



DUKE

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DOCUMENT TITLE:

Internal Quality Systems Facility Qualification/Requalification Audit Report JA6

DOCUMENT NOTES:

Document Information

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Control Information

Author: JPC27

Owner: JPC27

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COMM-QA-039 JA6
INTERNAL QUALITY SYSTEMS FACILITY
QUALIFICATION/REQUALIFICATION AUDIT REPORT JA6
(CONFIDENTIAL)

Date of Qualification Review:

Facility	
Facility: Address:	Facility Contact: E-mail: Phone: Other Contact Info:

PERSONNEL			
1. Training completed for applicable personnel. Personnel released to task.	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
• Initial Training	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
• On-site Training	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
• MasterControl	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
• SOPs	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
• cGMP	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
• Other, specify:	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
2. Qualifications documented	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
COMMENTS:			

FACILITIES			
3. Secure, limited access storage, collections and record retention areas.	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
4. Areas clean, orderly & monitored for temperature/humidity	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
5. Adequate supplies. Supply management reflects acceptable receipt, inspection & organization to support use of first expired supplies & when no expiration date, organized to support use of first received.	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
6. Shipping containers validated, clean (with test shipment completed).	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
7. Equipment validated & functioning	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
8. QC Records posted and maintained	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
9. Restricted access to computer(s) with log on capabilities to EMMES, MasterControl, or applicable computer systems.	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
10. Access to internet and EMMES, MasterControl, or applicable computer systems.	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
COMMENTS:			

EQUIPMENT LIST		
Equipment	Serial Number	Calibrated/Validated
		<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
		<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
		<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
		<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A

COMMENTS:

COMPLIANCE			
11. Business agreement(s) finalized	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
12. CCBB contact information available	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
13. Site personnel instructed to notify CCBB of all deviations & unexpected events	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
14. Site personnel instructed to notify CCBB of any audits/inspections by external agencies	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A
15. Signature Log initiated	<input type="checkbox"/> YES	<input type="checkbox"/> NO	<input type="checkbox"/> N/A

COMMENTS:

ITEMS for FOLLOW-UP	TASK COMPLETED
<input type="checkbox"/> N/A	<input type="checkbox"/> YES <input type="checkbox"/> NO

Representative Conducting Audit	
NAME	ROLE

By signing below, all follow-up items, if any, have been addressed and the facility is approved for operation or continued operation.

Auditor's Signature: _____

Date: _____

QSU Director's Signature: _____

Date: _____

Signature Manifest

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All dates and times are in Eastern Time.

COMM-QA-039 JA6 Internal Quality Systems Facility Qualification/Requalification Audit Report

Author

Name/Signature	Title	Date	Meaning/Reason
John Carpenter (JPC27)		31 Dec 2015, 09:57:38 AM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Austin Rudisill (ADR35)		04 Jan 2016, 12:50:31 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Sandy Mulligan (MULLI026)		04 Jan 2016, 06:37:14 PM	Approved