

- 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

- 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)



- User Requirement



Cost /
Payback



Patient /
Quality



Time / Go
Live



- What are Silos in your company ?

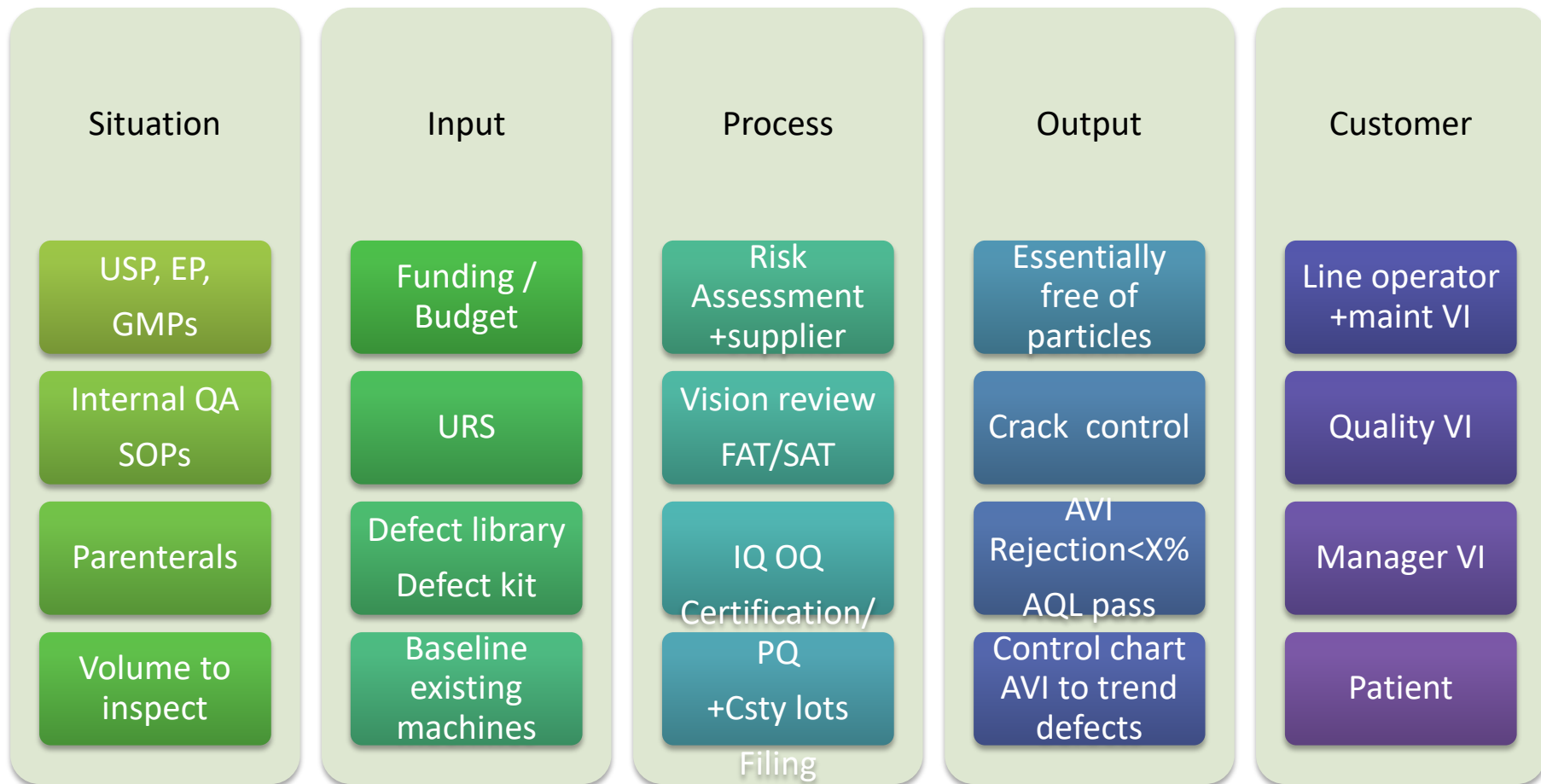


- Production
- Maintenance
- Engineering
- Procurement
- QA
- QC
- RA
- PMOs
- EHS : Ergonomy
-



1 URS+1 Contract

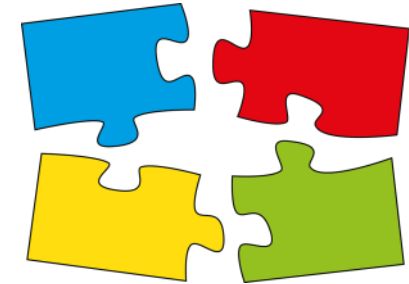
- Need for SIPOC before Deep Dive into details



- 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

- 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

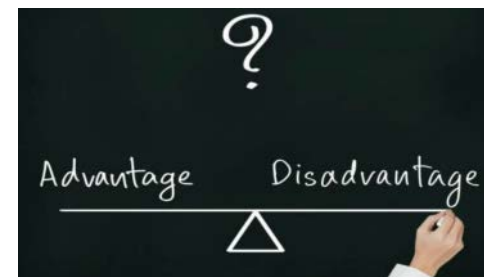


- Online versus offline
- Inline after filling
 - More appropriate in case cold chain
 - But influenced by process circumstances before
- Offline
 - Independent of the process circumstances before
 - But more labor
 - More handling, more risks, e.g. Mix-ups



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



Product behavior

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

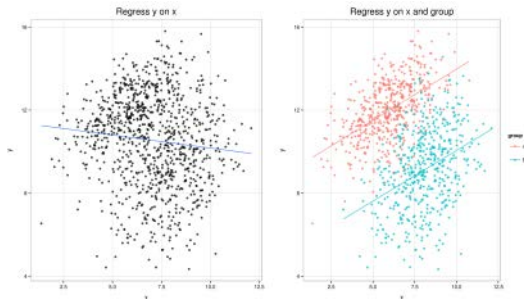


AVI in general

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

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

There are only 4 major 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



The Price?
GOOD QUESTION!

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



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?

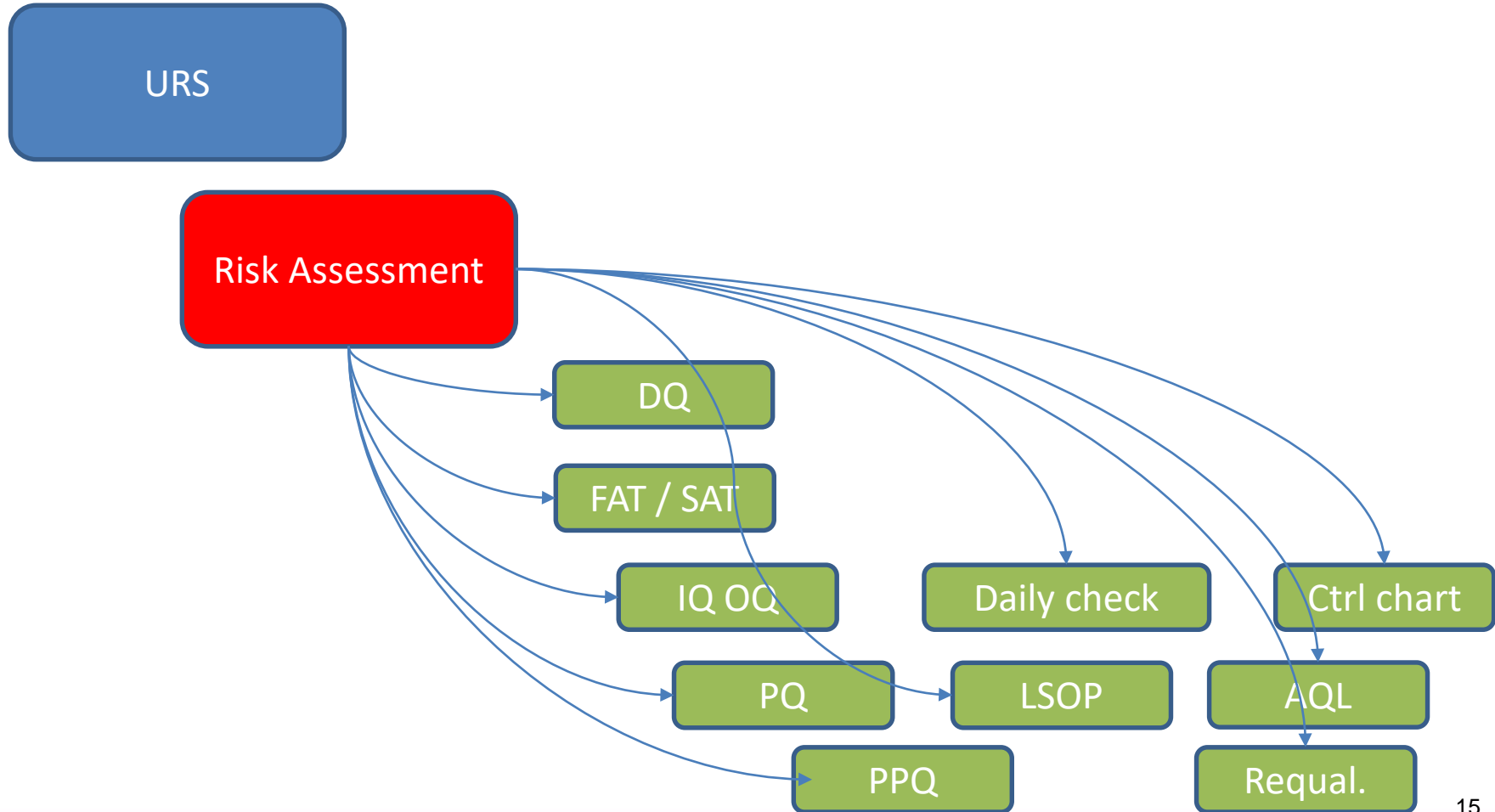
The FMEA approach

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

FUNCTIONS		POTENTIAL FAILURE MODES			
Item / Function	Sub-Item / Sub-Function	Potential Failure Mode	Potential Effects of Failure	SEVERITY	CLASS
	Body	Blind spot size	Travel in comfort [L]	8	Safety
			Have fun driving [M]	6	Safety
	Suspension	Cornering ability	Passenger safety (crash avoidance) [M]	10	Safety

POTENTIAL CAUSES							RECOMMENDED ACTIONS	
Potential Causes / Mechanisms of Failure	OCCURRENCE	Current Design Controls Prevention	Current Design Controls Detection	DETECTABILITY	RPN	CRITICALITY	Recommended Actions	
Line of Sight obstructions	6	Feedback from user evaluations	None	10	480	48		Review consumer test data
Line of Sight obstructions	6	Feedback from user evaluations	None	10	360	36		Review consumer test data
Unreliable components	5	Perform reliability predictions of critical components	Computer diagnostic system	7	350	50	Analyze reliability models and predictions	

FMEA can mitigate risks in multiples pathways :



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



- 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
