Author Acknowledgments

RAPS and editor, Robert Falcone, PhD, FRAPS, FTOPRA, thank the following subject matter experts for sharing their experience and knowledge and volunteering their time to contribute to this third edition of *Medical Device Validation Handbook*.

Editor
Robert Falcone, PhD, FRAPS, FTOPRA
Regulatory Manager
Integrated DNA Technologies IDT

Authors
Wes Bloemker, MBA
Retired

Anthony Carra, MAS, CMQ/OE, PMP
Owner/Principal Consultant
Business Improvement Group

Jay Crowley, MS
Vice President, Medical Devices and UDI Practice Lead
USDM Life Sciences

David W. DiVaccaro, MS
Principal
DiVaccaro Consulting Group, LLC

Courtney Divine
Senior Packaging Engineer
Network Partners Group

Brian K Farison
Technical Fellow
Network Partners Group

Brett D. Hofman
Senior Packaging Engineer
Network Partners Group

Beth Kroeger-Fahnestock
Director, Biopharma Production Chemicals, New Product Introductions
Avantor Sciences

John E. Lincoln
Owner, Principal Consultant
J. E. Lincoln and Associates LLC

Gerry A. O'Dell, MS, AAMI Fellow
Owner/President
Gerry O'Dell Consulting

Rod Patch, MBA
Senior Director, Package Engineering, Product Labeling & Digital Product Information
Johnson & Johnson Vision

James N Polarine Jr., MA
Senior Technical Service Manager
STERIS Corporation

Steven G Richter, PhD, MS, RAC-US
Senior Regulatory Microbiologist
Richco Laboratories LLC

Lisa A. Schaller, MS
Director, Quality Assurance
Varian Medical Systems, a Siemens Healthineers company

David W. Steinmeier, MBA
Owner
microJoining Solutions

Heather A. Valley, MS, RAC-Global
Director Regulatory Affairs
Network Partners Group

Steven L Walfish, MBA, MS
Director, Global Technical Operations Statistics
AstraZeneca

Timothy Wech, MSE, PE
VP, IT and PMO
Network Partners Group

Purchased from RAPS Library (library.raps.org) for the exclusive use of unknown.
© 2026 RAPS Library. Please report unauthorized use to raps@raps.org

Purchased from RAPS Library (library.raps.org) for the exclusive use of unknown.
© 2026 RAPS Library. Please report unauthorized use to raps@raps.org

1 Regulatory Basics of Process and Design Validation

Robert Falcone, Ph.D., FRAPS, FTOPRA

Introduction

Countless US Food and Drug Administration (FDA) warning letters and inspectional observation forms are issued by the agency each year, with many citing a failure to ensure that processes were validated or revalidated. While it is true that corrective and preventive action (CAPA), complaint handling, production and process controls, and design controls are also violations cited frequently by the FDA, process validation is the most challenging to address.[1]

Process validation was sixth on the list of reasons for issuing FDA Form 483s. Inadequate process validation was cited 86 times in 2022, or three out of the 10 most-cited violations.[2] The problem may lie in the definition of "validation" in the agency's Quality System Regulation (QSR), 21 CFR Part 820. Section 820.75 of that rule explains that validation is confirmation by examining and providing objective evidence that the requirements for a specific intended use can be consistently fulfilled. The QSR also divides process validation and design validation into two separate entities: "Process validation means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications."[3] The rule further says that "design validation means establishing by objective evidence that device specifications conform with user needs and intended use(s)."[4]

The definitions lack specificity, and companies must interpret the regulation independently. Even more head-scratching is that "process validation" is defined differently in a 2011 FDA guidance document as the "collection and evaluation of data, from the process design stage through the commercial production, which establishes scientific evidence that a process is capable of consistently delivering a quality product."[5]

The FDA's 2011 guidance updated a 1987 process validation guidance from the agency. Thus, the 2011 document replaces the 1987 version, but only for human drugs, veterinary drugs, biological and biotechnology products, finished products and active pharmaceutical ingredients (APIs or drug substances), and the drug constituent of a combination product. The 2011 guidance does not cover medical devices; rather, guidance for devices was provided in cooperation with the Global Harmonization Task Force (GHTF), the precursor to the International Medical Device Regulators Form (IMDRF).[6]

Purchased from RAPS Library (library.raps.org) for the exclusive use of unknown.
© 2026 RAPS Library. Please report unauthorized use to raps@raps.org