

Wipe it With a Cloth? Particle Contamination Risks of Cloth Wipes

Does your company use cloth wipes on equipment in aseptic manufacturing areas? Do you launder and reuse them? Can you document that the use of the wipes is not creating particulates?

At the [International GMP Conference](#) held virtually in March 2022 co-sponsored by the University of Georgia at Athens and FDA, FDA Office of Regulatory Affairs National Drug Expert Captain [Ileana Barreto-Pettit](#) shared agency concerns found during an inspection of a sterile drug manufacturer regarding cloth wipes.

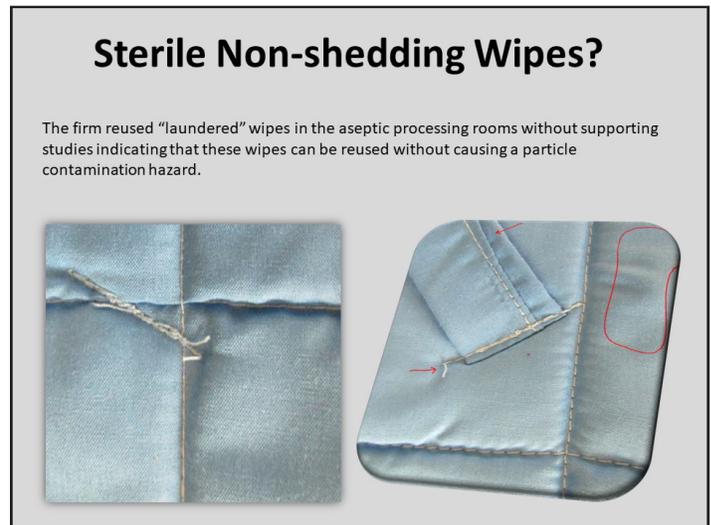
Investigators found that the company was using cloth wipes in the ISO 5 area. The cloth wipes were being laundered but the company lacked any documentation or supporting studies showing that the wipes can be reused without causing a particle contamination hazard.

Note that in the photo arrows show that there appear to be loose threads on one of the wipes, presenting a potential contamination risk.

“If you look at it closely, it may not be so obvious in this picture, but there are some fibers coming from the fabric as the wipe gets worn out,” Barreto-Pettit said.

“This doesn’t seem to be a non-shedding wipe. I assume they sterilize them. But, certainly, this could be a particle contamination hazard.”

Does your company use similar wipes?



ACCESS TO THE LATEST FDA 483 OBSERVATIONS

A search of 483 observations issued between 2017 and 2022 showed that seven cleaning-related observations involved wipes of some kind. To learn more about how we uncovered this information, [contact us](#) for a tour of Redica Systems.

Model	Primary Issue(s)	Secondary Issue(s)	Content
Human Drugs GMP	21 CFR 211.67(a)(b) Facilities and Equipment > Cleaning > Sterile	21 CFR 211.67(a)(b) Facilities and Equipment > Cleaning > Sterile	OBSERVATION 2 Records are not kept for the cleaning and sanitizing of equipment. Specifically, ... See More
Human Drugs GMP	21 CFR 211.67(a)(b) Facilities and Equipment > Cleaning > Sterile		OBSERVATION 2 Materials or supplies were not disinfected prior to entering the aseptic processing... See More
Human Drugs GMP	21 CFR 211.67(a)(b) Facilities and Equipment > Cleaning > Sterile	21 CFR 211.113(b) Production > Sterile Products > Smoke Studies	OBSERVATION 3 Materials or supplies were not disinfected prior to entering the aseptic processin... See More

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