

**Julian J. Wilkins**  
Vice President  
Senior Consultant  
PharmaConsult US, Inc.

## Education

Oxford School of  
Architecture 1966-72  
First Class pass  
Diploma in  
Architecture

## Registrations

Royal Institute of  
British Architects Part  
III

Registered Architect  
(Lapsed)

## Affiliations

Member ISPE

Founding member of  
the UK affiliation of  
ISPE

ISPE Committee  
Person of the year in  
1991.

Member of the ISPE  
Training Committee

Member of PDA

Member of the  
American Glovebox  
Association

Participated in the  
Occupational  
Toxicologists  
Roundtable 2001,  
2002, 2003

## Professional Experience

Julian has over 29 years of professional experience in architecture and containment solutions for the pharmaceutical industry. He has designed and managed the manufacture and qualification of containment systems for potent and aseptic compounds.

### Wyeth

Pearl River, NY

Provided conceptual design through construction administration for a new Bio-processing Facility. Processes included derivitization chemistry isolators for potent bioprocess and aseptic parenteral filling, lyophilization, etc. The project included options, recommendations, full process design and selection, and bid development. Design based on OEL of 20 nanograms/M<sup>3</sup>/shift.

Provided options review through bid documentation for reference standard filling for product and personnel protection. Project included options and recommendation report, ergonomic modeling and bid production.

Guayama, Puerto Rico

Retrofit of existing Oral Solid Dosage facility for potent material handling. The project included option and recommendation report, bid documents, bid evaluations, vendor selection, ergonomic modeling through vendor support, surrogate testing and training. Design based on OEL of 100 nanograms/M<sup>3</sup>/shift.

Rouses Point, NY

Options and recommendations report for charging and compaction of oral solid dosage products. Design based on OEL of 125 nanograms/M<sup>3</sup>/shift.

Carolina PR

Site wide evaluation for containment of the world's largest Lyophilization facility for Parenterals

### Pfizer

Groton, CT

API pilot plant retrofit. The project included option and recommendation report, design development, bid documents, bid reviews, drawing approvals, FAT, Functional and Surrogate testing (with SafeBridge) and Training. Design based on OEL of 30 nanograms/M<sup>3</sup>/shift.

Provided an options report for an upgrade for small scale manufacturing

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## **Published Material**

Given many papers worldwide at ISPE, PDA, PS, ICCCS, Cleanrooms and Interphex

*A Technical Review of Isolators,*  
Pharmaceutical Engineering, 1998

*Isolator Technology, Applications in the Pharmaceutical and Biotechnology Industries,* Interpharm Press, 1995

## **Seminars Given**

Course leader for the 2001, 2002, 2003 and 2004 Containment courses for ISPE

Speaker for 2002 Containment programs offered by Barnett International and IIR

Support services for wet chemistry isolators. The project included FAT and surrogate testing protocols and functionality testing. Design based on OEL of 30 nanograms/M<sup>3</sup>/shift.

Retrofit of the Clinical Parenteral facility to handle highly potent materials

### **Sanofi Synthelabo**

Malvern, PA

Provided ergonomic model, validation and training for Vacuum Tray Drying Isolator with an OEL of 1 microgram/M<sup>3</sup>/shift.

Provided ergonomic modeling, installation, modification, validation and training for laboratory Isolators with an OEL of 1 microgram/M<sup>3</sup>/shift.

Provided ergonomic modeling, installation, validation and training for analytical isolator with an OEL of 1 microgram/M<sup>3</sup>/shift.

New OSD and Parenteral clinical facility

### **Bristol Myers Squibb**

Syracuse, NY

Retrofit of existing filter dryer to handle potent compounds with an OEL of 5 nanograms/M<sup>3</sup>/shift. Project included options review, design, ergonomic modeling, bid documentation and bid support.

Retrofit of existing laboratory to handle potent compounds with an OEL of 5 nanograms/M<sup>3</sup>/shift. Project included options review.

Mayaguez, Puerto Rico

Options review and recommendations report for a highly potent parenteral filling line for new facility with an OEL of 20 nanograms/M<sup>3</sup>/shift.

Seven new isolated potent and non potent parenteral lines

### **Organichem**

Rensselaer, NY

Retrofit an existing facility for potent API manufacturing with an OEL of 300 nanograms/M<sup>3</sup>/shift. The project included options review, ergonomic and performance evaluation and surrogate testing (with SafeBridge) and Training.

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**Seattle Genetics**

Bothell, WA

Provided Aseptic Potent filling line options and recommendations with budget costs based on an OEL of 1 microgram/M<sup>3</sup>/shift.

**Schering Plough**

Kenilworth, NJ

Retrofit for oral solid dosage production. Project included containment issues options and recommendations report.

**AstraZeneca**

Mississauga, Canada

Provided options and recommendations report for aseptic powder filling for inhalation product.

**AstraZeneca**

Newark, DE

Provided options and recommendations for coater containment issues for multi product use including high potent compounds.

**BenVenue Laboratories**

Cleveland, OH

Provided options and recommendations report for processing multi-product high potent and cytotoxic compounds.

**Novartis**

East Hanover, NJ

Options and recommendations report for containment of oral solid dosage at development scale.

**KOS Pharmaceuticals/Aeropharm**

Edison, NJ

Options and recommendation report for formulation and filling cross contamination and operator protection issues. The project also included design development.

**Roxane Laboratories**

Columbus, OH

Conceptual design for Greenfield multi-product oral solid dosage facility to handle products down to 100 nanograms/M<sup>3</sup>/shift.

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**Merck**

Rahway, NJ

Review of A/E's design for Reactor Charging with an OEL of 10 micrograms/M<sup>3</sup>/shift. The project included re-design work and ergonomic modeling