OFFLINE TROUBLESHOOTING AND DEVELOPMENT FOR AUTOMATED VISUAL INSPECTION STATIONS

FIELD OF DISCLOSURE

[0001] The present application relates generally to automated visual inspection (AVI) systems for pharmaceutical or other products, and more specifically to techniques for performing offline troubleshooting and/or development for an AVI station.

BACKGROUND

[0002] In certain contexts, such as quality control procedures for manufactured drug products, it is necessary to examine samples (e.g., containers such as syringes or vials, and/or their contents such as fluid or lyophilized drug products) for defects. The acceptability of a particular sample, under the applicable quality standards, may depend on metrics such as the type and/or size of container defects (e.g., chips or cracks), or the type, number and/or size of undesired particles within a drug product (e.g., fibers), for example. If a sample has unacceptable metrics, it may be rejected and/or discarded.

[0003] To handle the quantities typically associated with commercial production of pharmaceuticals, the defect inspection task has increasingly become automated. Moreover, the specialized equipment used to assist in automated defect inspection has become very large, very complex, and very expensive, and requires substantial investments in manpower and other resources to qualify and commission each new product line. As just one example, the Bosch® 296S commercial line equipment, which is used for the fill-finish inspection stage of drug-filled syringes, includes 15 separate visual inspection stations with a total of 23 cameras (i.e., one or two cameras per station). As a whole, this equipment is designed to detect a broad range of defects, including container integrity defects such as large cracks or container closures, cosmetic container defects such as scratches or stains on the container surface, and defects associated with the drug product itself such as liquid color or the presence of foreign particles.

[0004] Because it can be cost-prohibitive to purchase additional pieces of AVI line equipment, troubleshooting and characterization activities for new products typically must be done *in situ*. Thus, troubleshooting and new product characterization typically require lengthy downtimes, resulting in suboptimal long-term production rates.

SUMMARY

[0004a] According to a first aspect of the present invention, there is provided a method for replicating performance of an automated visual inspection (AVI) station, the method comprising:

constructing a mimic AVI station that performs one or more AVI functions of the AVI station, wherein the mimic AVI station includes a mimic illumination system, a mimic imaging system, and mimic sample positioning hardware configured to hold and/or support containers containing samples;

capturing, by an imaging system of the AVI station while a container is illuminated by an illumination system of the AVI station, one or more container images;

capturing, by the mimic imaging system while a container is illuminated by the mimic illumination system, one or more additional container images;

identifying, by one or more processors, one or more differences between the one or more additional container images and the one or more container images;

generating, by the one or more processors, a visual indication of (i) the one or more differences, and/or (ii) one or more suggestions for modifying the mimic AVI station; and

modifying the mimic AVI station based on the visual indication, at least by modifying the mimic illumination system, the mimic imaging system, and/or the mimic sample positioning hardware.

[0004b] According to a second aspect of the present invention, there is provided a non-transitory, computer-readable medium storing instructions that, when executed by one or more processors, cause the one or more processors to:

receive one or more container images captured by an imaging system of an automated visual inspection (AVI) station;

receive one or more additional container images captured by a mimic imaging system of a mimic AVI station;

identify one or more differences between the one or more additional container images and the one or more container images; and

generate a visual indication of (i) the one or more differences, and/or (ii) one or more suggestions for modifying the mimic AVI station.

[0004c] According to a third aspect of the present invention, there is provided a system comprising:

an automated visual inspection (AVI) station comprising

an imaging system,

an illumination system, and

sample positioning hardware configured to hold and/or support containers containing samples;

a mimic AVI station that performs one or more AVI functions of the AVI station, the mimic AVI station comprising

a mimic illumination system,

a mimic imaging system, and

mimic sample positioning hardware configured to hold and/or support containers containing samples; and

a computing system configured to

receive one or more container images captured by the imaging system of the AVI station;

receive one or more additional container images captured by the mimic imaging system of the mimic AVI station;

identify one or more differences between the one or more additional container images and the one or more container images; and

generate a visual indication of (i) the one or more differences, and/or (ii) one or more suggestions for modifying the mimic AVI station.

[0005] Embodiments described herein relate to systems and methods in which a "mimic" AVI station is constructed or upgraded in an effort to replicate the performance of an existing AVI station, thereby allowing offline troubleshooting or new product characterization and/or qualification efforts that do not interfere, or interfere to a lesser degree, with production line operation. In some embodiments, the mimic AVI station is a dedicated offline (e.g., lab-based) station that mimics one or more AVI functions of a station in existing commercial line equipment (e.g., one of multiple stations in the line equipment). In such an embodiment, the mimic AVI station may be used to troubleshoot a problem with a particular, corresponding station in the commercial line equipment, or otherwise improve the performance of the corresponding station, without necessitating a lengthy shutdown of the line equipment. For example, offline modifications may be made to hardware components (e.g., lighting devices, starwheels, etc.), hardware arrangements (e.g., the distance or angle between a sample and a camera or lighting device, the configuration of a lighting device, etc.), and/or software (e.g., code that implements an inspection algorithm). Once the appropriate modifications are identified, the commercial line equipment may be shut down for a relatively brief time in order to implement those changes for the original AVI station, possibly followed by some amount of *in situ* qualification work. Because the mimic AVI station is offline, it offers the opportunity to conduct root cause investigations, recipe development and/or other support activities in the lab rather than on the commercial line equipment.

[0006] In other embodiments, the mimic AVI station is instead a station of the commercial line equipment, and the goal is to mimic the characteristics/performance of a lab-based AVI station. In such an embodiment, the lab-based AVI station may be used to characterize and qualify inspection for new drug products, which would otherwise/traditionally require extensive downtime of the line equipment and prevent its concurrent use for other drug products. Once the appropriate hardware