Equipment cleaning procedures are not adequately validated.
Specifically,

a) Equipment cleaning validation studies do not support a validated time period for holding dirty equipment before initiating the cleaning process. The equipment cleaning procedure, SOP AQA-020, effective date January 20, 2016, specifies the establishment of a holding period of [redacted] before cleaning dirty equipment through the completion of three acceptable cleaning runs; this activity has not been performed for all product-specific equipment trains. Current cleaning procedures rely on an unvalidated holding period of [redacted].

b) Equipment cleaning validation procedures do not include testing for the efficacy of bioburden or endotoxin removal from those equipment trains where product with a bioburden or endotoxin specification is manufactured.
The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."