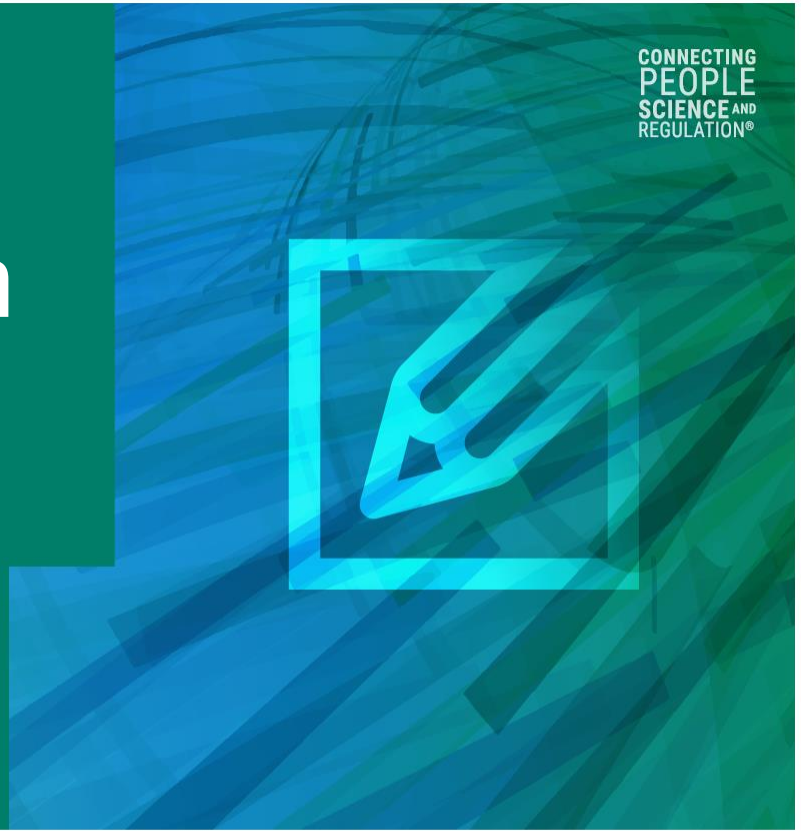
Pneumatic CCIT – Process safety from Lab to Production

WILCO AG



PDA Parenteral Drug Association

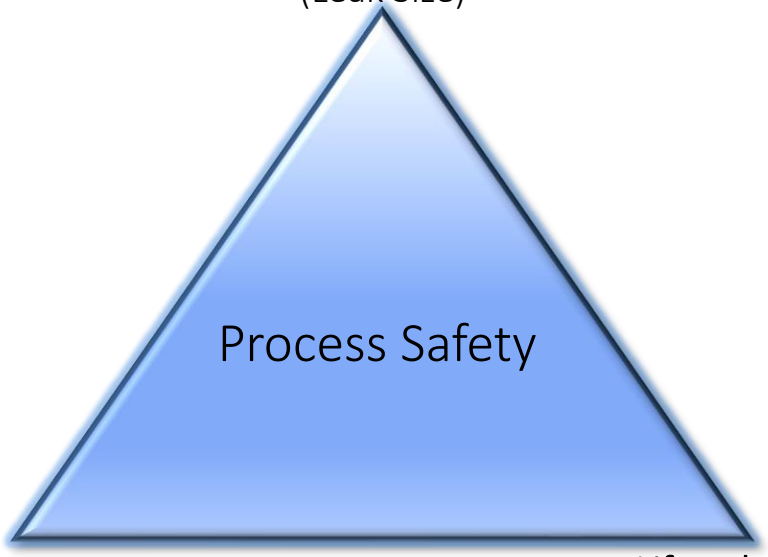
PDA TRAINING

Agenda

1. CCIT Key Requirements
2. Recap Pneumatic CCIT
3. Case Study PFS for autoinjector
4. Benefits + Summary

CCIT Methods – Key Requirements

Sensitivity
(Leak Size)



Flexibility
(Packaging / Product)

Lifecycle transfer capability
(Package Development -> IPC -> Production)

Recap Pneumatic CCIT technologies

Vacuum decay

- **Application:**
  - Primary packaging with dry content like powder or lyophilizates
- **Working principle:**
  - Pressure in test chamber is lowered to pre-defined level
  - In the presence of a leak, gas flows from the container into the test chamber
  - Differential pressure inside the chamber indicates a leak

Recap Pneumatic CCIT technologies

LFC method®– The advanced vacuum decay method

- **Application:**
  - Primary packaging with liquid contents that allow vaporization
- **Working principle:**
  - Gas around the container is evacuated to 5mbar absolute pressure
  - In the presence of a leak, gas flows from the container into the test chamber
  - Liquids covering a leak vaporize and generate a pressure increase
  - Differential pressure inside the chamber indicates a leak

Recap Pneumatic CCIT technologies

Pressure decay Differential pressure for highest sensitivity

- **Application:**
  - Primary packaging with liquids that don`t allow vaporization

- **Working principle:**
  - The volume around the container is pressurized with filtered air at a certain pre-defined pressure level
  - In the presence of a leak, gas from the outside of the container flows into the container
  - The decreasing pressure inside the chamber indicates a leak

Pros and Cons of pneumatic CCIT

Pros

- Quantitative determination of leakage
- No modified headspace required
- No conductivity of liquid required
- High sensitivity
- Entire container is tested
- Applicable for liquid and lyo products
- No impact on product
- Applicable for alcohols
- Wide range of applications and sizes
- Combination of technologies possible

Cons

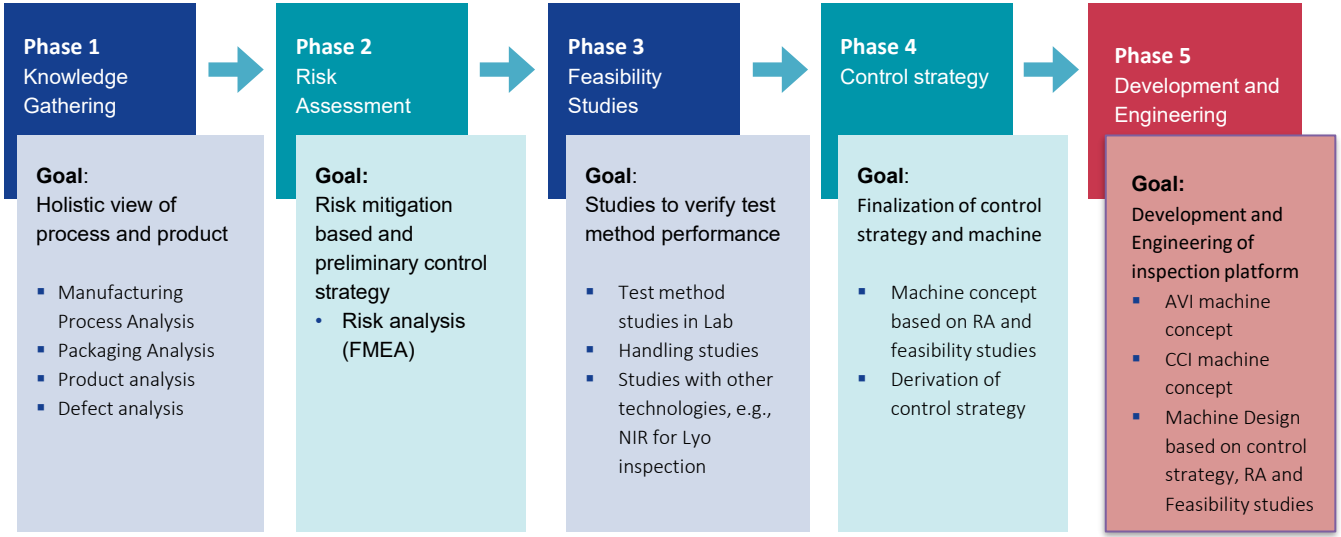
- Gas flow required at point of testing
- Clogging effect needs to be considered
- (Not all products may be vaporized) – LFC method®

Pneumatic CCIT – Packaging / Product Matrix

						
Liquid						
Low fill volume	✓	✓	✓	✓	✓	✓
Oily products	✓	✓	-	-	-	-
Water based	✓	✓	✓	✓	✓	✓
Non-conductive liquid	✓	✓	✓	✓	✓	✓
Flamable liquids	✓	✓	✓	✓	✓	✓
w/ modified HS	✓	✓	✓	✓	✓	✓
w/o modified HS	✓	✓	✓	✓	✓	✓
Sucrose	TBD	TBD	TBD	TBD	TBD	TBD
High protein content	TBD	TBD	TBD	TBD	TBD	TBD
Thermally sterilized	✓	✓	✓	✓	✓	✓
Powder						
w/ modified HS	✓	✓	-	-	✓	✓
Lyo						
w/ modified HS	✓	✓	-	-	✓	✓

Case Study: Solution Design Process

In 5 phases to the solution design



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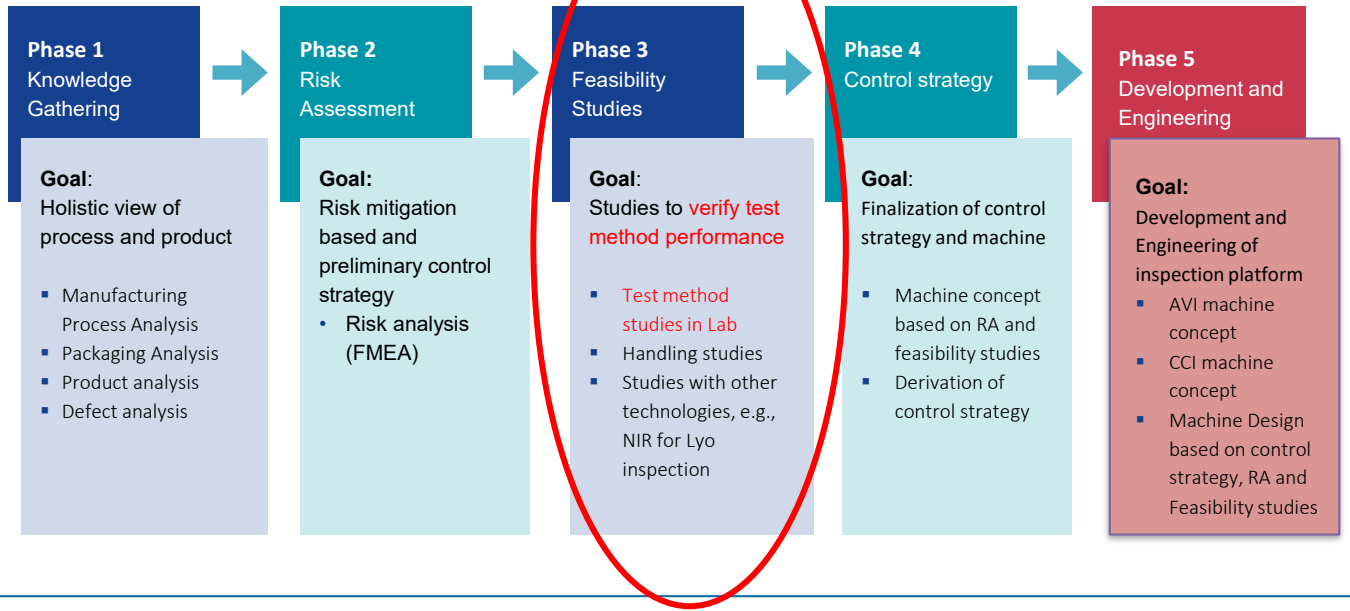
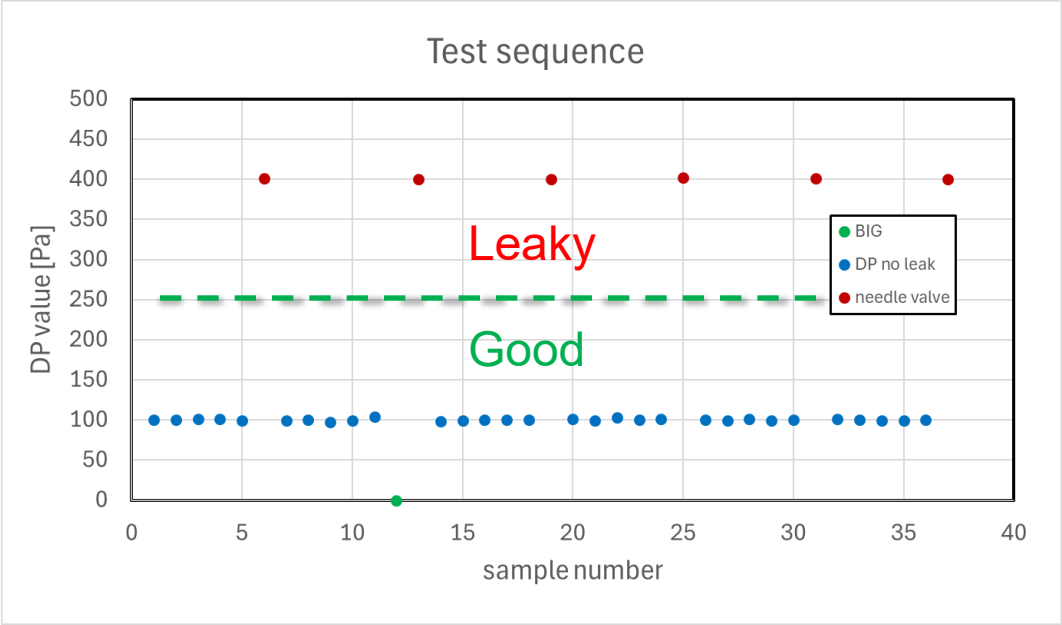
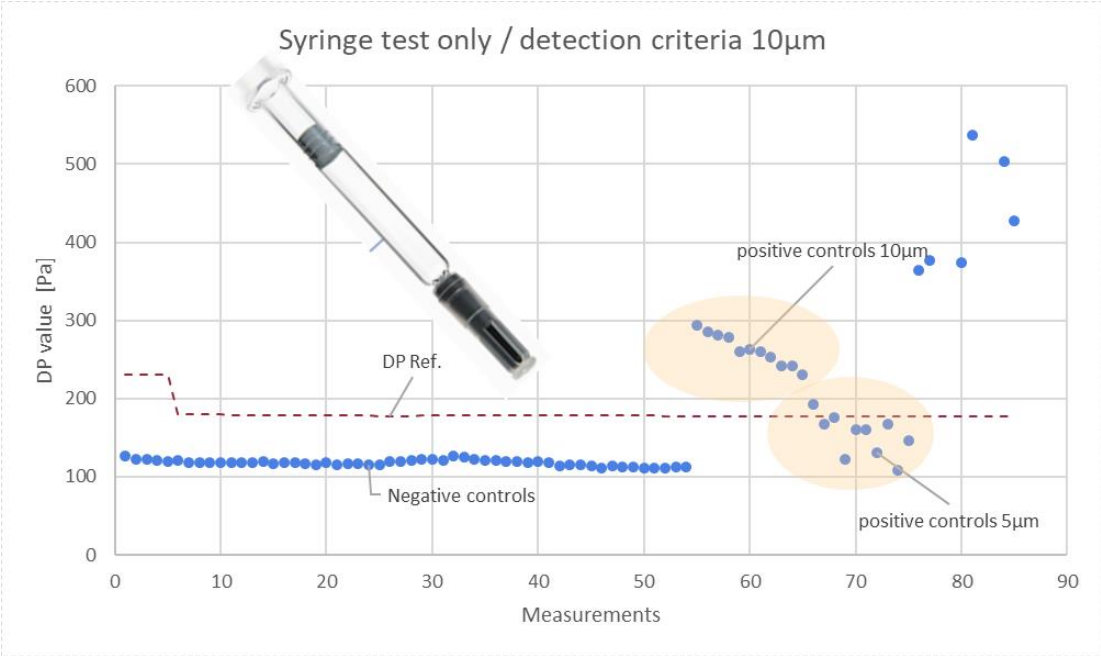


Recipe development – build in functions

- **Recipe development:**
  - Use 30 good samples
- **Testing sequence:**
  - 5 good samples
  - one of the 5 with needle valve
  - repeat sequence with 5 new good samples
  - All recipe parameters can be derived from the results of this sequence



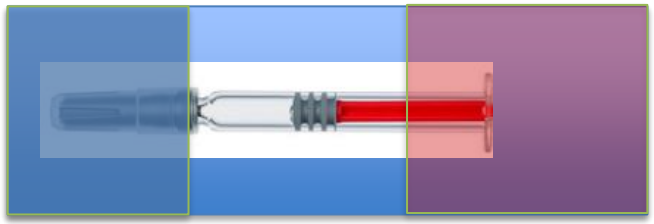
Method development – positive samples for validation



PFS positive sample for method validation

A quick glance at devices

Device
(for example auto injector)



Actuator
(spring, mechanics, ….)

Stopper position vs. plunger rod (+ mechanism)

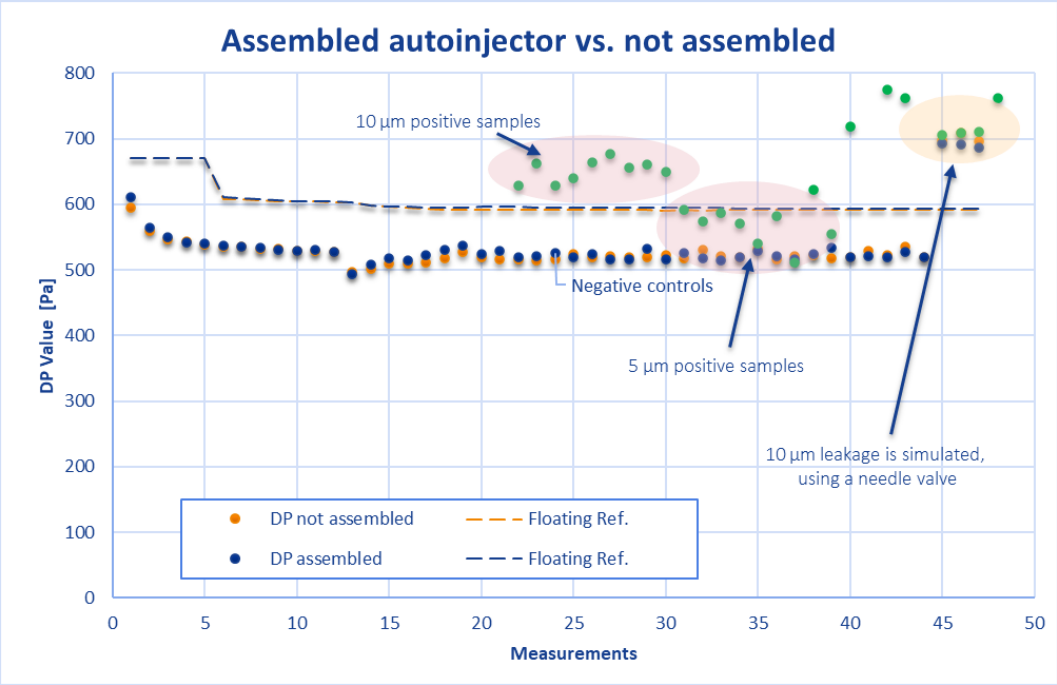
Design:

- Give some mechanical play to compensate for production tolerances

Testing:

- Stay within sterile zone
- Consider stopper movement during CCIT (-> feasibility study)

Case study lab testing: Ypsomed autoinjector

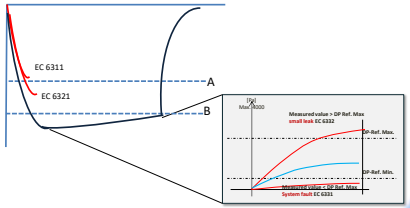


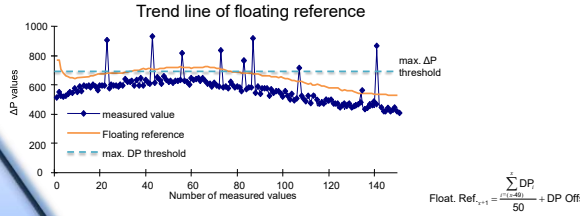
Assembled autoinjector

Disassembled autoinjector (PFS inside)

Pneumatic CCIT - Key Benefits & Summary

Sensitivity





A perfect fit for many container / product combinations

Flexibility

Transfer Lab ⇒ Production

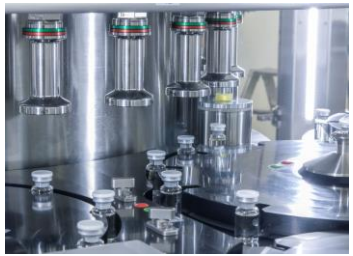
Pneumatic CCIT – The most flexible inspection technology

IV Bags

Pouches

BFS ampoule cards

BFS bottles



Vials and ampoules for parenterals

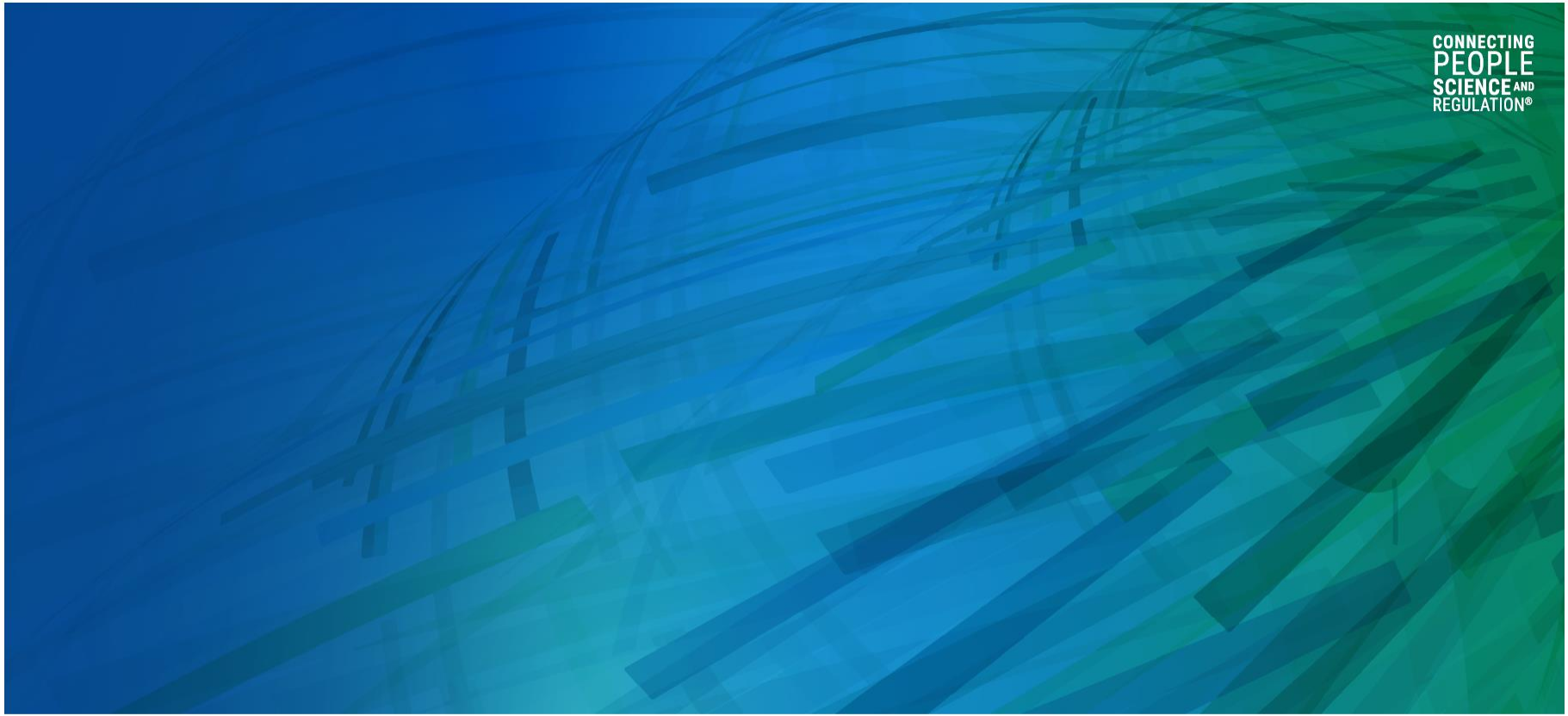
Dropper bottles, 3-piece containers

Primary container of combination product

Prefilled Syringes

Wilco - Product categories

Life Science & Pharma



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