Bonfiglioli™ Engineering

SAIL

Smart Automated Inspection Laboratory

SAIL is an automated inspection laboratory for different container types, sizes, and contents bringing together CCIT, AVI and HGA all in one machine suitable for in-process, clinical trials and laboratory use.

HIGHLIGHTS

- **All in one Industry 4.0 based laboratory**
- **Ergonomic workstation**
- **Scientific and objective inspection**
- **100 % traceability**
- **Time & cost saving**

TECHNICAL FEATURES

Container Application: BFS, Vials, Ampoules, PFS, Cartridges

Products: Lyo, Liquid, Powder

Container Dimensions: Ø [10 - 69] mm

Speed: 50 - 500 cph (depending on configuration)

Technology: CCIT - AVI - HGA

Inspection Features: A COBOT optimizes the collaborative non-destructive inspection processes

Inspection Capabilities: Integrity testing; foreign matters, cosmetic and cap defects; Oxygen/Moisture/ Carbon Dioxide level, Absolute Pressure value

ADDITIONAL PLUS

- **Single operator**
- **Single validation** & qualification procedure
- **Multiple inspections**, containers, formats
- Easy & fast evaluation thanks to **real time HD display**
- **Automatic Container Handling**
- New user-friendly **touchscreen HMI**, **Android-like**, 22" size adjustable panel
- Tool-less, **no format change** by means of automatic adjustments and regulations

TECHNOLOGY

SAIL modular structure provides adequate flexibility upon all **3 of testing technologies**:

- **AVI (Automatic Visual Inspection)**/ SAVI a collection of images is acquired using high resolution matrix cameras under designed illumination conditions.
- **CCIT (Container Closure Integrity Testing)** non-destructive integrity testing in packages by Vacuum Decay Method.
- **HGA (Headspace Gas Analysis)** inspection process is based on the Tunable Diode Laser Absorption Spectroscopy (TDLAS) method which accurately quantifies gaseous concentration levels.

QUALITY ASSURANCE

- Software designed to comply with **FDA 21 CFR Part 11** and **EU Annex 11**
- Visual Testing method conforms to current pharmaceutical regulations, such as USP – **United States Pharmacopeia** – **General Chapter <790>** and European Pharmacopeia **§ 2.9.20**
- Vacuum decay Method based on the approved industry standard **ASTM F2338-09**, recognised by the FDA
- HGA Testing method in conformity with provisions of **USP General Chapter <1207>**
- The Machines Qualification and Validation complies with requirements stated in **EU Annex 15**
- Machine manufacturing process and materials are compliant with applicable **GMP** requirements