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, wherein identifying the one or more differences includes generating one or more metrics indicative of imaging sensor noise for the one or more container images and the one or more additional 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 based on said one or more metrics; 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, wherein identifying the one or more differences includes generating one or more metrics indicative of imaging sensor noise for the one or more container images and the one or more additional container images; and

generate a visual indication of (i) the one or more differences, and/or (ii) guidancefor modifying the mimic AVI station based on said one or more metrics.

[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, wherein identifying the one or more differences includes generating one or more metrics indicative of imaging sensor noise for the one or more container images and the one or more additional container images; and

generate a visual indication of (i) the one or more differences, and/or (ii) guidance for modifying the mimic AVI station based on said one or more metrics.

[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

What is claimed is:

1. 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 wherein identifying the one or more differences includes generating one or more metrics indicative of imaging sensor noise for the one or more container images and the one or more additional 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 based on said one or more metrics; 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.

2. The method of claim 1, wherein generating the one or more metrics indicative of imaging sensor noise includes computing a Fast Fourier Transform on each container image and, optionally, generating a metric indicative of a level or relative level of high-frequency components.

3. The method of claim 1, wherein either (i) the AVI station is included in commercial line equipment and the mimic AVI station is a lab-based setup, or (ii) the mimic AVI station is included in the commercial line equipment and the AVI station is the lab-based setup.

4. The method of claim 1, wherein modifying the mimic station includes one or both of:

modifying a spatial arrangement of one or more of: at least one lighting device of the mimic illumination system, at least one imaging device of the mimic imaging system, or the mimic sample positioning hardware; and

modifying hardware components of one or more of: at least one lighting device of the mimic illumination system, at least one imaging device of the mimic imaging system, or the mimic sample positioning hardware.

5. The method of claim 1, further comprising:

installing, on a computer system of the mimic AVI station, AVI software that implements an inspection algorithm that is also implemented by the AVI station; and

after modifying the mimic AVI station,

capturing, by the mimic imaging system, one or more new container images while a test container is illuminated by the mimic illumination system, and

determining one or more characteristics of the test container, and/or a sample within the test container, by processing the one or more new container images according to the inspection algorithm.

6. The method of claim 5, further comprising:

troubleshooting or optimizing the mimic AVI station based at least in part on the determined one or more characteristics, wherein troubleshooting or optimizing the mimic AVI station includes modifying or further modifying the mimic illumination system, the mimic imaging system, the mimic sample positioning hardware, and/or the AVI software.

7. The method of claim 6, further comprising:

modifying the AVI station in accordance with the modifications or further modifications to the mimic illumination system, the mimic imaging system, the mimic sample positioning hardware, and/or the AVI software.

8. The method of claim 1, wherein:

the one or more container images includes a first plurality of container images;

the one or more additional container images includes a second plurality of container images; and

identifying the one or more differences between the one or more additional container images and the one or more container images includes identifying one or more differences between a first composite image derived from the first plurality of container images and a second composite image derived from the second plurality of container images.

9. The method of claim 1, wherein identifying the one or more differences between the one or more additional container images and the one or more container images includes identifying differences with respect to:

container alignment;

defocus;

intensity;

variation in intensity; and/or

motion blurring.

10. The method of claim 1, wherein identifying the one or more differences between the one or more additional container images and the one or more container images includes generating (i) a histogram of pixel intensity levels for the one or more container images or a composite image derived therefrom, and (ii) a histogram of pixel intensity levels for the one or more additional container images or a composite image derived therefrom.

11. The method of claim 1, wherein identifying the one or more differences between the one or more additional container images and the one or more container images includes computing (i) a Laplacian of the one or more container images or a composite image derived therefrom, and (ii) a Laplacian of the one or more additional container images or a composite image derived therefrom.

12. The method of claim 1, wherein (i) identifying the one or more differences, and (ii) generating the visual indication, are performed in real time as the one or more additional container images are captured.

13. The method of claim 1, further comprising:

generating, by the one or more processors, the one or more suggestions for modifying the mimic AVI station based on the one or more differences,

wherein generating the visual indication includes generating the visual indication of the one or more suggestions.

14. The method of claim 13, wherein generating the one or more suggestions includes generating:

a suggestion to modify one or more configurable settings of at least one imaging device of the mimic imaging system;

a suggestion to modify one or more configurable settings of at least one lighting device of the mimic illumination system;

a suggestion to modify a position of at least one imaging device of the mimic imaging system; and/or

a suggestion to modify a position of at least one lighting device of the mimic illumination system.

15. The method of claim 13, wherein:

the mimic sample positioning hardware is configured to move containers according to a movement profile; and

generating the one or more suggestions includes generating a suggestion to modify one or more characteristics of the movement profile.

16. The method of claim 1, further comprising:

receiving, by the one or more processors, one or more operational parameters of the imaging system and one or more operational parameters of the mimic imaging system;

comparing, by the one or more processors, the one or more operational parameters of the imaging system to the one or more operational parameters of the mimic imaging system; and

generating, by the one or more processors, an additional visual indication of at least one operational parameter that differs between the imaging system and the mimic imaging system.

17. 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, wherein identifying the one or more differences includes generating one or more metrics indicative of imaging sensor noise for the one or more container images and the one or more additional container images; and

generate a visual indication of (i) the one or more differences, and/or (ii) guidance for modifying the mimic AVI station based on said one or more metrics.

18. The non-transitory, computer-readable medium of claim 17, wherein generating the one or more metrics indicative of imaging sensor noise includes computing a Fast Fourier Transform on each container image and, optionally, generating a metric indicative of a level or relative level of high-frequency components.

19. The non-transitory, computer-readable medium of claim 17, wherein the instructions cause the one or more processors to identify one or more differences between the one or more additional container images and the one or more container images with respect to:

container alignment;

defocus;

intensity;

variation in intensity; and/or

motion blurring.

20. The non-transitory, computer-readable medium of claim 17, wherein the instructions cause the one or more processors to identify the one or more differences between the one or more additional container images and the one or more container images at least by:

generating a histogram of pixel intensity levels for the one or more container images or a composite image derived therefrom; and

generating a histogram of pixel intensity levels for the one or more additional container images or a composite image derived therefrom.

21. The non-transitory, computer-readable medium of claim 17, wherein the instructions cause the one or more processors to identify the one or more differences between the one or more additional container images and the one or more container images at least by:

computing a Laplacian of the one or more container images or a composite image derived therefrom; and

computing a Laplacian of the one or more additional container images or a composite image derived therefrom.

22. The non-transitory, computer-readable medium of claim 17, wherein the instructions cause the one or more processors to (i) identify the one or more differences, and (ii) generate the visual indication, in real time as the one or more additional container images are received.

23. The non-transitory, computer-readable medium of claim 17, wherein:

the instructions cause the one or more processors to generate the guidance for modifying the mimic AVI station based on the one or more differences; and

the visual indication indicates the guidance.

24. The non-transitory, computer-readable medium of claim 23, wherein the guidance include:

guidance to modify one or more configurable settings of at least one imaging device of the mimic imaging system;

guidance to modify one or more configurable settings of at least one lighting device of a mimic illumination system of the mimic AVI station;

guidance to modify a position of at least one imaging device of the mimic imaging system; and/or

guidance to modify a position of at least one lighting device of the mimic illumination system.

25. 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, wherein identifying the one or more differences includes generating one or more metrics indicative of imaging sensor noise for the one or more container images and the one or more additional container images; and

generate a visual indication of (i) the one or more differences, and/or (ii) guidance for modifying the mimic AVI station based on said one or more metrics.

26. The system of claim 25, wherein generating the one or more metrics indicative of imaging sensor noise includes computing a Fast Fourier Transform on each container image and, optionally, generating a metric indicative of a level or relative level of high-frequency components.

27. The system of claim 25, wherein the computing system is configured to identify one or more differences between the one or more additional container images and the one or more container images with respect to:

container alignment;

defocus;

intensity;

variation in intensity; and/or

motion blurring.

28. The system of claim 25, wherein the computing system is configured to identify the one or more differences between the one or more additional container images and the one or more container images at least by:

generating a histogram of pixel intensity levels for the one or more container images or a composite image derived therefrom; and

generating a histogram of pixel intensity levels for the one or more additional container images or a composite image derived therefrom.

29. The system of claim 25, wherein the computing system is configured to identify the one or more differences between the one or more additional container images and the one or more container images at least by:

high pass filtering the one or more container images or a composite image derived therefrom; and

high pass filtering the one or more additional container images or a composite image derived therefrom.

30. The system of claim 29, wherein the computing system is configured to identify the one or more differences between the one or more additional container images and the one or more container images at least by:

computing a Laplacian of the one or more container images or a composite image derived therefrom; and

computing a Laplacian of the one or more additional container images or a composite image derived therefrom.

31. The system of claim 25, wherein the computing system is configured to (i) identify the one or more differences, and (ii) generate the visual indication, in real time as the one or more additional container images are received.

32. The system of claim 25, wherein:

the computing system is configured to generate the guidance for modifying the mimic AVI station based on the one or more differences; and

the visual indication indicates the guidance.

33. The system of claim 25, wherein the guidance include:

guidance to modify one or more configurable settings of at least one imaging device of the mimic imaging system;

guidance to modify one or more configurable settings of at least one lighting device of a mimic illumination system of the mimic AVI station;

guidance to modify a position of at least one imaging device of the mimic imaging system; and/or

guidance to modify a position of at least one lighting device of the mimic illumination system.