

# Meet the Expert



**Mr. Sterling Kline offers a lifetime of expertise in strategic planning, master planning, programming, design, construction management and facilities management for the healthcare, pharmaceutical and biotech industries.**

Sterling is a subject matter expert in sterile facility design. He is considered the foremost expert in state-of-the-art sterile isolator technology. He is a well-known figure in the sterile industry and the sterile equipment vendor community. He regularly participates in speaking engagements on sterile facility design throughout the world and is currently involved with the FDA's auditor training program. Sterling has over 4 decades of experience working on aseptic projects for BMS CSO, BMS Manati, United Therapeutics, Pharmalucence, KSP, CSL, Bio-Manguinhos, Amgen, Catalent, Laureate, AstraZeneca, Mylan, Dr. Reddy's Lab, B+L Berlin, Ben Venue, Lantheus, Avid, Celgene, BBraun, Integra, Sigma tau, Corrium, Lonza, Ferring, Hospira, ProBiomed, Prolong, Teva, and Merck.

Sterling has completed pharmaceutical projects ranging from major R&D facilities including discovery, development and kilo labs; to clinical manufacturing pilot plants for sterile and oral solid dosage, including potent compounds; to manufacturing facilities for oral solid dosage products and sterile products using vials, syringes and devices incorporating both traditional and isolation technology. He has also completed pharmaceutical support facilities, including office, warehouse, quality lab, utility, parking, and hazardous material holding buildings.

## Presentations

- "cGMP Aseptic Facility Design Based on Barrier Technology", FDA Drug Inspector Training Program DG 330 Active Pharmaceutical, Pre-Approval, and Sterile Drug Inspections, Washington, DC, May 2014, September 2013, June 2013
- "Case Study: Multi-product International Greenfield Vaccine Filling Facility based on Isolator Technology", Barrier Seminar, February 24, 2014.
- "Current Trends in Advanced Aseptic Processing Technology", IPS Open House, Blue Bell, PA, September 2013.
- "cGMP Aseptic Facility Design Based on Barrier Technology", FDA Drug Inspector Training Program MP 302 Industrial Sterilization for Drugs and Devices, Portland, OR, June 2013, San Juan, PR, January 2013, Columbus, OH.
- "Design and Construction of BFS Facilities: A Unique Case Study", BFS IOA Annual Meeting, Washington, DC, September, 2012
- "Case Study: Brazil Fill/Finish Facility", 5th Annual IPS Advanced Aseptic Tour, INTERPHEX, New York, NY, April 2012
- "Regulatory Compliant BFS Facility Design", BFS IOA Annual Meeting, Charleston, SC, September 2011
- "The Costs of RABS versus Isolator Technology", ISPE European Isolator Conference, September 2011, Strasbourg, France
- "United Therapeutics: Advanced Aseptic Processing Case Study", 4th IPS Advanced Aseptic Tour, INTERPHEX, New York, NY, March 2011

**Sterling G. Kline, RA**

**Aseptic Technologies Expert**

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## Areas of Expertise

- Sterile Facility Design
- Advanced Aseptic Technology
- Master Planning
- Design and Construction Management
- Facilities Management