

Pneumatic CCIT – Process safety from Lab to Production

WILCO AG

CONNECTING
PEOPLE
SCIENCE AND
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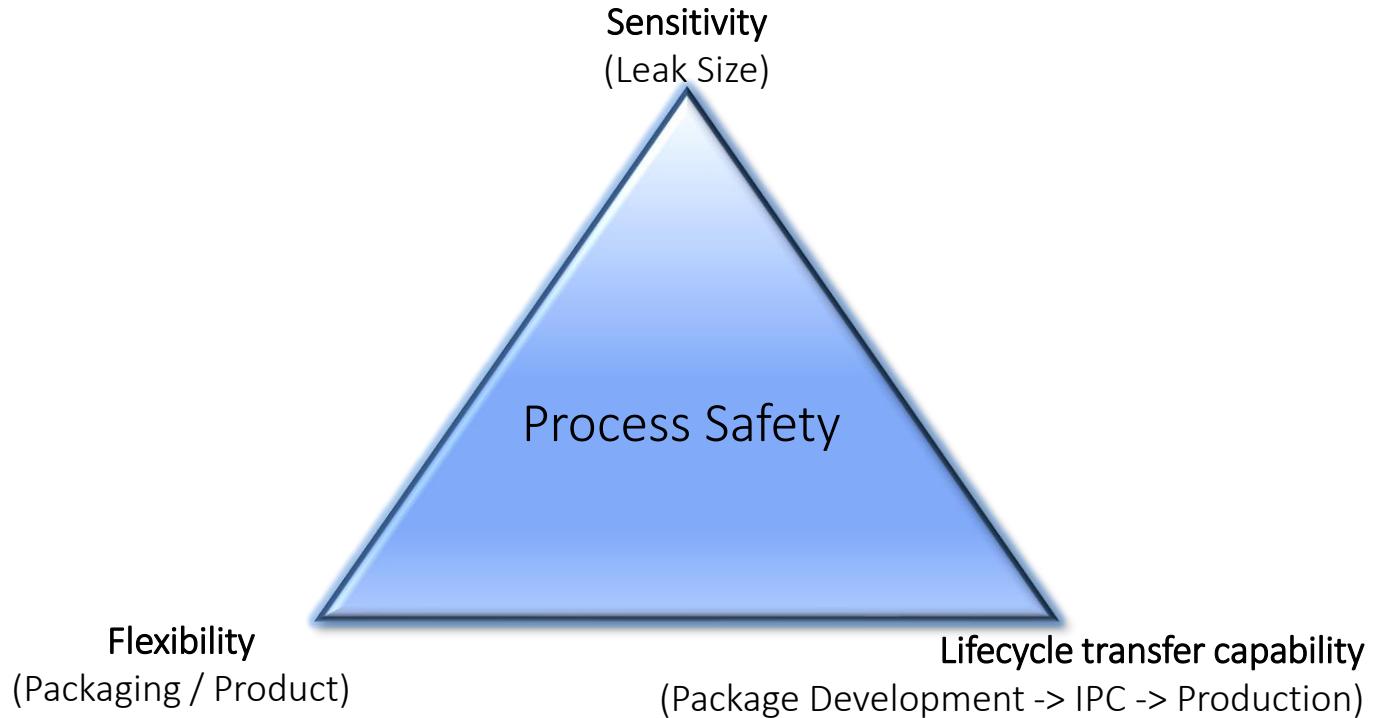


PDA
TRAINING

Agenda

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

CCIT Methods – Key Requirements



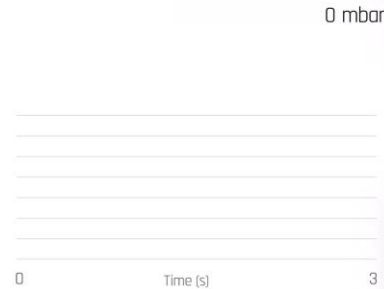
Recap Pneumatic CCIT technologies

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



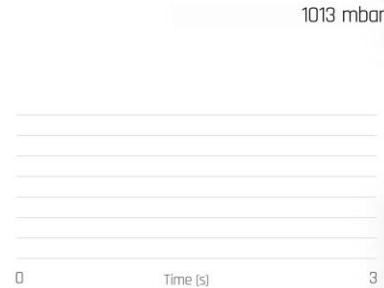
Recap Pneumatic CCIT technologies

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

Test pressure



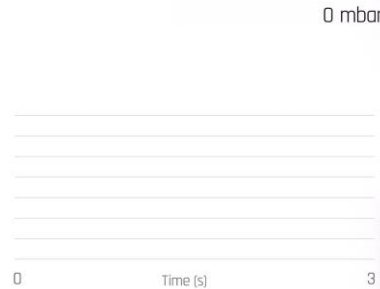
Recap Pneumatic CCIT technologies

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

						
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

Globaly leading CMO (US)

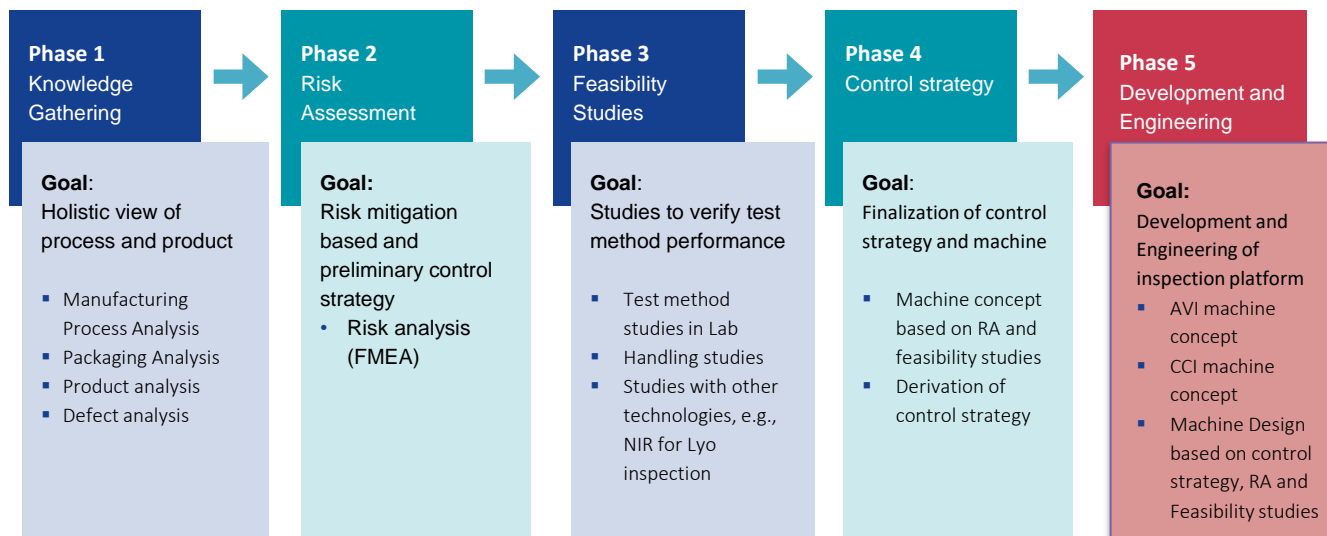
Key criteria: Flexibility, high sensitivity, high speed application

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



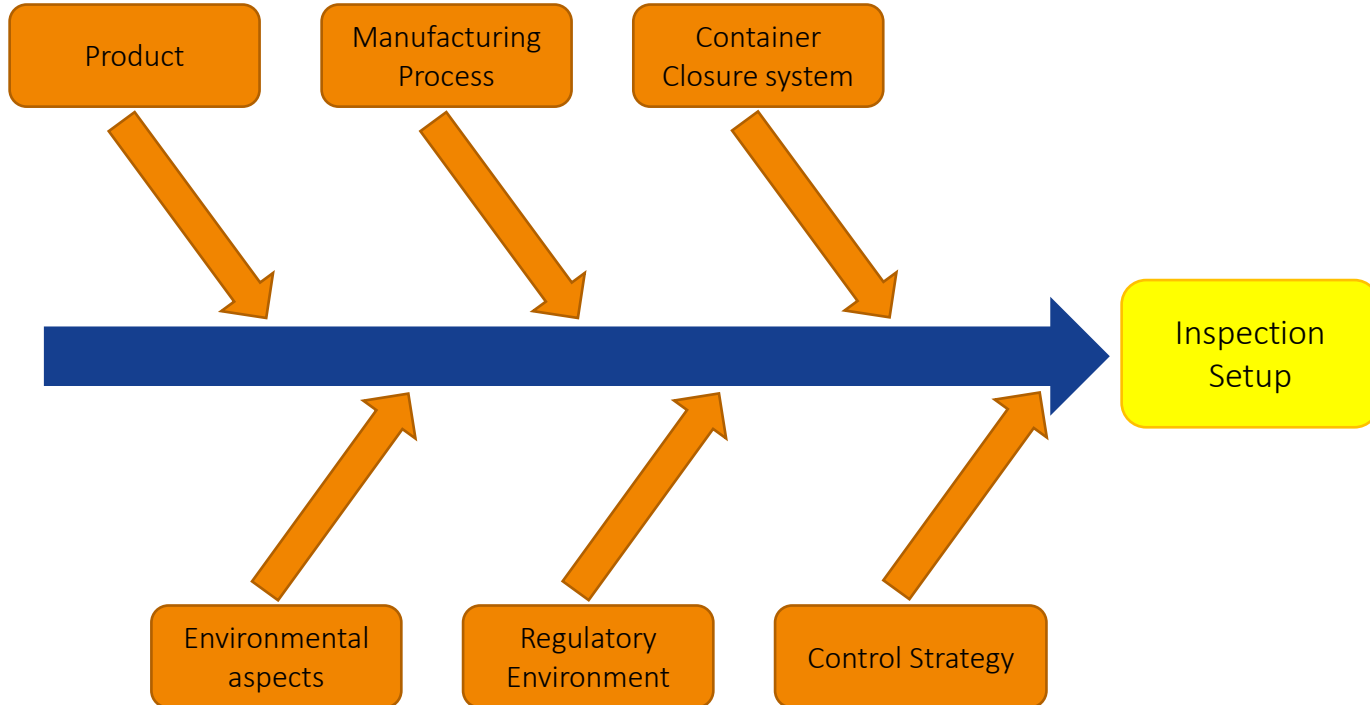
Case Study: Solution Design Process

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

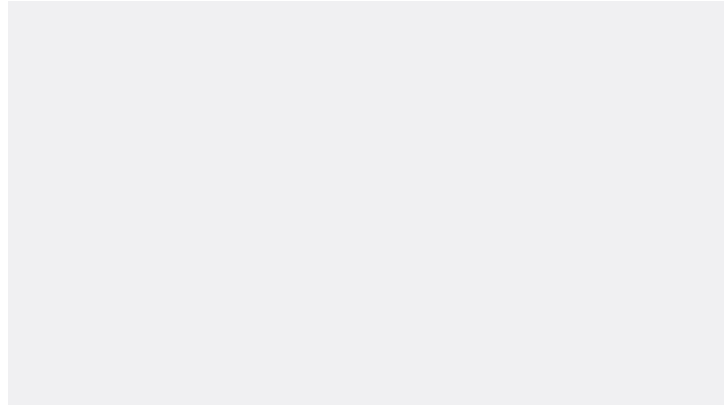
- MAVIS operation system
- 21 CFR Part 11 Compliance
- Integrated PLC, safe logic and IPC
- OPC UA Connection
- Windows 10 IoT
- Crate SDB (SQL based)

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

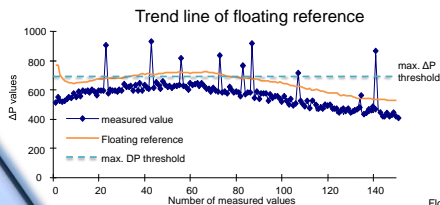
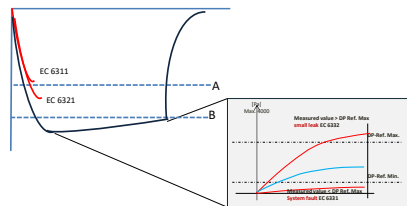
Key features

- 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



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

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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