

MOTIVA Lab Internal Audit Summary Page

Date of Audit: _____

| | | |
|--|---|---|
| <p>Step 1 – Select one process only</p> <p> <input type="checkbox"/> Executive / Management Processes <input type="checkbox"/> QMS Processes <input type="checkbox"/> Business / Support Processes <input type="checkbox"/> Technical Processes <input type="checkbox"/> Other Processes </p> | <p>Name of Process</p> <p>_____</p> <p>(Comments)</p> <p style="text-align: right;"><i>(See Summary of Findings Pages)</i></p> | |
| <p>Step 2 – Document Review</p> <p>Is system documented? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p> <p>Is system implemented? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p> <p>Note: Any “No” must result in a finding</p> | <p><i>(Review Documents – prepare Checklist Page)</i></p> | |
| | <p>Are These Things Available?</p> | <p>Are Records Maintained?</p> |
| Documents that govern the process | <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 |
| Supporting procedures | <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 |
| Necessary equipment and software | <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 |
| Necessary space and environment | <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 |
| Staff training | <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 |
| Staff qualification | <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 |
| Supporting QMS Procedures | | |
| • Feedback, disputes/appeals | <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 |
| • Identification of NCs, PNCs, OFIs | <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 |
| • Determining impact and root cause if needed | <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 |
| • Corrective / preventive action if needed | <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 |
| • Follow up for effectiveness if needed | <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 |
| <p>Step 4 - General Comments</p> <p>• Findings overleaf have been agreed</p> <p>• Recommendation for next audit: <input type="checkbox"/> As regularly scheduled</p> <p style="margin-left: 150px;"><input type="checkbox"/> On _____ (date)</p> | | |

(Lead Auditor)

(Date)

Internal Audit Summary of Findings

Step 4 – Complete one QF01 – IDR for each entry

| Finding No. | | Detail of Finding <i>(cite procedure/document/record)</i> | Recommend Level | |
|-------------|-----------|--|------------------------------|------------------------------|
| Int Aud # | IDR Log # | | | |
| | | | OK <input type="checkbox"/> | OFI <input type="checkbox"/> |
| | | | PNC <input type="checkbox"/> | N/C <input type="checkbox"/> |
| | | | OK <input type="checkbox"/> | OFI <input type="checkbox"/> |
| | | | PNC <input type="checkbox"/> | N/C <input type="checkbox"/> |
| | | | OK <input type="checkbox"/> | OFI <input type="checkbox"/> |
| | | | PNC <input type="checkbox"/> | N/C <input type="checkbox"/> |
| | | | OK <input type="checkbox"/> | OFI <input type="checkbox"/> |
| | | | PNC <input type="checkbox"/> | N/C <input type="checkbox"/> |
| | | | OK <input type="checkbox"/> | OFI <input type="checkbox"/> |
| | | | PNC <input type="checkbox"/> | N/C <input type="checkbox"/> |