

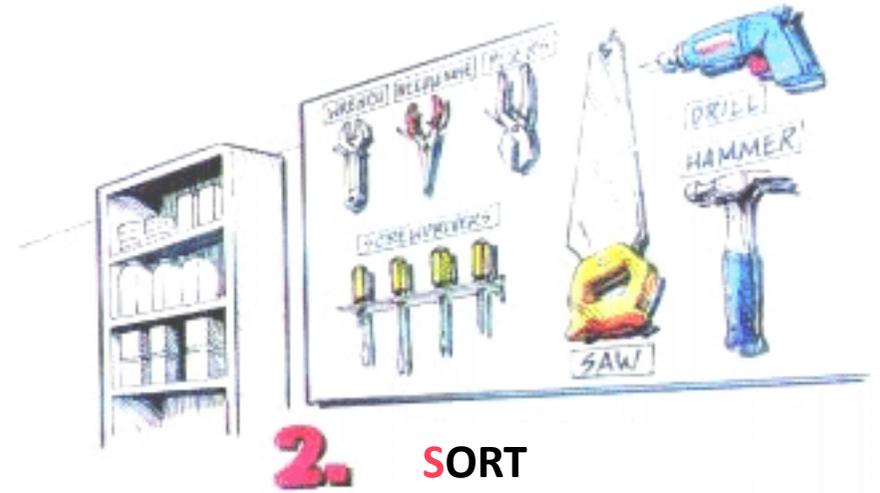


PHARMACEUTICAL
CONSULTANCY
SERVICES

TOOLBOX



1. SEPARATE

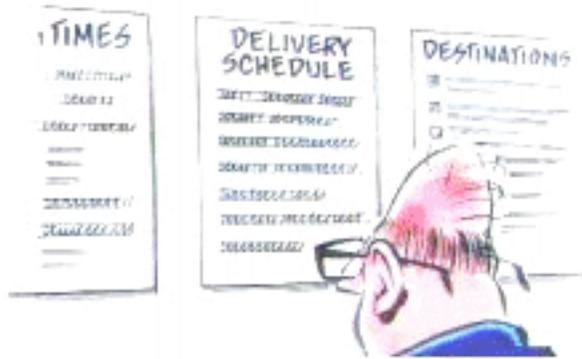


2. SORT

5S



5. STIMULATE AND MAINTAIN



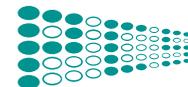
4. STANDARDIZE



3. SANITATE (CLEAN)

5 S SUPPORTS...

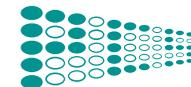
- Limiting distractions caused by “clutter”
- Increasing routine by introducing exact locations for materials/tools etc.
- Preventing mistakes
- Ease workplace-sharing



5 S EXAMPLE



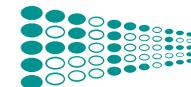
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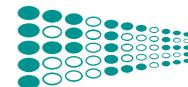
5S EXAMPLE



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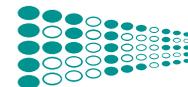


CONTROL CHARTS “6S”

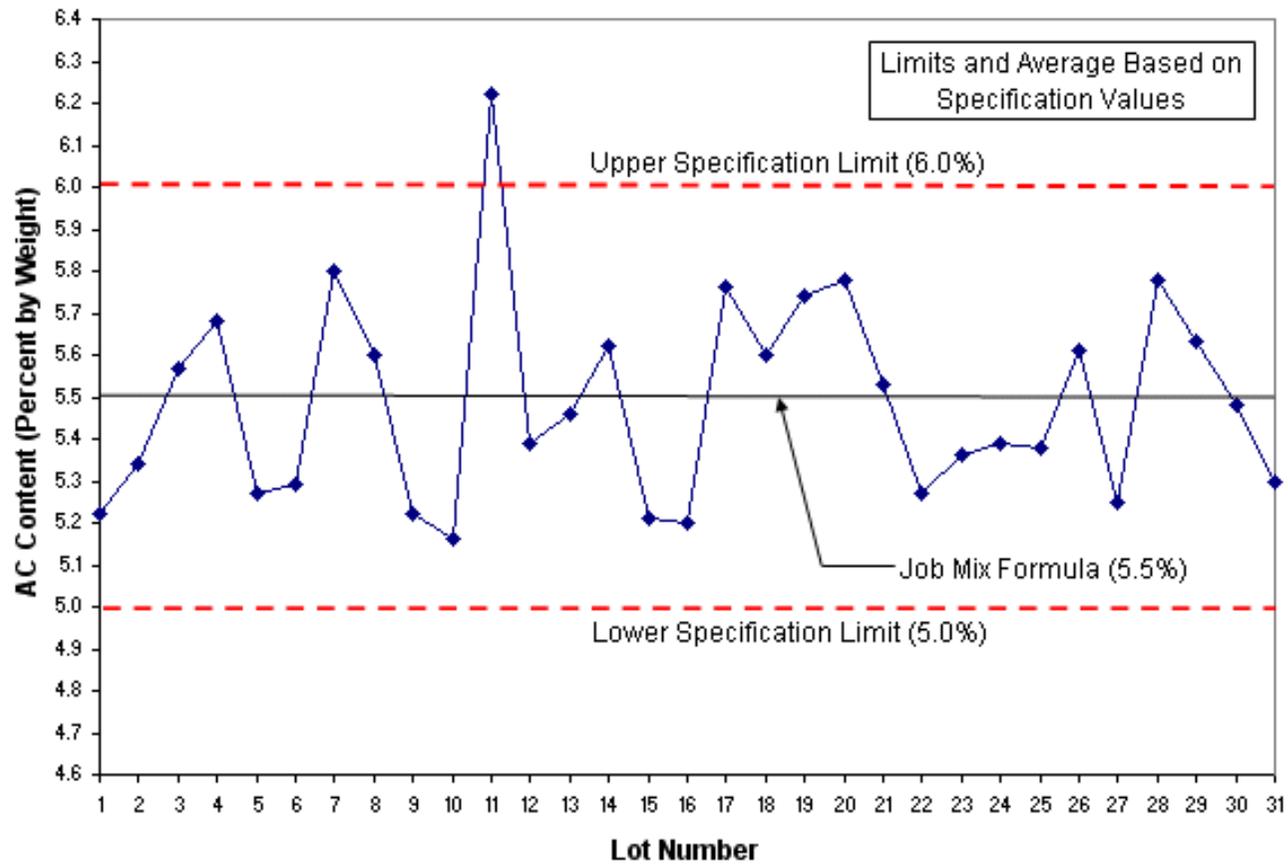


VISUAL MANAGEMENT

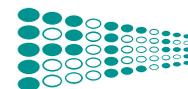
- Clarify / transfer information through visual “cues” to clarify certain steps in a process
- Control Charts are a form of visual management as well



EXAMPLE OF A CONTROL CHART

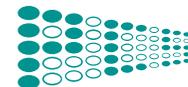


POKA YOKE

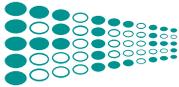


POKA YOKE

- Poka Yoke is a Japanese term, originating from lean manufacturing=fool proof (poka: unintended error, yoke: prevent)
- It's a method to form a production process in such a way that it is impossible for an error to occur. An operation is executed in a way that **forces** the correct procedure to be followed.
- The concept was launched by Shigeo Shingo as a part of the Toyota Production System.

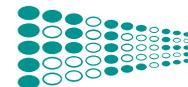


**EXAMPLE:
SIM CARD**



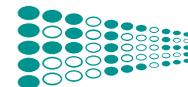
POKA YOKE

- warning poka-yoke: creates a warning when an error occurs (alert)
- control poka-yoke: ensures the mistake is prevented (prevent)



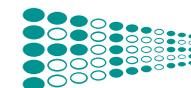
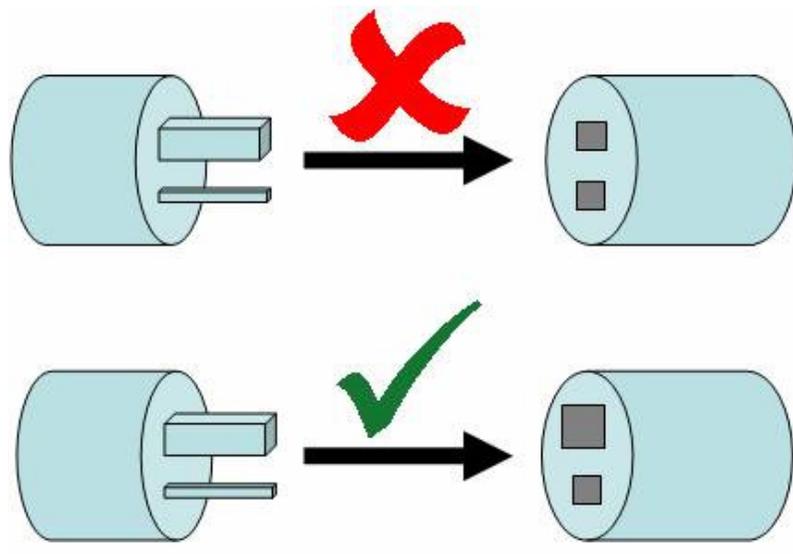
POKA-YOKE

- 3 Types of Poka-Yoke ensure detection and prevention of mistakes:
 - Contact-Method: defects are identified by testing on product forms, size, color or other physical characteristics
 - Fixed-Value-Method: alerts when a certain (amount of) movement(s) is not completed/executed
 - Logic-Order-Method: Determines whether or not the procedural steps have been followed



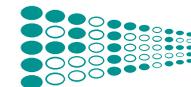
EXAMPLE CONTACT POKA YOKE

- The physical design is such that the mistake can not be made: wrong design = no “fit”.



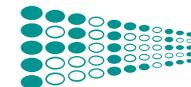
EXAMPLE FIXED-VALUE POKE YOKE

- A tray with 43 spaces for 43 bottles: all holes filled = tray complete
- A wrench that leaves a drop of yellow paint on every tightened bolt: all bolts yellow=all bolts securely fastened.

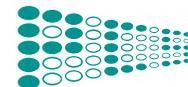


EXAMPLE LOGIC-ORDER POKA YOKE

- Preparing the different parts in a certain, fixed order: wrong order=surplus parts
- Numbering certain parts in the order of assembly: wrong order=wrong consequent numbering



QUALITY REPORTS (MQR'S)



MONTHLY QUALITY REPORT (MQR)

March/April 2014

Executive Summary

- The Manufacturing facility upgrade is in the final stages of completion:
 - Working on batch record and SOP revisions.
 - All deviations are closed out with CAPAs.
 - Overhaul of Quality Systems:
 - Raw Materials Program will be rolled out in 3 weeks
 - Documentation program has begun to be implemented
 - Training Program is being implemented
 - project Management on hold due to NNN. New management will take over.
 - Writing/Revising SOPs to prepare for JJJ.
- The report is being issued for both March and April since facility has been busy with NNN.

	This month	Last month
Deviation	0	0
OOS	0	0
Change Control	5	9
CAPA	1	1

Legend

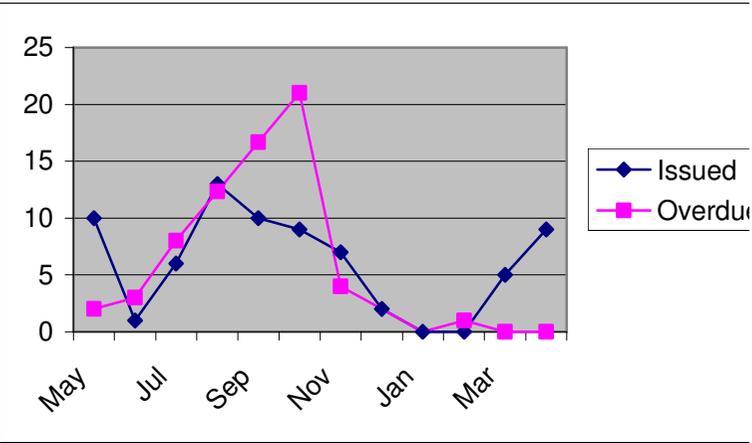
<3 green	acceptable
3 - 5 yellow	between
> 5 red	not-acceptable

1. DEVIATIONS

Commentary (details are in the attachments)

- NCMR is no longer active and will no longer be reported. One is currently open and will be closed as soon as it is returned to the QA office.
- A total of 3 CAPAs associated with 2013 deviations are open, but are pending the activation of SOPs. The expected activation date is first week of May 2014.

	Issued	Overdue
May	10	2
Jun	1	3
Jul	6	8
Aug	13	
Sep	10	
Oct	9	21
Nov	7	4
Dec	2	2
Jan	0	0
Feb	0	1
Mar	5	0
Apr	9	0
Total	72	



Overdue	Class	Dec	Jan	Feb	Mar	Apr
< 1 month	A	0	0	0	0	0
1-3 months	B	2	0	1	0	0
3-6 months	C	0	0	0	0	0
6-12 months	D	0	0	0	0	0
> 12 months	E	0	0	0	0	0
TOTAL OVERDUE		2	0	1	0	0

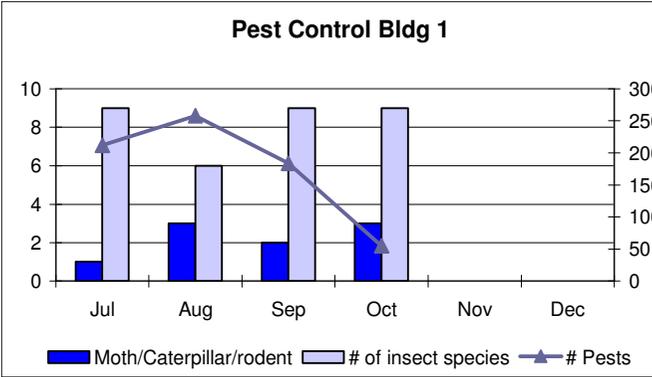
8. PEST CONTROL

Commentary

- No data was obtained for the month of April to date.
- See trending graphs below. Building 1 represents data from 2013 and Building 3 represents data from the years 2013 and 2014.
- There is currently no 2014 data due to the Manufacturing upgrade.
- Pest control layout needs to be revised to reflect facility upgrade (part of XXX).
- There are more traps for building 1 as opposed to building 3 due to higher monitoring requirements for building 1 for the GMP facility.

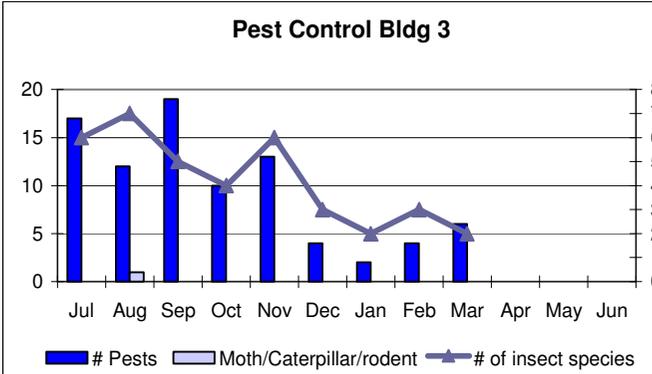
Pest Control Building 1

	# Pests	Moth/Caterpillar lar/rodent	# of insect species
Jul	212	1	9
Aug	258	3	6
Sep	184	2	9
Oct	55	3	9
Nov			
Dec			
Total	709	9	33



Pest Control Building 3

	# Pests	Moth/Caterpillar lar/rodent	# of insect species
Jul	17	0	6
Aug	12	1	7
Sep	19	0	5
Oct	10	0	4
Nov	13	0	6
Dec	4	0	3
Jan	2	0	2
Feb	4	0	3
Mar	6	0	2
Apr			
May			
Jun			
Total	87	1	38



10. WATER MONITORING

Commentary

- Water monitoring has taken place, but no new data has been reviewed by QA to date.

11. VALIDATION

Commentary

- VMP's are either done or in final stages of review for the major validation studies (cleaning, computers, QC).
- A list with open Validation Protocols can be found in the attachment
- XXX will deal with Equipment validation/revalidation status.
- Shipping validation: VMP is drafted, however is not part of NNN. Priority lowered.
- A consultant has been hired to work on the retrospective IQ/OQ for the Manufacturing equipment and the organization of the files in the data room to prepare for the JJJ.
- CLV = Done
- AMV = Done
- CSV = Being sent around for signatures.
- Process Validation Report has been completed.
- Shipping Validation = 2nd rough draft being worked on

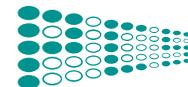
12. CALIBRATION

Commentary

- A Managerial SOP is in place.
- Individual SOPs (e.g. how to calibrate a pressure gauge) should be drafted or approved in ca is out-sourced.
- The calibration documents will be filed in the data room.
- Part of XXX

Executive Summary

- The Manufacturing facility upgrade is in the final stages of completion:
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 - All deviations are closed out with CAPAs.
 - Overhaul of Quality Systems:
 - Raw Materials Program will be rolled out in 3 weeks
 - Documentation program has begun to be implemented
 - Training Program is being implemented
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 - Writing/Revising SOPs to prepare for JJJ.
 - The report is being issued for both March and April since facility has been busy with NNN.

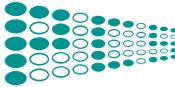




	This month	Last month
Deviation	0	0
OOS	0	0
Change Control	5	9
CAPA	1	1

Legend

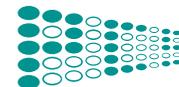
<3 green	acceptable
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Commentary (details are in the attachments)

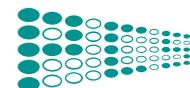
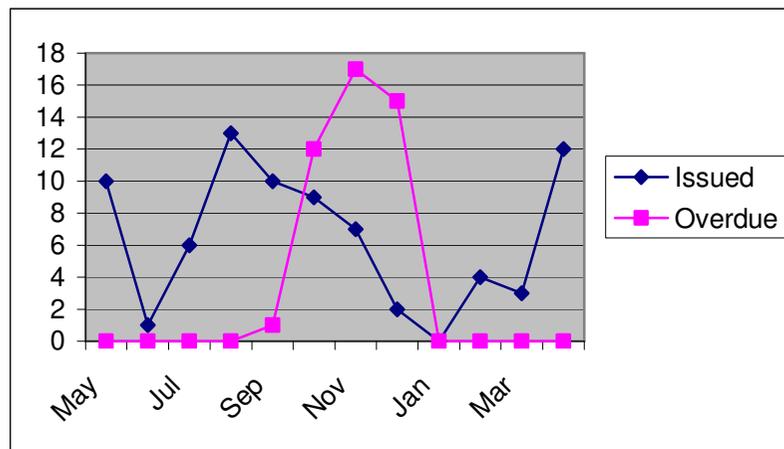
Information: CAPA = Corrective Actions Preventative Actions

- A deviation can be closed once a CAPA has been opened.
- If a department cannot meet the CAPA target implementation date, please contact QA via email as to why an extension is necessary, and QA will assign an extended target implementation date.
- QA will be tracking how many times a CAPA target implementation date has been extended. QA will not issue extended target implementation dates multiple times.
- A mega CAPA has been issued (08-001) to cover the multiple CAPAs assigned in 2013 with regards to the Harvest and cell viability issues issued to J. Koster.



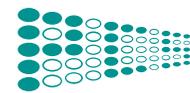


	Issued	Overdue
May	10	0
Jun	1	0
Jul	6	0
Aug	13	0
Sep	10	1
Oct	9	12
Nov	7	17
Dec	2	15
Jan	0	0
Feb	4	0
Mar	3	0
Apr	12	0
Total	77	

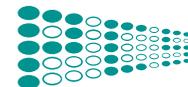




Overdue	Class	Dec	Jan	Feb	Mar	Apr
< 1 month	A	4	0	4	0	0
1-3 months	B	9	0	0	0	0
3-6 months	C	2	0	0	0	0
6-12 months	D	0	0	0	0	0
> 12 months	E	0	0	0	0	0
TOTAL OVERDUE		15	0	4	0	0

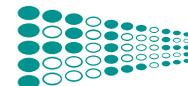


LEAN MANAGEMENT

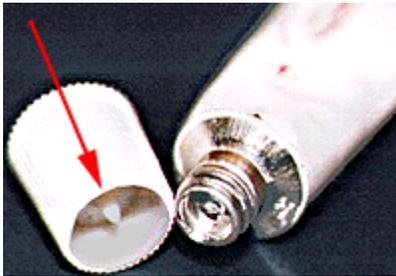


LEAN MANAGEMENT

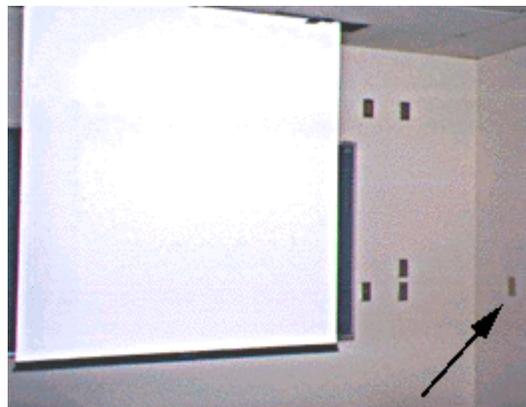
- Remove all un-needed activities
 - *elimination of waste ("Muda")*
- *making obvious what adds value by reducing everything else.*
- Use of flow-charts to make visible how work is flowing



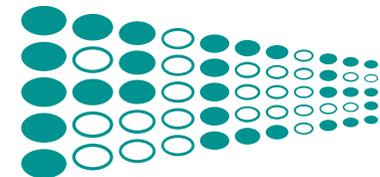
EXAMPLES MISTAKEPROOFING.COM



Waterproof



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