



- Vials, Ampoules, Syringes, Blow – Fill – Seal
- Closure systems
- Viscous liquids, Air bubbles / scratches,
- Refrigerated product containers

# Mastering AVI

## Part 3: Considerations on primary containers and product properties

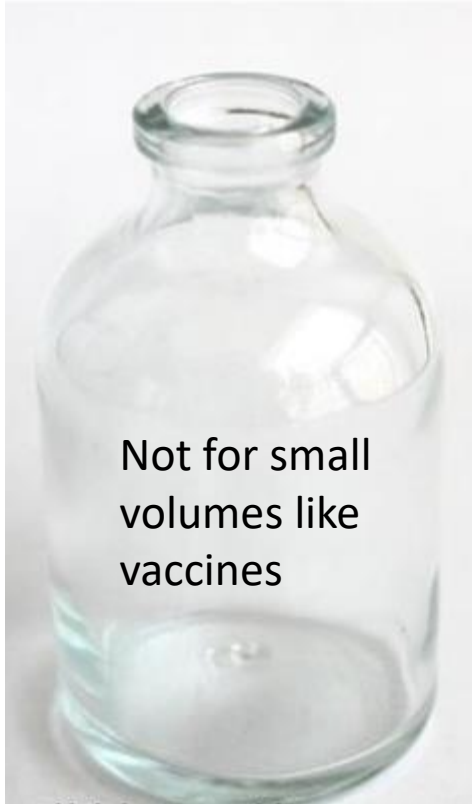


Instructor Lead: Romain Veillon / Fernand Koert / Sébastien Koch

- Molded vs tubular glass
- Glass defect
  - Ref PDA TR 43
  - Crack
- Closure defect
  - vial crimping
  - syringe closure
- Size Tolerance impact on AVI
- Multiple supplier
- workshop with practical glass defect reviewing:
  - Forming defect / Airline / inclusion / scratches / size
  - Product fill level / Opacity / color / Viscosity
  - Lyo product aspect



- Molded Glass



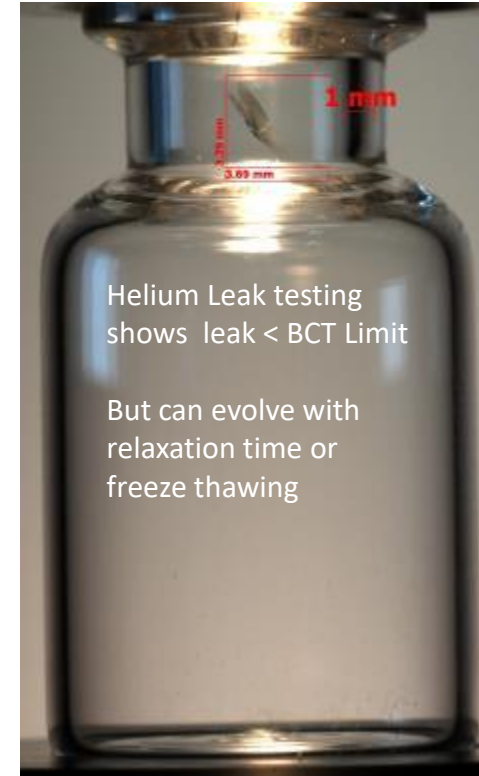
- Tubular glass



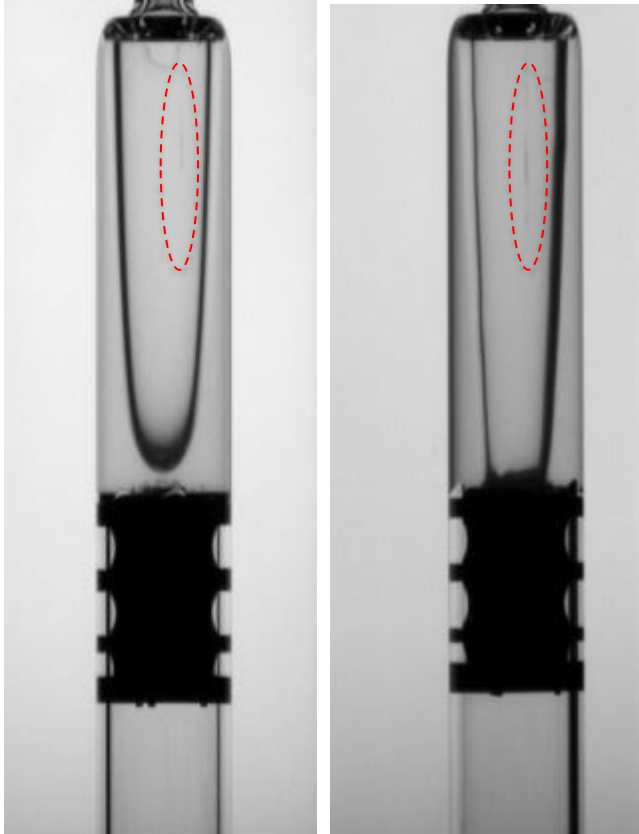
- Crossing crack



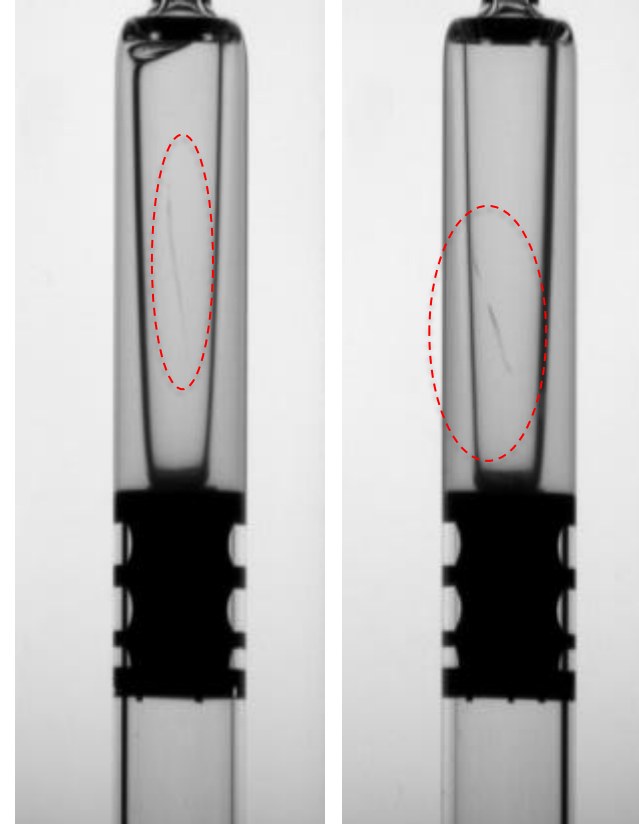
- Non-Crossing crack



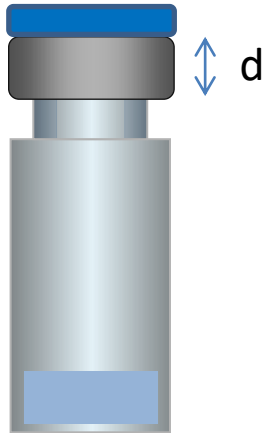
- Scratch : **minor**  
Metal parts contact



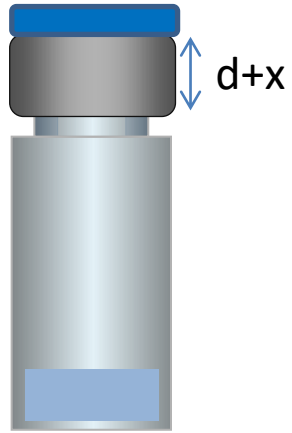
- Crack: **critical**  
Glass to glass contact or thermal shock



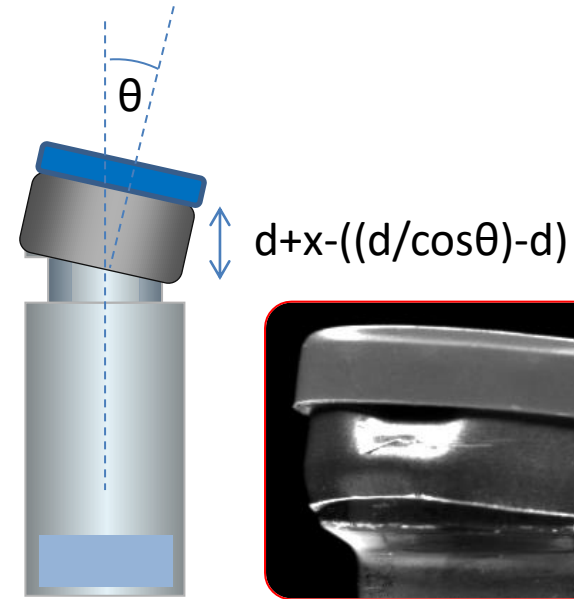
Conform crimp



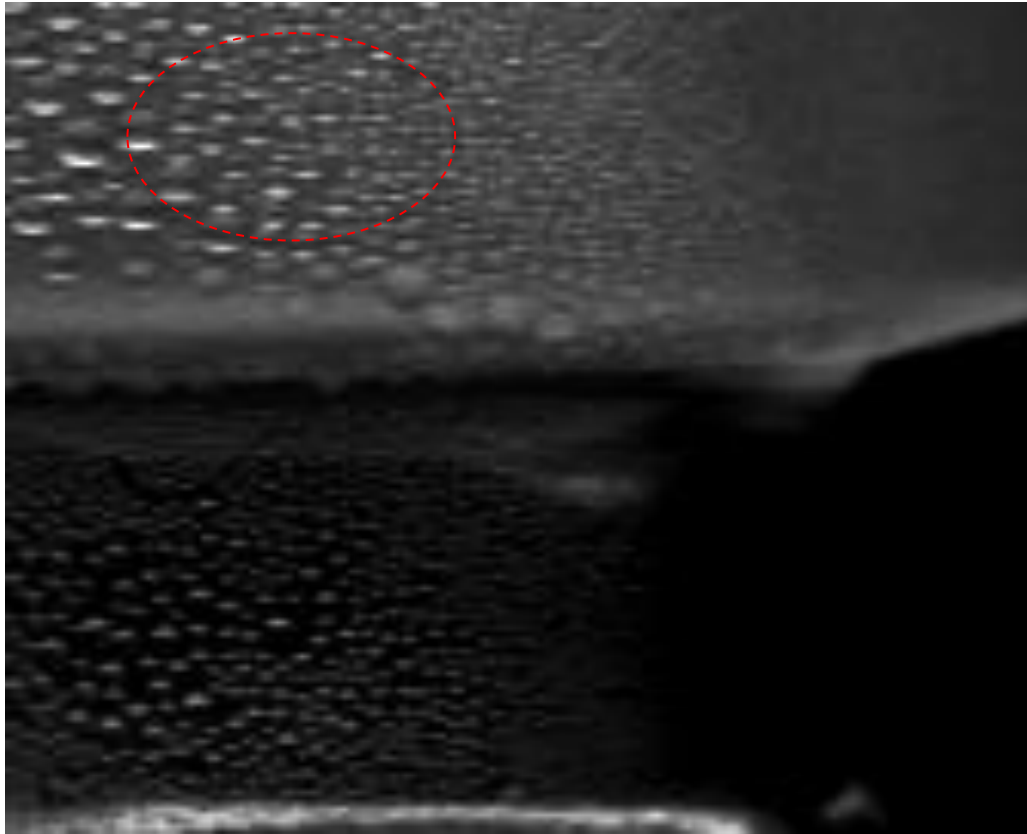
Not crimped



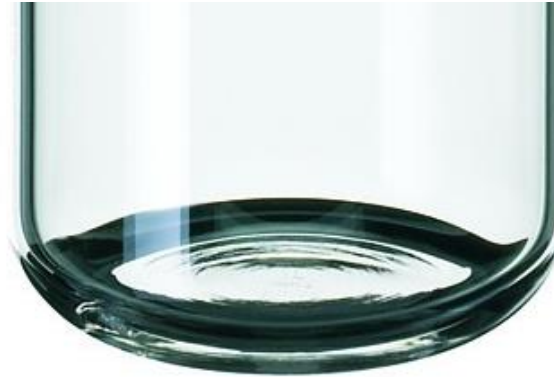
Partially crimped



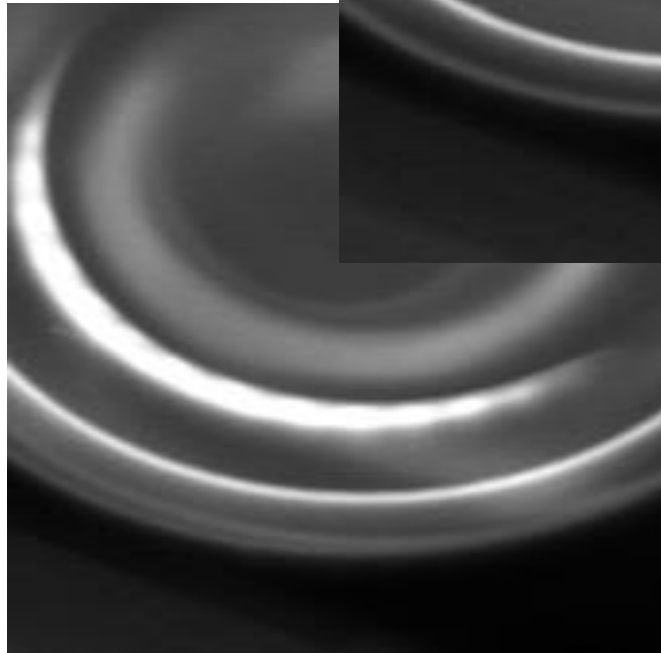
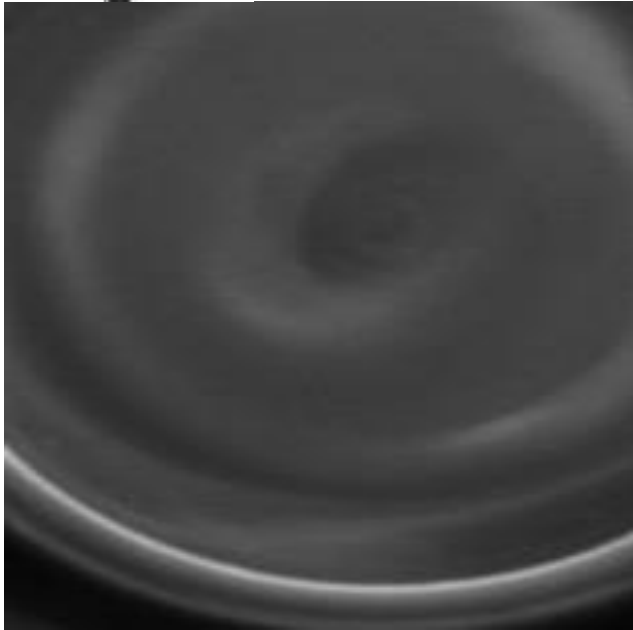
**Defective crimping can be defined regarding cap height or angle**

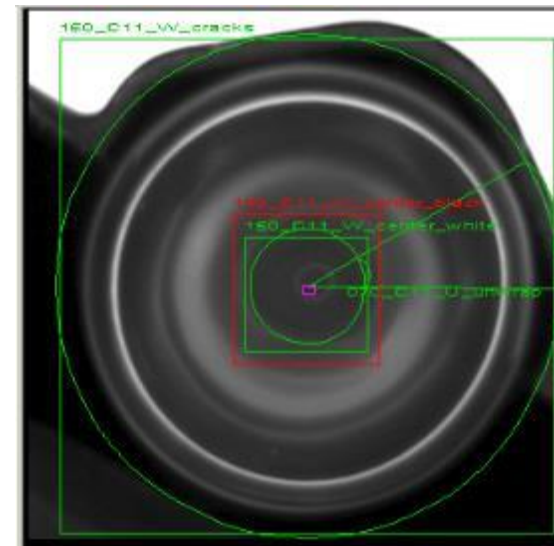
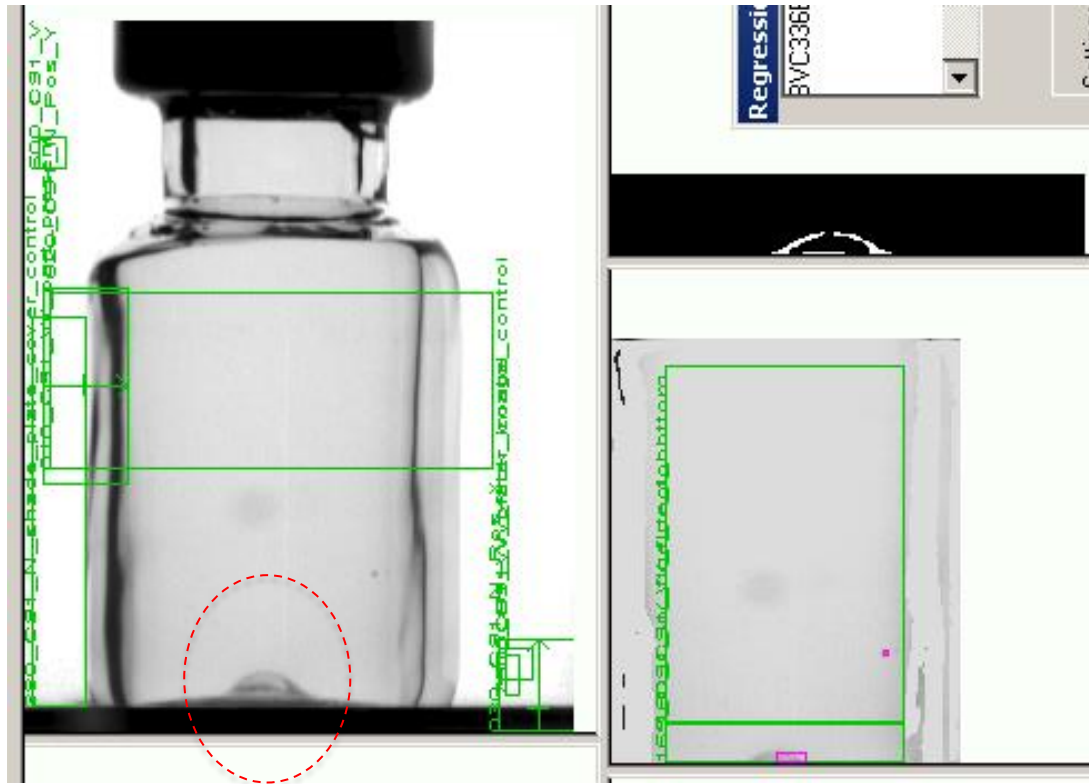


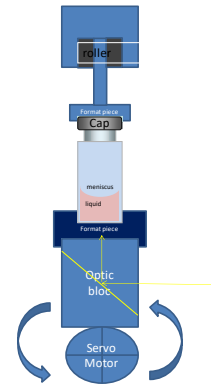
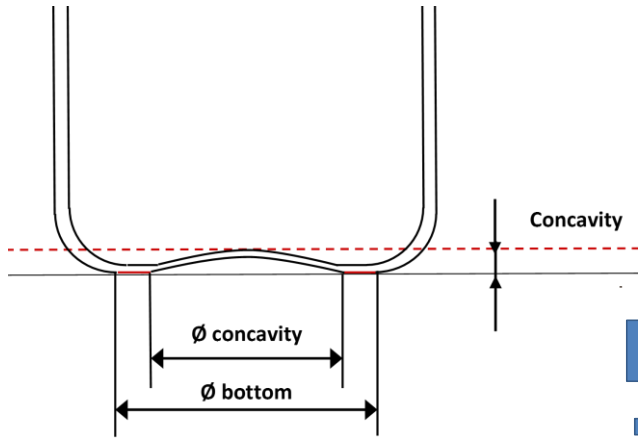
Micro droplet due to condensation will generate false rejects











Best case →



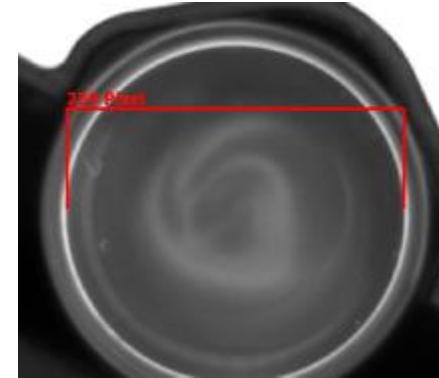
Worst case →



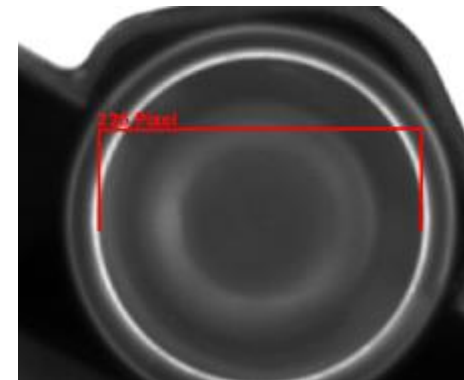
Vials are being rotated fast (3600t/min) from bottom, in order to obtain thin layer suspensions. And 'transparent' window for small particle inspection

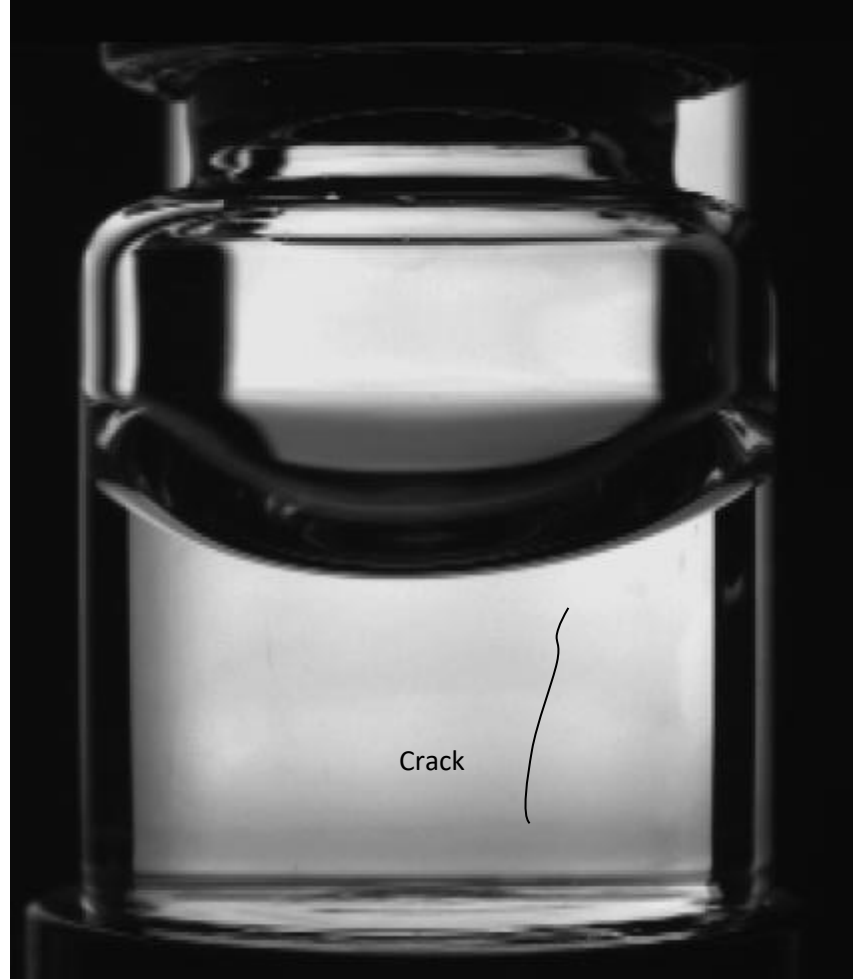
**=> Cavitation and wave creation in liquid = seen as defect**

Supplier A

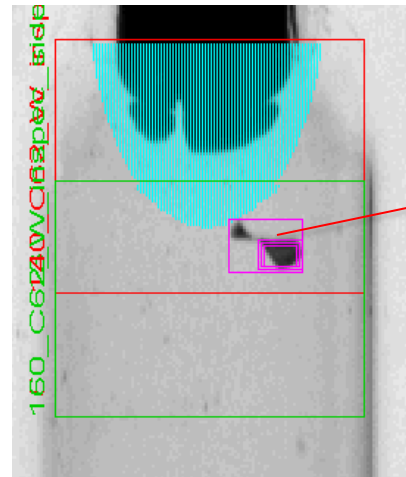
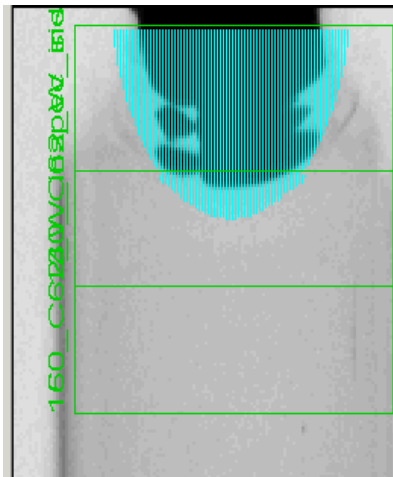


Supplier B





## Practical impact of primary packaging impact Shoulder inspection tool and longer stopper impact



With the mask present for reflects of stopper (blue) the crack control windows is reduced

**Supplier A**  
**Round shoulder**  
**No reflects**

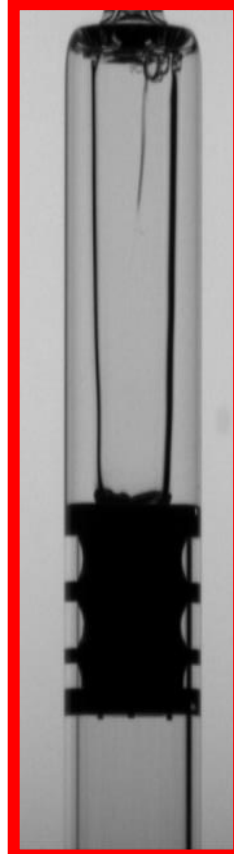
**Supplier B**  
**Wave shoulder**  
**many stopper reflects**



Normal



Distortion due to waves







White inclusion

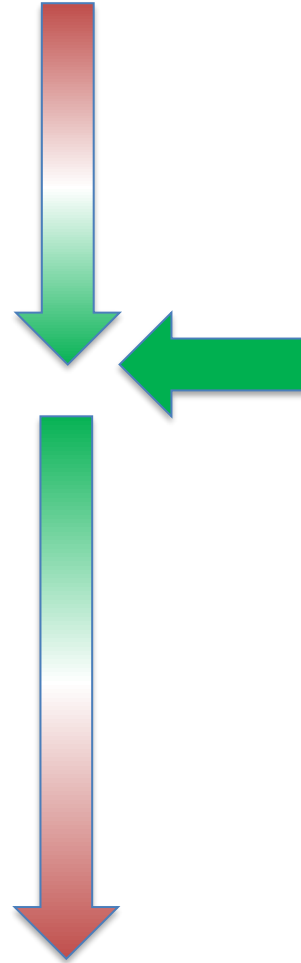


Dark inclusion

Plunger molding can also create darkness as not in contact to the glass



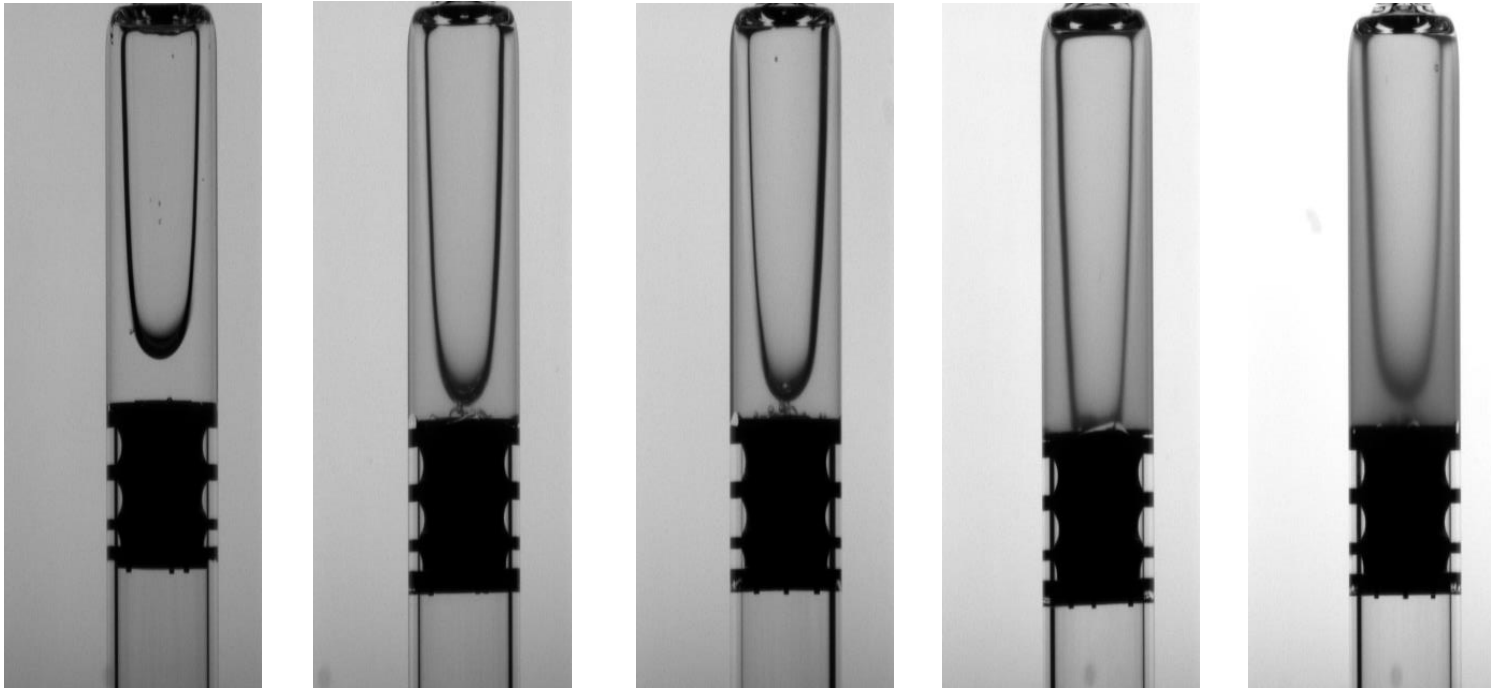
	Image 1	Image 2
735rpm		
2206rpm		
3350rpm		
3676rpm		
4412rpm (4 images)		
5000rpm		
5147rpm		
6618rpm		
7353rpm (4 images)		



For each product fill level/viscosity DOE to conduct to find optimum image stability

Grouping products into families

1. Main aspect is viscosity, since viscosity sets rotation speed
2. Transparency can be compensated with light intensity to get equal images



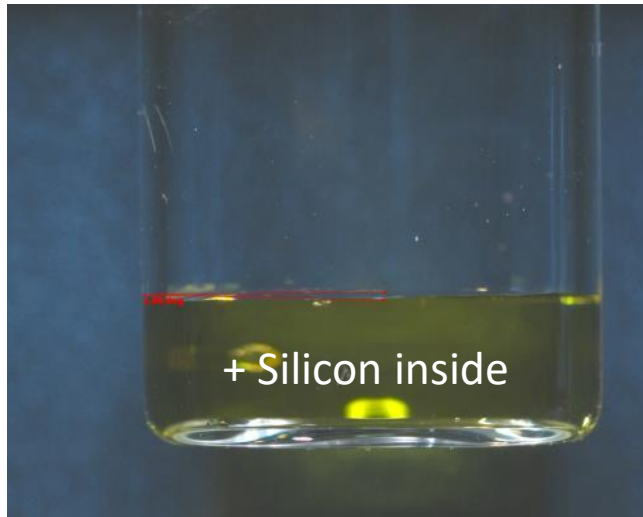
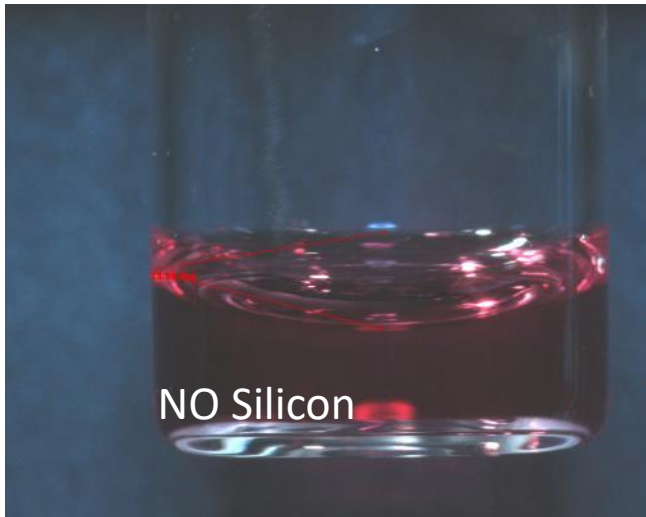
Product A

Product B

Product C

Product D

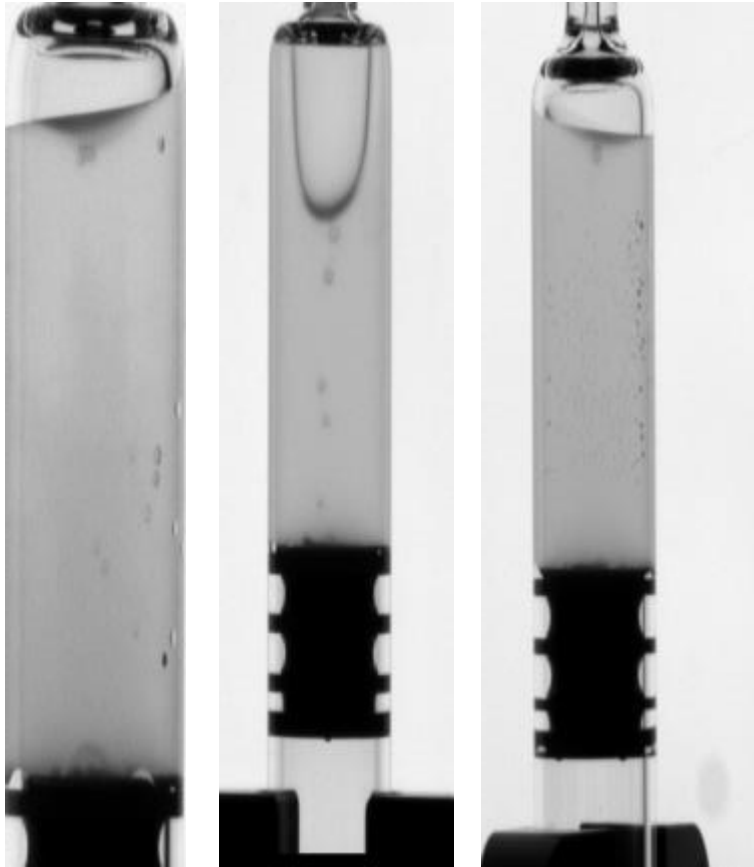
Product E



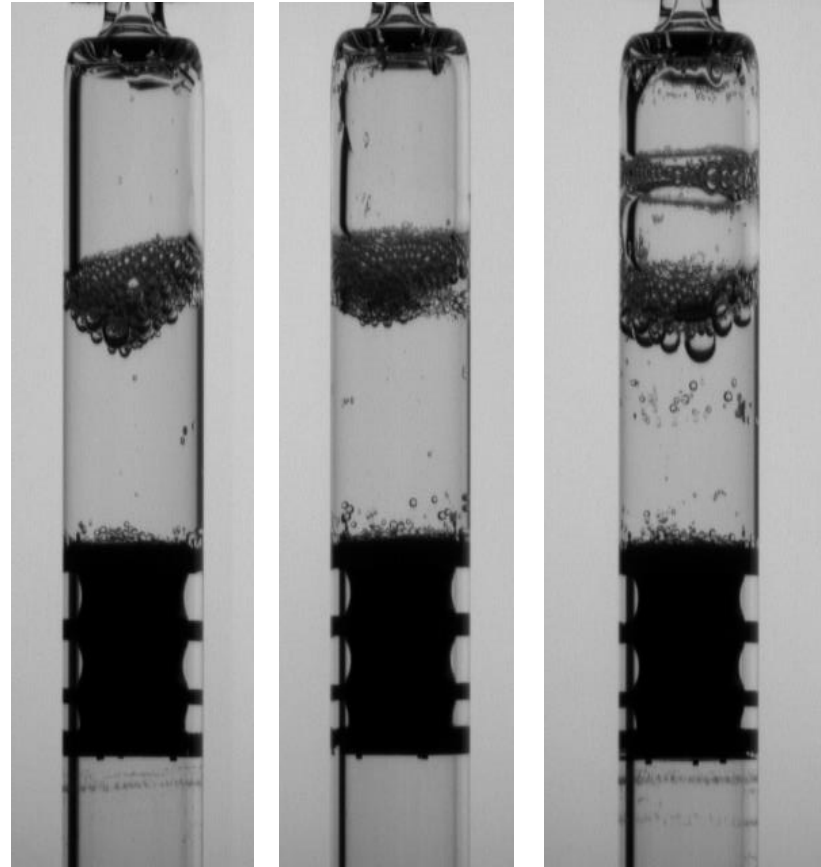
- Product Opacity



## Product micro bubbles



## Foaming



# Lyo defects are linked to process and they are gradual => need clear limit

- Lyo product aspects

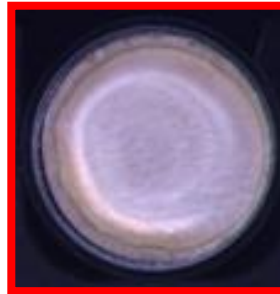
Conform



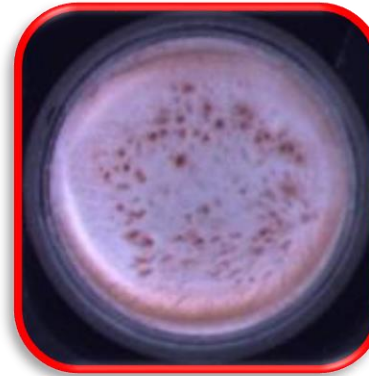
Conform with slight color change side



Fail



Fail



Fail





# RECAP



## You have learnt

### AVI and Containers

- molded vs elongated glass
- reflects / geometry
- condensation
- fill level
- Silicon
- Lyo defects
- opacity.....

## AVI

- What's the disadvantage of molded glass
- What's to consider coming out of cold storage
- How important is glass quality related to rotation
- What's meant with family bracketing