American Red Cross Biomedical Services	Doc No 12.3.1	Version 1.0
Work Instruction: **Requesting and Evaluating Production Data from the Supplier (PPAP)**	Approved by Kathleen C. Glackin Vice President Biomedical Services Operations 03, 2005	

What this work instruction is about

This work instruction is about

- requesting production parts approval process (PPAP) data from a supplier
- evaluating that data, and
- making decisions based on that data.

Who should know how to perform this work instruction

This work instruction applies to the supplier engineer.

Introduction

The supplier engineer must have the following before beginning this procedure:

- BSD36.304T, Regulated Supplier Approval
- proposals from suppliers
- requirements and specifications
- confirmation of supplier approval, and
- the job aid on solicitation requirements. **[12.4.ja4]**

Requesting materials and equipment production and support data

1. Classify the material, equipment, or service according to BSD 36.304T, Regulated Supplier Approval.

2. Request production parts approval process (PPAP) data from the supplier. [12.4.ja4]

The supplier will provide PPAP data.

Evaluating PPAP data

3. Review the PPAP data from the supplier.

- If the supplier did not submit sufficient data, or if there are areas of concern with the data, determine the appropriate course of action. Actions taken may include requesting additional information, visiting the supplier, or sending an inspector to the facility to ensure production process is in control.

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Job Aid: **PPAP Solicitation Requirements**	Approved by Kathleen C. Glackin Vice President Biomedical Services Operations	
	Approval date 03/2/2005	

What this job aid is about

This job aid shows examples of information that can be requested as production parts approval process (PPAP) data for materials, equipment, and services.

Who should know how to use this job aid

This job aid applies to the supplier engineer.

		Class 1	Class 2
Material	Consumables	***Example: pipette tip*** • Certificate of conformance / certificate of analysis • Customer support capabilities • Finished product inspection and test data	***Example: blood collection set*** • Certificate of conformance / certificate of analysis • Process capability studies • Process control plan • Statistical process control data • Customer support capabilities • Finished product drawings • Finished product inspection and test data • Sterility assurance (if applicable)
	Non-Consumables	***Example: temperature stabilization pack*** • Certificate of conformance / certificate of analysis • Customer support capabilities • Validation studies **OR** finished product inspection and test data	***Example: blood shipping box*** • Certificate of conformance / certificate of analysis • Customer support capabilities • Validation studies • Finished product inspection and test data
Equipment		***Example: leukoreduction cart*** • Reliability studies • Customer support capabilities • Process control plan	***Example: apheresis machine*** • Reliability studies • Customer support capabilities • Control plan • Validation data • Design failure mode effect analysis (DFMEA) (if available) • Process failure mode effect analysis (PFMEA) • Finished product inspection and test data
Service		• Customer support capability • Conformance to applicable standards (for example, OSHA, EPA, state, local)	• Customer support capability • Conformance to applicable standards (for example, OSHA, EPA, state, local)

Risk associated with not performing an operational trial

Risk	Impact of Risk	Likelihood of Occurrence	Likelihood of Detection/Mitigation prior to Implementation
Procedures (Directives, work instructions, job aids, etc.) are not tested prior to release to the field	Instructions cannot be followed	☐Low ☐Medium ☐High	☐Low ☐Medium ☐High
	Instructions can be followed, but result in incorrect action being taken	☐Low ☐Medium ☐High	☐Low ☐Medium ☐High
	A wide variety of interpretation occurs resulting in nonstandard actions between facilities	☐Low ☐Medium ☐High	☐Low ☐Medium ☐High
	Gaps in instructions are not identified	☐Low ☐Medium ☐High	☐Low ☐Medium ☐High
Training materials are not tested prior to release to the field	Training materials cannot be followed	☐Low ☐Medium ☐High	☐Low ☐Medium ☐High
	Training occurs, but the skills/knowledge are ineffective	☐Low ☐Medium ☐High	☐Low ☐Medium ☐High
	Training activities are inconsistent due to variation in interpretation of training material	☐Low ☐Medium ☐High	☐Low ☐Medium ☐High
	Gaps in training are not identified	☐Low ☐Medium ☐High	☐Low ☐Medium ☐High
Equipment qualification materials (Validation plans, calibration and maintenance instructions) are not tested prior to release to the field	Validation scenarios are not in correct order for efficiency	☐Low ☐Medium ☐High	☐Low ☐Medium ☐High
	Qualification plans/procedures are not executable as written	☐Low ☐Medium ☐High	☐Low ☐Medium ☐High
	Qualification plans/procedures are inconsistently understood resulting in nonstandard execution between facilities	☐Low ☐Medium ☐High	☐Low ☐Medium ☐High
	Gaps in qualification instructions are not identified	☐Low ☐Medium ☐High	☐Low ☐Medium ☐High