

## The Future of Process Validation - Going Back to Basics: The New FDA Perspective as a Refocus on the Original Definition of Process Validation

By **Miguel Montalvo** May 25, 2013 6:04 pm EDT

Just to give you an historical perspective on the evolution of PV thus far: During the 1980's - companies (especially sterile and parenteral manufacturers) started to perform Process Validation without guidance from the Food and Drug Administration (FDA). During this time, companies developed aseptic processing and sterilization validations. 1987 - PV Guideline document from FDA is released<sup>3</sup>. Solid dosage and oral products manufacturers start implementation of guideline. There is a great deal of confusion created by the terms "worst case" versus set-up at nominal value with a range of variability...

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