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1.0 PURPOSE

The purpose of this Operational Qualification (OQ) Protocol is to define and execute a process that will validate the capabilities of the MISys software to satisfy the requirements of Good Automated Manufacturing Practices fifth edition (GAMP 5) published by the International Society for Pharmaceutical Engineering (ISPE). More specifically this application will be tested in conjunction with the relevant procedures SOP's (Standard Operating Procedures) and WI's (Work Instructions) that are or will be used by the Company in its operating environment.

2.0 SCOPE

This protocol will be used to qualify elements of the MISys manufacturing software that will be used to support the company's manufacturing and quality processes. Within the MISys application and the related business processes, the focus will include:

2.1 MISys Components
- **2.1.1** Loading and maintenance of product information
- **2.1.2** Loading and maintenance of supplier information
- **2.1.3** Processing purchase orders for production-related materials
- **2.1.4** Processing inventory movement and physical inventory and transactions
- **2.1.5** Processing manufacturing orders
- **2.1.6** Transferring finished products to the sales management system (Quickbooks)
- **2.1.7** Tracing Lot and Serial # data (including expiration dating) to support requirements of a product recall
- **2.1.8** Management reporting

Other business software - Note: list here any other "relevant" software applications; e.g. Quickbooks, which may integrate or interface with MISys and indicate whether or not they will be included in this validation protocol.)

3.0 REFERENCES

4.1   References - *(NOTE: Here it is suggested that you list the applicable SOP's or Work Instructions that will be referenced during the Validation process such as "Adding and Maintaining Bills of Material", "Processing Purchase Orders", etc.*

DOCUMENT NUMBER	TITLE
GAMP 5	A Risk-Based Approach to Compliant GxP Computerized Systems – Fifth Edition
SOP	
SOP	
WI	
WI	
WI	
WI	

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4.2 **Definitions: (*Note: Here you should list and define the various terms that will be used repeatedly throughout the document. Some examples are provided below)***

TERM	DEFINITION
Application	Computer software that automate a specific business process or processes.
Hardware	Computer equipment including servers, printers, disk drives, tape drives, I/O equipment, communication equipment, workstations, and other devices as required to host and interface with software.
Interface	Shared boundary across which information is passed between systems.
Standard Operating Procedure (SOP)	Instructions for executing a process.
Work Instruction (WI)	
Traceability Matrix (TM)	Document that links user requirements and/or functional specifications contained in the SRS to the tests conducted in the IQ, OQ, PQ test protocols, in order to verify that all requirements and specifications have been verified.
Validation	Documented evidence that provides a high degree of assurance that a system performs its intended functions accurately and reliably.
Risk	The possibility of incurring harm.

4.0 SYSTEM DESCRIPTION

4.1 MISys Application Software - MISys Small Business Manufacturing Software (MISys modular software application that is designed to set up and maintain master files of component items, bills of material for its products, and supplier information. In addition it will be used to process transactions for all purchasing and manufacturing activities, including recording and tracking all required lot and serial # activity. **Note: here describe any applicable interfaces to other relevant software applications.** .

    4.1.1 Software Design - the MISys software application is modular in nature and does not allow for any modification or customization of the underlying software code by the user organization. It does, however, enable the user organization to select from a number of pre-defined configuration variables, so the company can adapt the software to more closely match its unique business requirements.

    4.1.2 Software Version and Modules – Note: here describe the release of the basic (BMS) MISys software and any additional modules that will be installed. Additional MISys modules may include:

        4.1.2.1 Advanced Purchasing

        4.1.2.2 Advanced Production

        4.1.2.3

    4.1.3 Implementation Process – Note: provide a brief description of the implementation process including training, changes to current procedures, etc.

4.2 Primary documents to be released or updated: **Note: here you s list the primary documents (SOP's, etc) that will be either updated or newly released during the implementation process.**

4.2.1 .
4.2.2 .
4.2.3

4.3 Hardware Environment - *Provide a detailed description of the computer environment (hardware and network) that the application will be processed on.*
    4.3.1 .
    4.3.2

4.4 Software Environment – *Provide a description of the network operating system and all related software applications*
    4.4.1 Operating Systems – Microsoft Windows Server ….
    4.4.2 Software Packages
        4.4.2.1 Intuit QuickBooks ….
        4.4.2.2 MISys Manufacturing Version….
        4.4.2.3 Microsoft SQL ….
        4.4.2.4

4.5 Security - the server is housed (***Describe where it is housed and who has physical access)*** System administration - is currently provided by: ***Provide a description of the IT organization or outside provider.*** The specific components of the security environment include:
    4.5.1 Operating system –
    4.5.2 Database – Stored on:
    4.5.3 Server console – Access limited to:
    4.5.4 MISys Manufacturing – Defined security roles are established within the application. Users are assigned to security roles based on their job responsibilities

4.6 Operational Support – *Describe responsibilities for:*
    4.6.1 Daily operational support-
    4.6.2 Installation and maintenance manuals for vendor-supplied equipment - Maintained by:
    4.6.3 Equipment operating procedures – Maintained by:
    4.6.4 Equipment maintenance procedures – Maintained by:
    4.6.5 Application source code – Maintained by commercial software providers

4.7 Disaster Recovery Plan - the disaster recovery plan includes the computerized systems and associated equipment. The plan defines the business procedures in order to continue business operations (including possible interim manual operations). The resources for the disaster recovery plan include the following:
    4.7.1 Hardware inventories – Maintained by:
    4.7.2 Software inventories - Maintained by:
    4.7.3 System recovery includes:
        4.7.3.1 Full back up including system state of all servers to local and offsite storage medium – ***Describe frequency and provider including audits, etc.***
        4.7.3.2 Email is maintained by:
        4.7.3.3 All other servers (file, application, etc.) are hosted at:
            4.7.3.3.1 Server Disasters – *Describe how they will be handled*
            4.7.3.3.2 Site Disasters or Regional Disasters – (flooding, earthquake, etc.) that impacts more than one single hardware server will be treated on a case by case basis as follows:
                4.7.3.3.2.1 Assess damage – An inventory and assessment of functional equipment will be performed to determine proper course of action.

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4.7.3.3.2.2 Service restoration – Depending on the severity of damage to equipment, service may be restored using the following methods:

4.7.3.3.2.3 Use existing undamaged hardware. If restoration is possible using the existing hardware, service will be brought back on line.

4.7.3.3.2.4 Acquiring new hardware (in case of regional disaster), the process will require new hardware to be purchased as soon as practical after service has been restored.

5.0 TEST ENVIRONMENT

    5.1 MISys Software - the MISys test system will:

        5.1.1 *Define the release of MISys that will be installed:*

        5.1.2 be performed on the latest copy of the database that has been configured and prepared to meet the requirements for subsequent use in the production environment,

        5.1.3 have all of the configuration parameters set to be identical to those that will be used in the subsequent production environment,

        5.1.4 contain the Company's most current item master and bill of material data,

        5.1.5 contain the current set of "Approved Suppliers" and the associated items for which they are approved,

        5.1.6 have "zero" inventory balances for all items to be utilized in the protocol, and

        5.1.7 contain the same user security settings as will be used in the production environment

6.0 **Note:** *nothing defined here – should renumber*

7.0 RESPONSIBILITIES

Role	Responsibilities
Project Manager	• Project management and planning • Control of project activities, resources and costs • Monitor progress and initiate corrective actions where necessary • Ensure issues and project objectives are addressed and resolved • Setting-up and monitoring the test database environment and validation process • Report to sponsor and/or senior management • Work with quality to ensure compliance by submitting a summary report describing the results of this OQ exercise, which shall then be approved by Operations, Manufacturing and QA/RA
Quality	• Ensure compliance with appropriate regulatory and quality requirements as well as company policies and procedures • Review and approve deliverables • Approve system release for production use
System Owner/Business Owner	• Implement and manage the system for the user community • Review and approve deliverables
Functional Business Users	• Executing protocol, collecting test data, and signing off test cases they perform
Validation	• Author deliverables • Review and approve deliverables • Assist with execution of protocols

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Role	Responsibilities
Information Technology	• Establish and maintain computer infrastructure equipment per corporate policies and procedures

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8.0 DATA MIGRATION

8.1 Pre-Qualification - The initial migration phase of critical data into the MISys database shall be done as described below. This phase will be completed prior to execution of this validation protocol.

8.1 **Item Master data** – the <u>controlled</u> list of components, assemblies and their associated data values shall be transferred to pre-formatted Excel spreadsheets. After initial review and verification, the data from these spreadsheets shall be electronically imported into the MISys database using standard data import functionality contained in the application software. Subsequent to the initial data loading, MISys-generated standard reports shall be used to verify the accuracy of the data loading process and results of the Item Master data load shall be documented in the trace matrix in Section 9.0.

Item Master Data	
Source Data	**Target Data**
Part Number	Itemid
Description	Descry
Revision	Ref
Unit of Measure	uOfM
Purchasing Unit of Measure	poUOfM
Conversion Factor	uConvFact
Account Set	Glld
Part Type	Type
Lot/Serial Track	Track
Standard Cost	cStd
Lot/Serial Method	lotMeth

8.1 **Product Structure data (bills of material)** –the <u>controlled</u> source of product structure data, including both prior and current revisions, shall be transferred to pre-formatted Excel spreadsheets and imported into the MISys database in a manner similar to 8.1. Again, MISys-generated standard reports have been used to verify the accuracy of the data loaded into the MISys database and results of the Bill of Material data load shall be documented in the trace matrix in Section 9.0.

Bill of Material Header	
Source Data	**Target Data**
Bill of Material Item	bomItem
Bill of Material Rev	bomRev
Rollup	Rollup
Multiples	Mult
Yield	Yield
Auto Build	autoBuild
Last Maintenance Date	lstMainDate
ECO Number	ecoNum
Overide	Ovride
Assembly Lead Time	assyLead
Quantity Per Lead Time	'qPerLead
Revision Date	revDate
Effective Start Date	effStartDate

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Bill of Material Detail	
Source Data	**Target Data**
Bill of Material Item	**bomItem**
Bill of Material Rev	**bomRev**
Bill of Material Entry	**bomEntry**
Bill of Material Number	**lineNbr**
Part ID	**partId**
Quantity	**Qty**
Source Location	**scrLoc**

8.1 **Supplier Master** – The Company's principal source of supplier information is contained in the QuickBooks accounting software application. The MISys software functionality will have been used to import supplier data into the MISys database. Subsequent to the data loading, MISys-generated standard reports will have been used to verify the accuracy of the data loading process and results of the Supplier data load shall be documented in the trace matrix in Section 9.0.

8.2 Post Qualification - following the successful conclusion of this protocol, the following additional critical data will be migrated into the MISys database just prior to "going live":

8.2 **Inventory data –** a complete physical inventory will be taken of all items used in the Company's production environment including their lot # and serial # identification data. This will be done for all stocking locations. After management audit and acceptance, this data will be loaded into the MISys database using the MISys software's standard physical inventory functionality.

8.2 **Supplier commitments** – all relevant data pertaining to outstanding purchase order commitments for production-related materials will be manually loaded into the MISys database. Again, standard MISys reports will be printed and user shall verify the accuracy of this data.

8.2 **Production orders** – at the onset of using MISys in the production environment, the users shall begin loading entirely new manufacturing orders into the MISys database following the established procedures.

9.0 TRACE MATRIX - FUNCTIONAL REQUIREMENTS, TEST CASES, ACCEPTANCE CRITERIA

The trace matrix lists the business requirements, test case summaries, and acceptance criteria. The detailed test cases are included in **Appendix A**.

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Requirement	Test Case	Acceptance Criteria	Verification
A. Loading and maintenance of product information			
A1. The system shall import item master detail data from Excel.	TC-A1: Import an entire list of existing items (part numbers) from Excel. Run MISys Item Master Detail report and compare each item's data to the data in Excel.	TC-A1: All imported item data must match Excel data with zero (0) errors.	
A2. The system shall allow production items to be entered manually.	TC-A2: Add the following new items manually – 1 component specification, 1 DHR with 2 existing items and new item, 1 manufacturing material on it. Run MISys report and compare each item's data to the source data.	TC-A2: All item data must match source data with zero (0) errors.	
A3. The system shall allow R&D items to be entered manually.	TC-A3: Add the following new items manually – 1 component specification and 1 parent assembly item. Run MISys report and compare each item's data to the source data.	TC-A3: All item data must match source data with zero (0) errors.	
A4. The system shall import bills of material (BOM's) data from Excel.	TC-A4: Import a list of existing BOM's from Excel. Run MISys Bill of Material Detail report and compare each BOM's data to the data in Excel.	TC-A4: All imported Bill of Material data must match Excel data with zero (0) errors.	
A5. The system shall allow BOM's to be entered manually.	TC-A5: Add a new BOM which also contains an assembled item as a component. Run MISys Indented Bill of Material Detail report and compare the data on the report to the source data. Confirm also that the component data for the assembled item from the source BOM are also displayed.	TC-A5: All updated Bill of Material data must match source data with zero (0) errors.	
A6. The system shall allow items (both production and R&D) to be changed.	TC-A6: Change the following existing items – 1 component specification, 1 DHR, 1 manufacturing material, and 1 R&D. Run the MISys report and compare each item's data to the source data.	TC-A6: All updated item data must match source data with zero (0) errors.	

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B. Loading and maintenance of supplier information

B1. The system shall import suppliers from QuickBooks.	TC-B1: Import (5) existing suppliers from QuickBooks and confirm the accuracy of the data between the two databases.	TC-B1: All imported supplier data must match source data with zero (0) errors.	
B2. The system shall allow supplier data, including status, to be updated and changed.	TC-B2: Add additional data fields (required by MISys) to the newly imported supplier records and change status for one of the suppliers.	TC-B2: All newly enter entered supplier is accepted and updated with zero (0) errors	
B3. The system shall allow items to be linked to suppliers.	TC-B3: Link (5) existing item #'s to each of the newly imported suppliers (including their product codes) and also link each of these items to a manufacturer and their product code.	TC-B3: All newly linked supplier and manufacturer product code values are updated and linked with (0) errors.	

C. Processing purchase orders for production-related materials

C1. The system shall allow purchase orders to be entered and printed. **Note:** that the item's revision # should display on the printed PO Document.	TC-C1: Enter separate purchase orders for an existing component specification item, a new component specification item, a manufacturing material item and an R&D component item.	TC-C1: All entered PO's print accurately including displaying the item's revision # on the documents.	
C2. The system shall allow purchase orders to be changed.	TC-C2: Make changes to purchase orders for quantity, unit price and scheduled delivery date.	TC-C2: All entered changes are updated correctly on the newly printed PO's.	
C3. The system shall allow purchase orders to be received complete, partial as well as overfilled.	TC-C3: Enter purchase order receipts for a complete quantity as well as a partial quantity and a quantity in excess of the order quantity. Record the Lot #'s being received using same "existing" format that is currently in use.	TC:C3: All types of receiving activity (complete, partial and overfill) are processed correctly and the existing lot # formats are accepted.	

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C4. The system shall perform a 3-way match between the purchase order, receipt, and invoice.	TC-C4: Process a vendor invoice and apply it to the purchase order receipt insuring that there is a 3-way match between the PO receipt transaction, the vendor's packing slip and the vendor invoice.	TC-C4: The invoice matching is performed accurately resulting in the correct updating of the Order Invoice Value report and the invoice is updated correctly in QuickBooks.	
C5. The system shall allow previously received materials to be subsequently returned to the supplier	TC-C5: Process transactions returning material to vendors. The first transaction is for a return against a purchase order which is still open. The second is done after the originating PO is closed.	TC-C5: Both types of return transactions are processed successfully and the appropriate data are updated correctly.	
C6. The system shall provide PO information to R&D to aid in disposition decisions.	TC-C6: Produce reports for all purchasing and Inventory-related transactions for the R&D location only thereby aiding R&D in its disposition decisions. The reports should be able to be filtered by both data and transaction type.	TC-C6: The reports correctly display all PO and Inventory-related transaction with appropriate filtering.	
C7. The system shall be able to report on purchase order receipts showing quantities, dollars, scheduled delivery and PO receipt date.	TC-C7: Produce detailed reports covering all purchase order receiving activities showing quantities, dollars, scheduled delivery and actual PO receipt date.	TC-C7: The system correctly displays the transaction detail for all PO receiving activities.	
C8. The system shall report on purchasing quantity and cost variances.	TC-C8: Produce detailed reports displaying variances in quantity and cost for all closed purchase orders.	TC-C8: The system reports the purchasing quantity and cost variances.	
C9. The system shall be able to report on supplier on-time delivery performance.	TC-C9: Produce a report summarizing a supplier's on-time delivery performance.	TC-C7: The report provides the ability to report on a supplier's on-time delivery performance.	

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D. Processing Inventory Movement and Physical Inventory transactions and Standard Cost maintenance			
D1. The system shall allow for moving stock between locations	TC-D1: Move specific lot quantities of a raw material item and an assembled item from their original location to a new location.	TC-D1: The reported lot quantity balances are updated in the new location.	
D2. The system shall allow for dispensing (issuing) inventory as well as returning (recovering) inventory and other adjustment transactions.	TC-D2: Use the Dispense and Recover transactions to issue or adjust the balances of a specific item.	TC-D2: The reported balances of the two items are adjusted accordingly.	
D3. The system shall allow for inventory adjustments due to physical inventories or cycle counts.	TC-D3: Use the Physical Inventory process to record new or adjust existing quantities of an item lot or serial quantity.	TC-D3: The new or adjusted quantities are reported correctly on the updated report.	
D4. The system shall allow for the transfer (dispense) of inventory from raw material to R&D for build purposes.	TC-D4:Transfer (dispense) a quantity of a raw material item from a manufacturing inventory location (STOCK) and "expense" it to R&D.	TC-D4: The inventory quantity is removed from the manufacturing location and is physically available to R&D.	
D5. The system shall allow for maintaining separate production and R&D environments for materials and assemblies.	TC-D5: Produce reports that display the inventory balances available for R&D use as well as the status of Purchase Orders for R&D purposes.	TC-D5: The reports display the R&D inventory balances available only to R&D as well as the open PO's for that are for R&D purposes.	
D6. The system shall provide the ability to notify of lots expiring within a given period.	TC-D6: Produce a report that shows item lots or serial number quantities that are scheduled to expire within a given time period.	TC-D6: The report displays the expiration dates for lots due for expiration within a given time period.	

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D7. The system shall allow a lot to be placed on hold.	TC-D7: Change a Lot's status from "Active" to "On-Hold." The lot is now longer able to be transacted while in this status.	TC-D7: The lot #'s status is changed to "On-Hold"	
D8. The system shall provide inventory quantity and dollar valuation reports by item.	TC-D8: Produce a report showing the inventory quantity and resulting dollar valuation for all items in the database.	TC-D8: The report displays a complete listing of all quantities and dollar valuation in the database.	
D9. The system shall allow for roll-up of standard costs for items & BOM's on a controlled basis.	TC-D9: Change the standard cost of a component item. Then roll-up the costs of its parent assembly. Run the MISys report and compare the cost data for each item (parent and component) to the previous data on the previous report run in Step (1) above.	TC-D9: All updated cost data must agree with source data and the assembled item cost must accurately reflect the rolled cost of its component items.	
D10. The system shall report the cost impact of changes to standard costs.	TC-D10: Run the accounting report of Unposted Transaction detail and identify the accounting entries generated by the cost change and cost roll-up activities from [D9] above. Review and confirm the accuracy of these entries.	TC-D10: The accounting entries on the report must agree with the accounting entries displayed on the source data.	

E. Processing manufacturing orders

E1. The system shall allow manufacturing orders to be entered and printed. The manufactured item's must Revision # be printed on the document	TC-E1: Open and release (2) manufacturing orders. The first one should be for an assembly that is also a component of the assembly of the second manufacturing order. The component material requirements listed for each manufacturing order must be compared to the bill of materials (BOM) listing for each of the parent assembly items. The revision must print for both the parent and component items.	TC-E1: The component requirements for each order must agree with the list of component requirements on their current BOM file.	

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E2. The system shall allow for issue of component materials to a Manufacturing Order but prevent use of unreleased lots.	TC-E2: Print the "Picklist" for the order and confirm that "unreleased" lots (Lots still in the Quarantine location) are not displayed as "available" for issue on the document or accessible on the screen on which components are transferred (issued) to WIP. Issue the required quantities of each component to WIP. The revision must print for both the parent and component items on the Picklist document.	TC-E2: The Picklist displays and allows issue of only "released" lots in the manufacturing area to WIP. Released components are correctly issued to WIP. The revision data prints correctly.	
E3. The system shall allow for the completion of assemblies to stock from Manufacturing Orders	TC-E3: Complete and close the manufacturing order for the first assembly including assignment of serial numbers and linking of component lots to the parent serial #'s. The Serial #'s being received is consistent with the "existing" format that is currently in use.	TC-E3: The order is completed and all parent and component requirements are transacted correctly. In addition, the Serial # format is the same as the current format in use.	
E4. The system shall allow for additional component issues to manufacturing orders.	TC-E4: Complete and close the manufacturing order for the second assembly after adding an incremental requirement for a component item to account for scrapping or other unplanned requirement.	TC-E4: The order is completed and the additional component requirement is processed correctly.	
E5. The system shall report manufacturing order quantity and cost variances.	TC-E5: Print a report showing the quantity and cost variances for the (2) closed manufacturing orders. Review and confirm the accuracy of the reported variances.	TC-E5: The reported variances are correct and consistent with the report printed in TC-E3.	

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F. Transferring finished products to sales management system (Quickbooks)

F1. The system shall allow finished goods to be transferred to Quickbooks.	TC-F1: Complete the transfer (dispensing) of a finished goods item into Quickbooks so that they can subsequently be shipped against customer orders in Quickbooks.	TC-F1: The transferred quantity and related serial #'s are updated and able to be transacted in Quickbooks.	

G. Tracing lot and serial # data to support quality system requirements

G1. The system shall be able to perform lot tracking from item receipt to subsequent update in Quickbooks.	TC-G1: Trace and print the reports showing the use of (1) Lot # and (1) Serial # into the manufacturing order on which they are consumed. Confirm the data agrees with that shown on the Input Document.	TC-G1: The lot and serial tracking data per the reports agree with the Input Document.	
G2. The system shall be able to perform lot tracking from a finished goods item to the lowest component part level.	TC-G2: Trace the source of component Lots & Serial #'s used on a serialized assembly. In addition, perform a multi-level trace for a parent assembly which has a lower level assembly and component parts on it. Confirm the accuracy of the lot/serial #'s reported.	TC-G2: The lot and serial # data reported are consistent with the data shown on the Input Document.	

H. System Administration – Security

H1. The system shall be able to create security groups which control access to menus, specific functions and ability to update vs. view certain data.	TC-H1: Set up a Security Group which will provide for controlled access to specific menus, screens and update vs. view only functionality.	TC-H1: A unique Security Group is able to be setup.	
H2. Users must be assigned a specific User ID, assigned to a Security Group and required to have a secure sign-on password.	TC-H2: Set up a new User ID and assign the User ID to a Security Group.	TC-H2: New User is able to be setup and assigned to an existing Security Group.	

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| H3. A user can only see and access the menus and screens and perform the functions for which they are authorized. | TC-H3: Sign on by testing the new User ID and Password. Confirm that sign-on is not able to be done with an incorrect password. Then confirm that the user is able to see the menus and screens set up for the User's Security Group as well as experience controls over view vs. update capabilities. | TC-H3: User is only able to sign-on using a valid User ID and Password. In addition, the User can only see the menus and screens for the Security Group and | |

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11.0   ACCEPTANCE CRITERIA

Test Cases will verify that the Business Requirements are met by the MISys Manufacturing system. Each Test case will be assigned a unique number, document the Business Requirement being tested by referring back to the Business Process Requirement and document the Pass/Fail result of the Test Case. All the Test Cases will be Pre and Post Approved by the Project Management team.

Test Cases which have failed will be evaluated for the cause of failure, including inadequate procedures, inadequate test data, misunderstood Test Case execution and/or a Risk Mitigation proposed. Failed Test Cases can have the following activities performed:
- Revise the Business Procedure to correct the failure
- Revise the test data to correct the failure
- Re-execute the revised Test Case using a new Test Case number and referencing the old Test Case number

The test cases are included in **Appendix A**.