



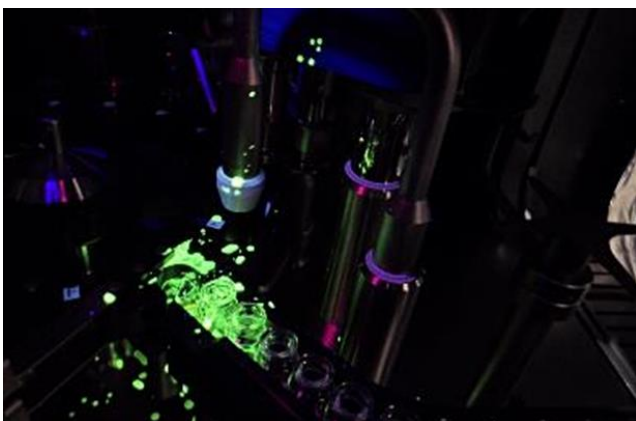
CLEAN Mapping

- ✓ Determine the mechanical transfer of contamination by using a fluorescent surrogate (riboflavin)
- ✓ Simulate process malfunctions like vial crashes to visualize critical contamination levels
- ✓ Definition of worst case positions
- ✓ Risk assessment support

Application of CLEAN Mapping

Riboflavin is used as a tracer to visualize potential locations of contamination during normal manufacturing operations or in case of process malfunctions.

According to the new EU GMP guidelines, risk assessment studies must be performed to address potential cross-contamination inside a manufactured product. The riboflavin test is performed to determine how the active substance spreads (mechanical transfer) within an aseptic isolator during the filling process.



Example of simulated vial crash in an aseptic filling line.

Your Challenge

- Development of a suitable cleaning strategy

Our Solutions

- Definition of worst-case positions on the basis of riboflavin tests
- Simulation of several malfunction scenarios for the definition of suitable cleaning strategies

Your Advantages

- Test development on the basis of scientific Know-How
- Interdisciplinary team with extensive experience
- Overall approach for the identification and evaluation of risk factors associated with your specific process
- Different failure modes can be simulated or provoked to test your planned cleaning process

Our Services

- Decision support and recommendations for action
- Risk assessment on the basis of the CLEAN Mapping tests