**DOCUMENET NUMBER:** COMM-QA-039 JA6

**DOCUMENT TITLE:**
Internal Quality Systems Facility Qualification/Requalification Audit Report JA6

**DOCUMENT NOTES:**

**Document Information**

| Revision: 01 | Vault: COMM-QA-rel |
| Status: Release | Document Type: COMM-QA |

**Date Information**

| Creation Date: 07 Dec 2015 | Release Date: 07 Jan 2016 |
| Effective Date: 07 Jan 2016 | Expiration Date: |

**Control Information**

| Author: JPC27 | Owner: JPC27 |
| Previous Number: None | Change Number: COMM-CCR-032 |
COMM-QA-039 JA6
INTERNAL QUALITY SYSTEMS FACILITY
QUALIFICATION/REQUALIFICATION AUDIT REPORT JA6
(CONFIDENTIAL)

Date of Qualification Review:

<table>
<thead>
<tr>
<th>Facility</th>
<th>Facility Contact:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>E-mail:</td>
</tr>
<tr>
<td></td>
<td>Phone:</td>
</tr>
<tr>
<td></td>
<td>Other Contact Info:</td>
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</table>

**PERSONNEL**

1. Training completed for applicable personnel. Personnel released to task.
   - Initial Training
   - On-site Training
   - MasterControl
   - SOPs
   - cGMP
   - Other, specify:

2. Qualifications documented

**COMMENTS:**

**FACILITIES**

3. Secure, limited access storage, collections and record retention areas.
4. Areas clean, orderly & monitored for temperature/humidity
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.
6. Shipping containers validated, clean (with test shipment completed.
7. Equipment validated & functioning
8. QC Records posted and maintained
9. Restricted access to computer(s) with log on capabilities to EMMES, MasterControl, or applicable computer systems.
10. Access to internet and EMMES, MasterControl, or applicable computer systems.

**COMMENTS:**
EQUIPMENT LIST

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Serial Number</th>
<th>Calibrated/Validated</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>YES</td>
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<tr>
<td></td>
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<td>YES</td>
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COMMENTS:

COMPLIANCE

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

COMMENTS:

ITEMS for FOLLOW-UP

□ N/A

TASK COMPLETED

□ YES □ NO

Representative Conducting Audit

<table>
<thead>
<tr>
<th>NAME</th>
<th>ROLE</th>
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</table>

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: ____________

COMM-QA-039 JA6 Internal Quality Systems Facility Qualification/Requalification
Audit Report JA6
QSU, DUMC
Durham, NC

CONFIDENTIAL - Printed by: SH259 on 07 Jan 2016 07:52:32 am
## Signature Manifest

**Document Number:** COMM-QA-039 JA6  
**Title:** Internal Quality Systems Facility Qualification/Requalification Audit Report JA6

All dates and times are in Eastern Time.

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

### Author

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<th>Date</th>
<th>Meaning/Reason</th>
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<tr>
<td>John Carpenter (JPC27)</td>
<td></td>
<td>31 Dec 2015, 09:57:38 AM</td>
<td>Approved</td>
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### Quality

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<tr>
<td>Austin Rudisill (ADR35)</td>
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<td>04 Jan 2016, 12:50:31 PM</td>
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### Document Release

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<td>Sandy Mulligan (MUL1026)</td>
<td></td>
<td>04 Jan 2016, 06:37:14 PM</td>
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