# Common Issues Found in Nonsterile Drug Facilities

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

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<thead>
<tr>
<th>U. S. FDA issued</th>
<th>EMA issued 112 noncompliance reports (NCRs)</th>
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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**