CLEAN VALIDATED

FIELD NOTES / 01 • CLEANING VALIDATION

CLEANING VALIDATION

Design the process. Challenge it. Keep it in control.



Illustration · Clean Validated

A lifecycle with decisions at every step

Reliable cleaning combines process knowledge, justified residue limits, suitable sampling and continued oversight. Each stage must produce evidence for a clear decision.

KEY QUESTION: What does this evidence let us decide?

DIRTY HOLD

Time before cleaning can change how strongly a residue adheres.

CLEAN HOLD

Storage after cleaning also needs defined conditions and a justified duration.

FOLLOW THE EVIDENCE

01 — Understand

Map residues, surfaces, equipment and cleaning variables.

EVIDENCE TO KEEP
Risk map + rationale

02 — Set the basis

Justify limits and identify the challenge cases.

EVIDENCE TO KEEP
Limits + worst-case basis

03 — Build the method

Define sampling locations, recovery and analytical capability.

EVIDENCE TO KEEP
Recovery + method data

04 — Demonstrate

Execute the protocol and explain the results and deviations.

EVIDENCE TO KEEP
Results + deviations

05 — Maintain

Trend routine evidence and assess relevant changes.

EVIDENCE TO KEEP
Trends + change review

THREE SUCCESSFUL RUNS ARE NOT THE WHOLE STORY

The number of runs needs justification. Routine performance still matters after the study.

Four variables worth putting on the wall

TIME

A shorter cycle or a longer delay before cleaning can change the challenge.

ASK ABOUT
Drying • delay • contact time

TEMPERATURE

Define the operating range that the cleaning process can tolerate.

ASK ABOUT
Heat loss • cold spots

CHEMISTRY

Specify the agent, concentration and preparation. Control the rinse as well.

ASK ABOUT
Concentration • rinse endpoint

MECHANICAL ACTION

Flow, coverage and manual technique influence residue removal.

ASK ABOUT
Spray coverage • dead legs

CHANGE DETECTED? REOPEN THE RIGHT QUESTION.

NEW PRODUCT

Does the existing challenge still cover its residue and safety basis?

PRACTICAL TRIGGER
A new residue, not just a new name.

NEW EQUIPMENT

Are access, materials, geometry and sampled locations still represented?

PRACTICAL TRIGGER
A gasket change can alter cleanability.

NEW RESULT

Investigate the cause. Define the evidence needed before the next decision.

PRACTICAL TRIGGER
A trend can matter before a failure.

SOURCE & SCOPE

Health Canada · Cleaning validation guide (GUI-0028), lifecycle approach, hold times and ongoing control. Visual synthesis; site procedures define the actual programme.

Educational field guide
Examples are illustrative.
Apply site-specific assessment.