Mastering AVI

Part 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

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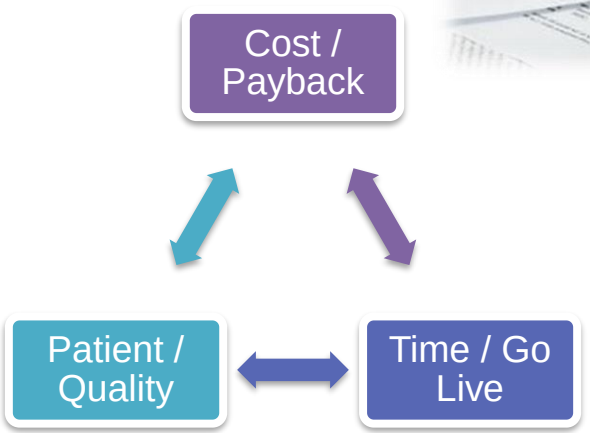
Where to start?

- 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)
  - Performance based contract

Some challenges



Company culture

- What are Silos in your company ?

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

1 URS+1 Contract

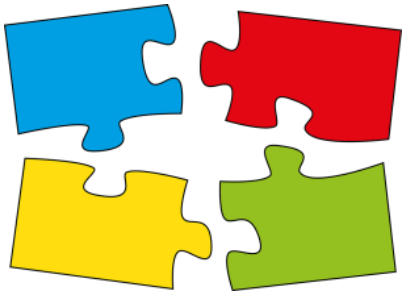
Topics to cover in URS

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

Integration into existing process

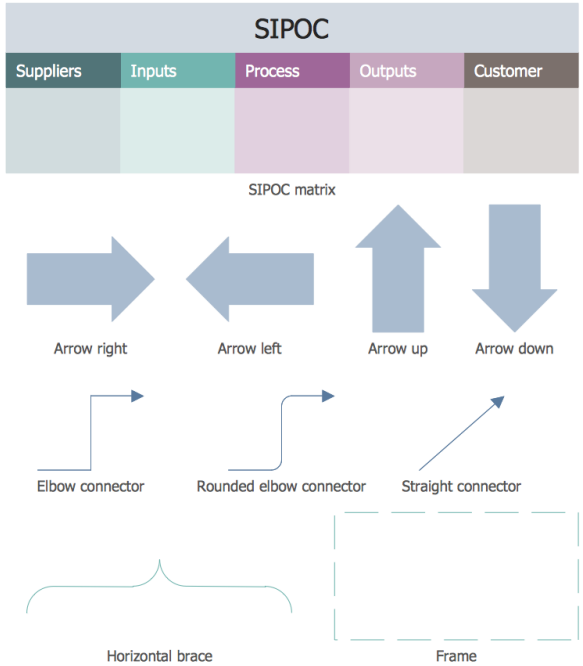
- **Where does it fit in?**

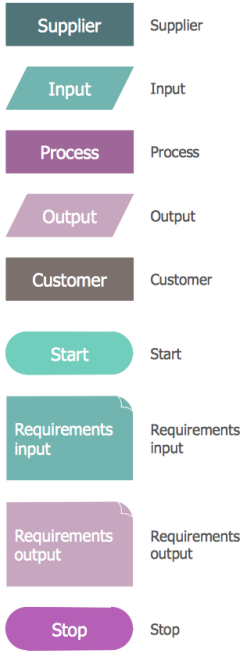
- **Inline after Filling**
- **Standalone “island concept”**
- **Before labelling**
- **Or all in one line / feedback or bottlenecking ?**
- **How to maintain clean room conditions**
- **When integrated in existing line**
  - **How to connect the parts**
  - **Who will be responsible for this**
  - **What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



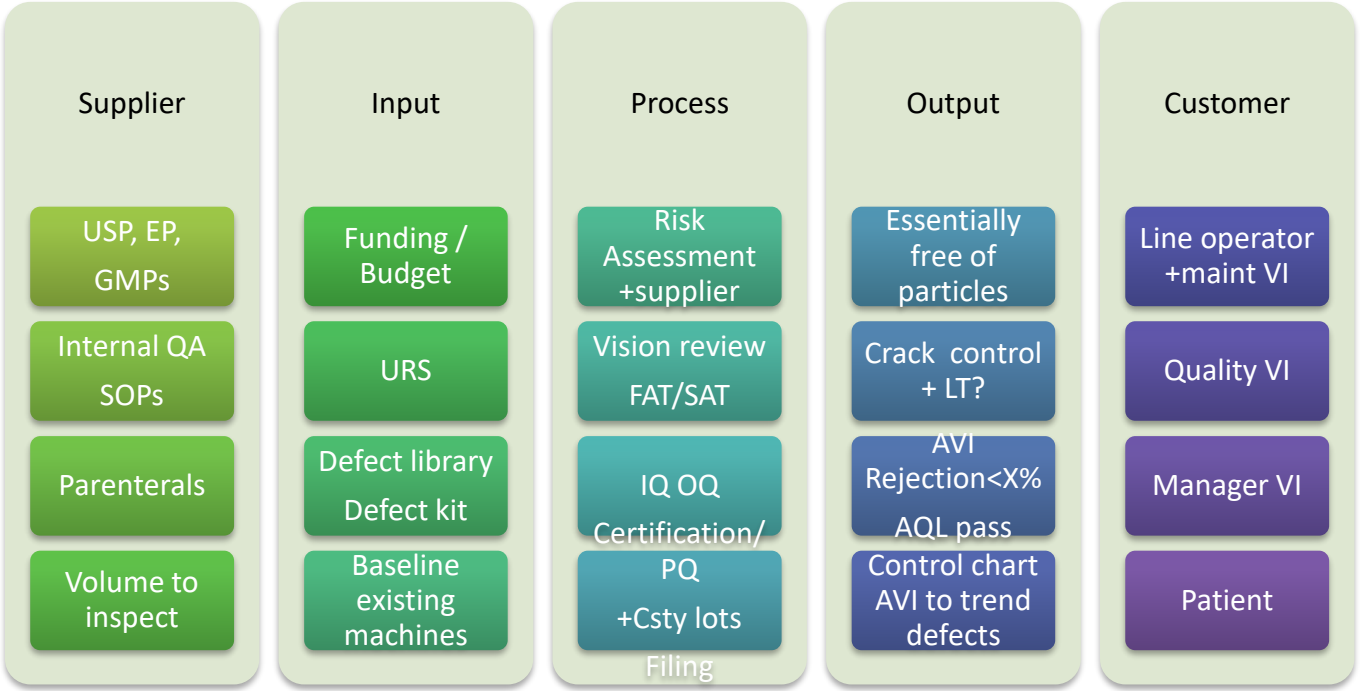
➔ Need to build a Business Process Mapping

Business Process Mapping





- Need for SIPOC before Deep Dive into details



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

Integration into existing process

Product behavior

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

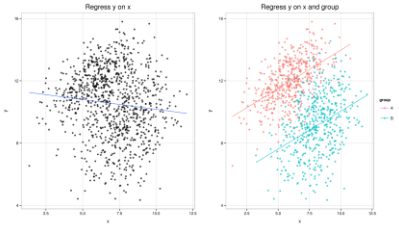
AVI in general

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

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 known

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

Considerations when Selecting

There are only few mayor machine suppliers

Your URS and engineering specs are the basis

- The machine supplier must meet these requirements / time /Cost
- 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

Total Cost ?

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?
  - Total Cost of Ownership
  - Ressources on project to secure planning

Mechanical you can get everything

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

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
- Certification by geographic area Eur / US / Can / JP …..

Cameras/LEDs

- Innovation vs long term solutions

Machine supplier guaranties

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

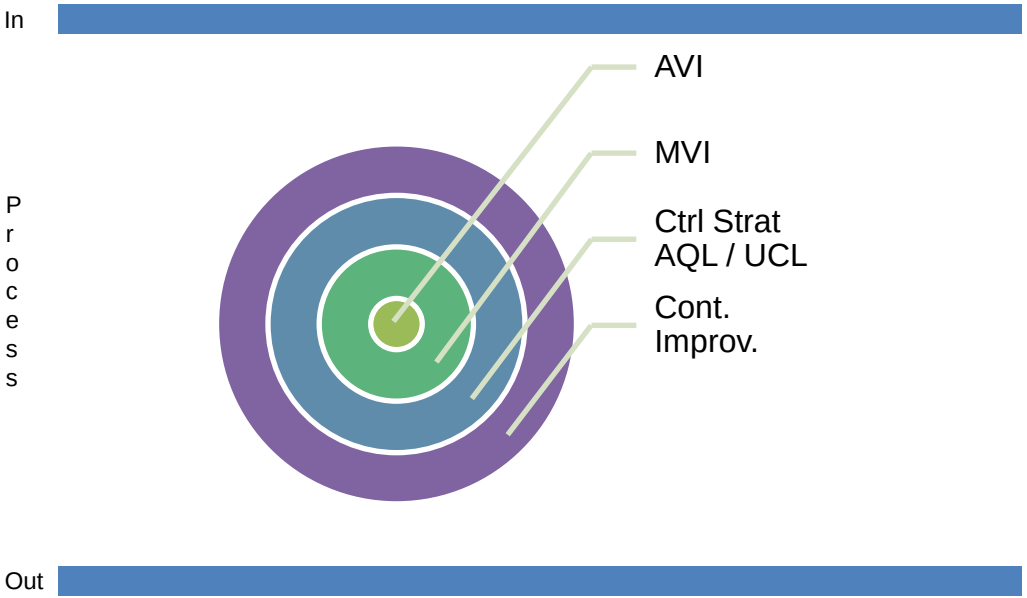
Supplier decision matrix

- ❑ **Technical & Engineering Design**
- ❑ **Performance**
- ❑ **Automation**
- ❑ **Quality**
- ❑ **EHS Process Safety**
- ❑ **Commercial - Support**

Why a Business Process Mapping ?

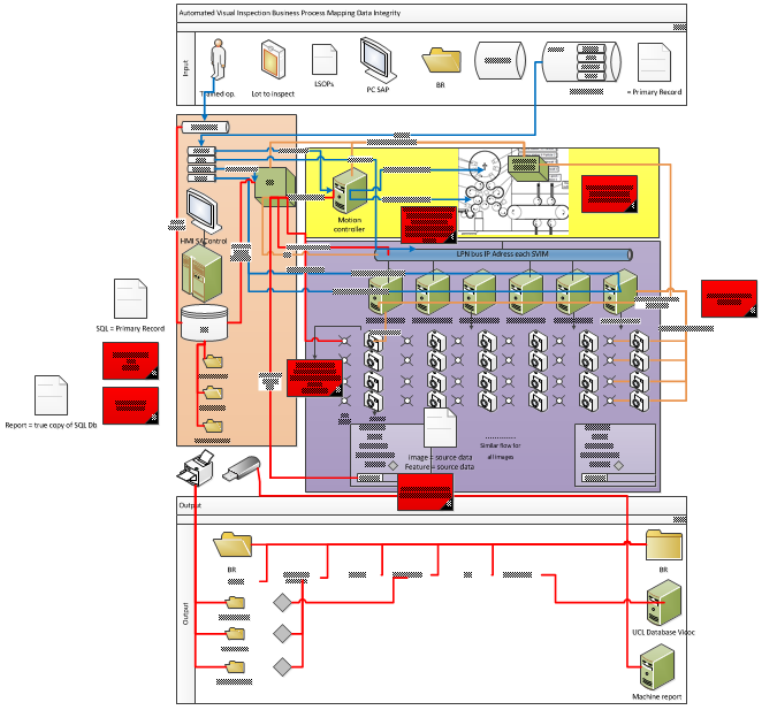
Mapping of information flow

Focus VI entire Process not only AVI equipment



Business Process Mapping

- …. And move forward to elaborate a fully transparent flow of information inside AVI



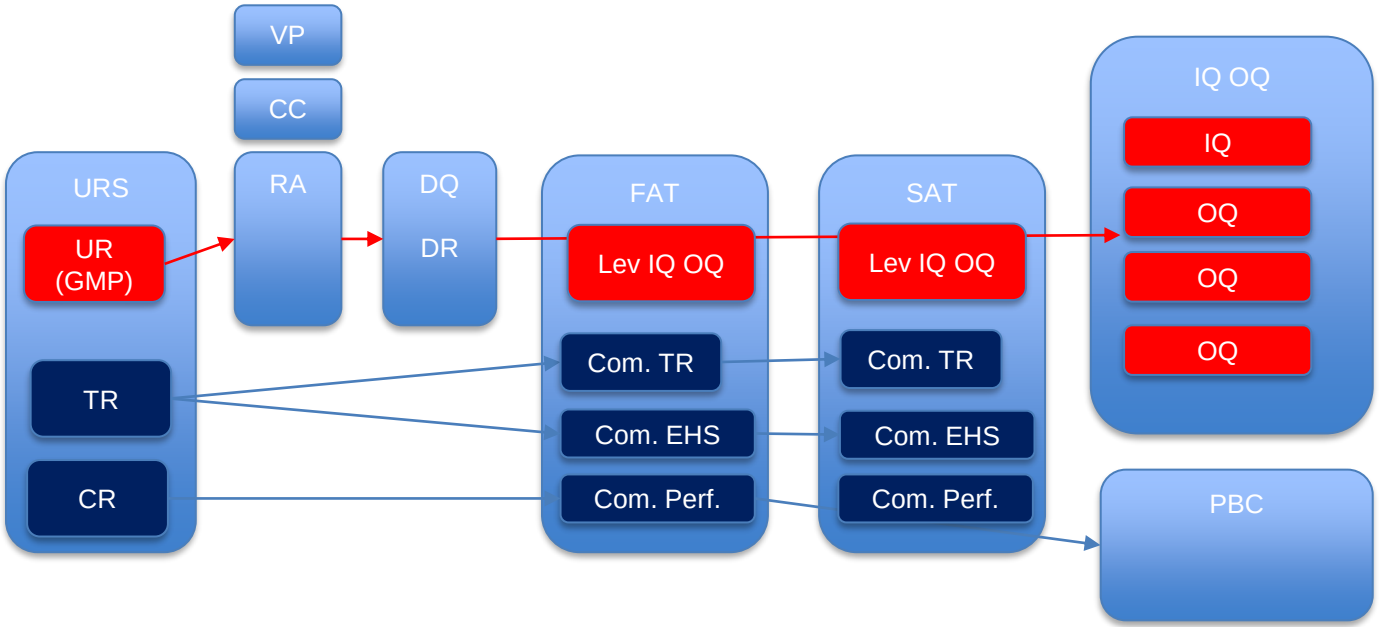
Automation

Mechanic

Vision

Still a V Model ? => No

Qualification Path with QbD



Key learning: GSK new validation framework puts strong effort on initial RA and DQ
IQ OQ test must only mitigate risk identified during RA no additional test must be done if not critical

IQ OQ test must only be driven by RA and GMP UR

Why Risk Assessment is key?

Process System Risk Assessment

1. Divide the process is sub process steps
   - ✓ Pre requisite
   - ✓ Warehousing
   - ✓ Handling unit Deconditioning
   - ✓ AVI
   - ✓ Leak Testing HSA
   - ✓ AVI control strategy
   - ✓ Handling unit reconditioning
   - ✓ 2 nd stage
   - ✓ MVI Control Strategy
   - ✓ End of operations

- Unit presentation to camera by mechanical handling
- Unit presentation to camera with product rotation
- Unit presentation to camera with glass & product dependent parameters
- Refeed transport mode
- Lightning to camera
- Image acquisition
- Digital Image Processing
- Result transfer to shift register
- Physical unit ejection
- Inspection result archiving (SQL)
- Functional test kit, after operations
- Batch closure and local report creation
- Central reporting & archiving

Risk Assessment

Identify CQA CPP and Critical Design Elements

✓ **Some CQAs for VI**

Atributes						
CQA	**CQA**	**CQA**	**CQA**	**CQA**	**CQA**	**PA**
Identity	Essentialy free of glass Defect/Particles/Stopper defect/Closure defec. fill level/Empty/Lyo defect	Leak absence	Container Integrity	Stength, Potency	Potency (sheer stress)	Equipment Performance

✓ **If at least 1 CQA is impacted the parameters becomes a CPP**

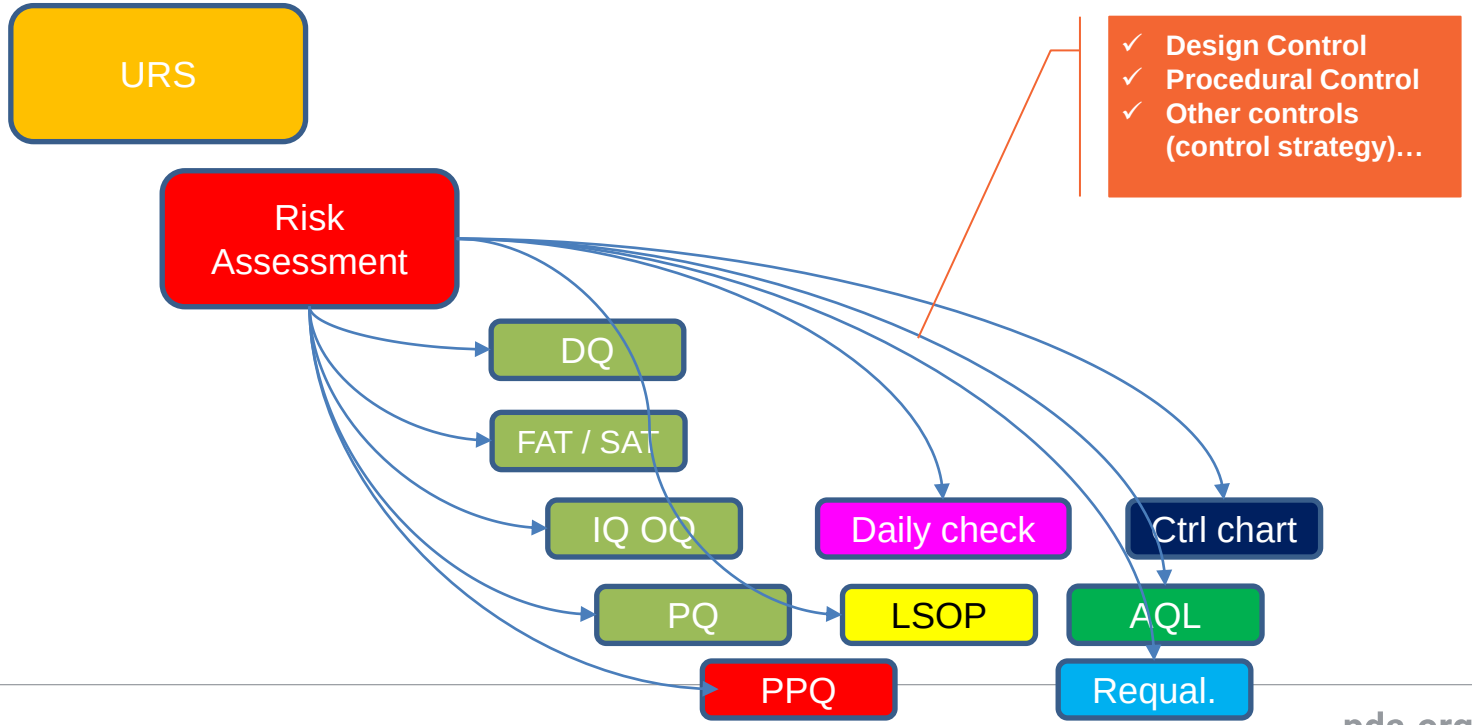
✓ **Data criticality has to be evaluated**

Risk Assessment

Identify the risk (unwanted event / cause / consequence) Example

Phase 1 : Process Analysis				Phase 2 : Risk Identification & Evaluation		
				Unwanted events		
#	Process Step	Process Sub-Step/Description	Parameter or critical aspect	Unwanted event description	Because of	With the consequences
1	Prerequisite	Set up AVI recipe loading	Recipe name and versioning choice for all sub-config (motion, light, handling, image processing), and product	Wrong selection of recipe parameters	Previous recipe available for selection	Use of wrong parameters for lot inspection

Risk Ass. can mitigate risks in multiples pathways : not only IQ OQ PQ

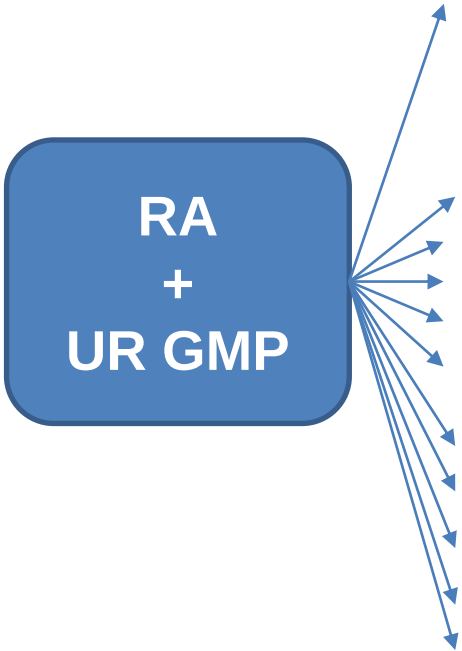


Risk Assessment: Risk control

- ✓ Design Control
- ✓ Procedural Control
- ✓ Other controls

Phase 3: Risk Control Strategy							
To draft during URS and finalize in DQ							
To avoid occurrence		To limit impact		To increase detectability		Justification / Comment	Critical Design Element / Function
Type	Description	Type	Description	Type	Description		
Design	In production mode only validated recipes can be loaded. Previous version of recipe are present but not visible to the operator in production mode. Copy of parameters from an old recipe using configuration mode is allowed on not validated product.	Other	Not applicable	other	Not applicable		Only validated recipes can be loaded in production mode

Design your qualification:



Installation Qualification

- **Documentation verification , component data verification, drawings, system Installation verification , utilities, Software and IT verification**

Operational Qualification

- **HMI Layout verification**
- **Alarms verification**
- **Screen navigation, access verification, security verification**
- **ER/ES verification (electronic Records and signatures)**
- **MES (Manufacturing Execution System) server communication**
- **Backup / Restore and disaster recovery**
- **Containers handling**
- **Counters and cells control**
- **VI critical parameter control (baseline)**
- **Recipes version verification**
- **…….not exhaustive list**

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

⇒ All key ressources are at supplier site Do not postpone

Key take away:

- In this section you have learnt:

URS	Risk Assessment
	UR / Eng. spec. / Contracts
	Cost-Benefit / Patient / Delivery
	Silos vs Holistic URS
	Need for SIPOC / Business Mapping
	Other considerations