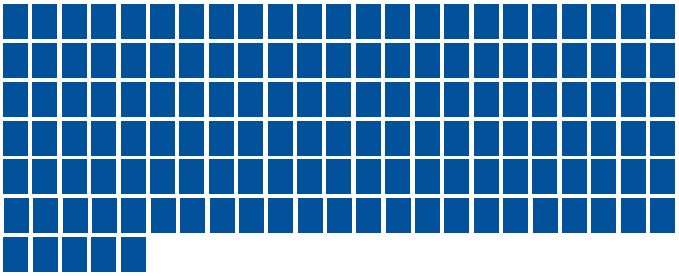
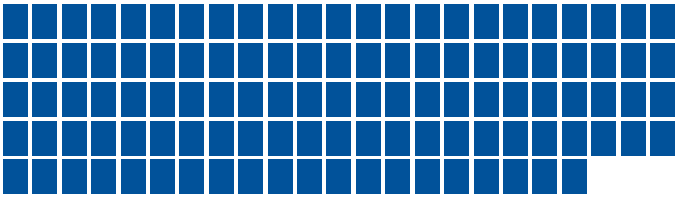
Common Issues Found in Nonsterile Drug Facilities

U.S. FDA issued **143** warning letters



EMA issued **112** noncompliance reports (NCRs)

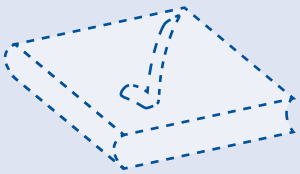


From January 2008 to February 2016

31% of warning letters and **25%** of NCRs were issued to manufacturers of nonsterile drugs.

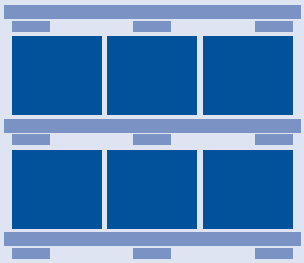
Of these, 115 CGMP violations were identified

What were the most frequent violations?

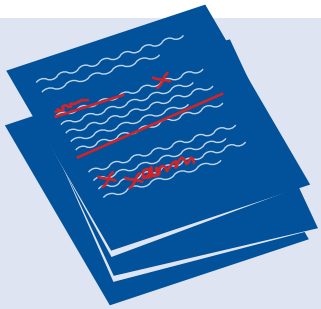


Lack of written production and control procedures

Failure to investigate discrepancies or batch failures



Inadequate stability testing program



Altered records

How can these be prevented?

- Regular training and awareness
- More effective documentation reviews

Source

1. Santos, A.M.C., et al. "A QRM Discussion of Microbial Contamination of Non-sterile Drug Products, Using FDA and EMA Warning Letters Recorded between 2008 and 2016." *PDA Journal of Pharmaceutical Science and Technology* 72 (2018) 62–72.