



BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title: Format, Content, and Identification of Standard Operating Procedures
SOP Number: 21400
Revision: 07

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1. PURPOSE

This SOP defines the format, content, and identification system for Standard Operating Procedures (SOPs) and forms for each department in the Biopharmaceutical Development Program (BDP)

2. SCOPE

This procedure applies to Standard Operating Procedures written for the BDP. For origination, modification, and control of SOPs, see **SOP 21418 - Control and Request of Documents/Records** and **SOP 21419 - Origination, Modification, and Approval of Documents**.

3. RESPONSIBILITIES

3.1 Director Regulatory Compliance

- Defines and implements this procedure.
- Provides quality oversight.

3.2 Biopharmaceutical Quality Assurance Documentation (BQAD)

- Formats the final SOP before routing for approval.
- Verifies the identification, numbering, and revision of the document matches the information in the eDMS.
- Ensures the document meets 508 compliance.
- Works with the the author to create required alternate text for 508 compliance

3.3 Author

- Uses the current SOP template for new SOPs.
- Provides SOP content.

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4. DEFINITIONS

- **Standard Operating Procedure (SOP):** A document that describes a policy, system, and/or operation.
- **508 Compliance:** Federal agencies must provide comparable access to information with persons with disabilities.
- **Alternate Text:** Alternate text is read aloud by screen readers to convey meaning of an image or other non-text element to someone who is vision impaired.

5. PROCEDURE

5.1 General Format

- 5.1.1 A Microsoft Word document is provided in the eDMS as a template for new documents. BQAD updates revisions to a new template when the document is updated.
- 5.1.2 The font is Arial, point size 11. A smaller size font is acceptable for tables, but is not recommended below a point size of 9.
- 5.1.3 Acronyms used are identified fully the first time used in the document. Subsequent references within the document can use the acronym.
- 5.1.4 The use of bold should be used when requiring emphasis.

5.2 Identification

- 5.2.1 SOP or Form number(s)
 - 5.2.1.1 SOPs are numbered automatically through the eDMS. See Attachment 1 for the numbering for all SOPs.
 - 5.2.1.2 Forms are uniquely identified with the SOP number they are associated with, immediately followed by a hyphen and a two digit number starting at -01, and incrementing by 1 for each new form.
 - 5.2.1.3 SOPs and Forms can be revised independently. SOPs and forms are required to be revised at the same time if the change to one impacts the other.

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5.2.2 Revision

Revision levels start at 00 for new documents and incrementally increase by 1. Revision levels only increase after a document is revised after it has been approved.

5.2.3 Effective Dates

Effective dates for SOPs are automatically included on the pdf published document. Effective dates for forms are found on the form infocard.

5.3 SOP Headers

The header includes the current FNLCR logo, the directorate name, the SOP Number, SOP Title and the revision.

5.4 Form Headers

The current FNLCR logo is optional. Form headers must include:

FNLCR, BDP
Form Number: XXXXX-XX
Revision: XX

5.5 Pagination

SOPs and forms are paginated as:

- Page X of Y
- Bottom center of the footer
- Arial, 8 point

5.6 Headings and Styles

Styles are predefined in the SOP template.

5.7 Referenced Documents

Documents referenced within the text of the SOP are identified the first time with the document number and the title. Subsequent references to the same SOP or form may use the document number, bolded.

5.8 Using Step Numbering or Bulleted Lists

5.8.1 Steps are numbered consecutively as defined in the styles. No paragraph is numbered with a terminal 1 (e.g., 4.2.1, 5.3.1, 6.4.1) unless it is followed by a 2.

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5.8.2 Bulleted lists may be used to draw visual attention to items in the list without implying that the items go in a certain order. (e.g. chronology, importance, priority)

5.9 Tables and Figures

5.9.1 Tables, figures, and diagrams may be incorporated within the body of the text. Pages may be oriented as portrait or landscape to accommodate the tables or figures.

5.9.2 Tables, figures, and diagrams are consecutively numbered within the document and must include a title. (e.g., Figure 1 Orientation of the XYZ, Table 1 Summary of the Alpha Beta Zeta). The exception is for the tables defined by the template (e.g. Materials and Reagents).

5.9.3 Tables are designed to have the header row repeat in case the table breaks across the page.

5.9.4 Alternate Text is included with every table to make it 508 compliant.

5.10 Table of Contents (TOC)

A table of contents is used for any SOP with more than five (5) pages. It is not required if the SOP is five (5) pages or less. For longer documents, the author can request a TOC that goes to the second heading level.

5.11 SOP Sections

5.11.1 Required Sections

All SOPs require:

- Purpose
- Scope
- Responsibilities
- Procedure (or Use for Equipment specific procedures)

5.11.2 Recommended Sections for Technical SOPs or Equipment SOPs

- Safety
- Materials and Reagents
- Equipment
- Calibration
- Preventative Maintenance
- Cleaning

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- System Suitability
- Data Analysis
- Calculations
- Documentation and Records

5.11.3 Optional Sections

- Definitions
- Abbreviations
- Overview
- References and Related Documents
- Attachments

5.11.4 Other sections can be added by the authors as required.

6. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
21418	Control and Request of Documents/Records
21419	Origination, Modification, and Approval of Documents
21 CFR58.81(a)	GLP – Testing Facilities Operation
21 CFR 211.100(a)	Drugs – Written Procedures

7. ATTACHMENTS

Attachment 1: SOP Numbering Series



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Attachment 1: SOP Numbering Series

Number Series	Description	Abbreviated	Start at Number
10000	Manufacturing Operations	Mfg-Ops	10306
11000	Facilities and Equipment	Fac-Equip	11170
12000	Late Process Sciences – Fermentation	Mfg-Ferm	12247
13000	Early Process Sciences Cell Culture	Mfg-Cell Cult	13251
14000	Late Process Sciences – Purification	Mfg- Purif	14154
15000	Late Process Sciences - Fill/Finish	Mfg- Fill/Fin	15155
16000	PA Development – Analytical	PA-Dev	16163
17000	Early Process Sciences – Virology	Virus Dev/Mfg	17130
19000	Late Process Sciences – Support	Mfg-Support	19507
20000	Materials Management and Inventory Control	MMIC	20405
21000	Quality Assurance	QA	21927
22000	Process Analytics	PA-QC	23015
24000	Regulatory Affairs	RA	24415
25000	Early Process Sciences - Research and Development	EPS-RD	25125
26000	Safety	Safety	26303