Authors: Paul L. Pluta, Bernard Hsu, Alan M. Mancini, and Richard Poska

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COMPLIANCE CASE STUDY #16: MICROBIAL CONTAMINATION FROM FOODS

"Compliance Case Studies" provides a forum for compliance practitioners to share information about actual compliance experiences. Previous discussions addressed a wide range of compliance activities. Previous case study titles discussed in this series include the following:

1. Equipment Cleaning and Visual Evaluation, Journal of GXP Compliance (JGXP), V13, #1, Winter, 2009.
2. Questionable Equipment Qualification, JGXP, V14, #1, Winter, 2010.
3. Manual Processes – Performance, Responsibilities, and Training, JGXP, V14, #1, Winter, 2010.
4. Cleaning Validation Unknown HPLC Peaks, JGXP, V14, #1, Winter, 2010.
5. Secondary Packages with Defective Glue Joints, JGXP, V14, #2, Spring, 2010.
6. Identical Mixing Tanks, JGXP, V14, #3, Summer, 2010.
7. Broken Punches, JGXP, V14, #3, Summer, 2010.
8. White Spots on Tablets, JGXP, V14, #4, Autumn, 2010.
9. Substandard Data and Documentation Practices, JGXP, V15, #2, Spring, 2011.
10. Change Control for "Like-For-Like" Changes, JGXP, V16, #2, Spring, 2012.
11. "Glass" Fragments in a Parenteral Product, JGXP, V18, #3, Autumn 2014.
12. Yellow Discoloration on White Coated Tablets After Commercial Distribution, JGXP, V18, #4, Winter 2014.
13. Consistent Sampling, Results, and Original Data. JGXP, V18, #4, Winter 2014.
14. "Like-for-Like" Changes – What, if Anything, Should be Done? JGXP, V19, #1, Spring, 2015.
15. Manufacturing Support Audit Observations. JGXP, V19, #2, July, 2015.

Readers are invited to participate and contribute manuscripts for this series – please share your successful practices with others. Please contact journal editor-in-chief Paul Pluta at paul.pluta@comcast.net or journal managing editor Stacey Bruzzese at mailto:Stacey.Bruzese@informa.comwith comments or submissions for publication.

INTRODUCTION

Several recent news stories describing fatalities caused by microbial contamination of food have been widely reported. These stories described the potential dangers of microbial contamination associated with food preparation in the home. They should be viewed, however, in a broader context – why did contamination occur and how might the fatal effects be prevented. Much can be gained from considering the possible applications of these events to work and personal circumstances. This brief discussion is intended to remind compliance professionals of potential sources of microbial contamination associated primarily with food, discuss potential occurrences in the work and home environments, and suggest practices and methods for prevention.

Product Contamination Considerations

A primary concern in GMP pharmaceutical manufacturing is prevention of product contamination. In general, contamination may be chemical, physical, or biological. Manufacturing facilities, materials, equipment, processes, and product may all become contaminated with any of these contaminants. Numerous policies, programs, procedures, and testing address contamination. Related personnel training preventing contamination is a major compliance activity. Preventing microbial contamination is an especially difficult problem; microbial contamination is everywhere, has numerous causes, and is easily transmissible throughout a facility.

Product Contamination from Food. Food in the manufacturing facility is a potential source of product microbial contamination. Manufacturing sites may have cafeteria services with food preparation activities. Lounge areas and internal department rest areas in which employee eating/snacking occurs are available. Departments have internal parties with food, anniversary celebrations, and other events requiring food. Employees bring food into a facility for their lunches. Microbial contamination from food-related sources may be transferred by employees to manufacturing areas. The cafeteria and other site eating areas must be treated as rigorously as the manufacturing facility in general cleanliness and sanitization, prevention of cross-contamination, and food handling practices.

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Personnel Health. Aside from product contamination, food safety practices are critical for the health of employees. Employees may eat food prepared in the site cafeteria, may purchase food from vending machines, or may bring prepared food from home. Food brought from home must be stored at appropriate temperature and under sanitary conditions. Refrigerator cleanliness, accumulation of old food, and food spoilage is often a recurring problem; unrefrigerated prepared food stored in personal clothing lockers is a potentially serious issue.

Beyond work, food safety considerations are also relevant in the home. Personal knowledge of food safety may be from long-ago college biology courses. Unless we have direct connection with a microbiology work function, we may simply be unaware of potential harmful situations and opportunities for food contamination. Food safety must not be taken lightly; USA CDC estimates foodborne illnesses annually sicken 48 million people, hospitalize 128,000 people, and kill 3,000 people (1) – testament to general lack of knowledge or carelessness regarding safe food practices. Food safety in the home is important to our employees and to their families.

Discussion Topics

This discussion reviews recent news stories describing fatal events caused by microbial contamination. Potential causes for the harmful effects are addressed. Application to pharma operations and food handling in the manufacturing facility is discussed. Recommended safe food handling practices are described. Information provided should be helpful in both workplace and home applications.

MICROBIAL CONTAMINATION EVENTS

Two fatal incidents demonstrating the potentially serious consequences of microbial contamination in home food preparation have recently been reported.

In October 2020, nine members of a Chinese family died from eating contaminated noodles prepared from fermented corn flour (2,3). The food had been prepared one year ago and then frozen. Prolonged freezing did not negate the toxic effects; freezing does not kill contamination -- it preserves contamination. Death was caused by bongkrek (aka bongkrekic) acid, a mitochondrial toxin produced by specific Pseudomonas and Burkholderia species. Bongkrek acid is very stable to heat and often fatal (4).

This same toxin also killed 75 and hospitalized more than 200 people from contaminated beer at a Mozambique funeral in 2015. The beer involved utilized contaminated corn flour thought to be safe for beer fermentation. Tempeh bongkrek, a fermented coconut preparation, has been banned by the Indonesian government after many reported poisonings and deaths. The high fat content in coconut has been correlated to bacterial growth and fatalities in tempeh bongkrek (5).

Another fatal microbial contamination incident involved a 20-year-old Belgian student who prepared a pasta mixture but did not refrigerate the prepared food (6). He ate the mixture after 5 days of room temperature storage, and then died approximately 10 hours after eating. *Bacillus cereus* contamination was determined to be the source of contaminating toxin. *Bacillus cereus* produces multiple toxins that may cause mild to severe food poisoning symptoms including diarrhea and vomiting. See YouTube video (7) for a more complete discussion of this incident. Fried Rice Syndrome is also caused by the same Bacillus toxins. It has been estimated that more than 60,000 people in the USA are stricken with Bacillus food poisoning every year (8).

Causes of the Fatal Events

Fatalities in the above events were caused by microbial organisms that produced lethal toxins. These toxins were resistant to temperature far above standard cooking temperatures. Sources of the bacteria / toxins were unknown, i.e., we do not know when contamination was introduced into the cooking process. Potential areas of concern include ingredients (starting materials), utensils (equipment), preparation areas (facilities), water (utilities), cooking methods (processes), and refrigeration (storage). We liken the cooking process described above to GMP pharma manufacturing.

Ingredients. Contaminated starting materials used in preparing foods may have caused the fatal events. Bacillus contamination in all types of foods has been widely reported (9). Even dried spices have been determined to carry Bacillus contamination. Fermented corn flour was used to prepare noodles in the China fatalities. Spoiled ingredients were used in the Mozambique beer fermentation processes. Coconut fat content was critical to toxin production in the banned Indonesian dish.

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Utensils, Prep Areas, and Water. These were not specifically addressed in any news stories. Cooking utensils and water were used in preparation of all recipes. The Mozambique beer fermentation required large equipment for preparation judging from the number of people who poisoned by the beer. Equipment cleanliness is always a potential cause for contamination.

Cooking Methods. Cooking processes used in the above were conducive to microbial proliferation and toxin production. Fresh noodles are prepared by kneading flour, water, and other ingredients and forming into noodle shapes. Pasta is cooked in boiling water. The causative microorganisms are resistant to heat; Bacillus species form heat-resistant spores. Warm cooking temperatures may actually stimulate microbial proliferation and toxin production.

Refrigeration. The cause of death of the Brussels student was inadequate storage of prepared food. The student did not refrigerate the pasta dish; the dish was at room temperature for 5 days before consumption. Although corn noodles in the bongkrekic acid case were frozen for one year before consumption, freezing and cooking for eating had no effect on toxins within the noodle preparation.

People. There was no information regarding education or experience of people involved in these fatalities. The Brussels student was 20 years old. Nine adult members of the Chinese family died; three children who did not eat the noodles were unaffected. Personnel involved were obviously unaware of potential contamination or of food safety procedures.

MANUFACTURING APPLICATIONS

Each of the above general food preparation considerations are potential sources of microbial contamination in pharmaceutical manufacturing. Starting materials received from suppliers should be tested for microbial or other unwanted contaminants before being accepted for processing. Suppliers who utilize subcontractors to provide suppliers must in turn confirm the absence of contamination before they begin their respective processes. Products using natural products may have a greater risk of microbial contamination. Active drugs, excipients, and supporting ingredients such as growth medium components may be a source of microbial contamination. GMP equipment and facilities used in manufacturing must be clean and free of contamination. Porous surfaces such as plastics, gaskets, and similar non-steel surfaced must be adequately cleaned. Equipment and components must be dried; standing water and residual moisture are favorable for microbial growth. Processes must be carefully designed and correctly executed according to approved procedures. Upstream biotech processes are especially susceptible to contamination since growth media are intrinsically supportive to intended microbial proliferation. Personnel who perform manufacturing processes for products susceptible to microbial contamination must receive appropriate training. The training should be periodically retrained to maintain knowledge, techniques, and other relevant practices. Routine handwashing by employees is mandatory and must be continually encouraged. Personnel compliance in performance of procedures is critical. Case studies below describe specific examples of equipment, facility, and process contamination in the pharma manufacturing environment.

FOOD SAFETY CONSIDERATIONS

Every manufacturing facility with employees must consider the potential for microbial contamination from food. Facilities with cafeteria operations have significant risk. Department rest areas in which employee eating/snacking occurs are problematic. Employees bring food into a facility for their lunch or other use. Departments have internal celebrations and other events involving food; storage of leftovers and consumption by employees several days thereafter may potentially result in serious effects. All of the above have the potential to introduce microbial contamination into the manufacturing plant.

There are numerous websites providing information related to food safety. Comments provided below are from various USA government websites (10-12) that are focused on food preparation in the home; these general principles are applicable to all food handling. Differences in various country practices are possible; for example, eggs are not refrigerated in some countries because chickens are vaccinated with Salmonella vaccine (13).

US CDC Recommendations

The US Center for Disease Control has issued clear and concise recommendations for food preparation (10). Their general guidelines provide simple fundamental practices for food handling. Four general steps for food safety are recommended.

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1. **Clean**. Wash hands and surfaces often. Food preparation must be clean. Germs causing food poisoning can survive in many places and spread around the kitchen. Clean work surfaces, cookware, and utensils with hot soapy water. Thorough handwashing is required before and after working with food, and before eating. Rinse fresh fruits and vegetables.
2. **Separate.** Do not cross-contaminate -- uncooked food may contaminate cooked food. Use separate cookware and utensils for cooked food and for uncooked food. Keep cooked food separate from uncooked food in the refrigerator. Do not use marinating liquid (used on raw food) later as gravy or seasoning on cooked food.
3. **Cook.** Cook to the right temperature. Foods must be cooked to their required internal temperature to kill microbial contamination. Use a food thermometer to test temperature.
4. **Chill.** Refrigerate promptly. Keep refrigerator at 40°F or below. Prepared food must be promptly stored under refrigeration – within 2 hours (or within 1 hour if outside at >90°F). Thaw frozen food in the refrigerator; do not thaw foods at room temperature.

WHO Recommendations

The World Health Organization has published a 30-page booklet "Five Keys to Safer Food Manual" applicable for training on food safety (14). It adds a fifth consideration to items listed in the CDC document: Use safe water and raw materials. This additional section emphasizes the use of uncontaminated food starting materials, discarding spoiled food; using clean water (not river water), pasteurized dairy products, and food within dating (not expired); adequate cleaning of food, and related activities. This booklet also provides introductory information about contaminating organisms, symptoms, and other fundamental information.

Other Considerations

Other useful comments related to food handling in pharmaceutical facilities and in the home kitchen are as follows.

Handwashing. Fundamental to food preparation as well as general cleanliness is handwashing. The world learned of the importance of thorough handwashing and its recommended frequency associated with Covid-19 prevention. Numerous discussions and videos describing handwashing techniques are available. Twenty seconds of handwashing is suggested in several documents; however, healthcare professional's handwashing is much more methodical and prolonged requiring several minutes. Thorough handwashing before handling food, after handling food, and before eating is encouraged. Problem washing-areas in the hands have been identified (15).

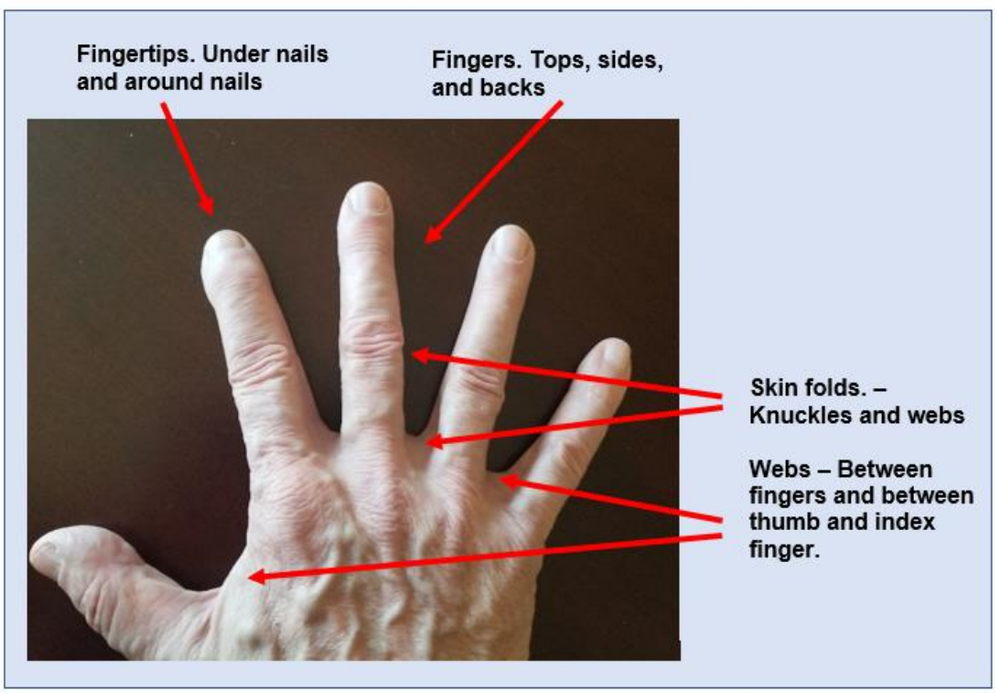

Figure 1. Handwashing General Problem Areas

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Hand Sanitizers. Use of hand sanitizer in the kitchen in lieu of handwashing is not recommended; soap and water is available in the kitchen. Hand sanitizers are not effective in killing all organisms. Notable organisms not affected include norovirus, HPV, Giardia, *Clostridium difficile*, *Cryptosporidium parvum*, *Enterococcus faecium*, Poliovirus, MRSA, Pseudomonas, Staphylococcus, and *E. coli* (16). Numerous hand sanitizer recalls due to Pseudomonas contamination have been reported.

Washing Fresh Food. Washing meat, chicken, turkey, and similar food is not recommended. Washing is thought to spread surface bacteria to sink and counter surfaces. Washing fresh fruit and vegetables is recommended, especially when dirt residue is visible on the food.

Surfaces, Washing, and Drying. Surfaces in food preparation areas must be non-porous surfaces. Wooden cutting boards made of porous wood are not recommended. Washing of cutting boards and utensils must be thorough and complete. Cutting boards must be dried soon after washing and not allowed to air-dry. Standing water is favorable to microbial growth.

Thawing Frozen Foods. Never thaw frozen foods at room temperature. Thawing food at room temperature allows the food surface to warm supporting microbial growth while inner food remains cold. Foods may be safely thawed in the refrigerator, under cold running water, or in the microwave. It is not necessary to always thaw food before cooking; frozen food may be cooked without thawing; extra cooking time will be required.

Temperature Measurements. Use a food thermometer to measure cooking temperature. Do not rely on food appearance or cooking experience to judge adequate cooking temperature. Do not rely on oven temperatures for a specific time; oven temperature may not be accurate. Microwave ovens may lose power over time; also, microwave ovens may not cook food evenly. When using a food thermometer, use correct technique, e.g., center of roast, thickest section of chicken, not touching bones, not touching cooking dish. Thermometers should be periodically calibrated using ice and boiling water to verify acceptable temperature accuracy.

Pets. Cats and dogs carry contamination. Keep pets away from food preparation areas. Keep leftover food in closed containers. Remove waste quickly and transfer to outside closed waste bins (17-19).

Figure 2. Pets in the Kitchen

Outdoor Markets. Food for sale in outdoor open markets are common practice around the world. Wet markets are still believed to have contributed to the Covid-19 pandemic (20,21). Wildlife markets are another potential source of contaminated food. The need to thoroughly clean food purchased at these markets, and to thoroughly cook products that support microbial contamination to required temperatures is recommended.

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Figure 3. Food in Outdoor Markets

Contaminating Organisms. FDA has published the Bad Bug Book (22), which describes organisms and toxins causing various disease. Topics include pathogenic bacteria such as gram-negative bacteria including E coli bacteria, gram-positive bacteria; parasitic protozoa and worms; viruses, other pathogens, and natural toxins. This 300-page book may be downloaded.

FDA Recall Notices. Individuals may register with FDA to receive email notification of food product recalls. See reference (23).

CASE STUDIES

The following are case studies describing examples of microbial and related contamination in the work environment. These examples were communicated to *JGXP* by multiple QA or Validation managers from multiple companies.

Cafeteria Soft Drink Machine. Several employees complained about the appearance and taste of soft drinks and water from the cafeteria soft drink machine. This machine used site water to dilute soft drink concentrates. Microbial testing was requested from the water system. The water outlet was sampled; test results were "TNTC" – too numerous to count. The cafeteria water system was ultimately shut down. The system required extensive flushing and several sanitization procedures to provide acceptable water.

Department Refrigerator. A department in which nearly all employees brought prepared lunches from home did not have a refrigerator for food storage. The department budget did not allow for unplanned expenses; a refrigerator was never identified for future purchase. Employees stored food in their clothing lockers. If they did not eat lunch, food remained in lockers for more than one day at room temperature – note similarity to Belgian student *Bacillus cereus* fatality discussed above! When a new manager who had knowledge of food safety practices was assigned to the department, he obtained a refrigerator from within the company at no cost to the department; he also purchased an inexpensive microwave for department use. A potential source of food contamination was eliminated – and department morale was significantly improved.

Pseudomonas in Equipment Gasket. Compressed tablets were found to be contaminated with Pseudomonas. Contamination was uniformly distributed throughout the entire lot. Investigation indicated the source of contamination to be a gasket in the discharge chute of manufacturing equipment. The discharge valve on the bottom of equipment was not disassembled for

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cleaning and drying. The silicone rubber gasket absorbed moisture from the washing process. Pseudomonas grew in the moist gasket environment and was distributed into product upon discharging the equipment. Contaminated powder blend was then compressed into tablets. Corrective action was to change the cleaning SOP to require removal, washing, and drying of all of the parts in the discharge valve assembly.

Contaminated Manufacturing Liquids. A project to justify granulating liquid hold times for a small molecule solid product process was initiated. A large batch of cellulosic granulating liquid was prepared for use during multiple runs during one week of product manufacturing. The cellulosic polymer was known to support microbial growth; the liquid formulation did not contain a preservative. Liquid was tested for microbial content every 8 hours; results "TNTC" occurred after only 36 hours hold time. Processing was changed to prepare a one-day volume every day to be used within 24 hours; granulating liquid was also stored under refrigeration during the day. This same project was expanded to include testing of aqueous unpreserved coating liquids. Results were essentially equivalent; daily preparation of coating liquids to be used during the same day with refrigerated storage was implemented.

Penicillin Cross-Contamination. A manufacturing site had separate buildings for penicillin manufacturing and non-penicillin manufacturing. A common cafeteria building serviced all employees at the site. Employees who worked in the penicillin facility freely used the site cafeteria without restriction, change of clothing, or other measures. A regulatory audit identified the potential for penicillin cross-contamination in the cafeteria, and a regulatory citation was issued. Concern in this case was that the people working in the penicillin facility would inadvertently bring penicillin drug into the common cafeteria; non-penicillin employees in the cafeteria would then bring penicillin residue into the non-penicillin facility – potentially contaminating non-penicillin product.

New site rules were implemented in which penicillin-facility employees were not allowed to use the site cafeteria. Interim corrective action was to create a separate cafeteria for the employees working in the penicillin facility. The longer-term solution was to move the penicillin manufacturing to a separate off-site facility.

Wood Sink in Equipment Washing Area. A sterile product CMO had a wood sink in the formulation and washing area. The wood surface is not a cleanable surface. The CMO preferred a wood sink as it was a softer surface and should therefore be gentler if an operator accidently hit the sink when washing a large glass vessel. The facility utilized glass 5-gallon glass carboys in their manufacturing processes. The CMO later received a regulatory citation for using the wood sink. Interim corrective action was to line the wood sink with plastic rather than replace it. The long-term solution was replacement with a stainless-steel sink.

Department Refrigerator Policy. A manufacturing site reported unacceptable microbial test data in their environmental monitoring program. Departmental refrigerators were identified as a potential site for contamination. Some refrigerators contained departmental chemicals and reagents as well as employee food. Some refrigerators contained food for an extended time period. New policies were implemented. Refrigerators were designated "Food Only" for food storage alone and not for any chemicals. Refrigerators were cleaned late every Friday. Any food remaining in refrigerators at Friday cleaning was discarded in sealed containers. Additional policies regarding employee eating areas, no eating in the office area, and other rules to minimize potential contamination were also implemented.

SUMMARY AND FINAL THOUGHTS

This primary objective of this discussion was to remind readers of potential risks of microbial contamination associated with food. Recent news stories describing fatal contamination events have indicated the potential serious nature of microbial contamination. Pharmaceutical organizations are primarily concerned with preventing contamination in the products manufactured at their site. Manufacturing facilities must have detailed contamination control programs including screening of incoming materials, cleaning and sanitization procedures, employee training on related procedures, and routine testing to confirm program success.

Quality and Compliance professionals must look beyond the manufacturing floor for potential sources of microbial contamination in their facility. Review of routine site activities associated with food, e.g. cafeteria services, food preparation,

local eating areas, personal food storage, and other considerations may indicate definite food safety risks to product and personnel. Substandard food handling causing microbial contamination may be transferred to product. Deficient practices may also sicken employees. Related food safety practices such as cleaning and drying are applicable to routine manufacturing. Awareness of the potential for microbial contamination will safeguard products and employees against harmful effects.

Food safety practices should also be applied in the home. Reported data for sickness, hospitalization, and death from foodborne illness are staggering. Information on preventive measures is readily available. Attention to basic food safety recommendations such as those from FDA, WHO, and country organizations are fundamental to food safety. Simple and straightforward practices -- clean, separate, cook, and chill – are useful rules for work as well as home. Activities to combat microbial contamination are often overlooked or inadequate. Anyone who has suffered even minor consequences from food poisoning will attest to its importance. Implementing these fundamental rules in the home will also help to protect family members against harmful effects.

Microbial contamination is a critical concern for pharmaceutical manufacturing and for food handling in the workplace and the home. Information in this discussion should cause readers to reflect on preventive contamination practices at work and at home, stimulate any needed corrective actions, and be generally useful to all.

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