IVT NETWORK
INSTITUTE OF VALIDATION TECHNOLOGY | an informa business
Unlimited Validation Knowledge Awaits...
Published on *IVT Network* (http://www.ivtnetwork.com)

Medical Device Process Validation: What We Can Borrow from the Pharmaceutical Process Validation Guidance

By 
Yeong-Lin Chen

Feb 22, 2019 3:38 pm EST

Introduction Medical device process validation is the one of the most frequently cited violations by the Food and Drug Administration (FDA) according to the presentation slides of “Quality System Regulation – Process Validation, FDA Small Business, Regulatory Education for Industry, by Joseph Tartal (1)”. In the document, it mentions that Subpart G – Production and Process Controls (P&PC) in 21 CFR Part 820 regulation is with the number one ranking in FDA 483 Observations in year 2014, and Section 820.75(a) (the most representative clause of process validation) is cited with the top...