Cleaning a contaminated personnel's behavior

Decontamination Tools for Quality Managers:

- Part 2 -

We concluded part 1 of our previous blog post finding the root cause of repeated violations related to employees' behavior: the absence of the training program. In today's blog post we will continue with **Step 3,** to see how we can eliminate the cause of nonconformity and also prevent the occurrence of the same undesirable situation in the future.

Step 3: Take corrective actions to remove the cause of nonconformity

Root-cause
The company did not implement a training program for employees on: - Good personal hygiene practices and - Sanitary food handling techniques. New employees are completely unaware of food production GMP practices. - Also, the employees who have cleaning and sanitation duties were not trained regarding the sanitation principles and sanitary practices applied in the production unit.
Corrective actions
1. The Quality Manager shall inform the top management on nonconformities.
2. The Quality Manager shall define, implement and verify a consistent, documented training program for operational employees. The company shall appoint a qualified Trainer in charge of training the employees and the proof regarding his qualification shall be documented.
3. The training program needs to provide documented evidence, for each employee, on:

- Planning and delivery of training sessions, with a content related to employee's daily tasks.
- Training frequency - training employees before they begin work with the food product, at regular intervals, and at a minimum annually.
- Languages – training sessions need to be performed in multiple languages, so employees who are not native English speakers can perfectly understand the information.
- The evaluation methodology used.
- The assessment evaluating the effectiveness of the training and its results.

4. In order to correct the nonconformity observed, all employees need to receive training on:

✓ Good personal hygiene practices

✓ Sanitary food handling techniques

Also, the employees who have cleaning and sanitation duties need to be trained regarding the sanitation principles and sanitary practices applied in the production unit.

To increase the degree of awareness and compliance of the employees, this training also has to offer information on:

✓ Why using the vat to rinse the bare hands is a violation of GMP regulations.

✓ Why is so important to wash and sanitize the hands after touching dirty equipment.

✓ The hazards which poor personal hygiene and improper food handling techniques bring to the consumer's health.

✓ Why rinsing the rags and buckets in the vat is forbidden. What physical, chemical and biological hazards these practices represent to consumers' health.

The QA Manager should request the Trainer to concentrate on the practical use of the personal hygiene practices, sanitary handling techniques and sanitary practices in daily operations performed by the employees.

So...it's done? No, the most important step needs to be taken: evaluating the effectiveness of the training. Two assessments should be performed, following the training:

✓ One regarding the information employees received and

✓ The other one observing how they apply the knowledge in their daily tasks.

The Trainer needs to document both. Also, if there are unsatisfactory results, he has to train and assess again the employees.

Of course, the QA Manager should not stop here company's operational training program. It shall be developed to cover all areas, from GMP requirements, sanitation principles and sanitary practices to health and safety regulations, SOPs, WIs, etc., and make sure all employees are regularly trained.

Step 4: Take preventive actions to eliminate the cause of a potential nonconformity and occurrence of the same undesirable situation in the future.

How can the Quality Manager prevent the occurrence of such undesirable situations in the future? Well, it needs to apply a combination of preventive measures.

First, it needs to understand that implementing a consistent, documented training program for operational employees is not sufficient. He has to verify permanently that all employees received the proper training and understood the content. Also, he needs to audit the unit and check if employees respect the good practices in their daily operations.

The QA Manager should also take a look at the upstream processes: which process "delivered" to production untrained employees? Which department has the responsibility of selecting and hiring employees? Well, the HR does, through recruitment, selection and HR administration.

So preventive measures need to start here. The QA manager can discuss with all – HR Manager, Recruiter, HR Administrator - and make them aware of the importance of training and development of specific skills. Also, together with the HR Manager, the QA needs to develop and implement operational HR procedures, in order to make sure that each and every newly hired employee is properly trained before starting to work in the production area.

Finally, the QA Manager needs to develop a tool allowing to permanently control the status of corrective and preventive actions taken, without having to check each and every nonconformity report.

Bellow we present an example of a fluent and easy-to-use CAPA plan. You can download the document by clicking here: .....

COMPANY'S NAME	QUALITY & FOOD SAFETY SYSTEM'S PROCEDURE NO. 9 – CAPA – Code: QSP – 9 – CAPA PLAN	Ed: 1 Rev: 0
		Date:
		Page: 1/1

Name of the employee responsible for monitoring the plan:	QA Manager

Nonconformities/ Improvements						
1. Employees used the vat containing rice soaking to rinse the bare hands after handling equipment. Employees also rinsed the rags and buckets in the vat containing soaking rice, after using them to clean the production area with detergent. In the packaging area, employees were allowed to grab rice noodles for packaging after touching dirty equipment, using their unwashed, bare hands.						
CAPA						
Root cause/ Nonconformity Report number/ Source of improvement	**Corrective actions taken/ Preventive actions taken/ Improvements made**	**Responsibility**	**Communicated from -> towards/ communication channel**	**Target date of completion/ Term**	**Actual date of completion**	**Accomplished/ Signature of QA manager**
The company did not implement a training program for employees on good personal hygiene practices and sanitary food handling techniques/ sanitation principles and sanitary practices applied in the production unit	CA - Implement a consistent, documented training program for operational employees	QA Manager	QA Manager -> CEO QA Manager -> Production Mg QA Manager -> HR Manager /by email	15th of May, 2016-15th of August, 2016/ 3 months	.....	.....

As you can see, the CAPA plan helps managers to verify each and every moment if all the necessary corrective and preventive actions were taken, communicated towards interested parties and completed in time. For example, if we analyze the enclosed document, it becomes obvious that the corrective actions were taken, but preventive actions are still missing, so the organization needs to follow the next step, to impede the appearance of a similar nonconformity in the future.

Besides managing CAPAs, the plan may also be a useful tool for a QA Manager the moment he is asked to present instantly the status of the CAPAs to top management, authorities, auditors, customers or partners, offering a positive image of the organizations' control on nonconformities and its quality culture.

We are hoping that our article and the three tools presented - cause and effect analysis, 5 WHYs, CAPA plan - will support your efforts in taking corrective and preventive actions, in order to avoid contaminations and offer customers a higher quality and a safer product.