

Hygienic inspection of processing machinery and manufacturing lines

in food, cosmetics and pharmaceutical industry

Are you designing, constructing or modifying processing lines? Are you responsible for the supervision of hygiene at your plant?

Thanks to Hygienic Design Audit you will find out:

- Whether individual line components have been constructed and installed according to hygienic design principles
- Which line components may not be cleaned properly and pose potential hygiene risk for the process or be the source of microorganism/ allergen/ API cross-contamination for other products produced on the line
- What is a condition of product contact surfaces (surface roughness – Ra, Rz)

Modify your internal audit plan and change one of quality management SYSTEM / DOCUMENTARY AUDITS for hygienic design TECHNICAL AUDIT - product quality and product safety will be still in a main focus.

During the audit we will identify:



Dead legs

We will compare the length of the dead leg to its diameter, take into account direction of cleaning solution.



Non hygienic couplings

We will assess cleanability of dismantlable couplings and weld quality.



Non hygienic valves

We will verify whether there is no product retained in closed position of the valve or whether a product line is hygienically separated from the cleaning solution line.



Not fully drainable installation

We will inspect inside of installation (with 5 meters long endoscope) and document deviations.



Crevices

We will search for surface defects e.g. cracks, fissures, which could adversely affect cleanability.



Non hygienic bypasses

We will verify whether there is no product retained in bypasses.



Dead spaces

For dismantled equipment, we will indicate areas where cleaning solution has a poor access to.



Rough product contact surfaces

We will measure Ra / Rz roughness in few points of installation with calibrated roughness tester.



Not cleaned line components

We will search for line components which are not cleaned at all.

The audit process

Stage 1. Documentation review (prior to on site audit)

**When shared by the client:
Review of:**

- Information on type of the products produced, cleaning (and disinfection) methods used
- Information on construction materials used
- Line P&ID

Aim: To understand hygiene level required; to adjust audit scope

Stage 2. On site audit (1 small/ medium size line* per 1 day)

Inspection should take place when the line has been cleaned and is ready for production.

- The line is inspected 'equipment by equipment' / 'meter by meter' – both from outside and inside (with endoscope or after equipment disassembly, basic equipment disassembly is to be ensured by the client)
- During inspection, surface roughness will be tested with calibrated roughness tester in 5 - 10 points of installation (measured points will be indicated by the client or chosen by the auditor)
- For proper process understanding and risk evaluation of identified deviations, it is advised that during the inspection, a discussion should take place about both the technical, and process solutions employed (e.g. about possible line configurations during production and cleaning processes)
- An audit can be carried out in any production plant in Europe (audit and report in English)

*** Normally – up to approx. 50m of piping with valves/measurement devices etc., up to 3 product tanks**

Stage 3. Reporting (within 21 days after the audit)

Report will be prepared in English. It contains:

- Photos of identified deviations (from outside and inside of the line – from endoscope or after equipment disassembly)
- Description of deviation and its localization
- Basic risk evaluation and proposed corrective actions (if possible to determine based on information collected during audit)

Option

Hygienic design training workshop (1 day)



Develop competencies of your team in the area of Hygienic design principles.

- Training workshop will take place at Clients production line
- Methodology: 15 mins of 'theory' + 45 mins of common inspection (each module)
 1. Cleaning parameters affecting cleaning effectiveness
 2. Piping and couplings
 3. Pumps
 4. Valves
 5. Measurement devices
 6. Tanks
- Proposed date: day after Hygienic Design Audit

Price offer

Audit length „Hygienic Design” - 1 day	1700 Euro + travel cost*
Audit length „Hygienic Design” - 2 days	2700 Euro + travel cost*
Audit length „Hygienic Design” - 3 days	3500 Euro + travel cost*
„Hygienic Design” training workshop - 1 day	1700 Euro + travel cost*

*Travel cost

Hotels, planes, taxi, will be charged at real cost (flight ticket of reimbursable type), unless the auditee pays for them directly. For most European locations approx. 500 - 1000 Euro.



Auditor and trainer

Krzysztof Żarczyński
BNT SIGMA, Hygienic Process Design
and Cleaning Validation Expert

Master of Science in Food Technology. Worked in engineering and quality assurance in factories in pharmaceutical industry (IQ OQ PQ equipment qualification, cleaning process validation, ingredients changes – 4 years) and food industry (R&D of liquid foods – 4 years, Quality Assurance Manager – 5 years). Specialist in National Institute of Hygiene, Warsaw, Poland (attestation of products - 1 year). Consultant and trainer in area of hygienic and aseptic processing.

We work with leading companies in their fields



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