

International Reference on Equipment Cleaning under Good Manufacturing Practice

21 CFR 210: *Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding of Drugs: General*
As of April 1. 2019

21 CFR 211: *Current Good Manufacturing Practice for Finished Pharmaceuticals*
As of April 1. 2019

21 CFR 600: *Biological Products: General*
As of April 1. 2019

FDA Guide to Inspections, Validation of Cleaning Processes
FDA Office of Regulatory Affairs

Recommendations on Validation Master Plan, Installation and Operational Qualification, Non-Sterile Process Validation, Cleaning Validation (Document PI 006-3)
Pharmaceutical Inspection Co-operation Scheme

Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients (ICH Q7)
International Conference on Harmonization
(US-adopted version)

Cleaning Validation Guidelines (Guide-0028),
Health Canada
January 1, 2008

Guidance on Aspects of Cleaning Validation in Active Pharmaceutical Ingredient Plants
Active Pharmaceutical Ingredients Committee (APIC)
September 2016

The Rules Governing Medicinal Products in the European Community, Volume 4: *Good Manufacturing Practice, Medicinal Products for Human and Veterinary Use*
As of April 1. 2019