

Today's Topics

Main Reasons why we chose Maximo and EDI
and how we utilize Maximo in the
pharmaceutical industry

1

Compliance

2

Versatility

3

Oversight

4

Accessibility

21 CFR Part 11 Compliance

- To comply with industry regulations, Maximo records your calibration, corrective and preventative maintenance history to ensure that your assets are fully traceable.
- Creates a complaint calibration or preventative maintenance system appropriate for any federal agency.
- Features and approvals are customizable to fit regulations.
- Each editable field has revision control as changes are implemented.
- Capable of E-signatures and audit trails.
- The organizational structure of Maximo allows for concise execution of work orders and asset management.

**Asset
Classification**

Audits

**Going
Paperless**

Going Paperless

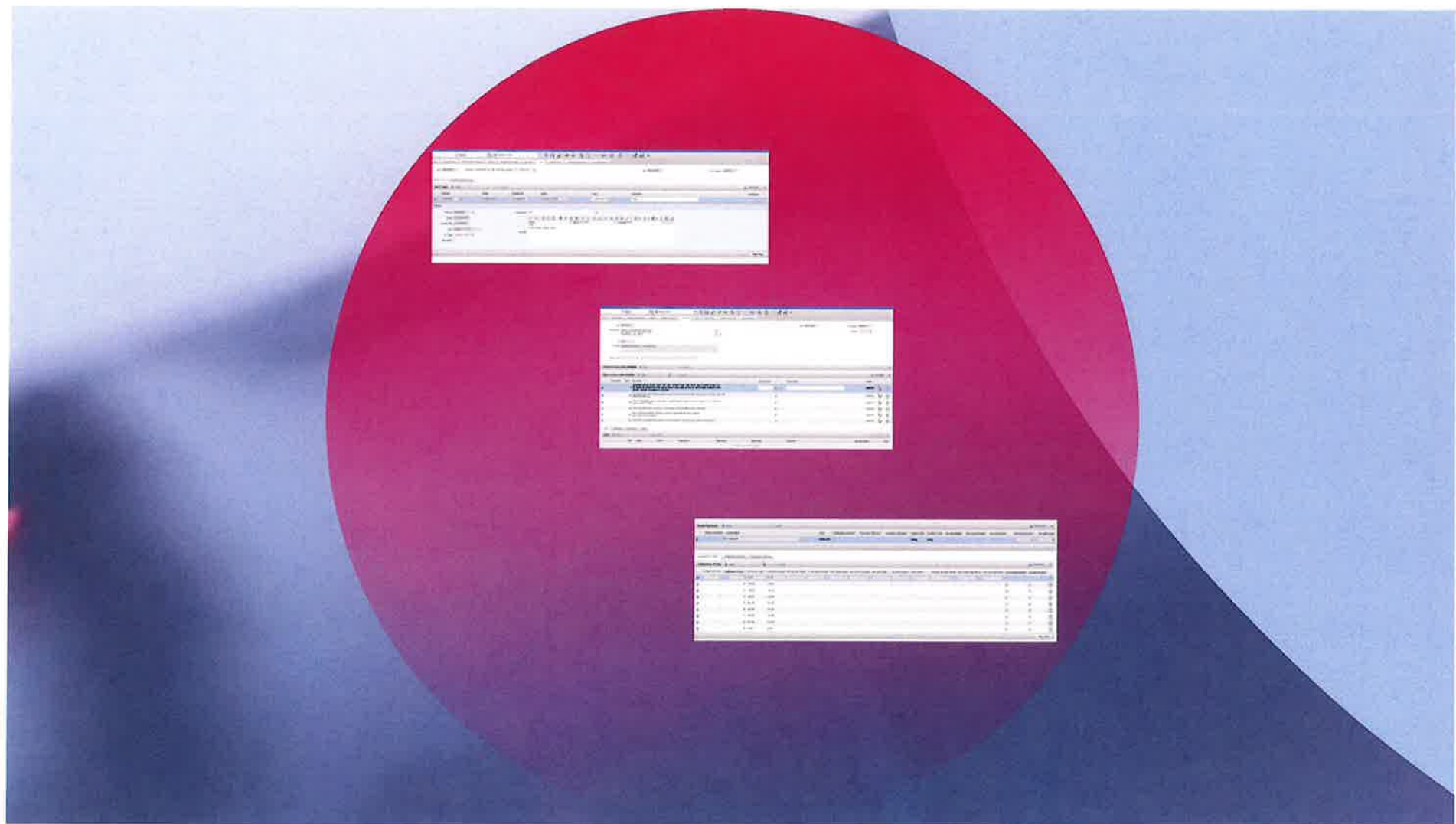


**paper
system**

**paperless
system**

- Previous process was the paper/file system and using Excel for Work Orders.
- Maximo provides the means to easily search information by different fields.
- Reduces man made errors.
- Review process is easier and faster.







Audits

- Regulatory Agencies comparable to FCC or FAA
- Contract Customers
- Internal/Corporate

Saved query template that was agreed upon with Compliance that narrows down the scope of what the auditors typically ask to see. Query is editable if more information is required at the time of an audit

Compliance Audit Report Template

WO	Description	Asset	Description	Actual Finish	Work Type	Classification
30031478	REPAIR VALVE ON TANK (EXAMPLE WORK ORDER)	13971	TANK, EXAMPLE	1/15/20 4:15:31 PM	CM	LEVEL 1
30031479	REPLACE DOOR GADGET ON STERILIZER (EXAMPLE WORK ORDER)	13972	STERILIZER, EXAMPLE	1/15/20 4:17:44 PM	CM	LEVEL 1
30031480	REPLACE HIGH SPIN BELT ON DABICO (EXAMPLE WORK ORDER)	13974	SYSTEM, DABICO, EXAMPLE	1/16/20 7:22:00 AM	CM	LEVEL 1
30031481	REPAIR HOT STAMP FOR LABELER (EXAMPLE WORK ORDER)	13975	LABELER, EXAMPLE	1/16/20 7:15:03 AM	CM	LEVEL 1
30031482	REPLACE IN PROBE IN LIP (EXAMPLE WORK ORDER)	13976	SYSTEM, CLEAN IN PLACE EXAMPLE	1/16/20 7:19:05 AM	CM	LEVEL 1

Number of Records: 5

Rowid Where Clause: workorder.workorderid IN (200304,200407,200440,200490,200711)

Dynamic Where Clause:

2/19/20 7:23 AM

8 / 1

Asset Classification

Classification Assessment is performed at the time of onboarding. Assessment is dependent upon if it is used in the laboratory environment or in the manufacturing environment. The assessment is reviewed by asset Owner, Quality, Validation and Maintenance/Engineering

Level 1: DIRECT PRODUCT CONTACT/DIRECT IMPACT

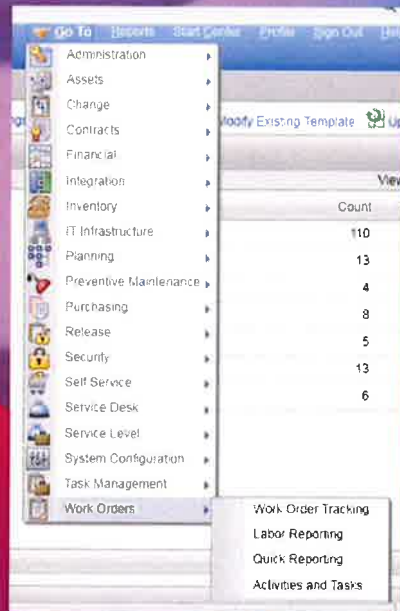
Level 2: INDIRECT PRODUCT CONTACT/IMPACT

Level 3: NON-GMP/NO IMPACT

The screenshot shows a software window titled "BATCH VIEW" with a "Name" field containing "1000". Below this is a table with two columns, "LEVEL_1" and "LEVEL_2". The table contains three rows of data: "LEVEL_1" and "LEVEL_2", "LEVEL_2" and "LEVEL_2", and "LEVEL_3" and "LEVEL_2". A "Cancel" button is located at the bottom right of the window.

LEVEL_1	LEVEL_2
LEVEL_1	LEVEL_2
LEVEL_2	LEVEL_2
LEVEL_3	LEVEL_2

Maximo Applications



Application	Count
Administration	
Assets	
Change	
Contracts	
Financial	
Integration	
Inventory	
IT Infrastructure	110
Planning	13
Preventive Maintenance	4
Purchasing	8
Release	5
Security	13
Self Service	6
Service Desk	
Service Level	
System Configuration	
Task Management	
Work Orders	

Work Order Tracking
Labor Reporting
Quick Reporting
Activities and Tasks

Data
Analytics

Workflow

Forecasting

Work
Type

Calibration

Suite Req

EDI Suite Req Application

The screenshot displays the EDI Suite Req application interface. At the top, there is a header bar with the logo "edi SuiteReq" and the text "Asset, Item & Work Requests". Below the header, there are two tabs: "OWR" (selected) and "MY REQUESTS". The main form area contains several input fields: "Work Requestor Staff ID" (with the value "1055784"), "Alternate Contact Staff ID", and "Request entered on behalf of". A "Category" dropdown menu is open, showing a list of options: "ADMINISTRATIVE WORK REQUEST", "CORRECTIVE WORK REQUEST", "MAXIMO ACCOUNT REQUEST - Add /", "Building Heating/Cooling", "Building Repair", "CAD Drawing", "Conference Room Setup", and "Door Repair/Service". Below the category list is an "Attach File" button. At the bottom of the form, there are "Cancel" and "Next >" buttons. A small red circle highlights the "Next >" button.

- EDI's use of Suite Req allows anyone to be able to submit a work order without having a specific license.
- Integrated with Maximo to populate information within Maximo without having to access it directly. How we use it is through a link on the company intranet page.
- Options include: OAR (Online Asset request), OIR (Online Item Request), OWR (Online Work Request) options. We currently only use the OWR option, however want to move toward using all these options in 2020.
- Application is modifiable to fit the company needs with Administrative rights

Work Type Categories

Select Value

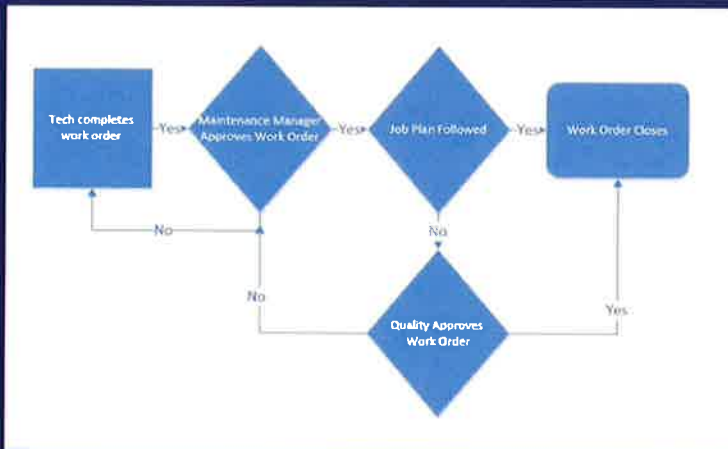
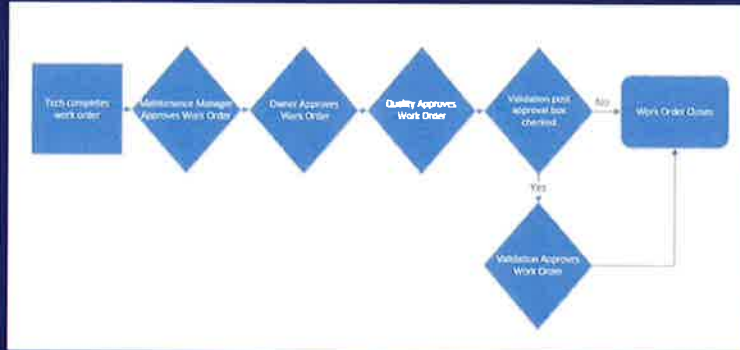
Filter > 1 - 14 of 14 Download

Type	Description	Organization
<input checked="" type="checkbox"/> AAE	Administrative Asset Entry	PAR
<input type="checkbox"/> CC	Change Control	PAR
<input type="checkbox"/> CE	Change Evaluation	PAR
<input type="checkbox"/> CM	Corrective Maintenance	PAR
<input type="checkbox"/> CMCAL	Corrective Maintenance Calibration	PAR
<input type="checkbox"/> CMCERT	Corrective Maintenance Certification	PAR
<input type="checkbox"/> GM	General Maintenance	PAR
<input type="checkbox"/> GMCAL	General Maintenance Calibration	PAR
<input type="checkbox"/> GMCERT	General Maintenance Certification	PAR
<input type="checkbox"/> IA	Investigation	PAR
<input type="checkbox"/> PPR	Proactive Preventive Repair	PAR
<input type="checkbox"/> RCA	Root Cause Analysis	PAR
<input type="checkbox"/> RTCAL	Reverse Trace Calibration	PAR
<input type="checkbox"/> SM	Service Maintenance	PAR

OK Cancel

- Utilization GM (General Maintenance) work orders for non-GMP work, ie. change light bulb or fix a sink.
- Utilization of SM (Service Maintenance) work orders for work performed by vendor technicians.
- Utilization of CM (Corrective Maintenance) work type for immediate repairs needed on GMP assets.
- Different workflows exist depending on the work type chose. For example, PM Work Orders typically do not require Quality Review.
- Options exist to use a workflow or Work Type for other Quality Systems such as Change Evaluation (CE) or Change Control (CC).

Process Flow Diagram



Types of Work Orders we use: CM, GM, PM, PMCAL, GMCAL, CMCAL, SM, and AAE

CM workflow and requirements: Log entry, failure codes, actual labor time from person performing the work (userid).

CM or GM Work Orders have the ability to attach a job plan or data sheet to this type of work order if one is required.

Workflow allows for the work order to travel forward or backward if additional information is required.



Tracking, Trending and Reporting

- Dashboard is shown in all the Maintenance Managers Start Center, but is distributed weekly to the Executive Leadership Team as well as discussed monthly at the Gemba walk for transparency throughout the organization
- Dashboard shows Work Orders sorted by type, status, aging time and project code
- KPIs vs Result Sets-all built from queries we create. Result Sets are interactive
- Public and private queries exist, based on security rights
- Utilization of graphs by craft so the entire group can see the open work orders and what location they are in
- Start Center default for each user is 'My Assignments' Result Set

Reverse-Trace Calibration

Dashboard

Queries

Reverse Trace Capability

The “out of the box” Maximo Reverse Trace Report simply identifies all Work Orders where the standard was used.

- Gives the ability to investigate which calibration possibly affected.
- This custom report identifies historical calibrations that "potentially" may have been affected by use of a "standard" that has since been identified to be "out of tolerance."

Scenario: Standard is calibrated and found to be out of tolerance. Investigation is performed to determine if calibrations that the standard was used in may have erroneous results in terms of pass/fail for the instruments under test.

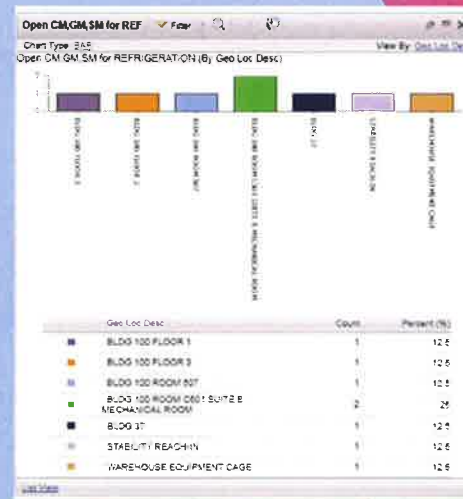
Revenue Traceability Report

IBM

Report Date: 01/01/2000
Report Period: 01/01/2000 - 12/31/2000
Report Type: Revenue Traceability Report

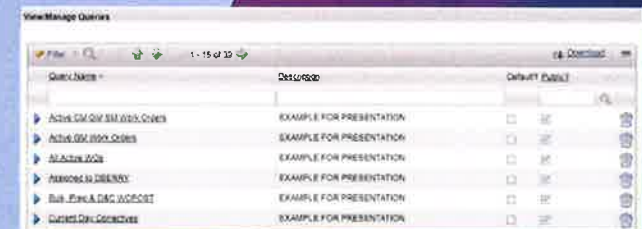
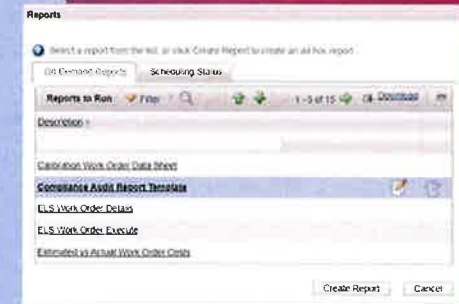
Product Line	Region	Revenue	Revenue %	Revenue Rank
IBM System/390	North America	1,234,567	34.5%	1
IBM System/390	Europe	987,654	28.7%	2
IBM System/390	Asia/Pacific	765,432	22.6%	3
IBM System/390	Latin America	543,210	15.9%	4
IBM System/390	Middle East	321,098	9.5%	5
IBM System/390	Africa	109,876	3.2%	6
IBM System/390	Other	87,654	2.5%	7
IBM System/390	Unassigned	65,432	1.9%	8
IBM System/390	Unassigned	43,210	1.3%	9
IBM System/390	Unassigned	21,098	0.6%	10
IBM System/390	Unassigned	9,876	0.3%	11
IBM System/390	Unassigned	7,654	0.2%	12
IBM System/390	Unassigned	5,432	0.2%	13
IBM System/390	Unassigned	3,210	0.1%	14
IBM System/390	Unassigned	1,098	0.0%	15
IBM System/390	Unassigned	876	0.0%	16
IBM System/390	Unassigned	654	0.0%	17
IBM System/390	Unassigned	432	0.0%	18
IBM System/390	Unassigned	210	0.0%	19
IBM System/390	Unassigned	98	0.0%	20
IBM System/390	Unassigned	76	0.0%	21
IBM System/390	Unassigned	54	0.0%	22
IBM System/390	Unassigned	32	0.0%	23
IBM System/390	Unassigned	10	0.0%	24
IBM System/390	Unassigned	8	0.0%	25
IBM System/390	Unassigned	6	0.0%	26
IBM System/390	Unassigned	4	0.0%	27
IBM System/390	Unassigned	3	0.0%	28
IBM System/390	Unassigned	2	0.0%	29
IBM System/390	Unassigned	1	0.0%	30

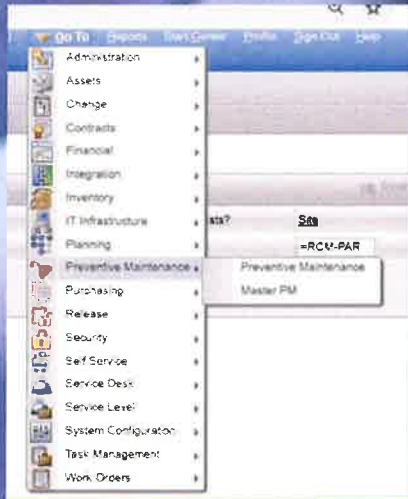
Dashboard and Information Sharing



Queries and Reporting

- Queries can be built from most applications and templates can be saved to be referenced at a later time
- Queries can be built by SQL where clauses or by inputting specific criteria into the search fields.
- Recurring reports are sent to multiple departments for Work Order visibility
- Reports can be exported as PDF or Excel





SMART Break Scheduling

- PM Forecasting allows for more accurate planning for site SMART (Scheduled Maintenance and Repair Time) breaks or shutdown periods for routine equipment and facility maintenance activities.
- The calendar application allows for visibility of scheduled work
- Assignment Manager application allows for allocation of resources



Forecast Details		Filter	
Forecast Data		Job Plan	
3/28/20	1606		
4/28/20	1606		
5/28/20	1606		
6/28/20	1606		
7/28/20	1606		
8/28/20	2117		
9/28/20	1606		
10/28/20	1606		
11/28/20	1606		
12/28/20	1606		
1/28/21	1606		
2/28/21	2117		
3/28/21	1606		
4/28/21	1606		



Calibration provides a solution to help you manage your calibration assets and the standards that are used to calibrate them.

Full access to calibration module on the go.

Ability to have full access to calibration history where ever you are for real time trending.

Work Order Oversight

- Ability to choose pre-approval for any of the workflows
- Each work order type pre and post approvals are configurable.
- We use our SOP to dictate work order type options and exceptions.
- Pre-approval as a method to notify a group of upcoming work or an administrative change.
- Quality Oversight mandatory on all Level 1 and Level 2 assets and optional for Level 3 assets.
- Minimally, Maintenance Managers review and approve all work orders, no matter what work type.
- Email options are available to notify when someone has a work order in their queue.

Approvals


ELSAM options that Par utilizes
are asset Owner, Maintenance
Manager, Validation and Quality
for pre and/or post approvals.

Approval & E-Signature

Owner Pre-Approval Req? <input type="checkbox"/>	Maint Mgr Post-Approval Req? <input checked="" type="checkbox"/>
Validation Pre-Approval Req? <input type="checkbox"/>	Owner Post-Approval Req? <input checked="" type="checkbox"/>
Quality Pre-Approval Req? <input type="checkbox"/>	Validation Post-Approval Req? <input type="checkbox"/>
Owner Cancel Approval Req? <input type="checkbox"/>	Quality Post-Approval Req? <input checked="" type="checkbox"/>
Quality Cancel Approval Req? <input type="checkbox"/>	Quality Cancel Approval Req? <input type="checkbox"/>

Libraries

Owner Pre-Approval E-Sig: _____	Maint Mgr Post-Approval E-Sig: CLAD	29/02/2021 PM
Validation Pre-Approval E-Sig: _____	Owner Post-Approval E-Sig: AMANUEL	21/02/2021 AM
Quality Pre-Approval E-Sig: _____	Validation Post-Approval E-Sig: _____	
Owner Cancel E-Sig: _____	Quality Post-Approval E-Sig: _____	
	Quality Cancel E-Sig: _____	



Easy Access to stored asset documentation/information

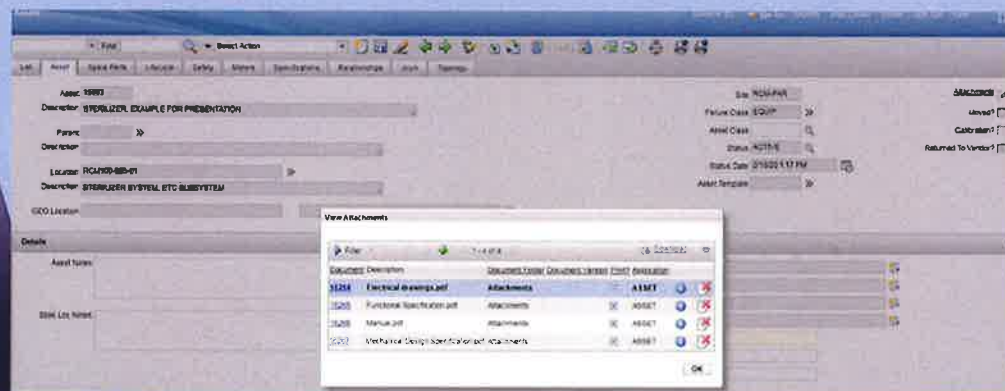
- Electronic storage for Functional Equivalent Forms, Process Automation System Forms and Onboarding Asset Forms, material certifications for equipment/spare parts inventory and outsourced work performed by vendors
- Ability to add a link to a file
- Work Instructions linked to Job Plans-scanned as an attachment and is included as an attachment when a work order is generated
- Manuals linked within the Asset Application- scanned as an attachment and is included as an attachment when a work order is generated
- Information can be found on the go or while performing the work

Manuals

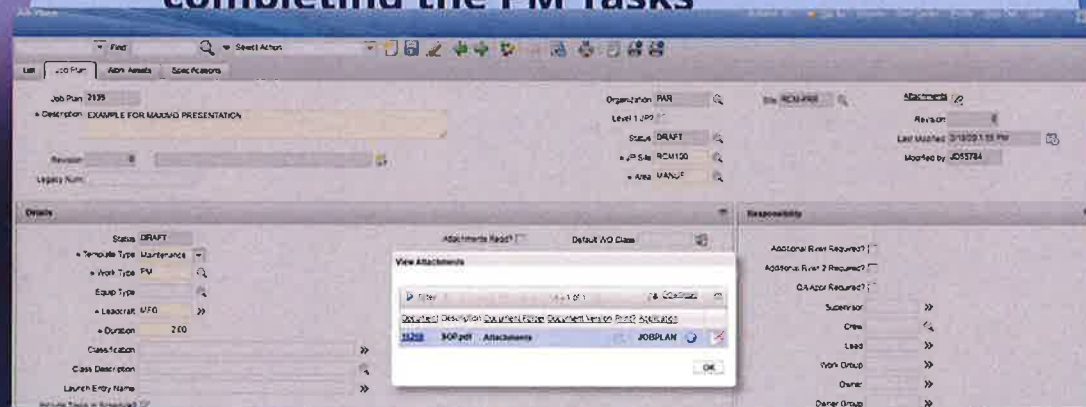
Job Plans

Wireless

Manuals linked within the Asset Application- scanned as an attachment and is included as an attachment when a work order is generated



Job plans can have attachments that provide additional work instructions, SOP references, data sheets and/or reference photos that aid in completing the PM Tasks





Maximo On The Go

- Maximo for Life Sciences also work with IBM Maximo Mobile applications, which has the ability to notify and assign work through mobile phones.
- Technician use laptops or tablets in the field for contemporaneous log entry and input of failure codes.
- Quick Reporting is available to reduce the tabs needed to complete the work-only shows what is required from the technician means it is “less busy” to look at.

