- Theory 4
- Selection and purchasing of an automated inspection system

- Technical requirements
- Integration into existing processes, lines/ machines and systems
- Cost and effort considerations
- Risk Assessment

Theory 4: Selection and purchasing of an automated inspection system

Some pre requisites

- When procurement of AVI machine is foreseen you may consider all these aspects:
- User Requirements, typically the URS document
- Engineering specifications
- EHS rules
- Contractual terms
  - Payment terms / conditions
  - Project mngt / key milestones
  - Target KPIs
  - Training
  - Key milestones (commisioning / validation / ramp up)

Theory 4: Selection and purchasing of an automated inspection system

Some challenges

- User Requirement

Cost / Payback

Patient / Quality

Time / Go Live

Theory 4: Selection and purchasing of an automated inspection system

Company culture : work across boundaries

- What are Silos in your company ?

- Production
- Maintenance
- Engineering
- Procurement
- QA
- QC
- RA
- PMOs
- EHS : Ergonomy
- ….

1 URS+1 Contract

Theory 4: Selection and purchasing of an automated inspection system

Build a SIPOC ?

- Need for SIPOC before Deep Dive into details

Situation	Input	Process	Output	Customer
USP, EP, GMPs	Funding / Budget	Risk Assessment +supplier	Essentially free of particles	Line operator +maint VI
Internal QA SOPs	URS	Vision review FAT/SAT	Crack control	Quality VI
Parenterals	Defect library Defect kit	IQ OQ	AVI Rejection<X% AQL pass	Manager VI
Volume to inspect	Baseline existing machines	Certification/PQ +Csty lots Filing	Control chart AVI to trend defects	Patient

Theory 4: Selection and purchasing of an automated inspection system

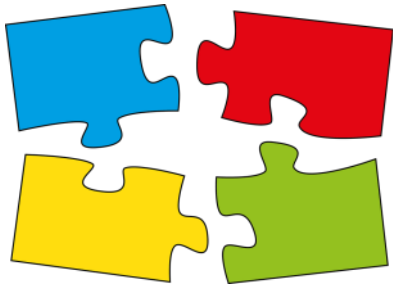
Topics to cover

- Topics to cover:

URS	Eng. Spec.	Contracts
✓ User needs	✓ electrical	✓ R&R
✓ Products	✓ Pneumatic	✓ certifications
✓ Prim. packaging	✓ Automation	✓ Document approval
✓ KPIs	✓ ERES	✓ User
✓ Kits	✓ Back up & restore	✓ KPIs target
✓ validation	✓ Alarms mngt	✓ Payment terms
✓ documentation		✓ Key milestones
✓ training		✓ KM
✓ maintenance		✓ Commissioning FAT SAT
✓ Spare part		✓ Support mentoring

Theory 4: Selection and purchasing of an automated inspection system

Integration into existing processes



- Where does it fit in
- Inline after Filling
- Standalone “island concept”
- Before labelling
- Or all in one line / feedback or bottlenecking ?
- How to maintain clean room conditions
- When integrated in existing line
  - How to connect the parts
  - Who will be responsible for this
- What about AQL sampling: manual, automatic

Theory 4: Selection and purchasing of an automated inspection system

Integration into existing processes

- Online versus offline
- Inline after filling
  - More appropriate in case cold chain
  - But influenced by process circumstances before
- Offline
  - Independent of the process circumstances before
  - But more labor
  - More handling, more risks, e.g. Mix-ups

Product behavior

- Viscous. If so the introduction of air bubbles is likely
- Humans can distinct air bubbles from particles far better
- Offline would be more appropriate

Theory 4: Selection and purchasing of an automated inspection system

Integration into existing processes

Product behavior

- If your products are a mix of waterlike to viscous
- Make it two ways. Partly inline, partly offline

AVI in general

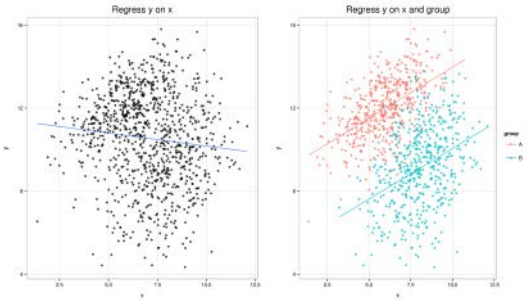
- These machines are complex
- They may go in error
- you might be confronted with unexpected high ejects
- Buffering and offline inspection should be considered

Theory 4: Selection and purchasing of an automated inspection system

Some Prerequisites

Representative test kits are prepared

- Defect units (defined and stable)
- Worst case
  - Product and/or container
- Good units



MVI results on these test kits are know

- Statistical results, e.g. through Knapp Kushner
- Human limits
  - Particle size
  - Areas not easy to inspect

Theory 4: Selection and purchasing of an automated inspection system

Considerations when Selecting

There are only 4 mayor machine suppliers

Your URS and engineering specs are the basis

- The machine supplier must meet these requirements
- The statistical result on these test kits must be equal or better than MVI

AVI must perform equal or better than MVI

- How much better
- Against what costs
- Is manual inspection of AVI ejects allowed
- AVI is not perfect
  - 100% detection of everything not wanted is impossible

Theory 4: Selection and purchasing of an automated inspection system

Considerations when Selecting

Apart from wanted performance, machine price only

- Printers are sold at/or below cost price
  - They earn in selling ink
- What about spare parts
  - What do you minimal need
  - Life cycle?
  - Costs?

Mechanical you can get everything

- OEM (Original Equipment Manufacturer)
- Third parties
- Unlimited in time

Theory 4: Selection and purchasing of an automated inspection system

Considerations when Selecting

Electrically

- Lifecycle is short
- Ongoing development is rapid
- Older parts become obsolete in short time
- Availability is limited in time
- Machine suppliers often don't produce these parts, they buy on the market

Cameras/LEDs

- The same

Machine supplier guaranties

- Spare parts are available for 10 ? 15 years?
- Equal with LEDs and cameras?

Theory 4: Selection and purchasing of an automated inspection system

Risk assessment

The FMEA approach

- Less intensive as a Hazop study, but necessary (see PDA TR 44)
  - You need to identify your possible pitfalls

FUNCTIONS		POTENTIAL FAILURE MODES				POTENTIAL CAUSES						RECOMMENDED ACTIONS			
Item / Function	Sub-Item / Sub-Function	Potential Failure Mode	Potential Effects of Failure	SEVERITY	CLASS	Potential Causes / Mechanisms of Failure	OCCURRENCE	Current Design Controls Prevention	Current Design Controls Detection	DETECTABILITY	RPN	CRITICALITY	Recommended Actions	Responsibility	Target Completion Date	Ac
Automobile	Body	Blind spot size	Travel in comfort [L]	8	Safety	Line of Sight obstructions	6	Feedback from user evaluations	None	10	480	48	Review consumer test data	Marketing Team	1-Jun-12	
			Have fun driving [M]	6	Safety	Line of Sight obstructions	6	Feedback from user evaluations	None	10	360	36	Review consumer test data	Marketing Team	1-Jun-12	
	Suspension	Cornering ability	Passenger safety (crash avoidance) [M]	10	Safety	Unreliable components	5	Perform reliability predictions of critical components	Computer diagnostic system	7	350	50	Analyze reliability models and predictions	Quality/Reliability Team	7-Aug-12	
	Storage Compartment	Cargo Space	Family vacations [H]	7	Comfort	Poor Design	7	Feedback from user evaluations	None	7	343	49	Review consumer test data	Marketing Team	7-Jun-12	
	Body	Blind spot size	Passenger safety (crash avoidance) [H]	10	Safety	Line of Sight obstructions	7	Investigate crash alert systems	Collision alert system	4	280	70	Implement plan for collision avoidance	Adv Concepts Team	7-May-12	
	Passenger Compartment	Headroom	Travel in comfort [H]	7	Comfort	Passengers outside of 10-90 percentile for height	5	Feedback from user evaluations	None	8	280	35	Review consumer test data	Marketing Team	1-Jun-12	
	Powertrain	Gas Mileage, Highway	Low cost of ownership [H]	8	Cost	Additional Passenger and Cargo loads	8	Proper powertrain design	Adjustments for light and heavy loads	4	256	64	Investigate new fuel economy concepts	Adv Concepts Team	7-May-12	
	Passenger Compartment	Headroom	Travel in comfort [H]	7	Comfort	Improper seat height adjustment	3	Feedback from user evaluations	None	8	168	21	Review consumer test data	Marketing Team	1-Jun-12	
			Family vacations [L]	5	Comfort	Passengers outside of 10-90 percentile for height	4	Feedback from user evaluations	None	8	160	20	Review consumer test data	Marketing Team	1-Jun-12	
	Brakes	Braking Distance at 30mph	Passenger safety (crash avoidance) [H]	9	Safety	Braking System Malfunction	4	Require preventative maintenance	Computer diagnostic system	4	144	36	Review warranty and maintenance data	Supportability Team	1-Jun-12	
	All	Reliability (mtbf)	Low cost of ownership [H]	6	Cost	Unreliable components	6	Perform reliability predictions of critical components	Computer diagnostic system	4	144	36	Analyze reliability models and predictions	Quality/Reliability Team	7-Aug-12	
	Storage Compartment	Cargo Space	Carry lumber [H]	5	Comfort	Inadequate Design	3	Feedback from user evaluations	None	9	135	15	Review consumer test data	Marketing Team	1-Jun-12	
	Suspension	Cornering ability	Have fun driving [H]	6	Safety	Unreliable components	5	Perform reliability predictions of critical components	Computer diagnostic system	4	120	30	Analyze reliability models and predictions	Quality/Reliability Team	7-Aug-12	
	Powertrain	0-60 Time		6	Cost	Engine/Powertrain malfunction	5	Require preventative maintenance	Computer diagnostic system	4	120	30	Review warranty and maintenance data	Supportability Team	1-Jun-12	
		Gas Mileage, Highway	Family vacations [M]	6	Cost	Additional Passenger and Cargo loads	5	Proper powertrain design	Adjustments for light and heavy loads	4	120	30	Investigate new fuel economy concepts	Adv Concepts Team	7-May-12	
	All	Reliability (mtbf)	Reliable transport to work [H]	6	Cost	Engine/Powertrain malfunction	5	Require preventative maintenance	Computer diagnostic system	2	60	30	Review warranty and maintenance data	Supportability Team	1-Jun-12	

Theory 4: Selection and purchasing of an automated inspection system After buying

FAT

- Should not be on user site
- Use supplier facilities / competencies
- If not passed
  - Due to minor issues
  - Due to mayor issues
- Never expect it will be solved during SAT

=> Punch list is key at supplier site

Key take away:

- In this section you have learnt:

URS	Exercise 1: scenario presentation
	UR / Eng. spec. / Contracts
	Cost-Benefit / Patient / Delivery
	Silos vs Holistic URS
	Need for SIPOC
	Other considerations