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When Risk is Not an Option: A Look at FDA 483's

Risk management involves both the assessment and minimization of risk. As pharmaceutical manufacturers continue to develop new technologies and processes become more complex, it's critical to understand the most common regulatory data to assess and manage these risks. Below are some interesting findings based on FDA 483 data from FDA from their FY 2006 through 2019, which highlight two key areas, cleaning and microbial control.

1,440
FDA 483's ISSUED

for violations of 21 CFR 211.113, control of microbial contamination[1]

2,666
21 CFR 211.67

412
21 CFR 211.182

483's issued for equipment cleaning and maintenance, and use log[1]

14%
of all 483's

include the words "cleaning" or "microbial control"[1]

30%

increase in inspection citations for manufacturers located outside of the United States from 2009 to 2019[2]

STERIS Life Sciences is your trusted partner in contamination control.
For over 100 years, STERIS has been known as a global leader, trusted part in the field of sterilization and contamination control. Today, STERIS continues building on this heritage by advancing the Science of sterilization, cleaning and infection control while offering solutions that meet our Customers' needs and high standards. STERIS is dedicated to helping you enhance the life of your patients and the life of your equipment. From Pharmaceutical Detergents, to Capital Equipment, and to Parts and Services STERIS Life Sciences is your Solutions provider.

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References:

[1]https://https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspection-observations

[2]https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspection-citation

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