

## APF Plumbing Fixtures Part I

### Introduction

Aseptic Production Facilities (APF) are a challenging environment for the design, operation, and maintenance of water sources and drains. A sanitary drain with a P-trap, for instance, is an open-air connection to a constantly dark, moist area where biological activity can occur, including the formation of biofilms and the growth of molds, fungi, and bacteria. A less obvious source of contamination is the potable water supply serving handwashing sinks and emergency plumbing fixtures (eyewashes, etc.); while far cleaner than drain/waste/vent (DWV) systems, these fixtures are still a possible source of microbiological flora.

All connections to the plumbing system are persistent – and potentially potent – sources of contamination in the aseptic environment. Risk mitigation should be incorporated where fixtures are necessary, including measures like:

- The number of fixtures should be reduced to the extent practicable.
- Fixtures should be placed in areas of the lowest classification possible, and are prohibited from areas with a classification of ISO-7 or better.
- Fixtures should be located as remotely as practicable from the areas of greatest risk for product contamination.
- Airflow and differential pressure should be considered to prevent the migration of aerosolized potable water droplets and aspirated/aerosolized DWV products towards higher classified areas.
- A low side wall exhaust or HEPA-filtered return grill should be placed in proximity to fixtures with the intent to efficiently capture fugitive aerosolized particles.
- Fixtures should be selected for cleanability and resistance to degradation from APF cleaning chemicals.
- Fixtures and components should be selected that produce the smallest amount of aerosolized particles, possible (i.e. laminar flow heads in lieu of aerators, etc.)
- All plumbing fixtures and drains should be enrolled in a regular cleaning and maintenance program designed to suppress microbiological activity.

- Fixtures and water should be regularly surveilled by an Environmental Monitoring (EM) program to detect uncontrolled growth and profusion of microbiological activity.

### Potable Water Supply Plumbing System

When tying an APF into existing domestic cold water and domestic hot water (DCW/DHW) systems, careful consideration should be given to disinfection beyond the code required minimum for new piping work. Factors worth considering include the persistence of established biofilms and the value of prophylactic measures in reducing the risk of recolonization. Consideration should also be given to monitoring residual disinfectant. Injecting additional disinfectant to maintain residual disinfectant levels should generally be avoided, as it requires additional labor, adds to system complexity, and has the potential for unintended consequences. DCW/DHW systems should be designed to eliminate dead-legs. The use of automated flushing to ensure water turn-over to maintain residual disinfectant levels should be evaluated on a case-by-case basis.

After risk assessment and engineering analysis, a duplex potable water filter which achieves not less than 0.2 microns can be installed on the DCW/DHW supplies. Filters should be placed in a remote yet accessible location outside of the APF. It should be noted that water filters require regular maintenance, including replacement, to reduce the likelihood that they become sources of microbial contamination.

### Drain/Waste/Vent Plumbing System

Specific drain/trap maintenance (i.e. cleaning) requirements should be included in a formal, change-controlled SOP. During regular facility cleaning, the strainer, tail piece, and p-trap (deep p-trap for higher Differential Pressure (DP) locations, as required) should be treated per the cleaning SOP throughout classified areas to suppress biological activity within exposed areas of the DWV system.

Next month, this article will continue with a specific discussion of hand sinks and emergency fixtures in classified APF environments.

