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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 findings to assess and manage these risks. Below are some interesting findings based on FDA 483 data from FDA from their FY 2009 through 2015, which highlight two key areas, cleaning and microbial control.

911
FDA 483's ISSUED

for violations of 21 CFR 211.113, control of microbial contamination

1800
21 CFR 211.67

321
21 CFR 211.182

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

13%
of all 483's

include the words "cleaning" or "microbial control"

101
483's were issued

to dietary supplement manufacturers for issues with cleaning and/or microbial control

STERIS Life Sciences is your trusted partner in contamination control.

For over 100 years, STERIS has been known as a global leader, trusted partner and solutions provider 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 Formulated Chemistries, to Capital Equipment, and to Parts and Services STERIS Life Sciences is your Solutions provider.

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References: https://www.fda.gov/iceci/inspections/ucm250720.htm

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