

## Steam sterilizer validation from FAT to PQ

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Validation of a steam sterilizer is a necessary task for any regulated lab or production environment. This presentation will explain the steps involved in these validations, from FAT to PQ, and everything in between. Specific subjects to be covered are: What to require in factory acceptance testing, utilities preparation at the site, installation qualification, operational qualification, and performance qualification, with reference to the relevant standards (ISO 17665, EN285). The need for steam quality measurement will also be covered. A basic review of steam system design will be provided as a means of ensuring that the steam quality is adequate per the standards.

### Biography

Jonathan A. Wilder earned his Ph.D. in physical chemistry from New York University, New York, NY, with postdoctoral studies in surface physics as Max Planck fellow at the Fritz Haber Institut, Berlin, Germany. He has worked in the sterilization field since 1990, first for MDT/Getinge as staff R&D scientist, and subsequently cofounded H & W Technology in 1998. He developed H & W's steam resistometers, which set the standard for performance in their field, and has been validating steam (and other) sterilizers since 2001. His focus throughout his career has been the automated control and measurement and validation of processes.

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