub Bond Force (3.5 lbs min)</td> <td style="text-align: center;">15.43</td> <td style="text-align: center;">Lbs.</td> </tr> <tr> <td>Shaft Bend Test</td> <td style="text-align: center;">① 9 8</td> <td style="text-align: center;">0</td> </tr> <tr> <td>Mold fill/adhesion verification</td> <td style="text-align: center;">① 9 8</td> <td style="text-align: center;">0</td> </tr> </tbody> </table> <p style="margin-left: 20px;">① 12096154 19 APR 18</p>	Start Up Inspection	Pass	Fail	Visual	① 9 8	① 0 1	Hub ID	① 9 8	0	Tubing ID	① 9 8	0	Side-Port ID	① 9 8	0	Slit Wall	① 9 8	0	Hub Bond Force (3.5 lbs min)	15.43	Lbs.	Shaft Bend Test	① 9 8	0	Mold fill/adhesion verification	① 9 8	0
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