

Implementation of Computerized Maintenance Management Systems (CMMS)

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Speakers Bio Juan Oscar Pérez

EXPERIENCE



PRESENTATIONS

Pharma IT Forum, Interphex/MDPR, PRTEC MD Cluster, IT & Automation Symposium

AFFILIATIONS

Editorial Review Board Member for **Pharma IT journal**

PUBLISHED ARTICLES

- IT Compliance in the Life Science Industry
- Validation Management Systems
- Implementing CMMS in an FDA Regulated Environment

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Why a CMMS?

CMMS-Computerized Maintenance Management System

- Manage maintenance activities effective and efficiently
 - Reduce/eliminate backlog
 - Measure KPI's
 - Determine real inventory on hand / reduce inventory levels
 - Plan / Prioritize preventive/corrective maintenance activities
 - Many others...
- Ensure compliance with regulatory requirements clearly defined in the cGxP's

Maintenance and FDA Regulations

21 CFR 211 Current Good Manufacturing Practice For Finished Pharmaceuticals		21 CFR 820 Quality System Regulation	
Sub Part C – Building and Facilities	Sec. 211.42 (a) Design and construction features	Subpart G - Production and Process Controls	Sec. 820.70 Production and process controls (g) (1),(2)and (3)
	Sec. 211.58 Maintenance		
Sub Part D – Equipment	Sec. 211.67 Equipment cleaning and maintenance		

These regulations ensure that facilities and equipment are in optimum functional conditions necessary for the safe manufacturing of food, drugs, or devices for use and consumption.

CMMS, Best Practices and Compliance

A CMMS (well implemented), will give you reliable, updated information on:

Inventory Levels	Response Time
Labor	Working Hours
OEE/MTTR/MTBF	Backlog
Future Spending	Enable workflow
Eq. Past Behavior	Mobile tools
Asset/Labor Availability	Reserve spare parts
WO Planning/Scheduling	Failure/Cause/Remedy

CMMS, Best Practices and Compliance

“A whopping 94.7 percent of plant maintenance managers feel they are not using their computerized maintenance management software system to its maximum capability, according to the results of a national CMMS survey conducted for Reliable Plant magazine by educator, consultant and author Kris Bagadia.

CMMS, Best Practices and Compliance

Best Practices	
Total Productive Maintenance (TPM)	Reliability Centered Maintenance (RCM)
Operational philosophy based on integrating equipment maintenance into the manufacturing process. Workers understand the way they perform their duties impact the equipment they operate.	Analytical Process to determine optimum maintenance to increasing equipment uptime and Overall Equipment Efficiency (OEE) by reducing breakdowns resulting in lower total cost of ownership of the equipment.
The main purpose is to eliminate any loss caused by maintenance activities and avoid downtime that is unplanned.	It uses Failure Modes, Effect and Criticality Analysis (FMECA) to pinpoint the maintenance required to avoid critical failures.

Value Proposition of CMMS

By using Best Practices to implement a CMMS, compliance becomes a direct result of the process; hence compliance comes for free.

Implementation options

- A) The consultants are doing everything for you.
- B) The consultants are doing everything – and you are providing occasional input.
- C) The consultants are taking day-to-day direction from Core Team
- D) The consultants are providing occasional advice whenever asked.

Implementation – other variables

- A) Size of the consulting force. Typically options A+B require more consultants.
- B) Cost can be a consideration (for the client). This factor would determine the type of implementation.
- C) If there is a desire to also improve process, then the consulting team should have proven knowledge in better/best practices and be providing periodic input on "why setup this way".

Speakers Bio

Ramón Yamil Pagán, President PCG Corp.:

1. Worked with Johnson & Johnson for over 7 years in the Engineering Department
2. Founded PCG Corp. in 2001 with the goal in mind to help today's engineers to stay updated with the new technologies and products of the market, and stay trained on them and one of the precursors in the Island in the Energy Conservation Initiatives.
3. Has had previous appearances at Interphex , Puerto Rico Techno-Economic Medical Device Cluster, Ultrasound World Convention Event.
4. He is also a Certified Energy Manager (CEM), Ultrasound and Infrared Inspector, Member of the AEE, IEEE, NETA. Write a report in the Pharma IT Journal, which is an international publication based in England. In addition to provide trainings in Puerto Rico Ramón Pagán has give trainings in the United States, Dominican Republic and Mexico.

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IMPLEMENTING A MAINTENANCE PROGRAM FROM AN ENGINEERING POINT OF VIEW

IMPORTANT POINTS

- 1.DEFINE THE MAIN PURPOSE
- 2.FIELD ASSESMENT OF EQUIPMENTS & LOCATIONS
- 3.STANDARD NOMENCLATURE
- 4.TASKS & FREQUENCIES EVALUATION
- 5.PM'S CONSOLIDATION
- 6.SOFTWARE UPGRADES (BOM,KPI's)
- 7.A HAPPY ENDING

DEFINING THE PROGRAM PURPOSE

Most of the failures cases that we have seen as an engineering firm in the field is that most maintenances programs are used for scheduling only. No planning, or reducing correctives maintenances are achieved through this type of operation of a maintenance program. Companies have paid a high price for licenses, implementation and validation of a program that is being used as an excel spreadsheet. Our favorite analogy is that you have acquired a Cadillac to deliver the mail.

PROGRAM MAIN OBJECTIVE

- WHY A PREVENTIVE PROGRAM?
 - WHAT FOR?
- WHAT ARE WE EXPECTING THE PROGRAM TO DO?
- WHAT BENEFITS WE EXPECT TO GET FROM THE PROGRAM INFO?
 - AT WHAT LEVEL WE WANT TO OPERATE THE SYSTEM?

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THE FIELD ASSESSMENT

An effective implementation of a maintenance program starts with a detailed field assessment. This looks to be the simplest part of integrating a maintenance system but for many the door to mistakes that lead to an unsuccessful implementation. In the field assessment we gather the general information of the site (locations) and the equipments (nameplate, specs).

**GARBAGE IN
—
GARBAGE OUT**

STANDARD NOMENCLATURE

- A simple task but there is something we have to keep in mind, standard nomenclature, yes something simple but if we want to be able to get information out of our maintenance system (KPI's) we need to name the similar equipments with an intelligent nomenclature so they can be recalled and be useful in reports.

MAINTENANCE INSTRUCTIONS

- These are just the instructions for the technicians of what to do to the equipments and how often. Our particular experience has told us that most of this instructions came from the manufacturer recommendations and it doesn't matter the life of the equipment the instructions remains the same.

PM'S CONSOLIDATION

- MAKE A REAL EVALUATION OF THE AMOUNT OF MAINTENANCES THAT ARE BEING PERFORMED IN THE FACILITY.
- WHY?
- STANDARIZE FREQUENCIES, WHEN POSSIBLE

COMMON MISTAKES

COMMON MISTAKES

- NO PRE-ENGINEERING
 - NO REAL EQUIPMENT EVALUATION
 - SAME MAINTENANCE FREQUENCIES FOR EVER
 - EXCESIVE AMOUNT OF PM'S

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CONSEQUENCES

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CONSEQUENCES

- OVER PRICE MAINTENANCES COSTS
- PROBLEMS WITH THE MAINTENANCE BUDGET
- RELIABILITY OF THE EQUIPMENT
- PROFESSIONAL COMMITMENT

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PROGRAM UPGRADES

- WHAT CAN WE GET FROM OUR MAINTENANCE PROGRAM?
- GOOD REPORTS
- COST ALLOCATION
- FUTURE PLANNING
- KPI'S, OEE, ETC

Cont.

- If we succeed in optimizing our Preventive maintenances, by a cause and effect process the corrective actions will start to reduce and we will start to have a more reliable operation and the costs of repairs will be reduced in a notable way.

A HAPPY ENDING

HOW?

- NOT ALL THE TIME
- WE HAVE TO LIVE WITH OUR MISTAKES
- NOT ABLE TO MAKE GOOD REPORTS
- JUST DELIVERING THE MAIL

THE KEY TO SUCCESS

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COMMITTMENT

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Cont.

- So commitment is the one of the most important step of this successful implementation. Don't try to run a Preventive Maintenance Program with a clerk behind it, please. This is an engineering tool that require resources to improve and reduce your actual repairs costs. Remember that one of the purposes of the program is to increase the reliability of your operation.

DEFINE YOUR TEAM

- PLANNER
- SYSTEM ADMINISTRATOR
- POWER USERS
- REGULAR USERS
- TECHNICAL SUPPORT

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Cont.

- COMMITMENT
- A GOOD IMPLEMENTATION REQUIRES RESOURCES AND TIME
- NO CUTS IF WE WANT TO GET A SUCCESSFUL RESULT OF OUR PROGRAM
- PRE-ENGINEERING
- INCREASE THE RELIABILITY OF YOUR OPERATION

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RESUMING

- So we can conclude that an effective preventive maintenance program requires: a detailed field assessment, a periodic evaluation of our maintenances and their frequencies and a serious commitment if we want our system to be one with a high reliability level. So more than from a compliance point of view or an engineering a successful implementation of a Preventive Maintenance Program will give us a business advantage by having a more trustworthy operation

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VALIDATION


CMMS Implementation and Validation Process

“The first rule of any technology used in a business is that automation applied to an efficient operation will magnify the efficiency.”

“The second is that automation applied to an inefficient operation will magnify the inefficiency.”

Bill Gates


CMMS Implementation and Validation Process

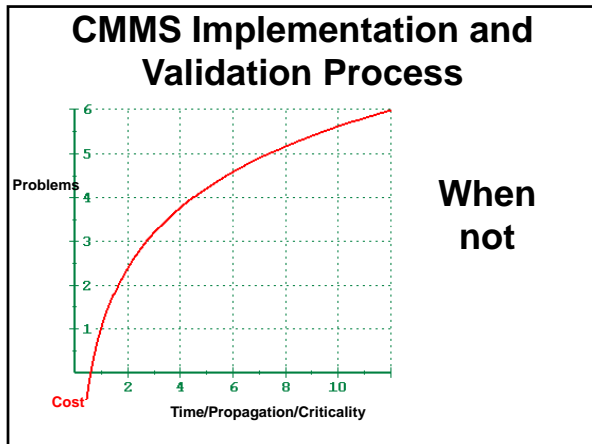


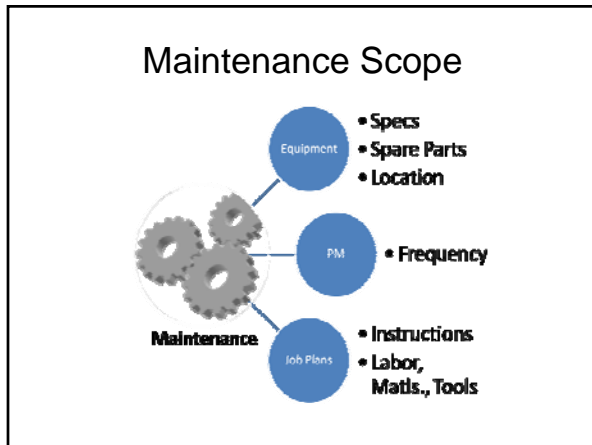
Decision Making / ROI

When properly implemented and validated

Processes







- ### Stakeholders
- Engineering & Maintenance – This is the system owner and usually becomes the Project Manager.
 - Information Technology – This is the technical owner of the system, ensures availability, security, and support among other things.
 - Quality Assurance – This is the regulatory owner and ensures that all applicable FDA regulations are met within the implementation.
 - Manufacturing – Impacted client.

As – Is / To Be

To identify the “As Is” state and the “To Be” state of the maintenance process, the stakeholders shall be assessed and brought on board on the early stage of the project.

As – Is / To Be

- What is the lifecycle of a WO?
- How much does it cost to move a WO? Paper v. Electronic
- Which information can be obtained with current data, is it reliable?
- Can the process be measured?
- Is the work performed on time and effectively?
- Is the process controlled?
- Is it fit for the intended use?
- How many resources do I have now? How many will I need?

Things to Remember

- Official Record – Paper or Electronic
- Failure Codes – to rapidly pinpoint Failure, Cause and Remedy, hence minimizing downtime.
- Service Level Agreements – to guarantee response time on pre-determined situations.
- Work Order (WO) Priorities – to help meet SLA's

Things to Remember

- Workflows – This helps establishing a uniform process for review and approval of work orders.
- Work Order Categories – This helps to pinpoint different WO's categories, costs, SLA's, etc.
- Backlogs – Define what is considered backlog according to business rules and regulatory requirements. Remember that this is a regulatory issue, the lower the backlog, the better.

Things to Remember

- Data – which data will be collected and for which purposes.
- Metrics – Establish the metrics that will be measured using the system and the formulas to be used
- Customizations – Document any customization performed in the CMMS.
- Reports – Most CMMS come with canned, one-size-fits-all reports that may not meet your particular needs.

Summarizing

- A) Just installing software is not CMMS/EAM implementation
 - mission statement, goals/objectives and KPIs
 - KPIs should be in a hierarchy such that the highest level defines overall company/business goals and then each lower level supports the higher level.

Summarizing

- B) System changes - with documentation - is important.
- C) Core Team should be adequately trained to take over the system (prior to go-live).
- D) Core Team charter should exist which defines how decisions are reached, voted on, and recorded.

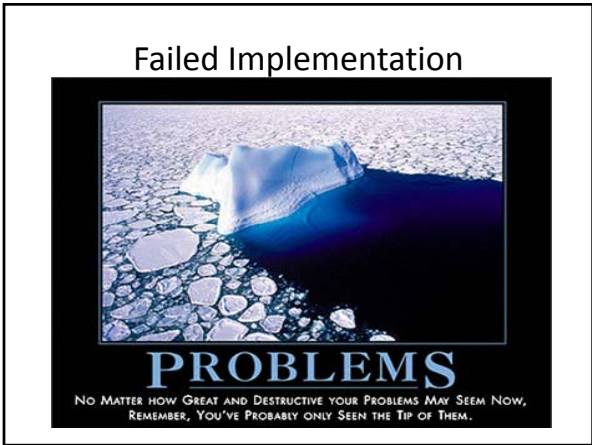
Summarizing

- E) CMMS Administrator and Planner positions are identified.
- F) CMMS operating procedures are defined.
- G) Be realistic, problems occur.

Summarizing

- H) It is never too early to start an internal punchlist of "things to be done".
 - Request Tracking #, description, requestor
 - Request type (screen, report, database, etc.)
 - Request date, priority, potential ROI, cost, hours, delivery, validation impact
 - Reason (regulation, business, etc.)
 - Responsible (contractor, internal staff)
 - Any item open for a year or more address why it was requested and by whom.

Tip of the session
Prior to GO-LIVE
Your organization should definitely
be in charge of the system.



ACKNOWLEDGEMENTS

<p>Juan O. Pérez QCSV Inc. – President (787)549-9052 joperez@qcsv-inc.com www.qcsv-inc.com</p>	<p>Ramón Pagán PCG Corp – President (787)647-8560 rpagan@pcgcorporation.com www.pcgcorporation.com</p>
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