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Microbiological Quality Management for the Control of Quality Costs

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abstract

The definition and implementation of measures to ensure microbiological product stability, the success controls for the established measures, the detection of internal and external failures as well as their corrections cause costs, the so-called quality costs. Cosmetic companies are interested in minimizing these costs during the production of cosmetics.
The aim of this document is to present a concept for a possible cost-saving potential for microbiological expenses in the development and production of cosmetics without compromising the product safety.
Every cost-saving consideration is first preceded by an analysis of the failure potentials that could lead to a negative impact on the end product. In every process - whether in product planning, product development or manufacturing of cosmetics - a multitude of such potential failure opportunities can be identified, which are evaluated according to the probability that they will lead to a significant reduction in the quality of the end product. Corresponding protective measures have to be defined and implemented.
The next step is to consider the potential for saving testing costs and to implement cost-optimized measures. It is obvious that such optimization measures should be defined at the earliest when it can be demonstrated over a longer period of time that the entire process regarding quality planning, development and manufacturing leads to consistently good results with regard to microbiological purity and stability of the finished product. Optimization measures should be defined with a sense of proportion and evaluated for suitability by considering the entire process.

1. Introduction

The aim of this document is to present a concept for possible cost-saving potentials for microbiological expenses in the development and production of cosmetics without compromising the product safety. The following are considered:

- Basic considerations on quality costs related to microbiological quality assurance and classification of quality measures to the types of costs (prevention costs, testing costs and consequential failure costs).
- Detection and avoidance of potential failures in product development and product realization (raw materials, formulation, manufacturing specification, manufacturing process, quality of production facilities (hygienic design) and testing equipment, GMP requirements incl. R&D measures, hygiene monitoring, staff training and documentation) to reduce consequential failure costs.
- Cost-saving potentials based on defined, assured process workflows and the application of state of the art methods.

Every cost-saving consideration is first preceded by an analysis of the potential failure opportunities that could lead to a detrimental effect on the finished product. In every process - whether in product planning, product development or manufacturing of cosmetics - a multitude of potential failure opportunities can be identified (e.g. quality of raw materials, quality of water, formulation assurance, manufacturing specification, compliance to GMP, efficiency of R&D measures, hygienic plant design, etc.). These must be evaluated according to the probability that an identified failure will lead to a significant reduction in the quality of the finished product. Corresponding protective measures must also be defined and implemented.

Cost-saving potentials based on defined, assured process workflows and the application of state-of-the-art methods. Modifications in existing processes that are intended to reduce quality costs must be carried out with a sense of proportion. In case of unexpected failures, the previously assured process workflow must be restored immediately. For example, transferring the incoming raw material control to the supplier according to previously agreed methods is a possible optimization of the process. The raw material release is carried out based on the supplied certificates. If a product contamination is caused by a contaminated incoming raw material, the relationship of trust between manufacturer and supplier is disturbed and internal incoming raw material controls have to be carried out again.

In the following, the systematic approach for identifying potential failures and cost-saving is presented. Practical examples show possible saving potentials.

2. Quality costs – General considerations

There are various models for quality costs and each of them represents a slightly differentiated approach and basic statements.

a) Activity-based model (according to J.M. Juran)
This most commonly used model assumes that a balance between disadvantages due to quality costs and advantages by the increasing income can be achieved. For this purpose, the trilogy of "quality planning, quality assurance and quality improvement" is to be used. In the course of the process, it is important to control the three types of costs mentioned below (see also 2.1), since the total quality costs strongly depend on their magnitude and temporal frequency.

- Prevention costs
- Testing costs
- Consequential failure costs

b) Impact-oriented model
In this newer model, the quality costs are assigned to their task:

- Conformity costs
- Non-conformity costs

While the costs required to reliably obtain the defined quality are summarized as conformity costs (i.e. prevention costs and testing costs according to point a), non-conformity costs derive from the non-fulfilment of the quality requirements as additional improvement measures (defect costs and testing costs that become additionally necessary according to a).

c) Failure costs „rule of ten"
A look at the failure cost "rule of ten" shows that the further an failure proceeds undetected into the late stages of a process or comes to light first at the customer's site, the higher are the costs to correct this failure. The costs of an undetected failure increases by a factor of 10 from stage to stage of the value added chain. The earlier failure detection occurs, the more cost-effective it is for the organization **(Figure 1)**.

"The more efficient the procedures and methods in the context of failure prevention and therefore quality improvement, the higher and more cost-effective is the required quality level of a company." (*)

(*) *Omachonu, V.K., Suthummanon, S. and N.G. Einspruch* (2004): The relationship between quality and quality cost for a manufacturing company; in: International Journal of Quality and Reliability Management, Vol. 21 No. 3, S. 277 – 290

2.1 Definition of failure costs according to DIN 55350 and their application to microbiological quality assurance

Classification of failure costs according to DIN 55350 applied to the microbiological quality assurance of cosmetics:

2.1.1 Prevention costs

Costs caused by the analysis and elimination of failure causes

For the systematic analysis of process workflows in microbiological quality assurance, the application of failure prevention analyses (e.g. FMEA, HACCP or a hazard analysis and risk assessment according to the IFS-HPC standard) can be helpful. The analysis is based on the compilation of the individual process or procedure steps, the identification of failures, the evaluation of the significance of the failure for the finished product and the definition of measures to eliminate the potential failure. With the help of such an analysis, existing quality assurance measures can be revised and corrected.

It is also worthwhile to carry out a failure prevention analysis for microbiologically highly sensitive and / or high-priced products. The result leads to a catalogue of measures for the entire process, correct procedures and test plans can be prepared.

Prevention costs originate from microbiological quality assurance. For example, define the following measures for the prevention / elimination of failure causes:

- Quality and test planning for:
  - Product development and scale up phase
  - Raw materials, packaging materials, incoming goods control, storage, risk-based dynamization of incoming goods control, release system

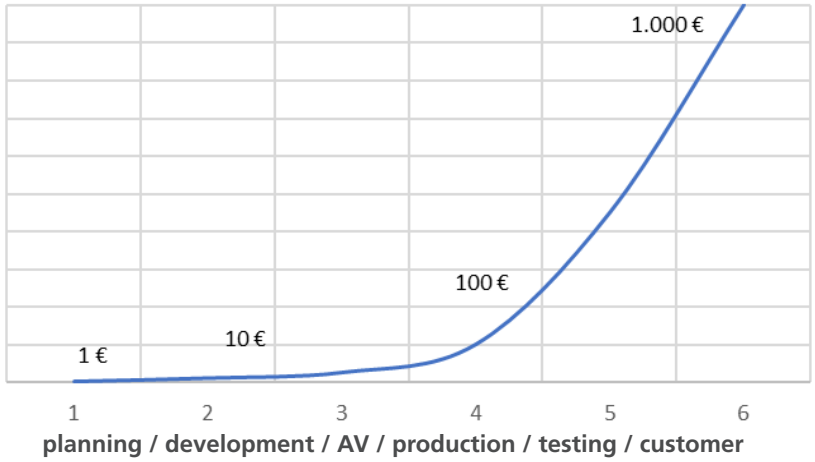

Fig. 1 Prevention costs according to different stages (schematic diagram)

- Hygiene measures
  - Personal hygiene / personal behavior, training
  - Industrial hygiene in production: hygiene plan / defined cleaning regulations (e.g. R&D in the development of new formulations, consider structural deficiencies in plant design)
- Product manufacturing and intermediate products: In-process testing, product / finished product testing, release processes, procedures in case of positive results

- Technical optimization:
  - Production facilities (hygienic design): microbiological considerations in planning / expansion
  - Water system: system design / test design
  - Preventive service plan
  - Computer-assisted weighing systems to avoid weighing failures and mix-ups

- Establishment of a documentation system
- Training / Employee motivation
- Supplier assessments
- Internal audits

2.1.2 Testing costs

Costs due to scheduled tests, which are not caused by a specific failure, but which are intended to avoid consequential failure costs

In the microbiological quality assurance of cosmetics, testing costs arise in the following cases:

- Microbiological tests and assessments as part of product development and the scale-up phase,
- incoming goods / storage controls of raw materials and packaging materials,
- Process water monitoring
- Process analyses, in-process controls, end product controls in the manufacturing process
- Hygiene monitoring,
- Market analyses, complaint management.

2.1.3 Failure costs / consequential failure costs

Failure costs are costs caused by a failure

- Internally occurring failures are detected and eliminated before the product is delivered
- Externally occurring failures detected through complaints or market analysis.

This can result in extremely high consequential failure costs. Such costs come from:

- Processing costs for contaminated batches
- Causal research and corrective measures to avoid a repetition of failures.
- Production losses
- Post treatment / destruction costs of contaminated goods
- Contractual penalties for non-compliance with delivery dates
- Recall / Image loss
- Additional expenses for extensive R&D measures

3. Systematic avoidance of failure costs

For systematical avoidance of (consequential) failure costs, it is advisable to prepare a very detailed analysis and planning for the entire development and manufacturing process (see 2.1.1). In this context, identify potential sources of failures, if necessary, evaluated by means of risk priority numbers, which are composed as follows:

Probability of occurrence of a defect X / importance of the defect for the finished product Y / probability this defect be noticed. FMEA, HACCP or hazard analysis and risk assessment according to IFS-HPC standard often used here.
Systematic failure analysis leads to a global observation of the system. Single measures out of context always run the risk of creating deficiencies in the protection of other process steps, which can easily be overlooked.

During the systematic failure analysis, in situ observations of the manufacturing process take place. Among other things, observation of parameters set by the development and production documents, formulations and documents for microbiological validation.

The following elements are essential:

- Assessment of raw materials for microbiological vulnerability, specifications and other supplier agreements
- Specifications for production water / Conformity with specifications / Test plans, sampling plans, methods
- Process instruction (VA) on the process starting with the incoming goods inspection until release, for documentation, sampling, for test plans and methods according to the current state of the art (the detection of microorganisms in small numbers in the sample must be ensured).
- Production specification, documents from the scale-up phase, securing of microbiologically relevant process phases and individual process parameters such as pH value, temperature, solubility, etc., securing of water-based raw material pre-solutions, comparison with routine process.

Described and implemented procedures exist for

- Process control, documentation
- Hygiene monitoring
- cleaning and disinfection measures
- Microbiological in-process testing, test plans
- End product release (sampling plan, reserve samples, analyses, methods, specifications)

- Handling of non-conforming end products, blocking, failure analysis
- Procedure for treatment or destruction of contaminated products, assessment of marketability
- Recall from the market
- Dealing with suppliers, customers, contract manufacturers
  - Critical process workflows, quality agreements, etc.

Careful planning and the systematic incorporation of empirical data enable the permanent avoidance of failure costs. Continuous process improvement (CIP) is part of every quality assurance. However, the corresponding planning and implementation also require time, which must be made available.

Examples for Continuous process improvement (CIP):

- Procurement management:
  - Raw material/packaging: Finding of the optimal balance between costs and quality, making concrete agreements with suppliers in advance.
  - Do not simply compare offers - modifications may also require additional testing.

- Scale up: ensure that no failures are generated when transferring a development formulation to production scale.

- Change control (internal changes to existing specifications - ensure that possible effects on other processes/parts of the process are considered).
  - For raw materials/packaging materials/formulations (scale up) depending on the process and production method (e.g. conversion to continuous production)
  - For Personnel (e.g. systematic training, also for temporary staff)
  - For equipment (new units or also repairs)

- How are microbiological analyses designed?
  - Identification in case of growth, testing if reproduction is possible; in case of deviations, modify the procedure according to the results.
  - Allowing early separation of affected batches due to the results of analyses.
  - Allowing early initiation of cleaning and disinfection measures.
  - Updating of process instructions for compliant and non-compliant finished products, if necessary.
  - Trend analyses (routine/monitoring)

- Open communication
  - Ensure interface communication, each sector is contributing to the overall result. If necessary, consider external partners.

Based on the measures determined for the avoidance of potential failure modes (failure prevention costs) and derived process instructions and tests (testing costs), a concept is created that helps to avoid later failures and subsequent failure costs. The PDCA Circle (plan, do, check, and act) can be used for this implementation:

4. Limitation of failure costs (in case of unavoidable failures)

When failures occur, the rule is to detect them as soon as possible in order to avoid an increase in failure costs (see rule of ten). Here, "simple mechanisms" can have a very positive effect if they are supported in a company. It is one of the keys to high efficiency.

In this context, it should be mentioned that regular employee motivation provides immediate reactions. The relationship of trust between supervisors and employees is an important requirement for this

- Employees have the confidence to report deviations
- Reporting chains are known and defined so that reports are always sent to the right decision-making authority.

A concrete example:

During bulk production, a plastic paddle falls into the production vessel.

- **Case 1**: The employee reports this immediately, there is no need to investigate the cause. The damage can be quickly localized.
- **Case 2**: If the employee does not report this immediately, in extreme cases the failure may only be detected by a customer complaint (foreign object in the product) and lead to a recall.

5. Quality costs - potential savings

5.1 General considerations

With the goal of reducing quality costs as set in this paper, it is mainly about avoiding cost from failure and failure correction

that may originate from microbiological failures. The second step is to determine the cost generated by the implemented measures. It is useful to sub-classify the costs into failure prevention costs, inspection costs, and failure correction costs.
In a further step, cost savings potential from failure prevention, inspection costs and application of cost-optimized measures are considered.

Optimized measures in terms of cost optimization can only be considered when proven that the entire quality planning, development and manufacturing processes leads to consistently good results over a longer an extended period of time, regarding microbiological purity and stability of the finished product.

Arbitrary reduction of preventive measures and the scope of testing is not conducive and can lead to fatal consequences. Properly thought-out and correctly defined processes that adapt to the settings, allow cost savings.

As shown with the practical example (see **Table 1**), a sense of proportion must be practiced by the savings on failure prevention measures and the inspection efforts. For example, employee-training serves to prevent failures and motivate hygienical work in the manufacturing plant, never consider economizing this measure.

The recommendation from the example described above, is to divide the manufacturing flow into critical and less critical process, and evaluate them in order to secure them accordingly.
It makes sense to regularly review existing processes and adapt them to the current circumstances. By redefining processes, several options arise through careful design and optimal planning of processes to avoid unnecessary steps.

Microbiological activities and hygiene are preventive measures. Furthermore, they must be as an effective system understood - i.e., effectiveness lies in the interaction of all measures together, so that it is hardly possible to prove the necessity of individual measures.

Consequently, it is also wrong to reduce testing efforts arbitrarily in such a way that problem identification at an early stage and trend tracking is no longer possible. Even after spending, a minimal effort on microbiological quality assurance over many years, and everything still „went well". A single major incident can mean the „end" for a company due to the recall of contaminated products and image loss. Rather, a person with experience on microbiological product safety based on the used system (integral view) should evaluate and systematically list the costs of microbiological and hygienic measures. The optimization potential can be only this way determined while maintaining to maximal the product safety.

5.2 Determinig saving potentials

The recommendation is to list and evaluate savings potentials based on defined process flows.

5.2.1 Optimization of testing costs / monitoring

5.2.1.1 Example from product development

a) Development
During the development phase of a cosmetic product, the stability assurance of the product is ensured by means of various microbiological tests.

Total viable count (TVC)
- Raw materials used
- Water used
- Lab sample product / intermediate product

Antimicrobial Effectiveness Test (AET)
- Fresh laboratory sample in the intended primary packaging
- Storage samples in the intended primary packaging
- TVC for In-Use samples, before and after use (min. 50 samples)
- TVC for market acceptance samples

b) Scale-up phase
- TVC for raw material + water qualities
- Assurance of water-based raw material pre-solutions (AET if necessary)
- Finished product from scale-up phase (TVC, AET)

c) Routine production
- Bulk / Intermediate (TVC)
- Finished product (TVC, spec. MO; AET)
- Market samples / complaints (TVC)

Savings:
How to minimize these expenses?
- *No minimization for new formulation developments.*
- *For minor product changes (e.g. change of color and fragrance, but process flow and the separation of water-based premixes remain the same):*
  - *Tests from **a** remain unchanged*
  - *Tests from **b** and **c** remain unchanged*
  - *Perform in **b** an AET of the finished product with a reduced spectrum of test microorganisms, consider the slowest microbial reduction rate from **a***
  - *Perform in **c** an AET with reduced spectrum of test microorganisms*

Caution: If the method of production change (e.g. conversion from boiler to continuous plant), it is essential to plan a new scale-up phase with all detailed tests.

5.2.1.2 Example from product development

Reception tests for microbiologically susceptible raw materials

a) Raw materials without delivery experience or with poor delivery quality)

The performed amount of tests should be according the specified sampling plan.

Take in account the requirements of ISO standard 17516 "microbial limits" (TVC and presence of spec. microorganisms) for testing and evaluation of results. Determine the expenses.

- What is the maximal content (%) of this raw material in the production portfolio? - Evaluate the formulation with the highest content of the raw material.
- How great is the risk for the finished product, if the raw material that does not comply with the specification is nevertheless processed?

Savings:
Allowing only reliable suppliers with goods that meet specifications contribute to reducing this expense. Note here that not all suppliers always check every batch sometimes may even supply a hazardous batch.

b) Raw materials with good supplying experience

Reduction to number X of test samples:
- Minimum 1 sample per batch or
- Interval testing (e.g. every 5th delivery) or
- Release via certificate (only possible after checking and comparing the testing method - see GMP 6.5.3).

Savings:
Are the savings potential of the approach used for suppliers with delivery experience larger than suppliers without or poor delivery experience?

What is the risk for the finished product, if timely detection of poor quality raw material does not occur?

Is the risk acceptable (quality and safety)?

5.2.1.3 Monitoring process water

Monitoring of quality of process water occurs usually at several points in the system: for example, quality at the intake point before and after the filter and disinfection unit, at the usage points for production, at the sampling points for cleaning procedures. The sampling points must be positioned in the system in such a way that contamination problems can be detected as early as possible (checks at the sampling points for production alone are not sufficient).

It is necessary to establish in house-specifications (microbial content specification as low as possible, but at least <100 CFU/ml). It is helpful to define warning limits and action limits, so that the water systems are regularly preventively cleaned, the "dead ends" are removed, valves and manifolds are check for leaks and cleaning methods are selected and verified.

In case of contamination:
Find the source of failure, start extensive microbiological testing. Disinfect the system.

Savings:
Equip the water sterilization system with an alarm signal and an automatic water stop. In case of failure of the sterilization system, it will minimize the risk of contamination.

If the process water quality is constantly good, the number of testing intervals and, if applicable, the number of test samples can be reduced. Nevertheless, the routine water quality monitoring has to include at least the downstream disinfection unit and at usage points (e.g. weekly).

For the analysis of larger volumes of water, it is recommended to use the filtration method (see ISO Norm), alternative methods with media immersion are much too inaccurate (only show bacterial counts >1000/ml).
In case of a deviation in the water quality, it is essential that bulk and finished products, produced with water out of the specification, are blocked and more thoroughly tested than usual.

5.2.1.4 Monitoring process water

In-process microbiological monitoring includes routine testing of raw materials, manufacturing water, water-based raw material pre-solutions, bulk product, intermediate storage container and finished product.

Savings:
How to minimize these expenses?

- *Reduce the number of samples if there are demonstrably well assured manufacturing processes (observe over a sufficiently long period, constantly low microbial count of the above-mentioned process stages).*
- *Sampling from boiler and storage tank (bulk): collect samples and only if the finished product is contaminated, carry out testing of these samples.*
- *Test the finished product at the beginning, middle and end of a shift. If the experience is good, i.e. increase of bacterial counts are not expected, savings can be made by examining mixed samples. Only in case of positive results, evaluate the complete process via the examination of individual samples and the retained bulk (boiler or storage tank) as well.*

Events / Process flow	Failure	Required improvements	Additional failure prevention costs (xx) / Subsequent failure costs
Container-preparation In a cosmetic company, the cleaning of IBC containers (Intermediate Bulk Container) starts manually, then on the inside with a high-pressure washer and afterwards disinfection with isopropanol (spray disinfection). An untrained leasing employee helps in the area. He is working under time pressure. Then employee sprayed isopropanol inside the completely clean container with residual water inside. Then the container stayed in the temporary storage area for 4 days before it is used.	1. Container not suitable, because reliable R&D is not possible. 2. Employee not sufficiently trained. 3. No controls of the leasing employee 4. Missing validated R&D procedure	1. Adequate Container 2. Sufficient Instructions / Training of leasing employee 3. Control by supervising personnel 4. Replace R&D process with validated/automated process	(1.Investment: different Containers) 2. Instruction / Training **15 Min. = 20€** 3. Basic procedure 4. Basic procedure / Investment
Day 1 (shower gel campaign) **Production:** Shower gel Var. 1 (3 ton, Prod.-Batch 1-1). Bulk filled in the container (see above) and 2 other containers.	No second disinfected was conducted on the container *(Not completely dry container. MO can multiply in the residual water)*	Essentially, due to the poor R&D situation, execute an additional disinfection step after storage.	Additional disinfection 15 Minutes/Container = **3 containers = 60€**
Day 2 Bulk (Ch. 1-1) transferred in 3 containers by truck to a sister company for filling.			
Day 4 **Filling:** Shower gel Var. 1 (Batch. 1-1) Transfer of 3 containers to a 3-ton storage tank then filled into 300 ml bottles. **Production:** Shower gel Var. 2 (3 ton, Produced-Batch 2-1). Shower gel Var. 3 (3 ton, Produced-Batch 3-1) Shower gel Var. 4 (3 3 ton, Produced-Batch 4-1) The only difference between shower gels is the pigment. Containers filled with bulk material and transported to filling location (see above). **Microbiological testing 1**: Filling Batch 1-1	No microbiological testing of the bulk material in the containers before for filling	Stored/transported bulk material should be microbiologically tested before filling	3 microbiological tests of the container goods **12 containers = 240€**
Day 5 Filling-preparation: Bulk Var.2 (Batch 2-1) filled in 3-ton storage container (previously used for Batch 1-1). Container and filling Water rinsed out only with water. Easy surfactant removal this way.	Increased risk when using the same equipment for all product variants, as there is no experience with the respective precursor.	Disinfect equipment if no microbiological information/ experience on precursor is available.	R&D costs for the equipment: 3 hours **3 times product change = 900€**
Day 6 **Filling:** Shower gel Var.2 (Batch. 2-1) **Filling:** Shower gel Var. 3 (Batch. 3-1) For **Filling:** All variants use the same feed tank and the same filling equipment. Rinsing conducted between shower gel variant changes. **Microbiological results 1**: Results are available for the filling Var. 1 (Batch 1-1) 20 CFU/g. The values are within the internal specifications limit. **Microbiological results 2:** Filling Batch. 2-1 **Microbiological results 3:** Filling Batch. 3-1	Investigation is carried out without identification of the found microorganism (risk assessment is hindered)	In the case of positive results, an identification provides a meaningful risk assessment.	Identification of microorganisms: **4 Findings = 120€**
Day 7 **Filling:** Shower gel Var. 4 (Batch 4-1) (Preparation: as previously described) **Microbiological results 2:** Filling Var.2 (Batch 1-2) (Preliminary reading) - 50 CFU/g. **Microbiological results 3:** Filling Var. 3 (Batch 3-1) (Preliminary reading) – 2000 CFU/g.		Repetitive positive findings in certain degree with significantly high values should trigger further decisions (blocking/ stop of production). This applies to the entire project, since the root cause has not yet been determined.	

Table 1: Practical example: failure costs

Events / Process flow	Failure	Required improvements	Additional failure prevention costs (xx) / Subsequent failure costs
Day 8 **Follow up results:** 2 further samples show uniformly > 30.000 CFU/g. **Production will be stopped.** All filled goods of the shower gel (Var.3 and Var.4) will be blocked. As the customer is waiting for the goods and is threatened with a fixed penalty - Var.1 and Var.2 (batches 1-1 and 2-1) will be released. Reason: existing findings were low in the limit range. The **root cause research** starts. Extensive **cleaning and disinfection** of the tank and filling system is carried out, which is successful.	The first 2 batches can not be released despite the low findings. Since the cause is not clear, the process must be considered as a whole.		**Subsequent failure costs:** 2 batches of 60,000 bottles are blocked = **Material costs = 20,000€** **Subsequent failure costs:** Cleaning/disinfection of the equipment **3 hours = 300€**
Day 12 Cause investigation shows that the origin of the contamination was most likely the transport container (see container preparation). Containers had not yet been cleaned and could therefore be examined.			**Subsequent failure costs :** Cause investigation with document inspection and microbiological analyses **approx. 700€**
Day 14 **Microbiological results:** The control sample of the 2 first batches (batch 1-1 and 2-1) are available - very high findings can now be detected here as well. The (released) goods have to be recalled. Fortunately, the goods were still available in the stores' individual warehouses and should not be recalled from the market. Customer no longer wants the goods.			**Subsequent failure costs:** microbiological follow-up analyses **approx. 350€** **Subsequent failure costs:** Blocked a total of **120,000 bottles = 40,000€** Collection / return shipping costs = **30,000€** Contractual penalty = **40,000€** Destruction costs = **5,500€** ---------- **TOTAL: 115,000€**
Additional activities Various microbiological follow-up analyses Internal processing (various areas) Damage to image *(for contract manufacturers: can be existence-threatening)*			**Subsequent failure costs: 1,000€** **Subsequent failure costs:** 20 employees/ 20 working days **= 25,000€** **invaluable**
		Total balance:	Reasonable additional prevention costs: **approx. 2,000€** Resulting direct follow-up costs: **approx. 115,000 - 120,000€**

Table 1: Practical example: failure costs - *continued*

IMPORTANT: Always test microbiologically at least one sample per batch. It is not possible to carry over the results from previous batches.

The release takes place under the internally defined specifications, which have to meet at least the requirements of the ISO 17516 standard „Microbiological limits".

In case of positive microbial detection within the specification, prove of no further microbial increase, differentiation, research of the causes and a risk assessment are the obligatory measures.

This expenses can be reduced if the process is sufficiently well assured so that a microbial limits of <10 CFU/g (detec-

tion limit of the plate count method) or non-detectable in 1 g (detection limit of the enrichment method) are achieved.

Since cosmetics production is not a sterile production, the recommendation is to carry out initial tests not until 8-24 h after filling, as very low bacterial counts are often no longer detectable over this period, and follow-up tests can be omitted.

An alternative approach to avoid failures is an early detection of the introduced microorganisms by promptly testing.

Practical example:
Excessive efforts in the wrong position

Cause: Planning failure
After testing three samples per batch based on ISO 17516, there was no differentiation and follow-up testing after detecting growth below the specification limit. Instead, numerous semi-finished products testing was conducted and no water quality monitoring.

This situation needs a procedure instruction describing the actions to carry out in case of growth detection below the set limit, and a list of list of actions required to detect possible sources of contamination.

5.2.1.5 Monitoring process water

The analysis of an obviously contaminated site within the routine environmental monitoring, does not give any additional benefit. Forehand knowledge about the poor cleaning of an examination site that may cause microbiological, chemical or physical contamination of the subsequent batch. Sites with standing water in direct contact with the product, address a risk.

Sometimes regular short inspections involving responsible persons and employees on-site are more efficient than a very extensive monitoring program.

A system based on hazard analysis, with variable monitoring points, can help to cover a larger area with fewer points.

5.2.2 Optimization of the Cleaning costs

- Optimize frequency of cleaning measures /
- Adjust the equipment usage exactly to the formulations (microbiological stability, formulation type and process/ equipment risk); if possible process several batches of a formulation in a row without intermediate cleaning.

Caution: Evaluate downtimes of more than 24h. Can contamination take place, for example via the pistons of a filling system, valves, distributors, pipes or condensate water?

- Adapt the frequency of cleaning measures to the circumstances. Are there any possibilities of contamination (risk assessment)? In case of low risk, disinfect only at the end/ beginning of a campaign. If the product is non-low risk (Aw-value and pH, etc.), then cleaning measures should be at least weekly.
- Investment in Cleaning in Place (CIP) systems (well-defined, reproducible cleaning processes without disassembly can be implemented).
- Investment in a pigging system. (Clean batch separation can be achieved, cleaning costs (product/water mixtures) can be minimized, as well as product loss due to cleaning processes.
- Optimal combination of chemical agents/temperatures/ manual cleaning effort (if CIP systems are not possible).
  - Before: W/O cream: 3 employees 5 hours
  - After: One employee, 2 hours in optimized processes.
  - Consultations on cleaning agents can be helpful.

Caution:
Check the water quality used for cleaning measures.
Frequent cleaning, but the water used is not microbiologically tested or comes from an old system that has not been disinfected. Standing water after cleaning, unless cleaned with steam, represents a major risk for product contamination within a few hours.
Remaining straightforward hygiene weakness: Carrying out many cleaning measures but the weakness remains. In this case, a complete modification is often less expensive than constant cleaning and measuring.

6. Concluding remarks

Expand the examples of cost savings listed here with more precise analysis and assessment considering the framework of each individual factory. Avoid selective reduction of the established measures; always assess first the potential effects on the finished product. The recommendation is to apply a systematic approach, taking into account all eventualities.

Establishing a very cost-effective microbiological quality management results from combining systematic risk-based analyses to avoid failure costs.

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