

# Cleanroom and Environmental Monitoring

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## Consultancy Services



**LIGHTHOUSE**  
WORLDWIDE SOLUTIONS

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800.845.5905

[golighthouse.com](http://golighthouse.com)



## Are you struggling with the installation of a Real Time Monitoring System?

**We get it — it can be a complex task!**

Many organizations face challenges when it comes to integrating new systems, especially when they're not familiar with the technical details. At LWS, we're dedicated to helping you navigate this process with ease. Our experienced team is here to provide the guidance and support you need to ensure everything goes smoothly.

We offer a range of services designed to assist you in planning and installing your RTMS effectively. From understanding your specific requirements to providing hands-on support during the installation, we're committed to making sure you feel confident every step of the way. Let's work together to tackle any hurdles you might encounter and set you up for success.

- Facility Maps and Drawings Review
- Facility Walkdown for Installation of RTMS
- Risk Assessment and Documentation Development
- Overview of Current GMP Requirements and Deployment
- Development of Environmental Monitoring Plan per ISO 14644-2:2015
- Development of User Requirement Specification (URS) from Risk Assessment
- Development of Facility Design Specification (FDS) Based on URS
- Development of Performance Qualification and SOPs for the RTMS
- On-Site Training on PQ and Deployment of SOPs
- Development of Alert and Action Alarms Based on PQ
- Integration of EM Program into LIMs Systems for Digital Data

## Applications Served

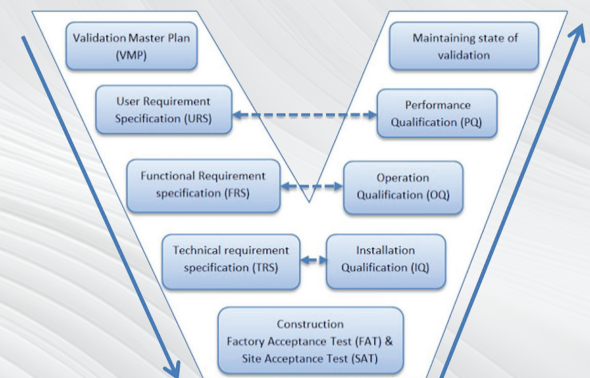
**We've learn a lot in the last 40 years.**

- Aerospace
- Aseptic Filling
- ATMP Cell & Tissue
- Automotive Spray Paint
- Biologics Production
- Biotechnology Research
- Cell Culture Laboratories
- Compounding
- Compressed Gases
- Containment Facilities
- Data Centers
- Display LED Production
- EV Battery facilities
- Food Service
- Isolators, BSC, LAFs
- Medical Device
- Radio Pharma
- Semiconductor
- Sterile Packaging
- Wafer Fabrication

## The GAMP V Model

**The go-to model developed by ISPE**

GAMP5's V-model is vital in regulated industries, acting as a roadmap for validating computerized systems. This structured, risk-based approach streamlines validation, reduces risks, and improves system quality. By guiding you through each step—from user needs to system performance—it makes tracking progress easier and boosts confidence in reliability, ultimately ensuring patient safety and product effectiveness.





# Empower Your Team with On-Site Training

Tailored Training Solutions to Enhance Skills & Boost Confidence

Our on-site program is designed to provide hands-on experience and in-depth knowledge, ensuring that you and your team are well-equipped to implement and manage RTMS effectively.

During the training, participants will gain practical insights into the installation, operation, and maintenance of RTMS. Our expert trainers will guide you through each step, addressing any questions or concerns you may have along the way. By the end of the program, you'll not only have a solid understanding of RTMS but also the confidence to apply what you've learned in real-world scenarios.



With offices and service centers worldwide, we stand ready to support you, no matter your location.

## Available Topics

- Air Sample Methods & Impaction Technology per EN17141 and ISO 14698 guidelines
- Cleanroom Certifications using Particle Counters
- Cleanroom Standards
- Cleanroom Technology Training
- Energy Savings in Cleanrooms based on ISO 14644-16
- GAMP5 Implementation and V model for RTMS lifecycle
- HEPA Filter Testing per ISO 14644-3
- ISO 14644 Standards
- Particle Counting Technology and Best Practices
- Particle Losses in Tubing Validation per ISO/TR 14644-21
- Overview of Cleanroom Technology and Design per ISO 14644-5
- Routine RTMS Monitoring: The Do's and Don'ts
- Sample Probe Placement based on Risk Assessment



# Jason Kelly

Applications Director

jasonk@golighthouse.com  
golighthouse.com

**Location:** Oregon, USA

**Experience:** Over 28 years in providing Environmental and Particle Monitoring Solutions to the Cleanroom Industry.

**Subject Matter Expert:** Monitoring Systems for Pharmaceutical, Medical Device, Life Science, Semiconductor, Aerospace, and Military Cleanroom applications. Particle Counter, Environmental Sensors and Air Sampling Systems service and integration.

**Expertise:**

- **ISO 17025 & ISO 21501: Cleanroom Standards**  
Implementation of LWS service facilities worldwide
- **Project Management:** Monitoring Systems Worldwide
- **Presentations:** Worldwide on current GMP and Environmental **Monitoring Publications:** Numerous technical webinars and papers available online related to Environmental Monitoring in Cleanrooms.

**Professional Involvement:**

**IEST (Institute of Environmental Sciences and Technology):**

Regular presenter at seminars, conducts IEST training classes in Cleanroom Technology/Certification and Monitoring Solutions

**PDA (Parenteral Drug Association) Ireland:** Committee member, assists with events and also presents on Cleanroom Monitoring topics

**ICCCS (International Confederation of Cleanroom Contamination Control Society):** Active participant. Presents on contamination control topics at global events as guest speaker and attends global ICCCS events.



Request Your  
Consult

## Real Experiences, Real Results

### Hear from Those Who Trust Us

#### Bart Groninger

Jason Kelly is a consummate professional. He is detail-oriented and effective. You may rest assured that he will apply an intelligent and sound approach to exceed any goal that has his commitment. At the same time, he will also be watching for additional opportunities worthy of pursuit. Jason is an exceptional businessman, salesman and service provider. Those who Jason has worked for, speak highly of him. More importantly, those who have worked for him, speak just as well of Jason. I am certain that Jason Kelly will provide tremendous value to whichever organization has the good fortune to employ him.

#### Alek Sivakov

Jason was engaged to provide a detailed design, install and commissioning of a new cleanroom EM system for the new Donor Tissue Bank of Victoria. Jason's thorough understanding of cleanroom facilities is second to none and he has shown tremendous knowledge of various processes undertaken in cleanroom environments. Jason compiled all relevant documentation ready for submission in accordance with TGA guidelines and creditation procedures. Jason is an awesome person to work with and have on your team.

#### Haşim Solmaz

Jason is one of the best target-oriented industry expert and he can manage any kind of cleanroom contamination projects with his deep knowledge and understanding. If you need more than sales support, I strongly recommend you to work with Jason. His guidance will help you to have better solution for different problems.

#### Trevor Schoerie

Jason helped many companies in Australia installing environmental monitoring systems, and was very polite and professional in all his dealings. I often recommended clients speak with Jason as I had confidence that they would be well served.



# Consultancy Rates:

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**Hourly Base Rate:**

**USD \$250 per hour**

**Travel Time:**

**USD \$175 per hour**

**Travel Expenses:**

**Quote based on Current Rates**

including flights, hotel, taxi or car hire and meal expenses.

**Outside of normal business hours:**

**Contact for Quote.**



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