Table of Contents

1.0 Purpose

This Standard Operating Procedure (SOP) defines the conditions and procedures whereby an alternate person may review and approve Biopharmaceutical Development Program (BDP) documents that require the signature of specific department management, in the event the person with primary signature responsibility is not available.

2.0 Scope

This SOP applies to BDP staff who have been given signature authority for documentation and to those individuals needing to obtain approval signatures on BDP documentation.

3.0 Authority and Responsibility

3.1 The Director, Regulatory Compliance/BQA has the authority to define this procedure.

3.2 Biopharmaceutical Quality Assurance (BQA) is responsible for maintaining approved copies of Form 21007-01, Alternate Signature Authority in a binder in the BQA office area.

3.3 BQA is responsible for the implementation of this procedure.

4.0 Procedure

4.1 An approved list of alternate signatures with the title of the alternate and the conditions under which they may act is provided in Attachment 1 for each BDP Director. Since each BDP Director has approved this SOP, they do not need to supply Form 21007-01 to BQA. If there is a new director before the approved list of alternate signatures is updated, they can supply Form 21007-01 to BQA.

4.2 Other Department Managers and Project Scientists that require approved alternative signatures should complete Form 21007-01 and forward it to BQA.

4.3 When the alternate signs a document (using black or blue ink), the alternate signs by signing his or her name followed by the word "for" and the name of the person being substituted. If a document is signed electronically then the “for” is not required.

4.4 On documents that require two or more signatures, the same person cannot sign twice.

4.5 Supervisors, Managers, and Directors have signature authority for individuals reporting to them.

5.0 References and related documents

Form 21007-01 Alternate Signature Authority

SOP 21409 Good Documentation practices

6.0 Attachments

6.1 **Attachment 1** Signature Authority List for BDP Directors

Attachment 1

Signature Authority List for BDP Directors

Title/Department	Responsibility	Primary Alternates	Secondary Alternates
Director, Regulatory Compliance/BQA	GMP and audit issues, lot status and release, raw material statuses, etc.	QA Manager, Compliance	Director, Regulatory Affairs
	SOPs, MPRs, and other document approvals, status, etc.	QA Manager, Compliance	Director, Regulatory Affairs
	Regulatory issues, status, etc.	Director, Regulatory Affairs	
	Training issues, status, etc.	QA Manager, Compliance	Director, Regulatory Affairs
	Quality Engineering, Validation, Calibration	QA Manager, Engineering	QA Manager, Compliance
	Distribution Forms	Director, Regulatory Affairs	QA Manager, Compliance
Director, Regulatory Affairs	Regulatory documents, issues, etc.	Director, Regulatory Compliance/BQA	
	Document Control issues, SOPs	Director, Regulatory Compliance/BQA	QA Manager, Compliance
Director, PA\QC	PA Administration, QC Reports, Certificates of Analysis, Assay Profiles, etc.	QC Manager /Program and Technical Director, BDP	Scientist, PA; Manager, Environmental Monitoring and Raw Materials
	Virology Testing, Cell Line Testing, Assay Reviews, Training, etc.	QC Manager or Scientist, PA	PA Analysts (who did not conduct the work)
	Product Testing, Stability Testing, Assay Reviews, Training, etc.	QC Manager or Scientist, PA	PA Analysts (who did not conduct the work)
	Environmental Monitoring, Utilities Monitoring, Raw Materials Testing and Release, Training, etc.	QC Manager	Scientist, PA; PA Analysts (who did not conduct the work)
Director, Late Process Sciences	Upstream Production	Manager, Upstream Production	Program and Technical Director, BDP
	Purification issues	Manager, Purification	Program and Technical Director, BDP
	Buffer/Aseptic Fill issues	Manager, Fill/Finish	Program and Technical Director, BDP
	General issues	Program and Technical Director, BDP	
Program and Technical Director, BDP	Administrative and scientific activities in the BDP	Director, Late Process Sciences	Director, Regulatory Compliance/BQA