

# Pneumatic CCIT – Process safety from Lab to Production

WILCO AG

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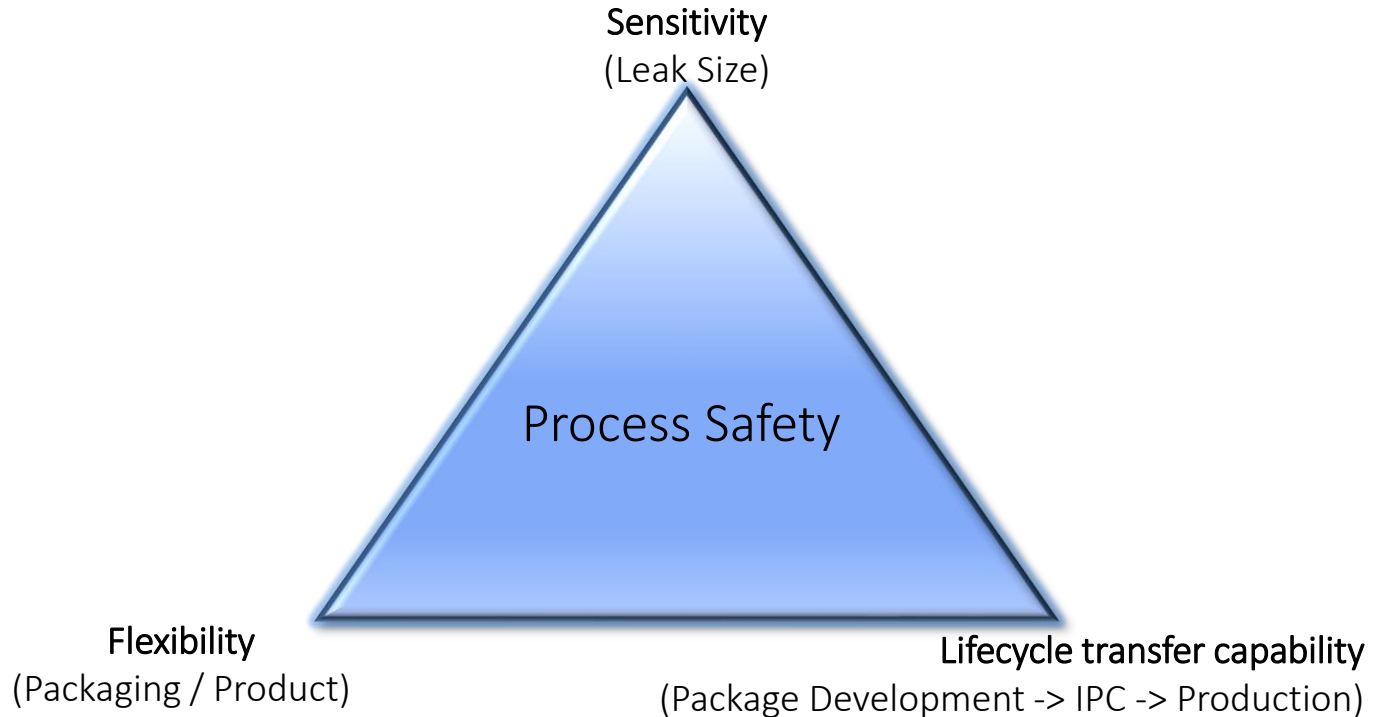


PDA  
TRAINING

# Agenda

1. **CCIT Key Requirements**
2. **Recap Pneumatic CCIT**
3. **Case Study**
4. **Benefits + Summary**

## CCIT Methods – Key Requirements

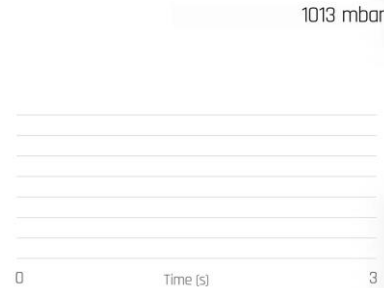


# Recap Pneumatic CCIT technologies

## LFC method<sup>®</sup>- 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

Test pressure

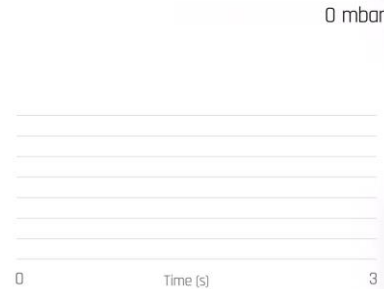


# Recap Pneumatic CCIT technologies

## 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

Test pressure

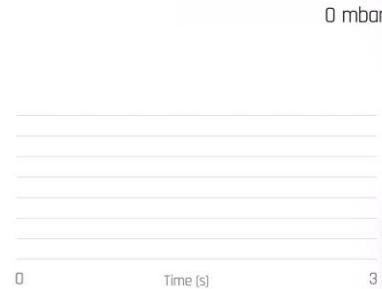


# Recap Pneumatic CCIT technologies

## 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

Test pressure



## 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

						
<b>Liquid</b>						
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	✓	✓	✓	✓	✓	✓
<b>Powder</b>						
w/ modified HS	✓	✓	-	-	✓	-
<b>Lyo</b>						
w/ modified HS	✓	✓	-	-	✓	-



# Case Study

## Globaly leading CMO (US)

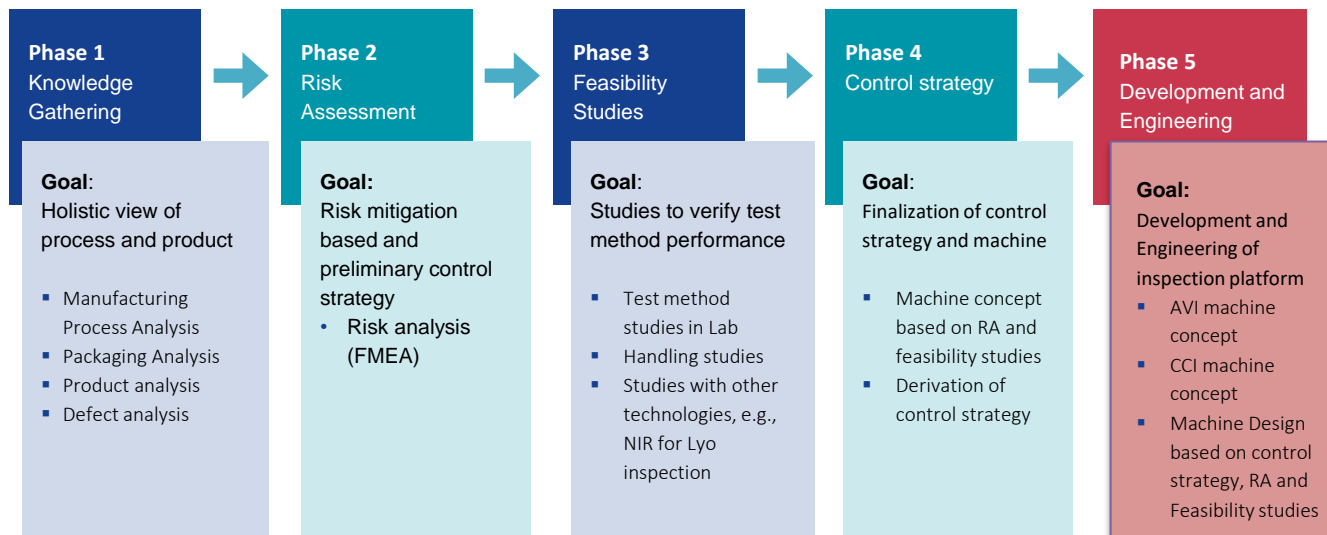
Key criteria: Flexibility, high sensitivity, high speed application

- Container: PFS
- Syringe Dia.: 5 – 15 mm
- Drug Product: aqueous liquid
- Throughput up to 600 c/min
- Sensitivity: 10  $\mu$ m



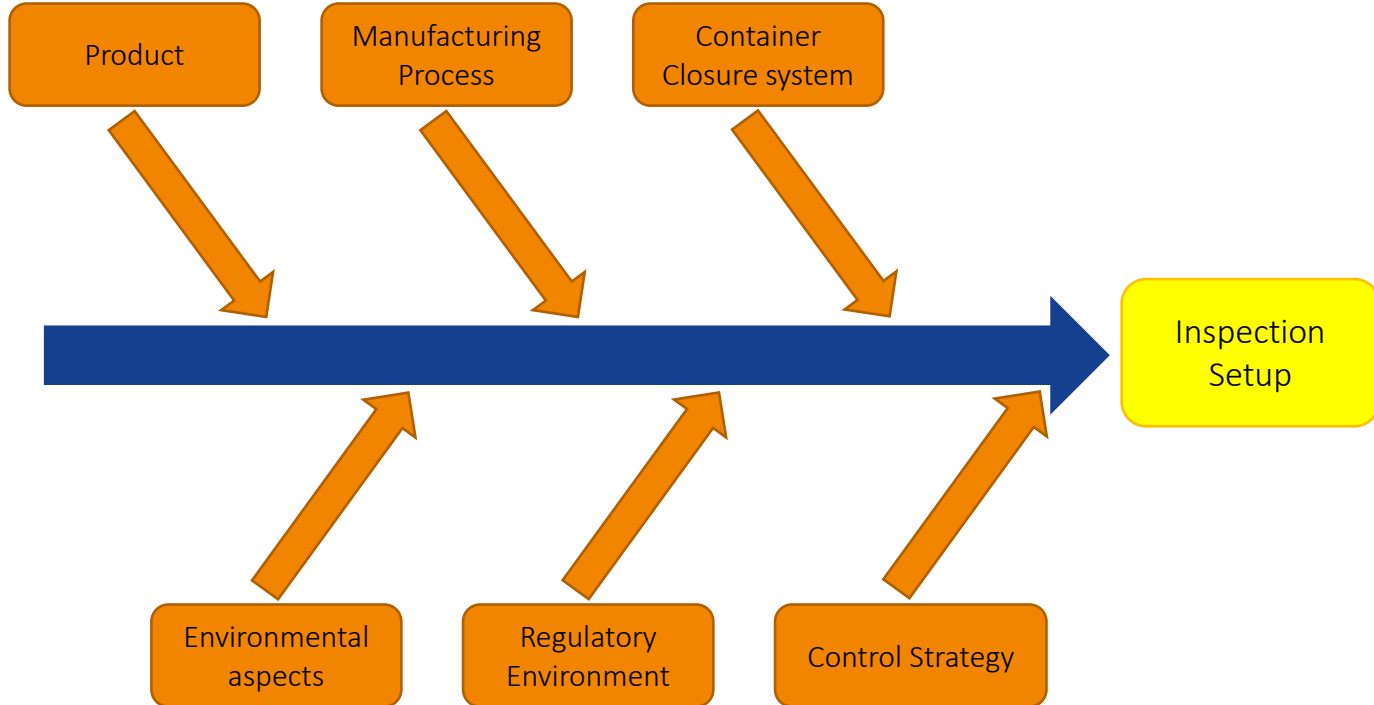
# Case Study: Solution Design Process

## In 5 phases to the solution design



# Case Study

## Method selection and inspection setup



# Case Study

## Check Feasibility - It all Starts in the Lab

### Key features

- Output up to 6 samples/min
- Versatile use in terms of packaging and product types and sizes
- Three DP measuring technologies
- Improved sensitivity of the DP technology
- MAVIS operation system
  - Intuitive HMI
  - Customizable interface by means of widgets
  - Enhanced recipe management system
  - Simplified connection to SCADA/MES systems
- Enhanced batch handling system



# Case Study

## Check Feasibility - It all Starts in the Lab

### NEO DPX



#### 1. Human Machine Interface (HMI)

- 12inch color touch display
- LED status bar
- Customizable widgets
- Process guidance system



#### 2. Differential pressure

- 3 DP measuring technologies
- Sensitivity of  $5.0e-04$  mbar.l/s
- Testing the entire container
- Versatile use with regards to packaging and product types
- Non-destructive test method according to USP 1207



#### 3. Control System & Data Management

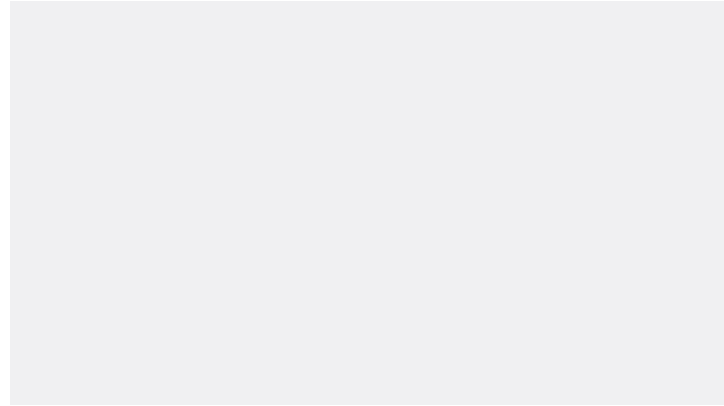
- MAVIS operation system
- 21 CFR Part 11 Compliance
- Integrated PLC, safe logic and IPC
- OPC UA Connection
- Windows 10 IoT
- Crate SDB (SQL based)

#### 4. Sample holder

- Different variants available
- Adjustable to various formats
- Guided change
- Toolfree exchangeable (plug&play)



# Case Study



# Case Study

## Automated leak testing for sterile products: Wilco R DPS

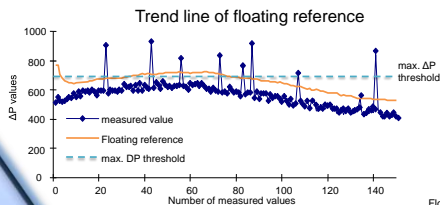
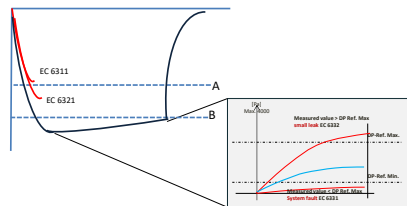
### Key features

- Output up to 600 samples/min
- 100% leak testing of prefilled syringes
- Stopper movement prevention system
- Adjustable gripper for multiple syringe sizes
- Non-destructive test method acc. USP1207
- LFC Method®
- Detectable leak size:  $\geq 10\mu\text{m}$

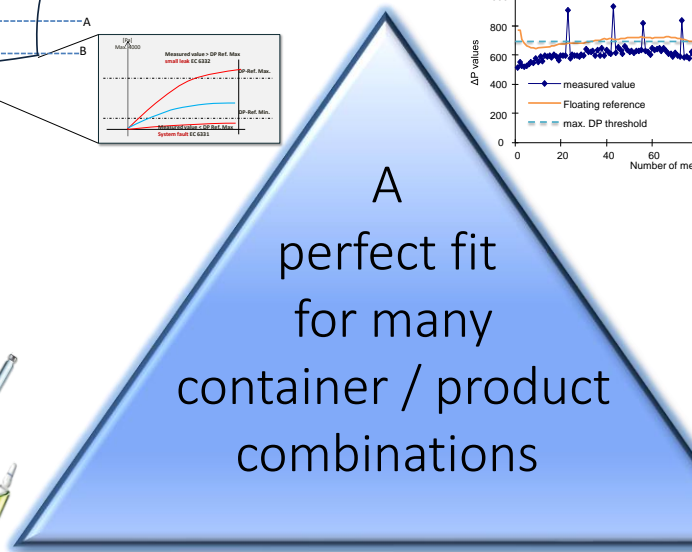


# Pneumatic CCIT - Key Benefits & Summary

## Sensitivity



$$\text{Float. Ref.}_{n+1} = \frac{\sum_{i=1}^n \text{DP}_i}{50} + \text{DP Off}$$



## 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



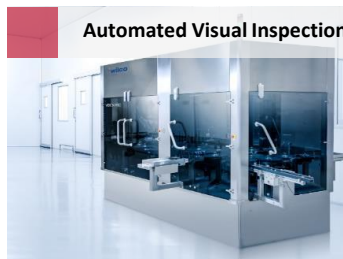
Primary container of combination product



Prefilled Syringes

# Wilco - Product categories

## Life Science & Pharma



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