

Meet the Expert



Paul is a leading expert in the application of engineering methods, Six Sigma tools and quality risk management to design, implement and optimize advanced aseptic systems, OSD processes and containment technology.

Paul's diverse and highly valued skillset has been developed over a two decade career working in various roles for a rare combination of multinational pharmaceutical corporations, a leading containment equipment manufacturer, and now a well-established technical consulting, design, engineering, construction, project controls, commissioning and qualification firm. A combination of strong technical ability, business acumen, interpersonal skills, and international experience make him a solid asset for the clients he supports.

The following examples of recent work demonstrate his ability to help clients facing a broad array of challenges:

- Developed configuration and specifications for an isolated vial filling line and freeze dryers with automatic loading/unloading
- Performed risk assessment and implemented risk mitigation for the tech transfer of a lyophilized product
- Performed risk assessment for atypical visual particle for a contract OSD manufacturer

Paul attended Lehigh University in Bethlehem, Pennsylvania where he earned a Bachelor of Science magna cum laude in Mechanical Engineering and a Master of Science summa cum laude in Applied Mechanics.

Paul's work has resulted in patents, co-authoring, as well as presenting at industry events. Recent engagements include:

- *"Facing Your Challenges without a Black Belt: Solve Problems and Achieve Consensus with Simple, Well Applied Tools"* – ISPE Annual Meeting, November 2014.
- *"Six Sigma is Not Just for Black Belts"* - INTERPHEX New York, March 2014.
- *"Critical Elements for Implementing Advanced Aseptic Technology"*, Pharmaceutical Processing, IPS Technologies Tours at INTERPHEX 2014, March 2014, pp 6-8.

Paul Valerio Sterile Expert

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Areas of Expertise

- Advanced Aseptic Design
- OSD Processes
- Design for Potent Compounds
- Vendor Management
- Risk Assessment & Mitigation
- Technical Consultancy
- Failure Modes & Effects Analysis (FMEA)
- Root Cause Analysis