• Evolution in the scope of supply.

• CIP&SIP integration into Scada Supervisor.

• Differences between URS and final design, different examples.

• New hybrid systems.

• Interfacing issues with customer systems.
“Once upon a time, there were an engineering company that now becomes a process-supply company”
Evolution in the scope of supply

ASEPTIC PROCESS
For filling lines

VIAL WASHER
DEPYROGENATION
TUNNEL
VIAL HANDLING
RTU

VIAL MANAGEMENT

AUTOMATION MANAGEMENT

ENVIRONMENT MANAGEMENT

PRODUCT MANAGEMENT

DECONTAMINATION TECHNOLOGIES
ENVIRONMENT MONITORING
ISOLATION TECHNOLOGIES

LIQUID PRODUCT FILLING CIRCUIT
FREEZE DRYING PROCESS

CFR 21 PART 11
GAMP5
LINE SUPERVISOR

PROJECT MANAGEMENT

Connecting People, Science and Regulation®
Why the interface with Isolator is different?

Process point of view (WIP-CIP-VHP-SIP)

Mechanical point of view
Evolution in the scope of supply

Old typical solution

Current typical solution

Increasing request to integrate the scope of supply into the filling machine CIP&SIP skid, moving also the sterility battery limit.
CIP&SIP integrated into Scada of the filling line. Interface with customer MES. In case of supply, possibility to integrate also:
- Preparation vessels
- CIP skid
Normally what is required in URS is different from the customer need.

- **URS requirements** → **Technical alignment** → **First P&ID**

- **Kick off meeting** → **New requirements** ↔ **Technical solutions** → **Final P&ID**

**TIME LINE**
Example 1

The product transfer line from sterile tank to filler shall be designed for an automatic CIP and SIP process with integration with the site Sterile Filtration System. The fill design shall include the required interfaces (mechanical, electrical, plumbing) within the system boundary.
During technical alignment:

CIP&SIP of filling machine is part of compounding system CIP&SIP.

The two systems have to work together with a “strong” software interconnection.

It’s not possible to test it during FAT but only on site.

The compounding and utility systems have to be available for several weeks of testing.

During kick off meeting:

Compounding will not be available, the two systems have to be independent.

Utilities management at customer care.

One product filter close to filling machine.

IT pre-production and WIT.

Conductivity meter + waste water sampling valve.

Temperature probe inside tank.
Differences between URS and final design, different examples

Example 1

- Flushing with product or WFI?
- Flushing to drain or tank (E&L)?
- First filter or redundant filter?

Confirmed with Product
- Flush to tank (small volume)
- Confirmed redundant filter
Differences between URS and final design, different examples

Example 1 (appendix product filter)

Unless otherwise stated in the URS, the filter cartridge is the sterile barrier. To make a correct wetting it is necessary to “purge“ from the upper side of the filter.
Example 2

ID ***

| Filler shall have the ability for continuous circulation and/or mixing of suspension products to avoid sedimentation in the product line |
Differences between URS and final design, different examples

Example 2 (appendix suspensions)

1. Long sedimentation time
   - «Not heavy» suspension
   - Easy to re-suspend after stops
   - Does not require constant turbulent flow for movement

2. Medium sedimentation time
   - «Medium weight» suspension
   - Long time to re-suspend it
   - Cannot stay stop before dosing system

3. Fast sedimentation time
   - «Heavy» suspension
   - The turbulent flow cannot re-suspend it
   - Has to remain always in turbulent flow
Differences between URS and final design, different examples

Example 2 (appendix trolley storage tank)
Example 2

During kick off meeting:

- Heavy suspension.
- Conductivity meter.
- Utilities unit.
Example 1

CIP&SIP system interfacing with peristaltic pump technology and predisposition for future volumetric pump technology.

Cytotoxic products.
New hybrid system
Combination between Single Use and Multi Use

Example 1
**Example 1**

**REASONS:**
- Multi-use compounding system.
- Utilities distribution already present.
- Requirement from customer to reduce SUS components.
- “Shear effects“ with differential pump technology for main product.

**ADVANTAGES:**
- CIP&SIP and Isolator Processes fully independent.
New hybrid system
Combination between Single Use and Multi Use

Example 2

- CIP&SIP system interfacing with a Single Use Redundant Filtration assembly SURF (support frame at IMA care).
- Utilities management.
- Conductivity meter.
- Toxic product.
- WIT in line.

The advantage is related to the possibility to use a single vent and utilities hydrophobic filter.

Connection required with Lynx-ST.
Example 2

Possibility to perform IT and flushing (E&L) off line.
Possibility to connect SURF immediately before production.
During kick off meeting:

Single use filling system with peristaltic pump technology.

Conductivity meter with by-pass for detergents.

Sampling valve for waste water.

Dedicated drain first rinse.

Double venting filtration.

Management of trolley storage tank and floor scale.

Transfer by overpressure or peristaltic pump.
Example 2

Usually customers forget the “encumbrance“ of a SURF assembly in the first line layout evaluation.
IMA needs some information when the customer is still defining them:

- **DRAIN INTERFACES**
  - Air Break or pass-through?
- **INTERFACE WITH WFI POINT OF USES**
  - Air flushing or SIP?
- **INTERFACES WITH COMPOUNDING SYSTEM**
  - Interconnected sequences?
- **POINT OF USE VALVE**
  - Managed by IMA or customer?
Thank you for your attention!

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