

Protocol - Allergen Cleaning Validation

Food Safety & Quality Template · Provided by GIFSQ

Allergen cleaning validation proves the changeover actually works - not just that it was done. Worst-case product, defined sampling, and a pass/fail line decided before you start.

Be specific and honest in every field; vague records help nobody during an investigation. If a field doesn't apply, write N/A rather than leaving it blank.

1. Document control

Field	Details
Document title	Protocol - Allergen Cleaning Validation
Document no.	[QA-FORM-024]
Version	[1.0]
Effective date	[YYYY-MM-DD]
Prepared by	[Name / Title / Date]
Approved by	[Name / Title / Date]
Review date	[YYYY-MM-DD]

1. Validation design

- Equipment/line: [] | Allergen(s): []
- Worst-case product (highest allergen load): []
- Cleaning procedure reference: []
- Test method: [Protein swab / ELISA - kit and detection limit]
- Acceptance criteria: [e.g., below detection limit at all points]
- Trials planned: [] (minimum 3 recommended)

2. Sampling plan

Sample point (worst-case locations)	Trial 1	Trial 2	Trial 3	Pass / Fail
[]	[]	[]	[]	[]
[]	[]	[]	[]	[]
[]	[]	[]	[]	[]
[]	[]	[]	[]	[]
[]	[]	[]	[]	[]

3. Conclusion

Validation passes the procedure, not the operator's good intentions. If it fails, fix the procedure (or the equipment design) - don't just clean harder on the day and call it validated.

- Overall result: [Pass / Fail]
- Corrective actions (if fail): []
- Revalidation triggers: [Procedure/equipment/product change]
- Validated by: [Name / signature / date] | Approved by QA: [Name / date]

Approval and control

Role	Name	Signature	Date
Prepared by	[Name]	[Signature]	[Date]
Reviewed by (QA)	[Name]	[Signature]	[Date]
Approved by	[Name]	[Signature]	[Date]

Keep completed forms for Retain for life of the procedure plus [3 years]. at [defined location] - and make sure someone besides you knows where that is.

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