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FACT SHEET

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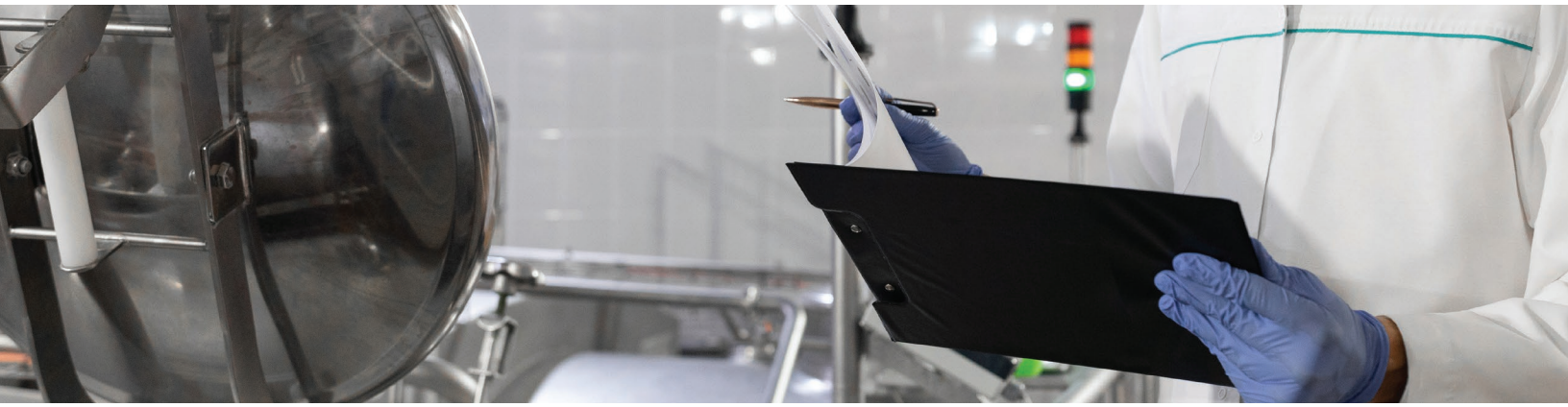

# PRE-OPERATIONAL INSPECTIONS

## WHAT IS A PRE-OPERATIONAL INSPECTION?

Pre-operational inspections, often referred to as pre-op inspections, are visual inspections conducted before operation begins. They are conducted to:

- Verify the cleanliness of equipment and production environment;
- Reduce the risk of product contamination from microorganisms and allergens on equipment and in the environment;
- Ensure the production of safe, quality products with a maximum shelf life.

## WHO PERFORMS THE PRE-OP INSPECTION?

Most often, quality assurance personnel are responsible for the pre-op inspection or someone separate from those that completed the cleaning. However, it is important that the individual who performs the inspection is qualified and properly trained. It is good practice to have a trained alternate in the event the responsible person is absent.

## HOW TO PREPARE FOR A PRE-OP INSPECTION?

- Be on time, and give yourself enough time, so you are not rushed! Production cannot begin until the pre-op inspection is completed, and the rooms/equipment are released.
- The inspection must be performed right before production (i.e. not 12 or 48 hours before as contamination can occur during this period).
- Obtain the equipment and tools required, such as records (hard copy or electronic), a flashlight, ATP swabs, proper PPE, litmus paper and sanitation personnel if possible, as they can address and correct issues as they are identified.
- Employ any safety precautions before you inspect, such as lockout or tagout. Remember to look with your eyes, not with your hands when you are around equipment.
- The person performing the inspection and the sanitation personnel should be the only staff permitted in the area during the inspection.

## WHAT TO INSPECT DURING A PRE-OP INSPECTION?

- Thoroughly inspect all equipment and areas to ensure they are adequately cleaned, and there is no food debris, chemical residue or pest activity.

**Tips:** Make sure equipment is disassembled when the inspection occurs. Be sure to check under equipment and use a flashlight.

- Verify that the concentration of the sanitizer is appropriate for the surface.
- Verify the effectiveness of the cleaning
  - ATP Swabbing
  - Microbial Swabbing
  - Allergen Swabbing
- Ensure production tools and equipment are cleaned and are properly stored, such as catch pans and garbage containers.
- Have QA and production staff sign off on the pre-op inspection record.

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## WHAT TO DO WHEN A DEVIATION OCCURS?

If a piece of equipment or an area is found to be inadequately cleaned or swabbing methods (e.g. ATP) yield readings that do not meet specifications, corrective actions must be initiated. If the deviation is reoccurring, a corrective action report must be completed as per the corrective action SOP, and the root cause must be identified and preventative actions established to prevent reoccurrence (e.g. type of chemical, type of cleaning tools, procedure clarity, etc.). Immediate corrective actions will include:

- Re-clean the equipment or area without re-contaminating the previously cleaned area/equipment;
- Re-inspect the area and equipment;
- Record the corrective action and sign off on the pre-op inspection record.
- Operation does not begin until items are re-cleaned, re-inspected and the record is signed off.

## PRE-OP INSPECTIONS CAN ALSO INCLUDE NON-SANITATION ITEMS SUCH AS:

- GMP checks
- Pest control activity
- Glass and brittle plastic inspection
- Knives and sharps inspection
- Foreign object inspection (e.g. metal, wood, etc.)
- Scale checks
- Best before dates/correct packaging and labelling check
- Wash stations are adequately stocked (soap, paper towel, sanitizer if necessary)
- Proper temperature in the processing area
- Temporary repairs (e.g. zip ties)

## FOR MORE INFORMATION

**Clarissa McIsaac & Pam Laffin**
**Quality and Food Safety Specialist**
**Tel:** 902-890-0544; 902-679-8678
**Email:** cmcisaac@perennia.ca; plaffin@perennia.ca