Cleaning a Contaminated Personnel's Behavior

Decontamination Tools for Quality Managers:

- Part 1 -

Every time a Quality Manager notices nonconformities related to personnel's behavior, he needs to find a rapid solution to correct it. This does not always come easy, as the QA Manager has to be firm in eliminating the cause of the nonconformity and, at the same time, have a diplomatic approach, targeting the staff's awareness and a long term compliant behavior.

But what can you do when you are facing a compliance disaster? Let's analyze the case of Kun Wo Food Products, a rice noodles producer from San Francisco. On 27th of April, the United States District Court for Northern District of California entered a consent decree of permanent injunction against this producer, based on FDA inspections' documented results proving a long "history of processing rice noodles under unsanitary conditions".[1]

Besides multiple violations related to good manufacturing practices, FDA also noticed important violations related to employees' behavior:

- In the production area, employees used the vat containing rice soaking to rinse the bare hands after handling equipment.
- Employees used the vat containing soaking rice to rinse also the rags and buckets, 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.

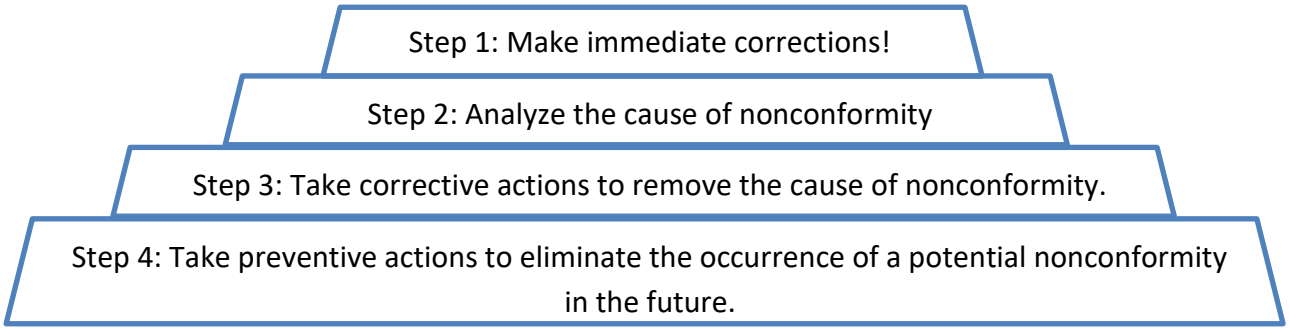
Consequently, company's rice noodle presented the risk of being contaminated with the dangerous pathogens. The swab sampling performed by FDA inspectors proved the bacterial contamination of surfaces and buckets utilized in production activities with Listeria monocytogenes, Bacillus cereus, Salmonella, Escherichia coli, and Staphylococcus aureus.

Truly, you would say, "any manager facing this GMP compliance disaster would feel overwhelmed". Yes, it is correct, but even such a disaster can be managed and the unit driven towards a satisfactory degree of compliance. Let's take it step by step, on the compliance way,

to correct nonconformities related to good personal hygiene practices and sanitary food handling!

1. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm499008.htm

So, what should be done to manage this compliance disaster?



We will concentrate, in our first blog post, on the practical approach a Quality Manager may take to apply steps 1 and 2 in the production unit.

Step 1: Make immediate corrections!

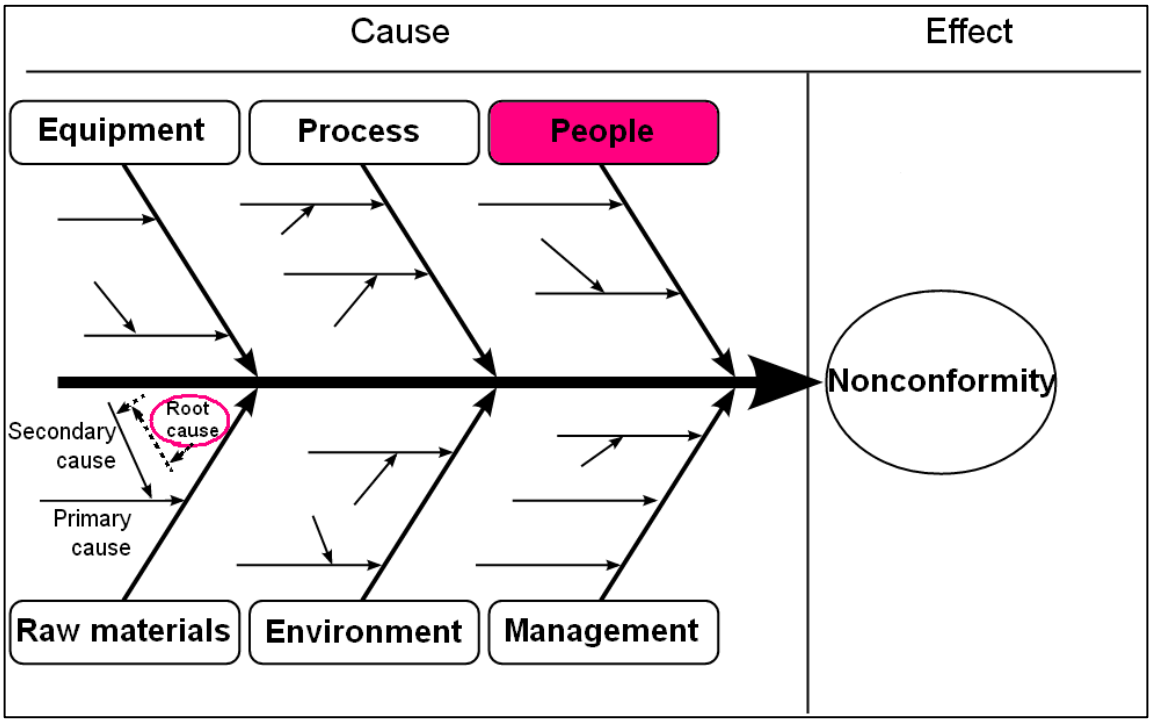
Yes, this calls for immediate corrections! A QA Manager has to remove the nonconformity, especially when dealing with a contaminated product. Let's see all corrections which must be made:

Nonconformities
In the production area, 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.
Corrections
1. Stop all production operations on that rice processing line 2. Remove the water and soaking rice. 3. Consider the rice as a contaminated product, presenting microbiological, chemical and physical risks, and treat it accordingly, taking measures for the identification, isolation, and disposal of the contaminated batch. Take identical measures for the packaged noodles batch. Please note that all the above-mentioned measures must be documented. Keep these documents filed, so they can be available for the next inspection or audit.

5. Perform at least two cleaning and sanitation operations of the contaminated equipment. 6. Take samples for the laboratory or perform rapid tests. 7. Validate the cleaning and sanitation.

Step 2. Analyze the cause of nonconformity

How? Well, it's quite simple! In order to analyze the root causes, we can use the classical cause and effect analysis, using a fishbone or Ishikawa diagram, along with the 5 Whys technique.



Tool 1: Fishbone or Ishikawa diagram

Let's take a look at the way it can be applied to our case study:

Cause and effect analysis	
Question	**Answer**
Which is the cause of nonconformities?	The nonconformities are generated primarily by people - employees are contaminating the rice, but within possible causes we may also find:

	- Insufficient equipment and facilities (for example hand washing stations missing or positioned too far from the areas employees handle food products) - The lack of an adequate space for cleaning and maintaining the cleaning equipment - Deficient implementation or management of GMP requirements.

The 5 WHYs	
Questions	**Answers**
Questions 1. Why did employees use the soaking rice vat to rinse the bare hands? 2. Why did they also utilize it to rinse the rags and buckets used to clean the floor with detergent? 3. Why did they not clean their hands before touching food products?	Primary possible causes: - The personnel did not receive a proper training to follow good personal hygiene practices and respect the sanitary handling of food techniques
	- The unit does not have functional hand washing facilities for employees' hand washing
	- These facilities are not functional or are too far from the areas employees handle food products, so the employees do not use them
	-The unit does not have an adequate, separate area for cleaning and maintaining the cleaning equipment or it is not functional
	- The employees who have cleaning and sanitation duties have not been properly trained regarding the sanitation principles and sanitary practices applied in the production unit
To continue our case study, we will select the first possible cause and discover the secondary ones:	
2. Why did the personnel not receive a proper training?	- Training sessions were not performed, the personnel is unaware of the requests - Training sessions were delivered in English but employees are not native English speakers - Workers received a simple theoretical training: the training in unit's work environment was never delivered, so workers do not know how to apply the sanitary food handling techniques to daily

	operations. Also, employees do not know which operation require sanitizing the hands, when to do it and why is it so important. - The employees who have cleaning and sanitation duties were not properly trained regarding the sanitation principles and sanitary practices applied in the production unit. - Training sessions were not followed by an assessment evaluating the effectiveness of the training, so nobody knows the level of knowledge and skills developed by each employee.
Now, let's select two secondary causes - training sessions missing/ lack of assessment - and continue the analysis, finding the tertiary cause:	
3. Why were the training and assessment missing?	- 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. - The company also did not employ qualified workers, with previous experience in food production; it preferred low-cost workers, with experience in other industries, completely unaware of food production GMP practices. - No manager or supervisor had the responsibility for training employees and no induction, regular or awareness training was delivered in the last 2 years. - The top management did not receive a proper training regarding the risks related to violations of food safety and hygiene regulations, so they were not aware of the possible legal consequences for the unit or the impact on consumer's health.

Now we can consider that we have found the answer representing the root cause, as the absence of a training program is a basic regulatory request. Once we found the root cause, we can move on to step 3: taking the corrective actions.

Into our next blog post, we will analyze together which corrective and preventive actions can be taken to achieve constantly a satisfactory level of compliance. We will also provide a CAPA plan example and document draft. It's an easy-to-use tool, allowing QA Managers to permanently control the status of corrective and preventive actions taken, without having to check each nonconformity report filled in.