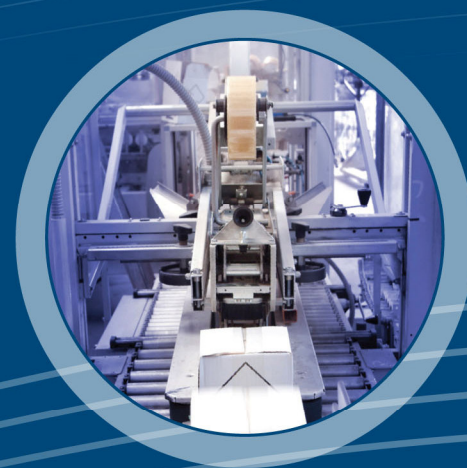




Connecting People, Science and Regulation®

100% Headspace Analysis for Characterization and Optimization of Sterile Manufacturing Processes



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LIGHTHOUSE.



Laser-based headspace inspection



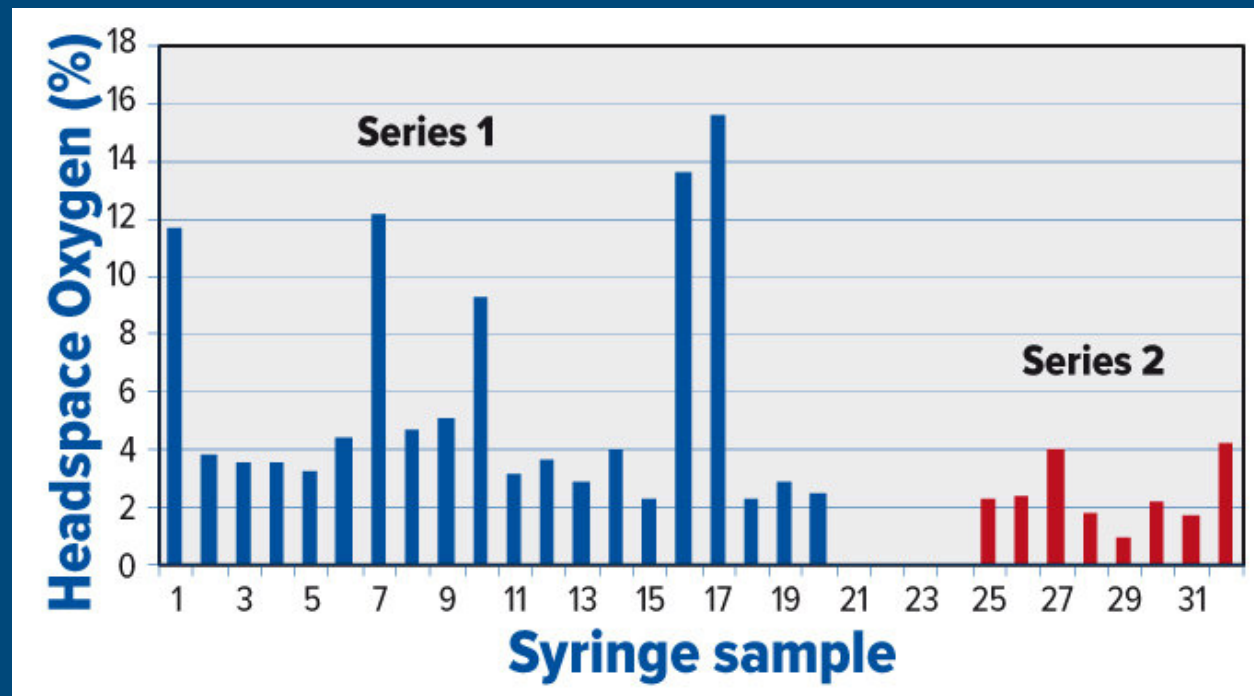
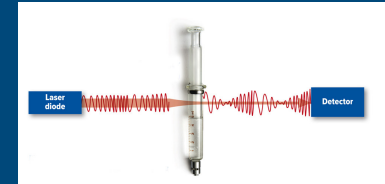
- Characterize physical headspace conditions
- Headspace molecules of interest for parenteral product
 - **Oxygen concentration**
 - **Nitrogen pressure**
 - **Water vapor**





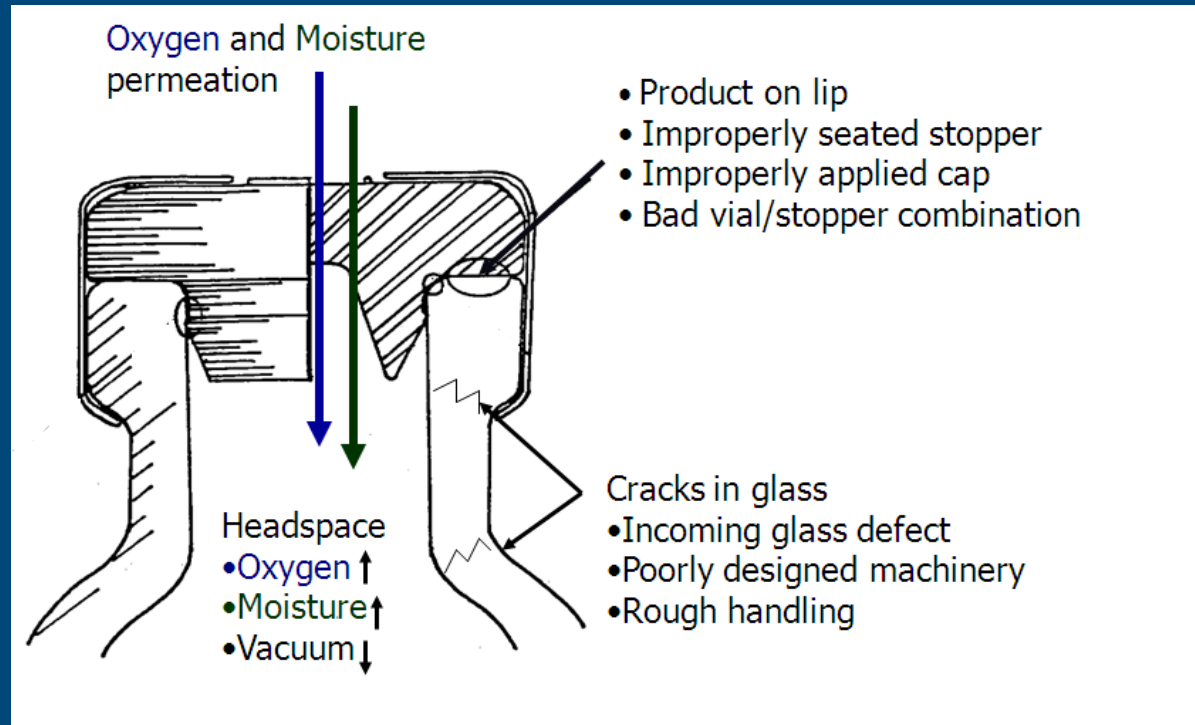
Industry case study: Syringe Headspace Oxygen

- 100% headspace oxygen monitoring to optimize and validate purging process on new syringe filling line
- Target headspace oxygen levels – 5%





Industry case study: 100% Container Closure Integrity

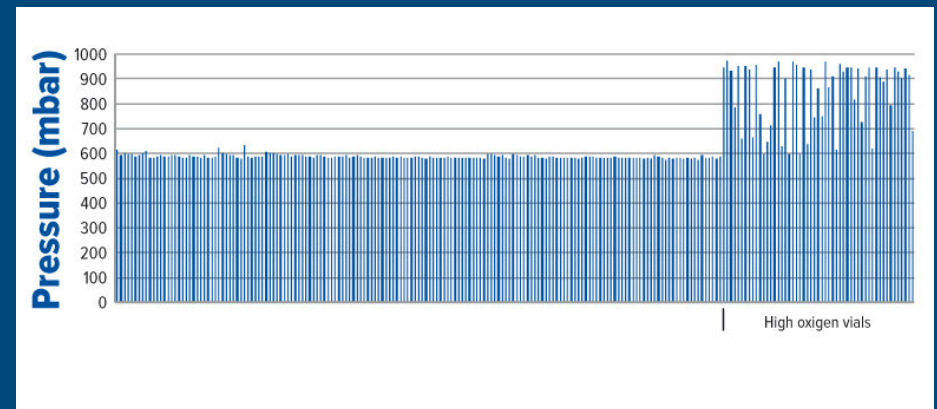
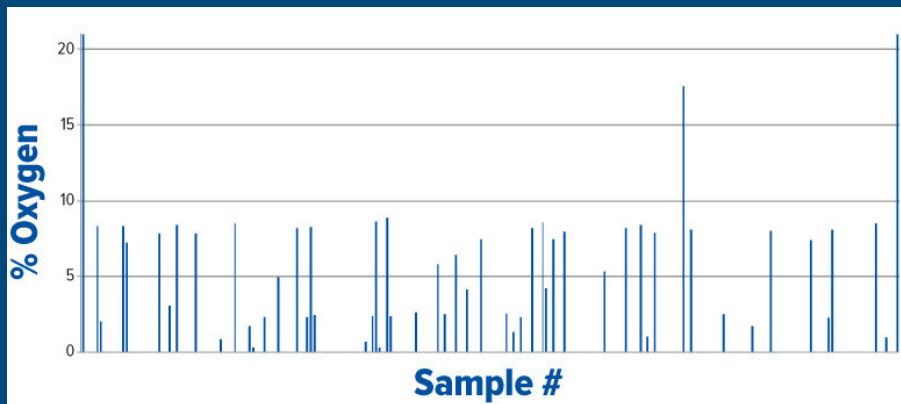


CCI failures result in gas exchange for modified headspace conditions



Industry case study: 100% Container Closure Integrity

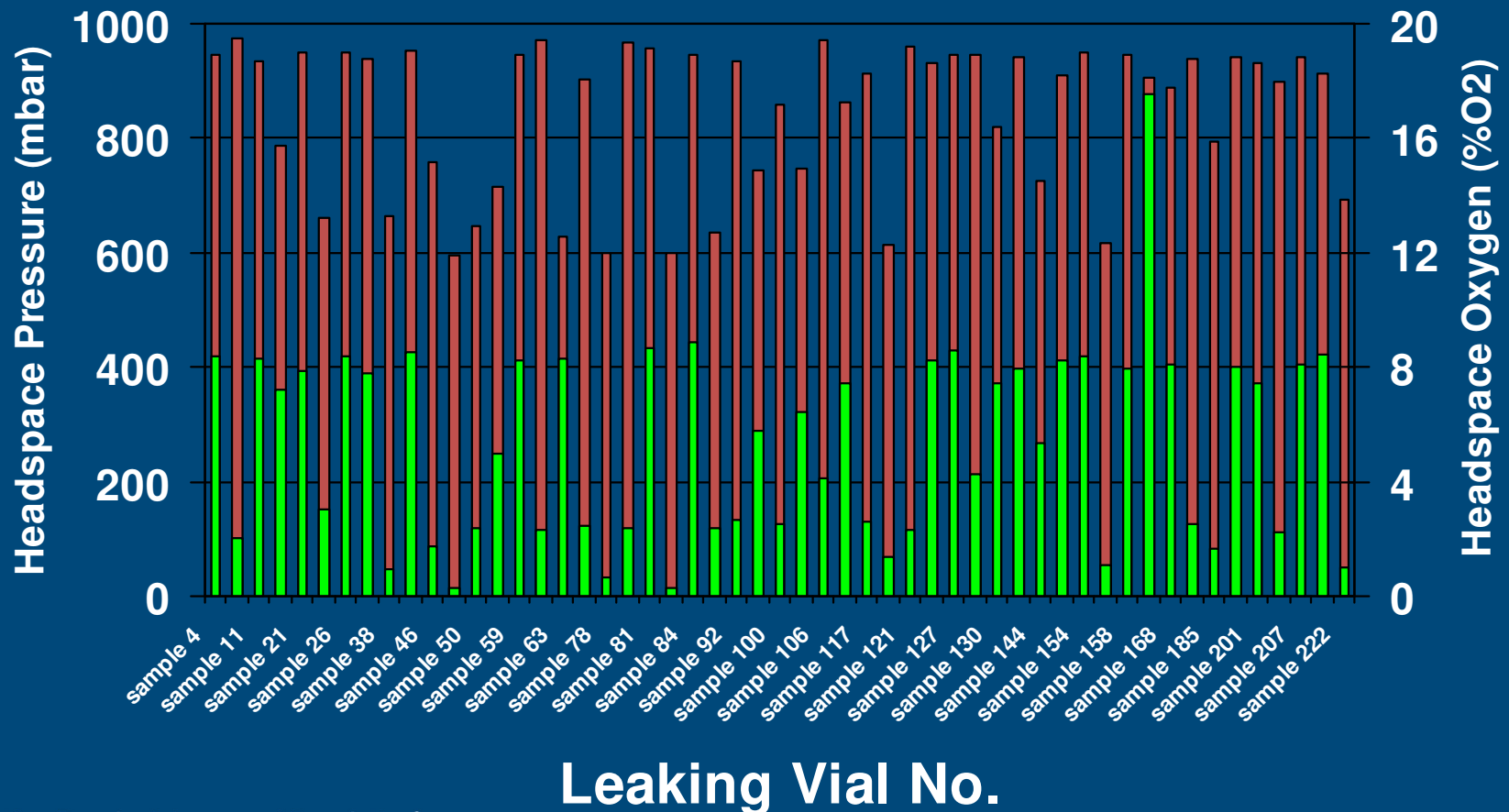
- Suspected raised stopper issue – batch of 11,000 lyo vials put into quarantine;
- 100% headspace inspection a few weeks after manufacture;
- Specified headspace conditions at stoppering was 600 mbar of nitrogen





Industry case study: 100% Container Closure Integrity

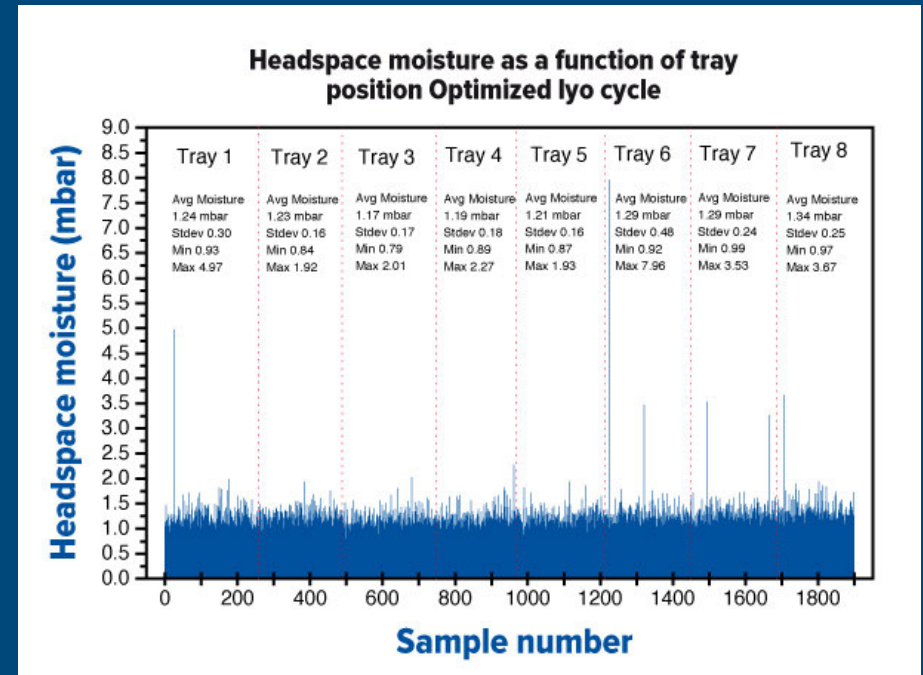
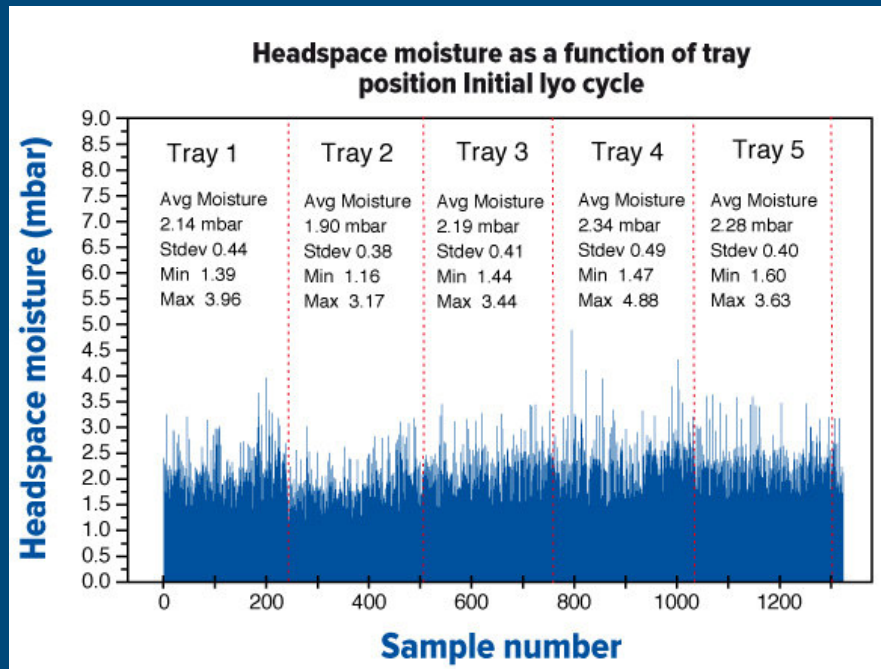
■ Pressure (mbar) ■ %Oxygen





Industry case study: 100% Lyo Moisture Determination

- Headspace moisture correlates to moisture content in the lyo cake
- 100% headspace moisture determination to characterize and optimize freeze drying cycle





- **Interesting??** Poster and Tabletop 25
- **Useful!!** New ideas, science-based insight

THANK YOU