



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

RISK ASSESSMENT FOR COMPRESSED AIR

| S. No. | Item / Function | Potential Failure Mode | Potential Effect of Failure | Potential Cause / Mechanism of Failure | Current Control | Reference Document no. | S | O | D | Risk Priority Number (S*O*D) | Recommended Actions (if any) | Post Risk | | | |
|--------|--|---|--|--|--|------------------------|---|---|---|------------------------------|---|-----------|---|---|-----------|
| | | | | | | | | | | | | S | O | D | RPN S*O*D |
| 1. | Size/Dimension of Machine/Components may differ from specification | May lead to unavailability of space or Machine may not be installed into the area | Productivity may be effected due to space constraint | <ul style="list-style-type: none"> Person Negligency Unavailability of qualification documents Involvement of Untrained persons/Vendor in qualification Procedure was not much established for qualification | <ul style="list-style-type: none"> Performane Qualification has been performed Standard Operating Procedure is in Place Equipment is already been installed Equipment/Machine is in operation for production | | 3 | 2 | 2 | 12 | Installation Qualification shall be performed and size/dimension shall verified in IQ | 3 | 1 | 1 | 3 |
| 2. | Functionality of machine may differ from specification | Machine may be Malfunction | Dust may not be extracted from the workplace. | <ul style="list-style-type: none"> Person Negligency Unavailability of qualification documents Involvement of Untrained persons/Vendor in qualification Procedure was not much established for qualification | <ul style="list-style-type: none"> Performane Qualification has been performed Standard Operating Procedure is in Place Equipment/Machine is in operation for production Equipments covered in PM Program | | 4 | 3 | 3 | 36 | Operational Qualification shall be performed and functionality shall be verified | 4 | 1 | 1 | 4 |
| 3. | Unavailability of vendor documents like operation and maintenance | It may lead to Lack of information of the Machine | During preparation of In-House Qualification documents, it | <ul style="list-style-type: none"> Person Negligency Unavailability of qualification documents | <ul style="list-style-type: none"> Performane Qualification has been performed Standard Operating | | 4 | 3 | 3 | 36 | All related In-house documents shall be prepared and | 4 | 1 | 1 | 4 |



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| | | | | | | | | | | | | S | O | D | RPN S*O*D |
| | manual, functional specification and design specification may happen | | may not cover all required test/Script | <ul style="list-style-type: none"> Involvement of Untrained persons/Vendor in qualification Procedure was not much established for qualification | Procedure is in Place <ul style="list-style-type: none"> Equipment/Machine is in operation for production | | | | | | shall be executed | | | | |
| 4. | Unavailability of GA drawing, Electrical drawings, components certificates and MOC certificates may happen | Arrangement of components and electrical wiring may not be identified | During any maintenance/Breakdown activity, Engineer may face problems related to components and wiring arrangement | <ul style="list-style-type: none"> Person Negligency Unavailability of qualification documents Involvement of Untrained persons/Vendor in qualification Procedure was not much established for qualification | <ul style="list-style-type: none"> Perform qualification has been performed Standard Operating Procedure is in Place Equipment/Machine is in operation for production | | 3 | 3 | 3 | 27 | Availability for drawing to be checked by Engineering/Vendor | 3 | 1 | 1 | 3 |
| 5. | Safety parameters like noise level, surface finish and limit switch may not be available | Machine may not have safety features | May lead to effect on Operator/Personnel safety | <ul style="list-style-type: none"> Person Negligency Unavailability of qualification documents Involvement of Untrained persons/Vendor in qualification Procedure was | <ul style="list-style-type: none"> Perform qualification has been performed Standard Operating Procedure is in Place Equipment/Machine is in operation for production | | 4 | 3 | 2 | 24 | If equipment is found producing in that case noise level shall be verified in OQ and surface finish and limit switch shall be verified in IQ | 4 | 1 | 1 | 4 |



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| | | | | not much established for qualification | | | | | | | | | | | | | |
| 6. | Utility requirements for the machine may differ from specification | May lead to abnormal behavior of the Machine | Electrical/Mechanical Fault in the Machine may be happen | <ul style="list-style-type: none"> Person Negligency Unavailability of qualification documents Involvement of Untrained persons/Vendor in qualification Procedure was not much established for qualification | <ul style="list-style-type: none"> Performane Qualification has been performed Standard Operating Procedure is in Place Equipment/Machine is in operation for production | | 4 | 1 | 3 | 12 | Equipment was using since many years still utility shall be verified in IQ | 4 | 1 | 1 | 4 | | |
| 7. | Operating parameters (e.g. Min-max speed) may not be fixed or validated | Machine may be Malfunction | Standard Quality of tablet not meet as per requirement – may cause complaint. | <ul style="list-style-type: none"> Person Negligency Unavailability of qualification documents Involvement of Untrained persons/Vendor in qualification Procedure was not much established for qualification | <ul style="list-style-type: none"> Performane Qualification has been performed Standard Operating Procedure is in Place Equipment/Machine is in operation for production | | 5 | 2 | 4 | 40 | All Operating parameters shall be verified in OQ | 5 | 1 | 1 | 5 | | |



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| | | | | | | | | | | | | S | O | D | RPN S*O*D |
| 8. | Machine Functions keys may not be work or work different | May lead to abnormal behavior of the Machine and may results in effects on Product/Human safety | Electrical/Mechanical Fault in the Machine may be happen | <ul style="list-style-type: none"> Person Negligency Unavailability of qualification documents Involvement of Untrained persons/Vendor in qualification Procedure was not much established for qualification | <ul style="list-style-type: none"> Performane Qualification has been performed Standard Operating Procedure is in Place Equipment/Machine is in operation for production Equipments covered in PM Program | | 4 | 2 | 3 | 24 | Operational Qualification shall be performed and functionality shall be verified in OQ | 4 | 1 | 1 | 4 |
| 9. | SOP may not be available or may not drafted accordingly | Operation and Cleaning of machine may effected | Dust may not be extracted from the workplace. | <ul style="list-style-type: none"> Person Negligency Unavailability of qualification documents Involvement of Untrained persons/Vendor in qualification Procedure was not much established for qualification | <ul style="list-style-type: none"> Performane Qualification has been performed Standard Operating Procedure is in Place Equipment/Machine is in operation for production | | 4 | 1 | 1 | 4 | NA | NA | NA | NA | NA |



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| | | | | | | | | | | | | S | O | D | RPN S*O*D |
| 10. | Safety interlocks may not work (Door or emergency) | Machine may not follow safety requirements | May lead to effect on Operator/Personnel safety | <ul style="list-style-type: none"> Person Negligency Unavailability of qualification documents Involvement of Untrained persons/Vendor in qualification Procedure was not much established for qualification | <ul style="list-style-type: none"> Performane Qualification has been performed Standard Operating Procedure is in Place Equipment/Machine is in operation for production | | 4 | 3 | 2 | 24 | Safety interlocks shall be verified in OQ (If Applicable) | 4 | 1 | 1 | 4 |



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| | | | | | | | | | | | | S | O | D | RPN S*O*D |
| 1. | Size/Dimension of Machine/Components may differ from specification | May lead to unavailability of space or Machine may not be installed into the area | Productivity may be effected due to space constraint | <ul style="list-style-type: none"> Person Negligency Unavailability of qualification documents Involvement of Untrained persons/Vendor in qualification Procedure was not much established for qualification | <ul style="list-style-type: none"> Performane Qualification has been performed Standard Operating Procedure is in Place Equipment is already been installed Equipment/Machine is in operation for production | | 3 | 2 | 2 | 12 | Installation Qualification shall be performed and size/dimension shall verified in IQ | 3 | 1 | 1 | 3 |
| 2. | Functionality of machine may differ from specification | Machine may be Malfunction | Dust may not be extracted from the workplace. | <ul style="list-style-type: none"> Person Negligency Unavailability of qualification documents Involvement of Untrained persons/Vendor in qualification Procedure was not much established for qualification | <ul style="list-style-type: none"> Performane Qualification has been performed Standard Operating Procedure is in Place Equipment/Machine is in operation for production Equipment covered in Preventive Maintenance Program | | 4 | 3 | 3 | 36 | Operational Qualification shall be performed and functionality shall be verified | 4 | 1 | 1 | 4 |
| 3. | Unavailability of vendor documents like operation and | It may lead to Lack of information of the Machine | During preparation of In-House Qualification | <ul style="list-style-type: none"> Person Negligency Unavailability of qualification | <ul style="list-style-type: none"> Performane Qualification has been performed Standard Operating | | 4 | 3 | 3 | 36 | All related In-house documents shall be prepared and shall be | 4 | 1 | 1 | 4 |



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| | | | | | | | | | | | | S | O | D | RPN S*O*D |
| | maintenance manual, functional specification and design specification may happen | | documents, it may not cover all required test/Script | documents <ul style="list-style-type: none"> Involvement of Untrained persons/Vendor in qualification Procedure was not much established for qualification | Procedure is in Place <ul style="list-style-type: none"> Equipment/Machine is in operation for production | | | | | | exuted | | | | |
| 4. | Unavailability of GA drawing, Electrical drawings, components certificates and MOC certificates may happen | Arrangement of components and electrical wiring may not be identified | During any maintenance/Breakdown activity, Engineer may face problems related to components and wiring arrangement | <ul style="list-style-type: none"> Person Negligency Unavailability of qualification documents Involvement of Untrained persons/Vendor in qualification Procedure was not much established for qualification | <ul style="list-style-type: none"> Performane Qualification has been performed Standard Operating Procedure is in Place Equipment/Machine is in operation for production | | 3 | 3 | 3 | 27 | Availability for drawing to be check by Engineering/Vendor | 3 | 1 | 1 | 3 |
| 5. | Safety parameters like noise level, surface finish and limit switch may not be available | Machine may not have safety features | May lead to effect on Operator/Personnel safety | <ul style="list-style-type: none"> Person Negligency Unavailability of qualification documents Involvement of Untrained persons/Vendor | <ul style="list-style-type: none"> Performane Qualification has been performed Standard Operating Procedure is in Place Equipment/Machine is in operation for production | | 4 | 3 | 2 | 24 | If equipment is sound producing in that case noise level shall be verified in OQ and surface finish and limit switch shall be verified in IQ | 4 | 1 | 1 | 4 |



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| | | | | <ul style="list-style-type: none"> in qualification Procedure was not much established for qualification | | | | | | | | | | | | | |
| 6. | Utility requirements for the machine may differ from specification | May lead to abnormal behavior of the Machine | Electrical/Mechanical Fault in the Machine may be happen | <ul style="list-style-type: none"> Person Negligency Unavailability of qualification documents Involvement of Untrained persons/Vendor in qualification Procedure was not much established for qualification | <ul style="list-style-type: none"> Performane Qualification has been performed Standard Operating Procedure is in Place Equipment/Machine is in operation for production | | 4 | 1 | 3 | 12 | Equipment was using since many years still utility shall be verified in IQ | 4 | 1 | 1 | 4 | | |
| 7. | Equipment may not be included in the Equipment master list, Preventive Maintenance Planner and Calibration Planner | Machine may not be scheduled for preventive maintenance and calibration | Dust may not be extracted from the workplace. | <ul style="list-style-type: none"> Person Negligency Unavailability of qualification documents Involvement of Untrained persons/Vendor in qualification Procedure was not much established for | <ul style="list-style-type: none"> Performane Qualification has been performed Standard Operating Procedure is in Place Equipment/Machine is in operation for production | | 5 | 4 | 4 | 80 | Master list of equipment, Calibration planner, PM Planner shall be verified in IQ for equipment presense | 5 | 1 | 1 | 5 | | |



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| | | | | qualification | | | | | | | | | | | | | | |
| 8. | Machine Functions keys may not be work or work different | May lead to abnormal behavior of the Machine and may results in effects on Product/Human safety | Electrical/Mechanical Fault in the Machine may be happen | <ul style="list-style-type: none"> Person Negligency Unavailability of qualification documents Involvement of Untrained persons/Vendor in qualification Procedure was not much established for qualification | <ul style="list-style-type: none"> Performane Qualification has been performed Standard Operating Procedure is in Place Equipment/Machine is in operation for production | | 4 | 2 | 3 | 24 | Operational Qualification shall be performed and functionality shall be verified in OQ | 4 | 1 | 1 | 4 | | | |
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| 10. | Safety interlocks may not work (Door or emergency) | Machine may not follow safety requirements | May lead to effect on Operator/Personnel safety | <ul style="list-style-type: none"> Person Negligency Unavailability of qualification documents Involvement of Untrained persons/Vendor in qualification Procedure was not much established for qualification | <ul style="list-style-type: none"> Performane Qualification has been performed Standard Operating Procedure is in Place Equipment/Machine is in operation for production | | 4 | 3 | 2 | 24 | Safety interlocks shall be verified in OQ (If Applicable) | 4 | 1 | 1 | 4 |



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| 5. | Safety parameters like noise level, surface finish and limit switch may not be available | Machine may not have safety features | May lead to effect on Operator/Personnel safety | <ul style="list-style-type: none"> Person Negligency Unavailability of qualification documents Involvement of Untrained persons/Vendor | <ul style="list-style-type: none"> Performane Qualification has been performed Standard Operating Procedure is in Place Equipment/Machine is in operation for production | | 4 | 3 | 2 | 24 | If equipment is sound producing in that case noise level shall be verified in OQ and surface finish and limit switch shall be verified in IQ | 4 | 1 | 1 | 4 |



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| | | | | <ul style="list-style-type: none"> in qualification Procedure was not much established for qualification | | | | | | | | | | | | | |
| 6. | Utility requirements for the machine may differ from specification | May lead to abnormal behavior of the Machine | Electrical/Mechanical Fault in the Machine may be happen | <ul style="list-style-type: none"> Person Negligency Unavailability of qualification documents Involvement of Untrained persons/Vendor in qualification Procedure was not much established for qualification | <ul style="list-style-type: none"> Performane Qualification has been performed Standard Operating Procedure is in Place Equipment/Machine is in operation for production | | 4 | 1 | 3 | 12 | Equipment was using since many years still utility shall be verified in IQ | 4 | 1 | 1 | 4 | | |
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| | | | | qualification | | | | | | | | | | | | | |
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| S. No. | Recommended Action | Responsible Person | Target Date of Completion |
|--------|--|--------------------|---------------------------|
| 1. | All identified qualification documents which are not available or not executed, shall be prepared and executed. | | |
| 2. | Further New equipments shall be qualified as per current SOP checklist. | | |
| 3. | GA/Electrical Drawing shall be prepared/arranged | | |
| 4. | Training shall be imparted to all concerned persons to ensure the adequacy, accuracy, completeness and correctness of the documents. | | |
| 5. | URS and SOP for the equipment shall be prepared/Updated | | |

CAPA (Required/Not required): Not required
If required mentioned the CAPA No.: NA



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| Quality Risk Management Team | | | Reviewed By Head Operations Sign & Date | Approved By Head QA Sign & Date |
|------------------------------|------------|-------------|---|---------------------------------------|
| Name | Department | Sign & Date | | |
| | | | | |
| | | | | |
| | | | | |

QUALITY RISK ASSESSEMENT AND MITIGATION SUMMARY REPORT

| | |
|---|--|
| Name of facility/ Equipement/Utility/System/Activity/Procedure/Unit Preparation: | Risk assessment for GAPs Identified in Qualification Documents as per Change Control No..... Position Paper No..... |
|---|--|

Verification of recommended action:

Remark (if any):

For Product Contact Equipments: All the product contact Machine/Equipment, which are covered in this risk assessment are procured from the vendor as on such basis and were used for routine production after performance qualification,Hence there is no significant impact on product quality due to identified GAPs in Qualification Documents.

Process Validation: All identified equipments in this quality risk assessment are also covered in many process validation batches of OSD area. On behalf of our process validation study, it can be concluded that there is no significant impact on product quality due to identified GAPs in Qualification Documents.

Verified By:
Officer/Executive QA
(Sign & Date)

Approved By:
Head QA
(Sign & Date)