ISPE Pharma Best Practices Webinar Series

Driving Patient Safety, Production Efficiency and Quality In Parenteral Manufacturing Through The Use Of Container Traceability

Tuesday, 26 January 2021, 1100 – 1200

Webinar Sponsored by:

Stevanato Group

Tod Urquhart
Product Manager and Core Team Leader
Stevanato Group

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Speaker

Tod Urquhart

Product Manager
Stevanato Group

Tod Urquhart has more than eleven years' experience of working in the field of product serialisation and traceability. He has an extensive knowledge of planning, managing and delivering cross functional serialisation projects for pharmaceutical regulatory compliance as well as product interaction and traceability.

Tod is currently the Product Manager and Core Team Leader and Product Manager for the Stevanato Group project which is focused on Primary Container Traceability [PCT]. The project covers product and process development, systems integration across the different pharmaceutical manufacturing steps and the creation of a common standard for the Pharmaceutical industry.

Objectives

- Outline the concept of the unique container and how it adds value to pharmaceutical manufacturing processes.
- How Stevanato Group has been working to make this an open-source solution.

Agenda

1. Concept & value proposition
2. Industry feedback
3. Standards
4. Automated inspection
5. Product availability
6. Summary

Chapter

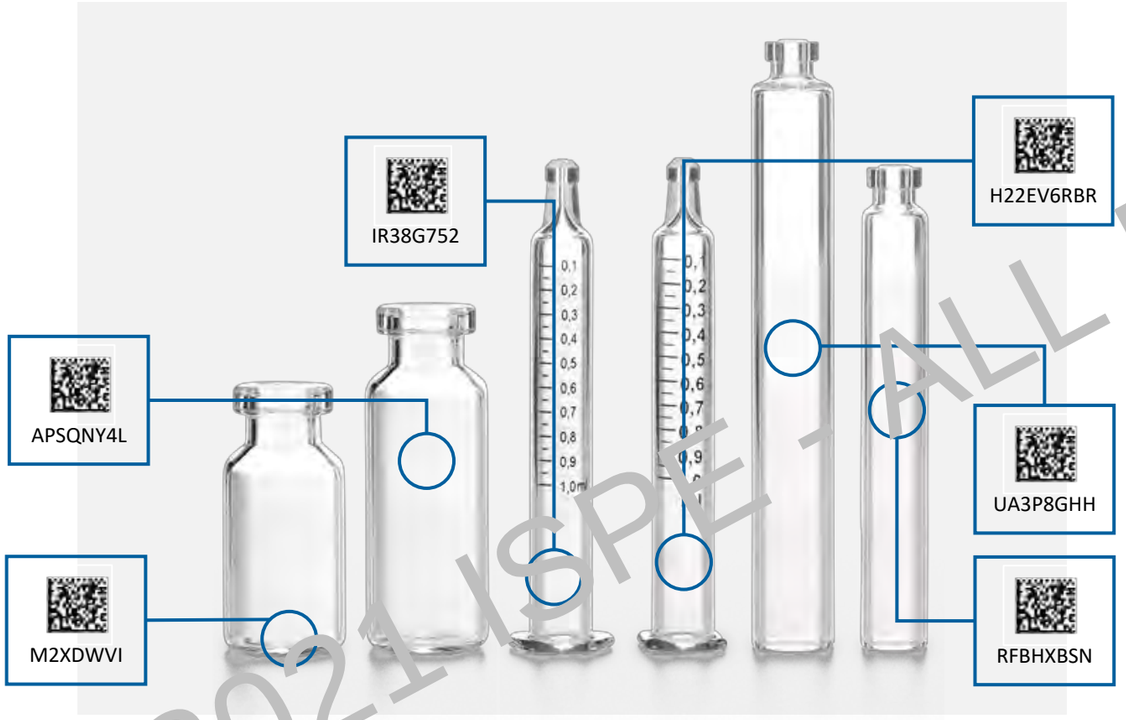
1

Concept & value proposition

Container Traceability - Serialisation Concept

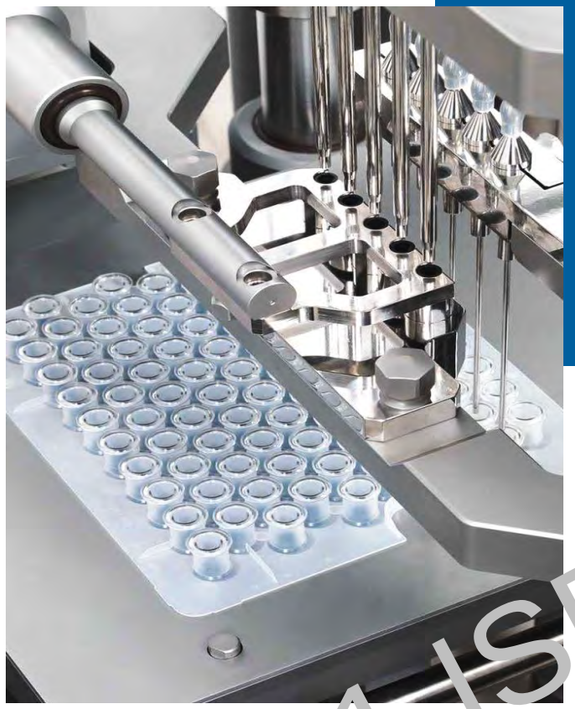
BP39HG72
Serial Number
Unique Identifier (UID)

2D Barcode



Value proposition - Filling & Inspection processes

FILLING



- **Limiting batch segregation processes in the event of a problem in the machine**
- **Mix up avoidance of filled containers**
- Automated of the reconciliation process
- Addition of process parameters to each individual container to provide a detailed manufacturing history

INSPECTION

- Reject cause tracking due to container production deviations
- **Reject analysis by type to facilitate detailed root cause analysis**

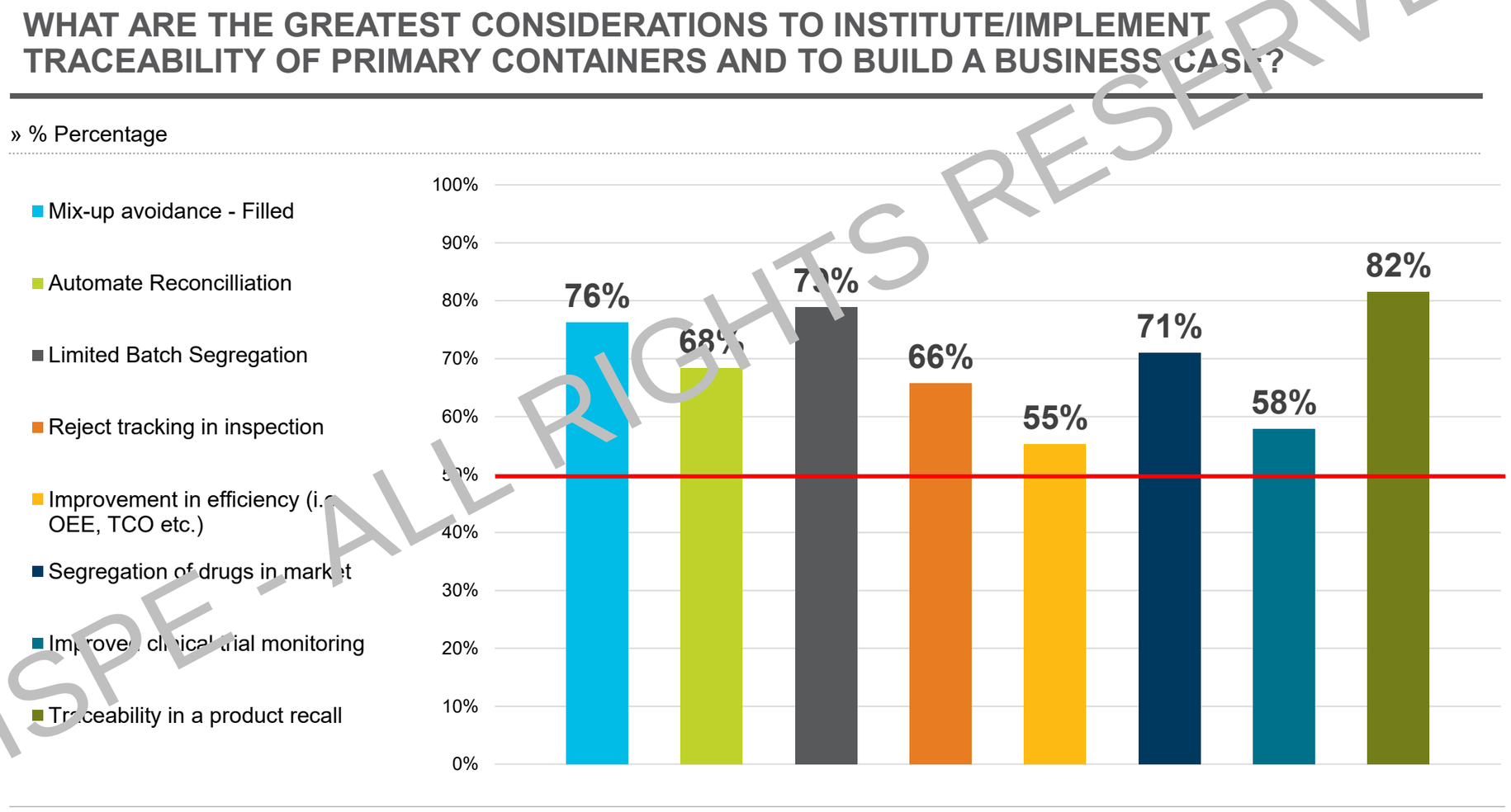
Chapter

2

Industry Feedback

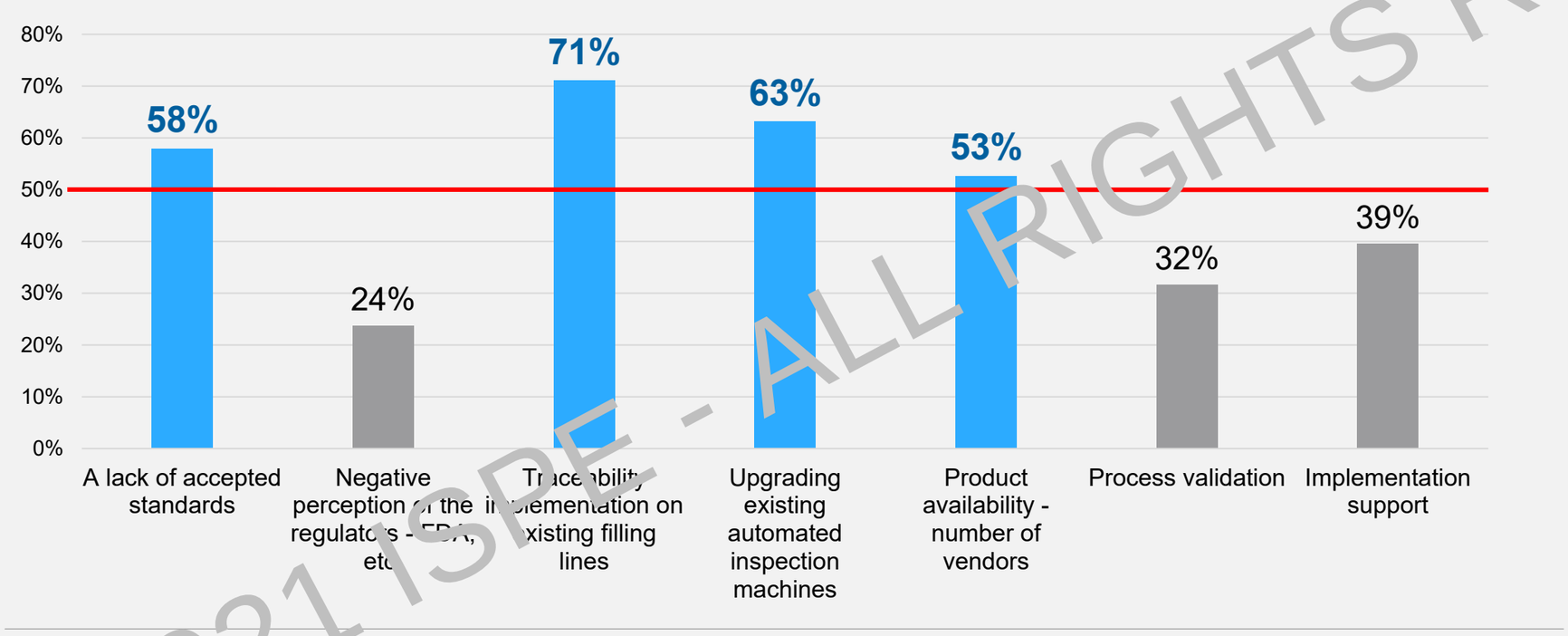
Survey data: Reasons for using marked containers

- There is increased regulatory scrutiny on traceability for manufacturing processes
- High level focus on traceability by most large pharma companies



2019 PDA Traceability of Primary Packaging Survey Published January 2020

Survey data – Key Challenges



2019 PDA Traceability of Primary Packaging Survey – Published January 2020

- The remainder of this presentation will demonstrate how Stevanato Group solution has been designed to work with existing platforms and remove these constraints

Chapter

3

Standards

Solution objectives & standards

OBJECTIVES

- No impact on the container integrity
- Passes all container sterilization processes
- Minimal impact on SG and pharma manufacturing lines
- Minimal impact on inspection machine performance
- Regulatory-compliant serialization platform
- Integration with existing pharma serialization investments – if needed

TESTING

- Readability - Full range of camera systems
- Ink migration study
- Abrasion
- Accelerated ageing
- Stress analysis
- Mechanical testing
- Acid attack test
- EP 2.6.1 Sterility tests or equivalent
- FE-SEM analysis
- VHP Testing

ISPE Guidance Document – Activity & participants

- Working group was established and supported by ISPE. Participants are shown opposite
- The aim has been to create a common industry standard for the use and implementation of primary container serialisation
- The group met weekly to cover all topics from glass through filling to automated inspection.
- *ISPE Discussion Paper: Unique Identification on Primary Containers to Drive Product Traceability and Quality has been approved by the ISPE and will be published W/C 25th Jan 2021.*
- *Feedback system will be provided by ISPE*

ISPE WORKING GROUP PARTICIPANTS	
Pharmaceutical Manufacturers	**4**
Contract Manufacturing Organisation	**2**
Filling Line Manufacturers	**2**
Inspection Machine Companies	**2**
Software	**1**
Independent ISPE Member	**1**
ISPE Italy	**1**

POLL 1

In your organisation who would be the key stakeholders to influence a decision to implement the container traceability solution?

Please choose the key areas in the list below

- ❑ Operations - Aseptic processing
- ❑ Operations – Visual inspection
- ❑ Engineering
- ❑ Quality
- ❑ Regulatory

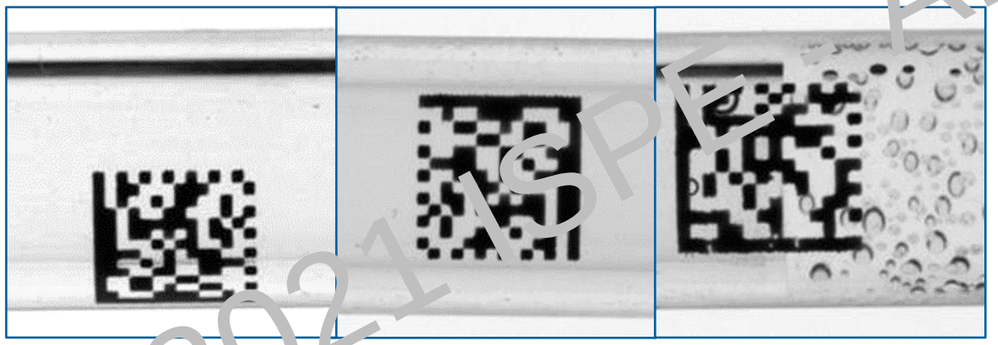
Chapter

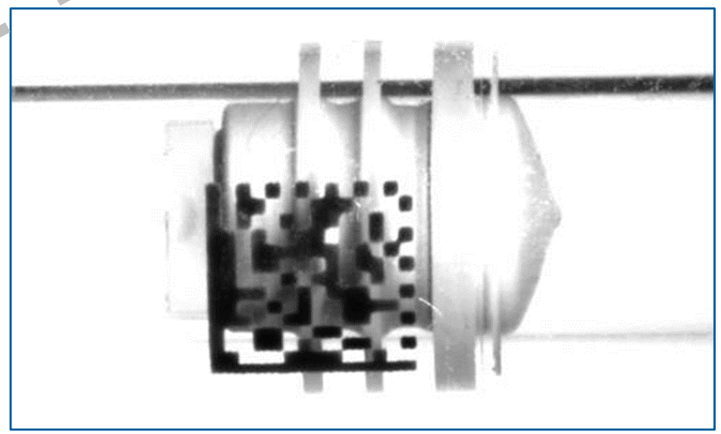
4

Readability & Test Results

0.5 ml syringe -Inspection Pictures

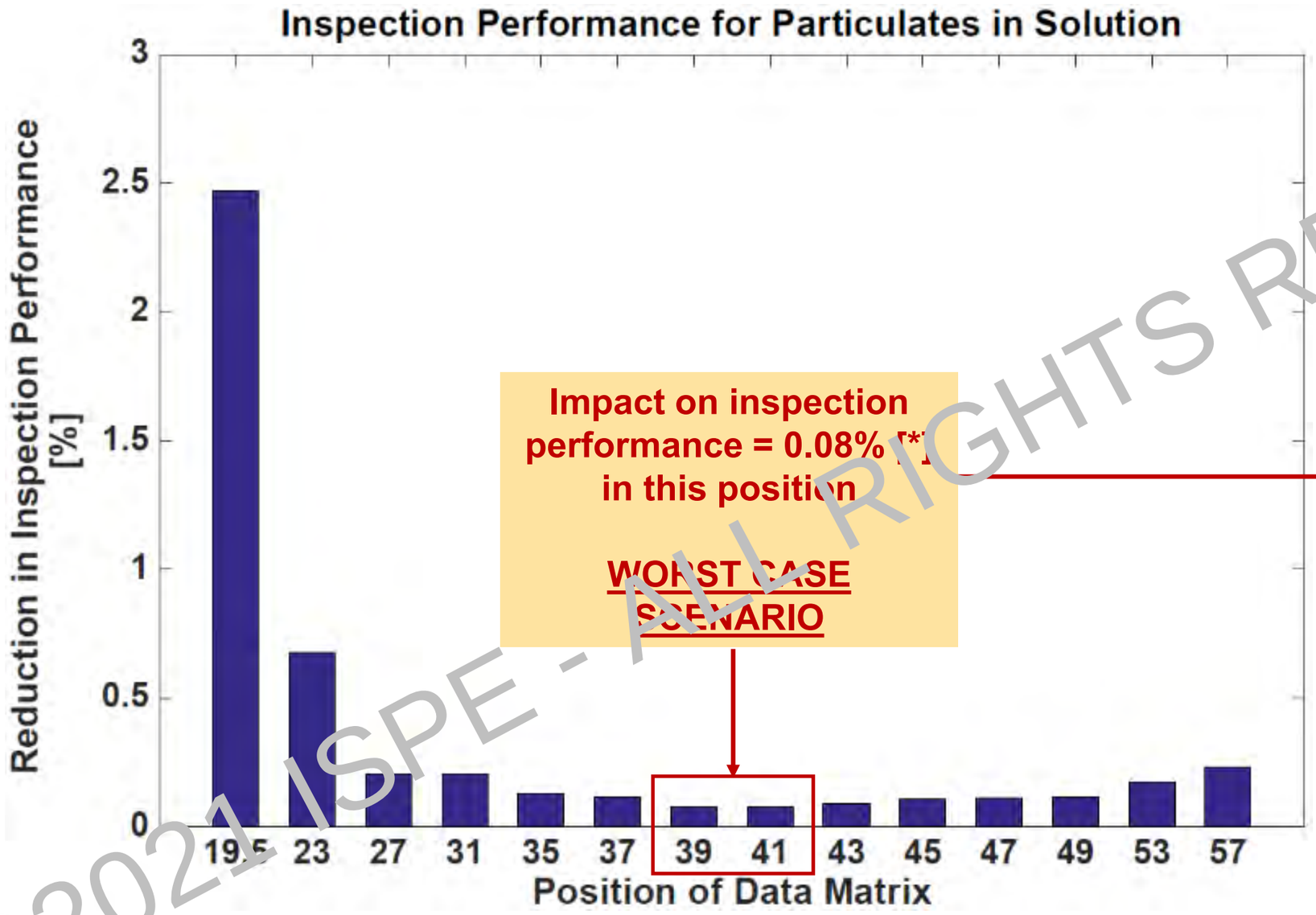
Standard 0.5ml syringes run though different inspection routines to check for defects [particles, cracks, CCI etc] with the barcode on the body of the syringe.





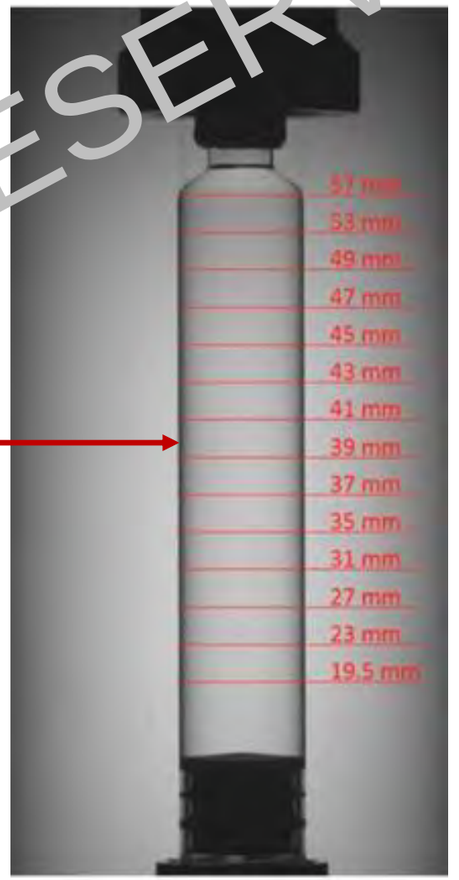
Inspection Test Method

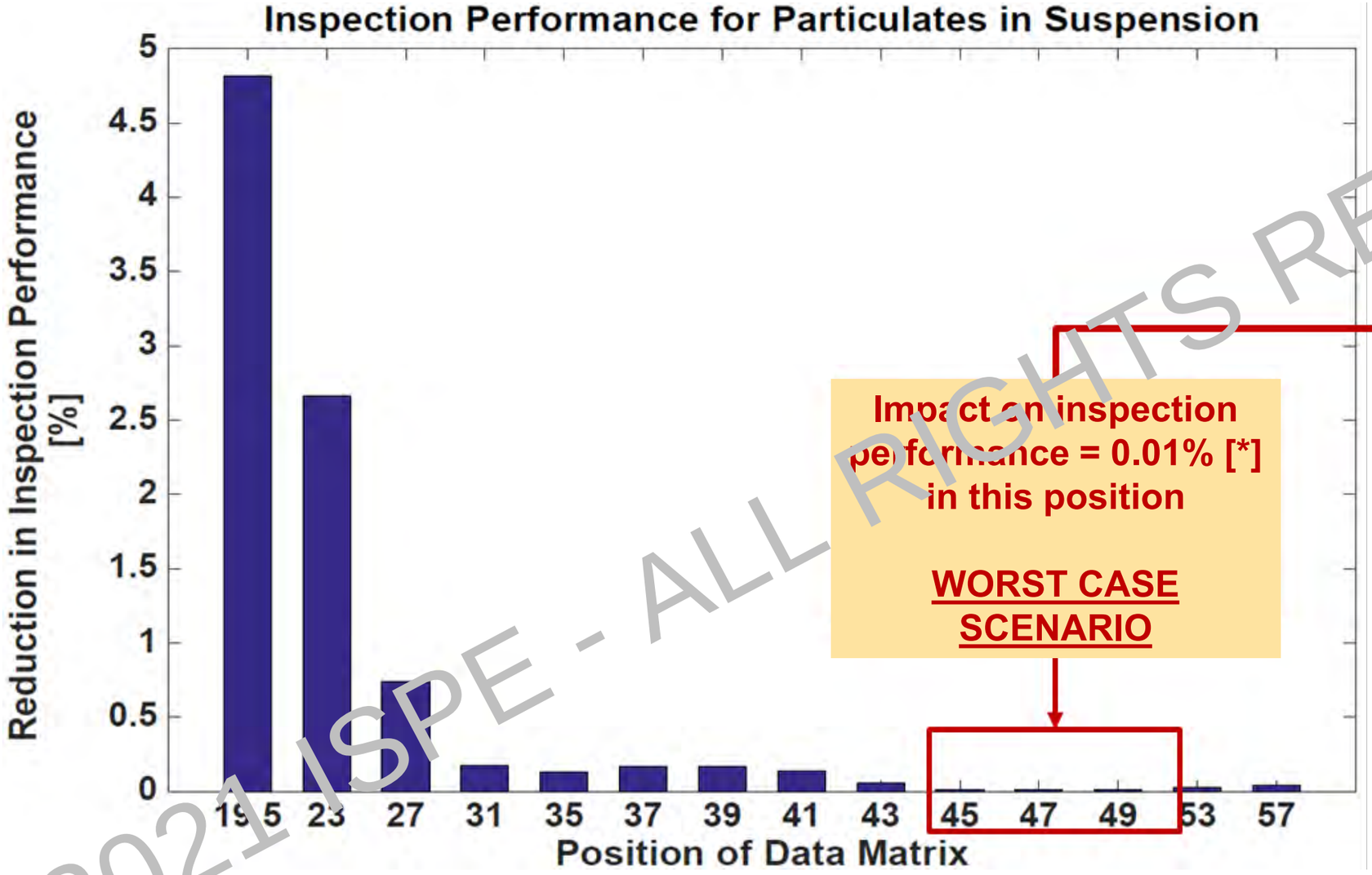
- 3ml standard cartridges - using two different types of liquid
  - Clear solution
  - Heavy suspension
- Tested for particulates only : 73 cartridges – 100X in the machine
- Glass, plastic, rubber, fibres, metal - size range: 50µm – 500µm
- Implemented a virtual mask on the machine
- Placed the masks at different positions on the length of the cartridge
- Tracked inspection performance for 7800 cartridges

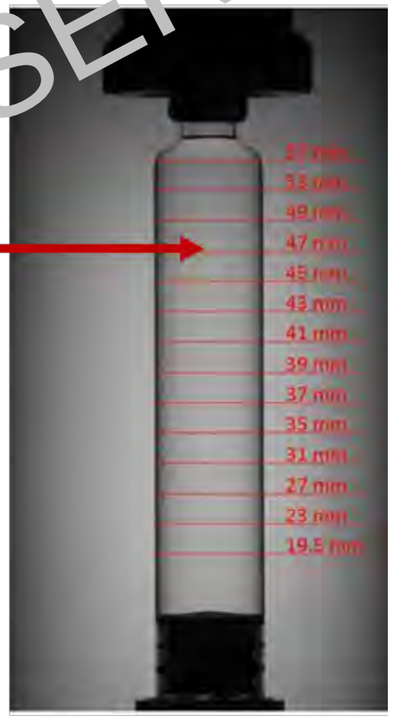


Impact on inspection performance = 0.08% [*]
in this position

WORST CASE SCENARIO







Chapter

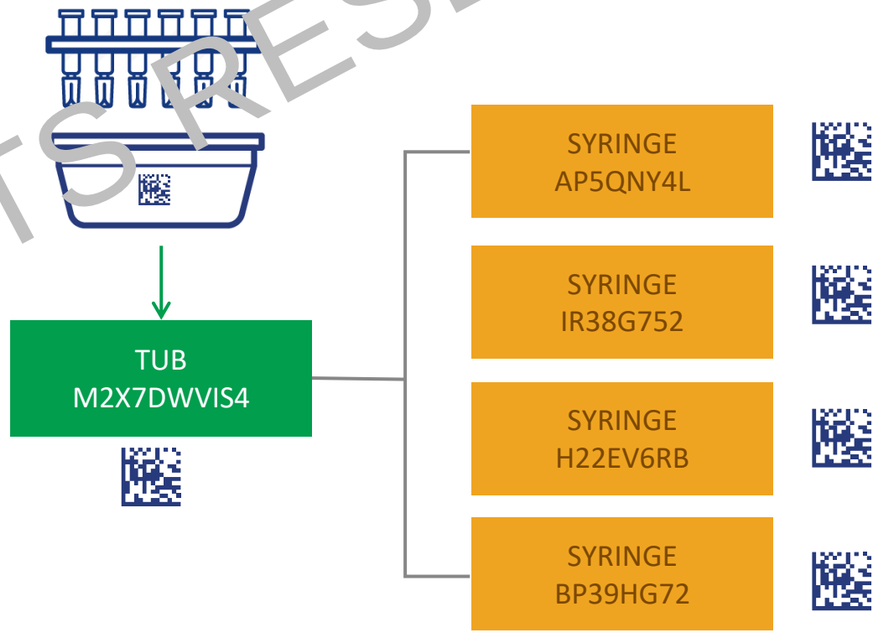
5

Product Availability

High Level Product Roadmap

- Marking process has been validated and is currently in production
- Process set up for all types of products - vials, syringes, cartridges
- **NFHU samples available from January 2021 in bulk format**
- Benefits supported by data and a product testing package
- **ISPE Discussion Paper: Unique Identification on Primary Containers to Drive Product Traceability and Quality expected to be published W/C 25th Jan 2021**
- Developinga “readabl estandtub” withindustrystakeholders– expected Q4 2021
- **FHU samples from Dec 2021**

Product formats



Bulk Products

Ready to Use [RTU] Formats

Readable RTU Formats

Key on-going activities to facilitate market adoption

- **Stevanato Group is committed to creating an “Open Source” technology & solution for the industry.**
- **Stevanato Group is working with three stakeholders to deliver the key filling line requirements**
  - Enabling the possibility to retrofit solutions to existing lines
  - Enhance the traceability and data collection in the machines
  - Minimal impact on existing systems, sterility and validation
  - Expected delivery: Q4 2021
- **Stevanato Group is working with two industry stakeholders to enhance inspection machines**
  - Testing additional product formats
  - Built in barcode reading algorithms
  - Expected delivery: Q4 2021

Chapter

6

Summary

Summary

- Increased regulatory scrutiny on traceability for manufacturing processes
- Value proposition has been validated by the industry
- Marking process has been validated and is in production [June 2020]
- Multiple stakeholders have been involved in driving a standardized approach
- Different supply options available to suit customer needs
- Early adopters are shaping the solution & standards
- **Samples are available for customers to start testing the solution**

POLL 2

In terms of barriers to acceptance of the container traceability solution, what areas do you feel need additional development or supporting data?

Please choose the key areas in the list below.

- ❑ Primary container solution
- ❑ Filling line integration
- ❑ Automated inspection
- ❑ Regulator backing
- ❑ Take up within the industry

Q&A

Contact Information

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  Extended Learning

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  Tuesday, 23 February 1000 – 1200 ET

  Extended Learning

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