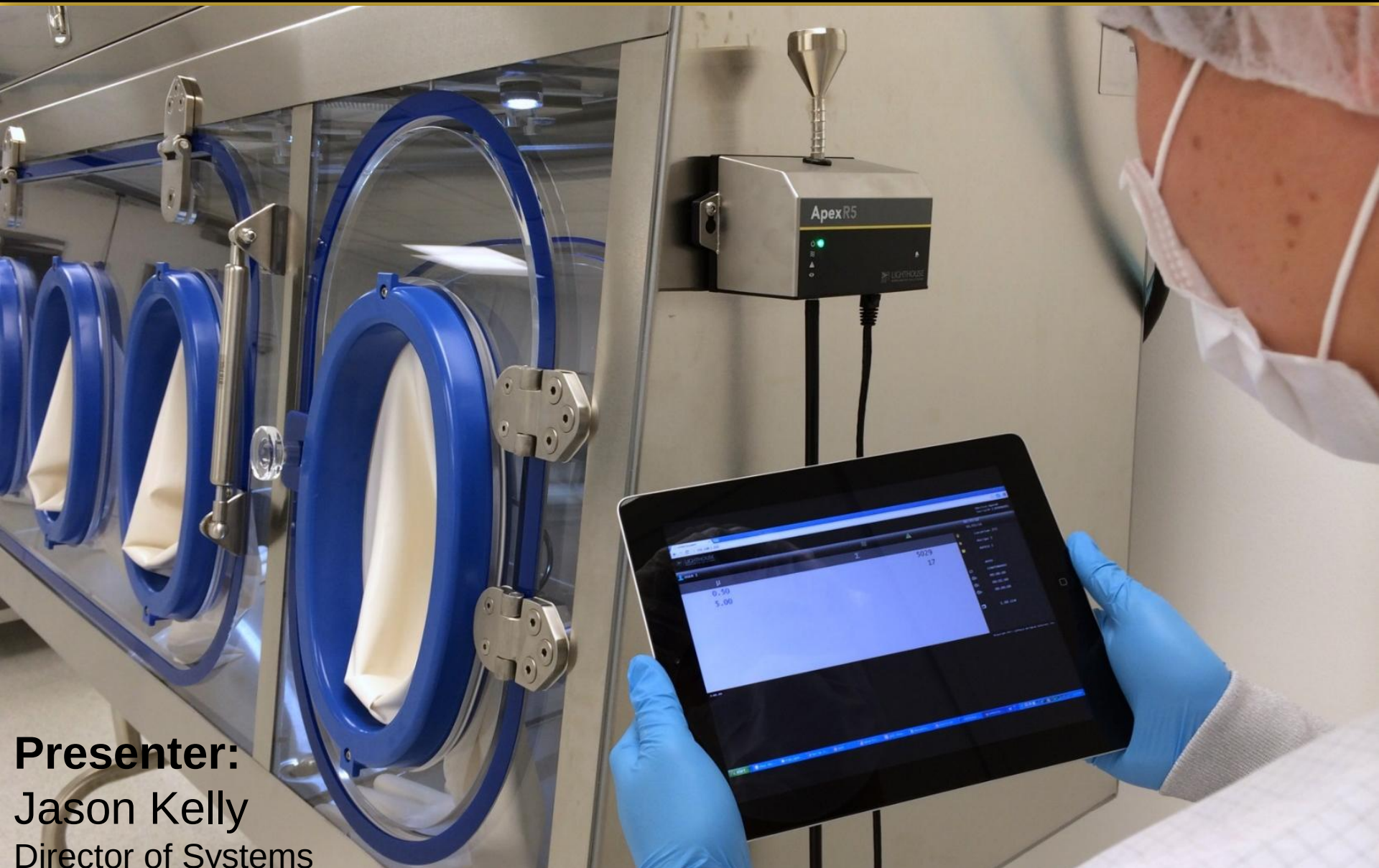
# Environmental Monitoring Systems
# Regulatory Compliance and Risk Mitigation

LIGHTHOUSE WORLDWIDE SOLUTIONS




**Presenter:**
Jason Kelly
Director of Systems

# Environmental Monitoring Systems
# Regulatory Compliance and Risk Mitigation

This presentation is broken into 4 parts and will give you the audience an overview of the following.

- **Part 1** – Good Manufacturing Practice (GMP)
- **Part 2** – Risk Assessment Overview
- **Part 3** – Environmental Monitoring System (EMS)
- **Part 4** – EMS System Design and Validation following GAMP

# GMP, What is it?

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## PART 1

# Good Manufacturing Practices (GMP)

# GMP Regulation

**GMP is REQUIRED to achieve a license to produce Medicinal Products !**

**A Regulatory Agency will Audit the Manufacturing Facility before a license is issued and cGMP is expected to be in place.**

# GMP Regulators

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Argentina

National Institute of Drugs
*Instituto **Na**cional de **Med**ican*

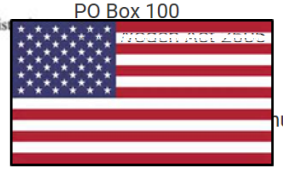
Inspection Department
Avda. Caseros 2161 – 1er Piso
AR - C1264AAB Buenos Aires

Accession to PIC Scheme January 2008

Australia

Therapeutic Goods Administration (**TGA**)
Departement of Health
Manufacturing Quality Branch
PO Box 100

Australian Government
Department of Health
Therapeutic Goods Administ



uary 1993 Accession to PIC Scheme November 1995

U.S.A

U.S. Food and Drug Administration (**US FDA**)

10903 New Hampshire Avenue
Building 31, Room 3502
Silver Spring, Maryland 20993

ASSURING THE SAFETY, QUALITY & EFFICACY OF VETERINARY MEDICINES

Canada

Health Canada / Santé Canada

***R**egulatory **O**perations and **R**egions **B**ranch (**RORB**)*
***D**irection **g**énérale des **o**pérations **r**églementaires et des régions (**DGORR**)*

13th floor, Jeanne Mance Building
200 Eglantine Drive
CA - Ottawa, Ontario, K1Y 1G9

Accession to PIC Scheme January 2011

Chinese Taipei

Taiwan Food and Drug Administration (**TFDA**)

Ministry of Health and Welfare
No. 161-2, Kunyang St.
Nangang District
TW - 115-61 Taipei City

Accession to PIC Scheme January 2013

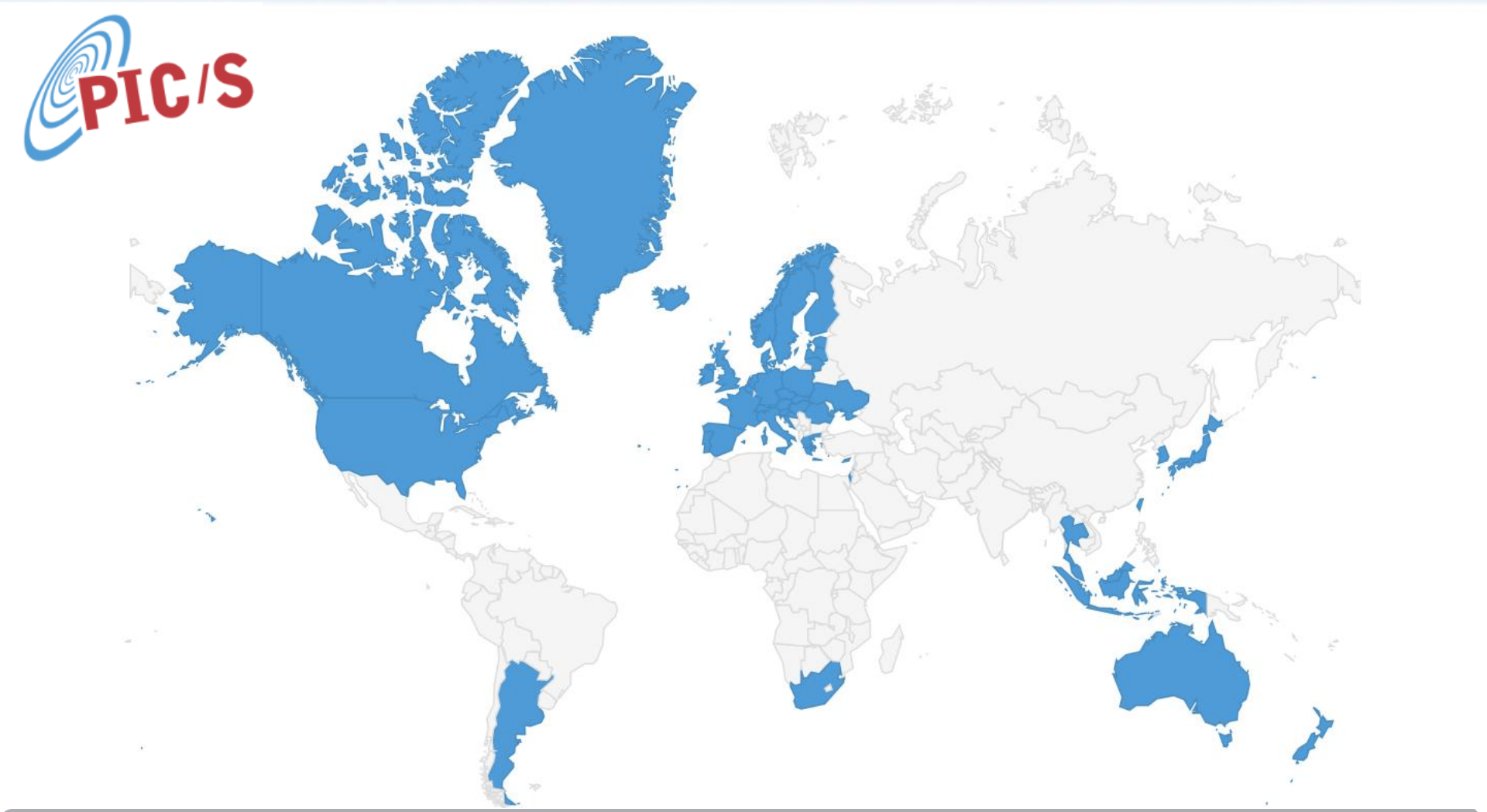
Thailand

Food and Drug Administration (**Thai**

Ministry of Public Health
88/24 Tiwanon Road
Nonthaburi 11000
Thailand

Accession to PIC Scheme January 1999

# PIC/s Worldwide Membership



PIC/S

Turkey along with Brazil, Mexico and Iran are the newest applicant Countries applying to join PICs

# EXITING NEW TEAMS TO JOIN

Technology That Counts

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Technology That Counts

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Technology That Counts

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About Members Publications Activities Events Accession PIA Academy

# Pharmaceutical Inspection Co-operation Scheme

Leading the international development, implementation and maintenance of harmonised GMP standards and quality systems of Inspectorates in the field of medicinal products

## Accession of Thailand / Thai FDA to PIC/S

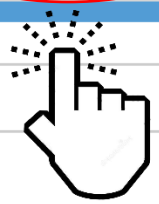
4 - 5 July 2016

At its meeting on 4-5 July 2016 in Manchester (UK), the PIC/S Committee invited Thailand's Food and Drug Administration (Thai FDA) to join the Scheme as from 1 August 2016. Thai FDA will become PIC/S' 49th Participating Authority.

https://picscheme.org/

All PIC/S documents publically available are listed below and appear in alphabetical order. Protected documents are for PIC/S Members-only and require a login.

All | GMP Guide | Latest | Drafts | Protected



Search | Category | Section

| Gmp | Reference | Category | Section |
|---|---|---|---|
| PIC/S GMP GUIDE (INTRODUCTION) | PE 009-13 (Intro) | Documents for Industry | PIC/S GMP Guide |
| PIC/S GMP GUIDE (PART I: BASIC REQUIREMENTS FOR MEDICINAL PRODUCTS) | PE 009-13 (Part I) | Documents for Industry | PIC/S GMP Guide |
| PIC/S GMP GUIDE (PART II: BASIC REQUIREMENTS FOR ACTIVE PHARMACEUTICAL INGREDIENTS) | PE 009-13 (Part II) | Documents for Industry | PIC/S GMP Guide |
| PIC/S GMP GUIDE (RELATED ANNEXES) | PE 009-13 (Annexes) | Documents for Industry | PIC/S GMP Guide |
| PIC/S GMP GUIDE (ZIP) | PE 009-13 | Documents for Industry | PIC/S GMP Guide |

# PART 2

# Risk Assessment

## CLEAN ROOM AND CLEAN AIR DEVICE MONITORING

8. Clean rooms and clean air devices should be routinely monitored in operation and the monitoring locations based on a formal risk analysis study and the results obtained during the classification of rooms and/or clean air devices.

# Risk Assessment Overview

Technology That Counts

LIGHTHOUSE WORLDWIDE SOLUTIONS

# Developing the Risk Assessment

## Useful References

- ICH Q9 Quality Risk Management
- WHO Quality Risk Management
- EUGMP Annex 20 Quality Risk Management

# Risk Assessment Overview

Technology That Counts

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- “The evaluation of the risk to quality should be based on scientific knowledge and ultimately link back to the protection of the patient; and

- The level of effort, formality, and documentation of the quality risk management process should be commensurate with the level of risk.”

# Risk Assessment Overview

Technology That Counts

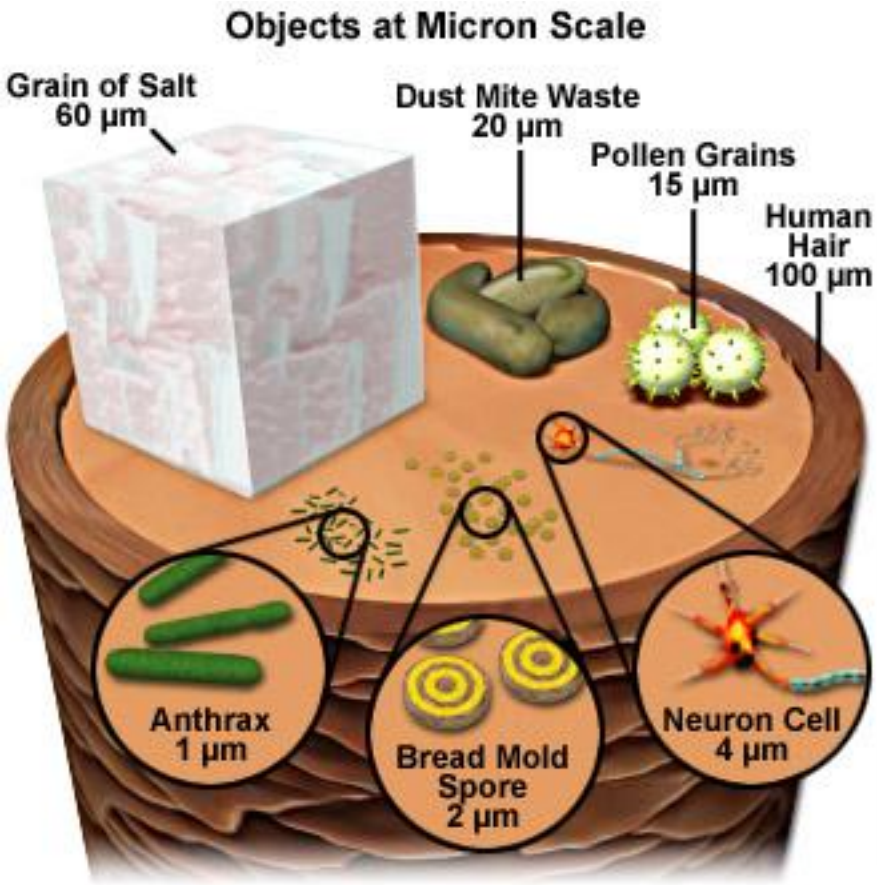
LIGHTHOUSE WORLDWIDE SOLUTIONS

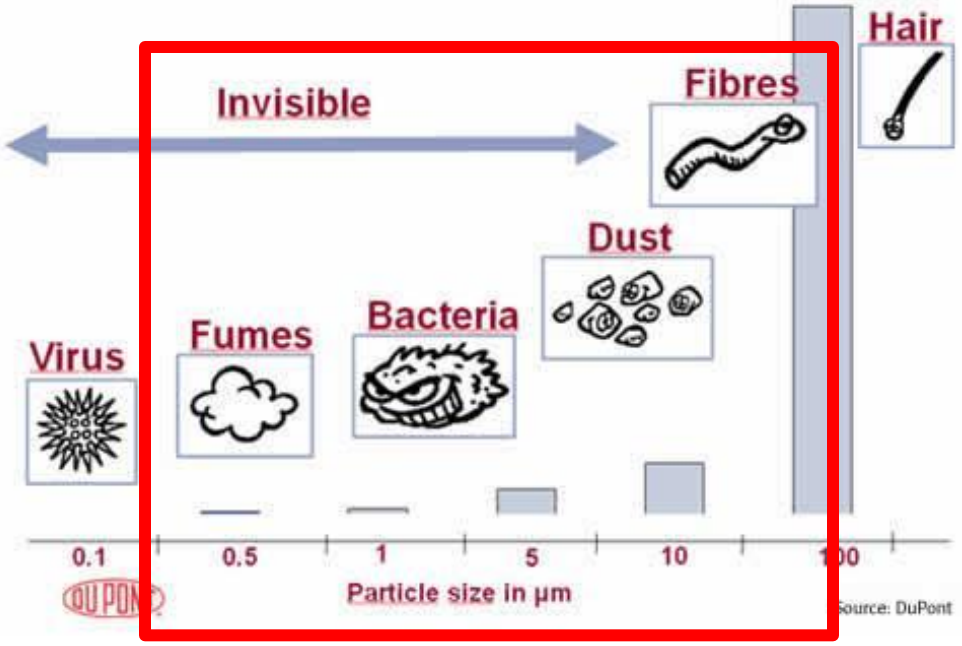
- Often rely mixed kinds of information:
  - **Quantitative**
  - **Qualitative**
  - **Expert judgment (Subject Matter Experts)**

- Focus on systematic thinking:
  - **Define the risk question**
  - ***Organize* information under categories, attributes**
  - **Build decision making paths**

# What are the Product Risks when performing Aseptic Product Manufacture?

# How big is one micron?



# Where are the Risks when performing Aseptic Product Manufacture?

# Risk Assessment Overview

Technology That Counts

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**Typically high risk areas in manufacturing are:**

- The filling zone (were containers are filled).
- Stopper bowls (were stoppers are loaded and kept prior to filling within the Grade A zone).
- Stopper insertion (the point stoppers are inserted into filled containers).
- Loading areas for freeze drying (where partially closed containers are loaded into freeze dryers (Lyophilizers).
- Isolator transfer devices.
- Transfer areas between Grade A and Grade B areas.
- Panels or access points (where operators are most likely to perform interventions or load components such as stoppers).
- Wherever there are open ampoules, viles and containers (turntables or the exit of a sterilization tunnel).
- Where there are aseptic connections.

# CASE STUDY

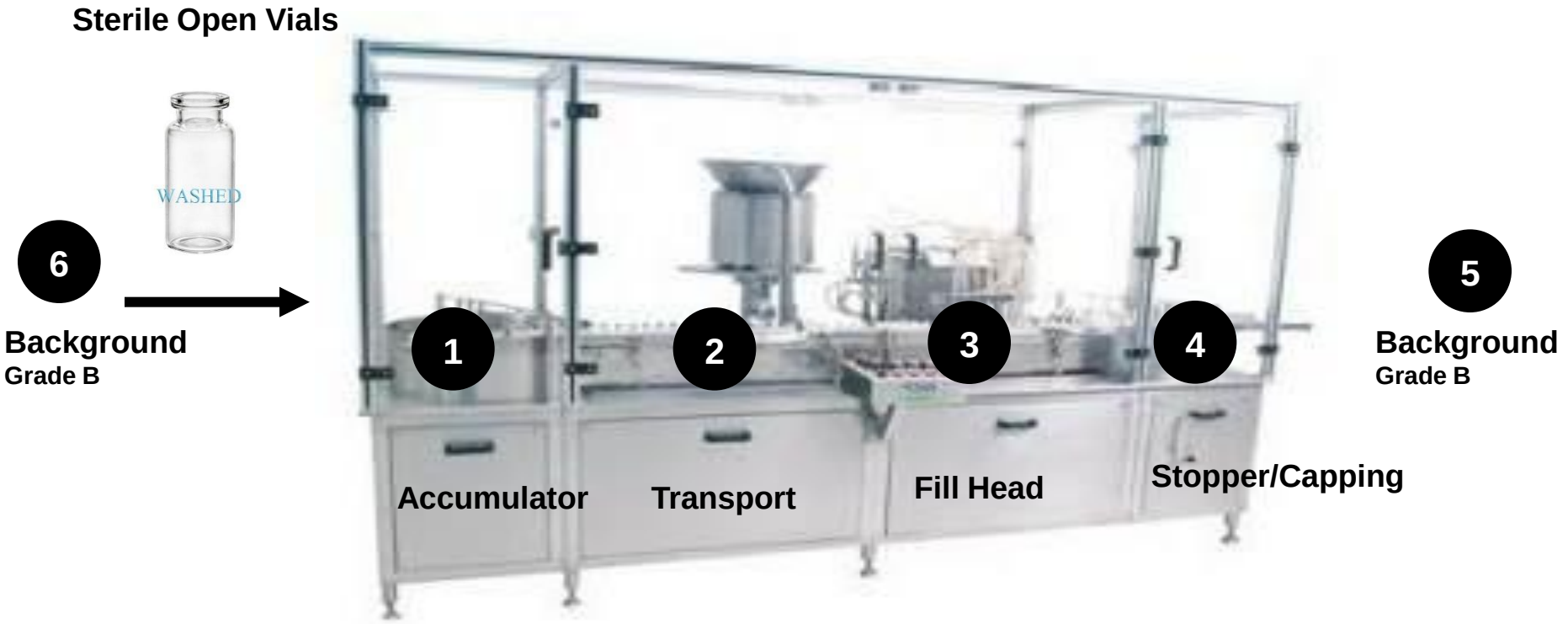
## Aseptic Filling Line Grade A with Grade B background

GMP Annex 1 states that cleanrooms and clean air devices are to be monitored in operation, with the monitoring locations based on a formal risk analysis study and the results obtained during the classification of cleanrooms and/or clean air devices.

## Considerations for the non-viable particle monitoring system:

1. Identify high-risk operations for particle monitoring.
2. Determine the optimal sample locations for monitoring.
3. Establish a monitoring frequency with alert and action levels.
4. Establish a system to verify the particle monitoring system is working effectively.
5. Establish and maintain the validated state of the non-viable particle monitoring system.

# 1. Identify high-risk operations for particle monitoring.




Aseptic Filling Machine Grade A

1. **Identify high-risk operations for particle monitoring.**

Critical areas are where an exposed product is vulnerable to contamination and will not be subsequently sterilized in its immediate container.

- **Locations Identified**
  - Along the filling machine (Grade A)
    – Critical Zones where product contamination risk is high
  - Background Locations (Grade B)

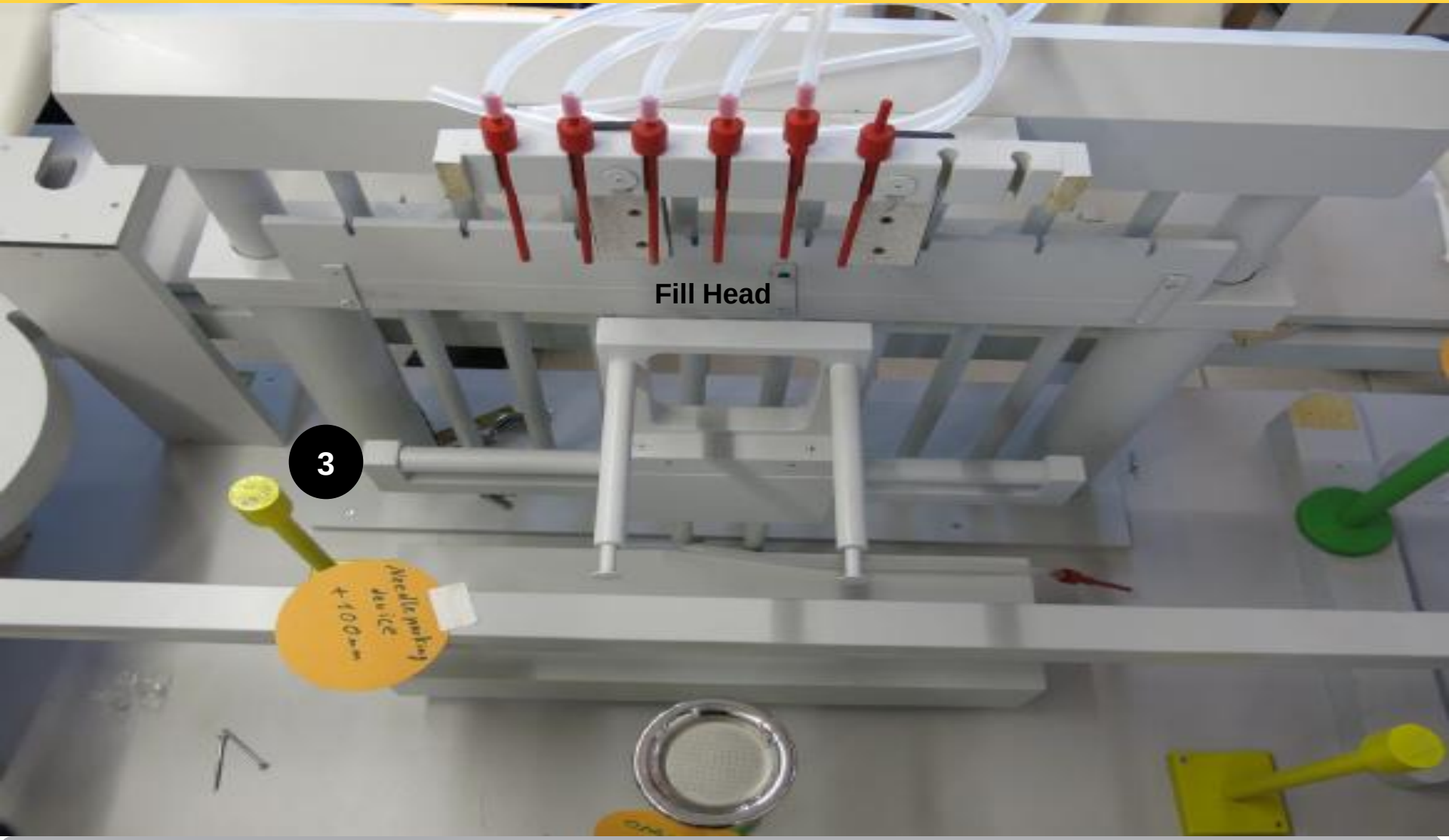
2. **Determine the optimal sample locations for monitoring.**

**Within Regulatory Guidelines…….**

- FDA 2004 Aseptic Guideline – 1ft (12inches) of critical zone
- Tubing bend radius
- Length of tubing PIC/s cGMP

1 **Accumulator**


2
Transport


Fill Head
3

4

Stopper/Capper


5
6
Background
Grade B

**3. Establish a monitoring frequency with alert and action levels.**

| Grade | Maxim… permitted number of particles/m³ equal to or …ater than the tabulated … | | | |
|---|---|---|---|---|
| | At rest | | In …ration | |
| | 0.5µm | 5.0µ… | …5µm | 5.0µm |
| A | 3,520 | 20 | 3,520 | 20 |
| B | 3,520 | … | 35…00 | 2,900 |
| C | 352,000 | 2,900 | 3,520,0… | 29,000 |
| D | 3,520,0… | 29,000 | not defined | not defined |

20. Appropriate alert and action limits should be set for the results of particulate and microbiological monitoring. If these limits are exceeded operating procedures should prescribe corrective action.

# What are “Appropriate Alarm Limits”?

4. Establish a system to verify the particle monitoring system is working effectively.

# IQ/OQ and PQ

5. Establish and maintain the validated state of the non-viable particle monitoring system

# Change Control Process

# EMS, What is it?

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## PART 3

# Environmental Monitoring System (EMS) Case Study

# EMS References

**Also referred to as the following;**

- **Particle Monitoring System**
- **Facility Monitoring System**
- **Cleanroom Monitoring System**
- **Real-Time Monitoring System**

# EMS Overview

## What is an Environmental Monitoring System?

It is a Monitoring System that collects environmental data in real time from sensors located in a Cleanroom or other environment.

Sensors used include, Particle Counters, Temperature sensor, Humidity sensor, Differential Pressure sensors.

These sensors monitor room and specific location conditions.

This sensor data is used to determine if the Cleanroom environmental conditions are within allowable tolerances to maintain the quality of the product being manufactured.

Tight Regulations are in place to make sure the product quality is maintained

# GMP ! Where do I Start?

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## Case Study:

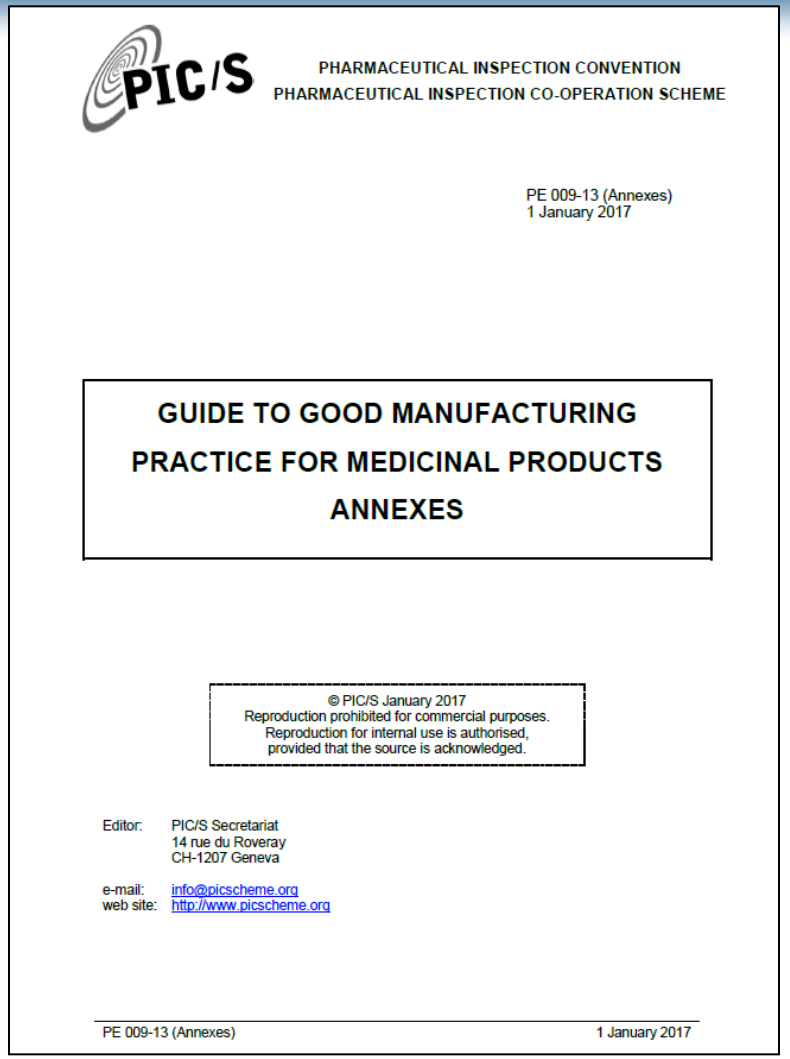
**Environmental Monitoring System to monitor a Grade A, Aseptic Filling Line**

# Manufacturing Sterile Injectables

- **Annexes** – Guide to Good Manufacturing Practice for Medicinal Products Annexes PE 009-13 (Annexes)

- The Annexes provide detail on specific areas of manufacture (e.g. annex on sterile manufacturing and radiopharmaceuticals)

- Annex 1 Manufacture of sterile medicinal products
- Annex 2 Manufacture of biological medicinal substances and products for human use
- Annex 3 Manufacture of radiopharmaceuticals
- Annex 4 Manufacture of veterinary medicinal products other than immunologicals
- Annex 5 Manufacture of immunological veterinary medical products
- Annex 6 Manufacture of medicinal gases
- Annex 7 Manufacture of herbal medicinal products
- Annex 8 Sampling of starting and packaging materials
- Annex 9 Manufacture of liquids, creams and ointments
- Annex 10 Manufacture of pressurised metered dose aerosol preparations for inhalation
- Annex 11 Computerised Systems
- Annex 12 Use of ionising radiation in the manufacture of medicinal products
- Annex 13 Manufacture of investigational medicinal products
- Annex 14 Manufacture of medicinal products derived from human blood or plasma
- Annex 15 Qualification and Validation
- Annex 16 Qualified person batch release
- Annex 17 Parametric Release
- Annex 18 GMP Guide for API's
- Annex 19 Reference and retention samples
- Annex 20 Quality risk management



PIC/S

PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

PE 009-13 (Annexes)
1 January 2017

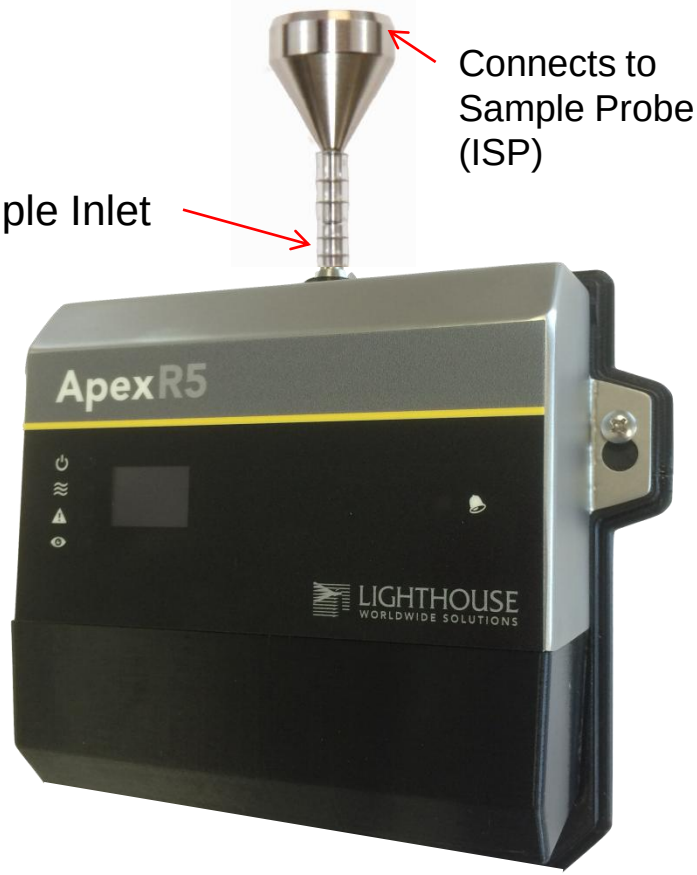
**GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS ANNEXES**



Editor: PIC/S Secretariat
14 rue du Roveray
CH-1207 Geneva

e-mail: info@picscheme.org
web site: http://www.picscheme.org

# EMS Sensors
# Remote Particle Counter





Vacuum Supply

Cat5 or 6 cable

Small size

0.5µm and 5.0µm size collection (Pharmaceutical Applications)

1 cubic foot/minute flow rate (28.3L/min)

Requires external Vacuum Pump

External power 24VDC

Transmits data using IP (preferred method)

Can be POE compatible (Power 48VDC and communication's run over single Cat5 or 6 network cable)

# EMS
# Particle Counter sample location

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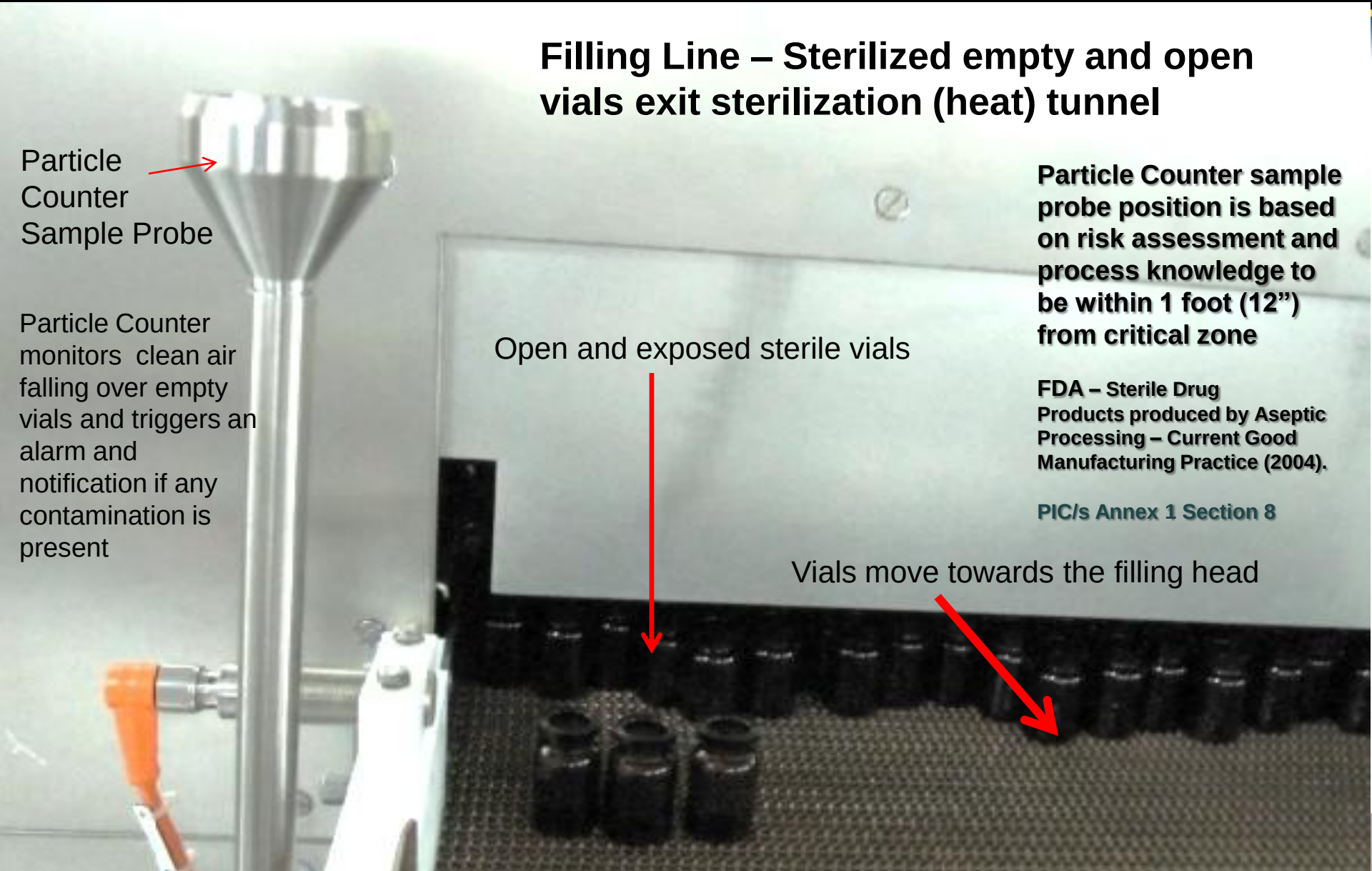
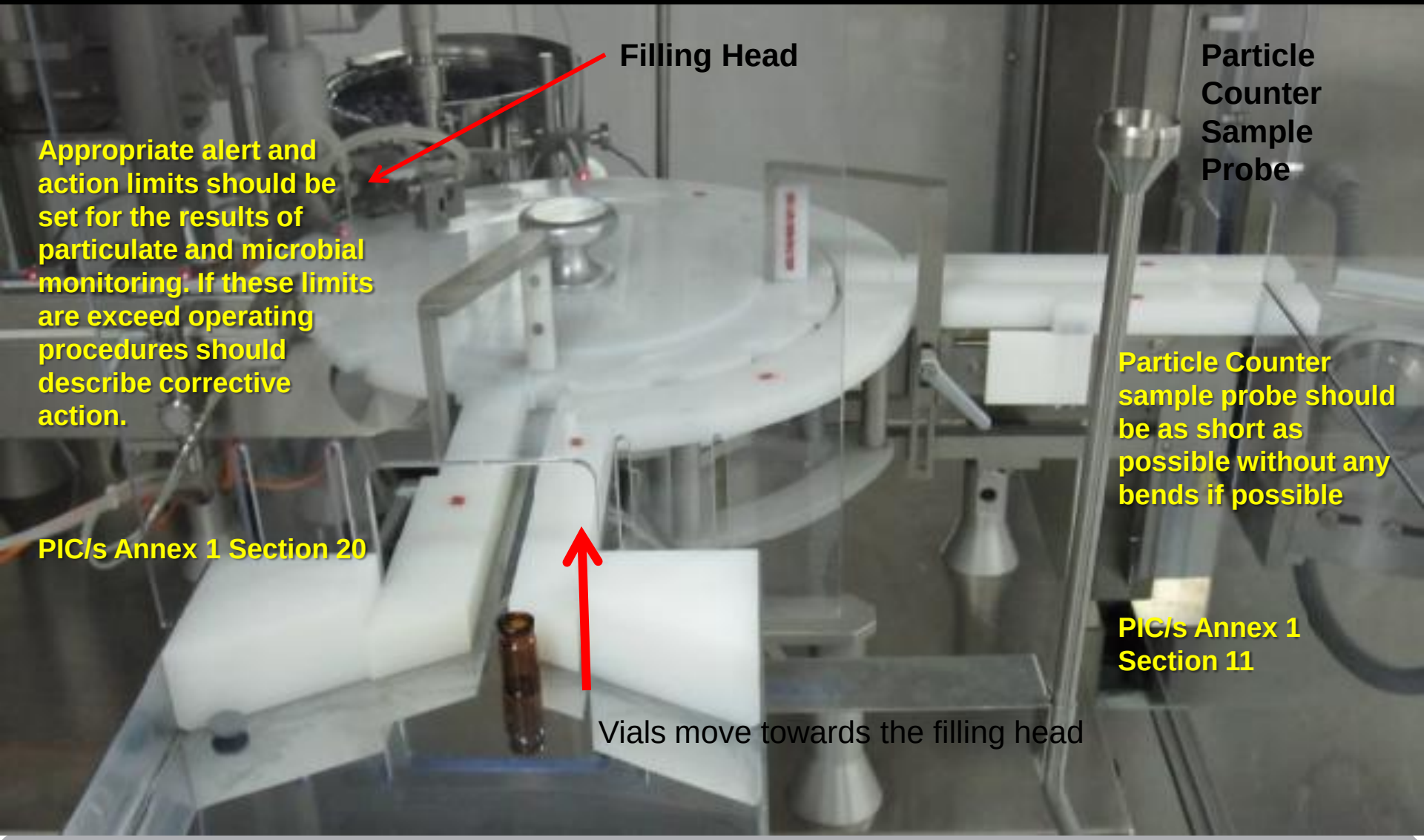
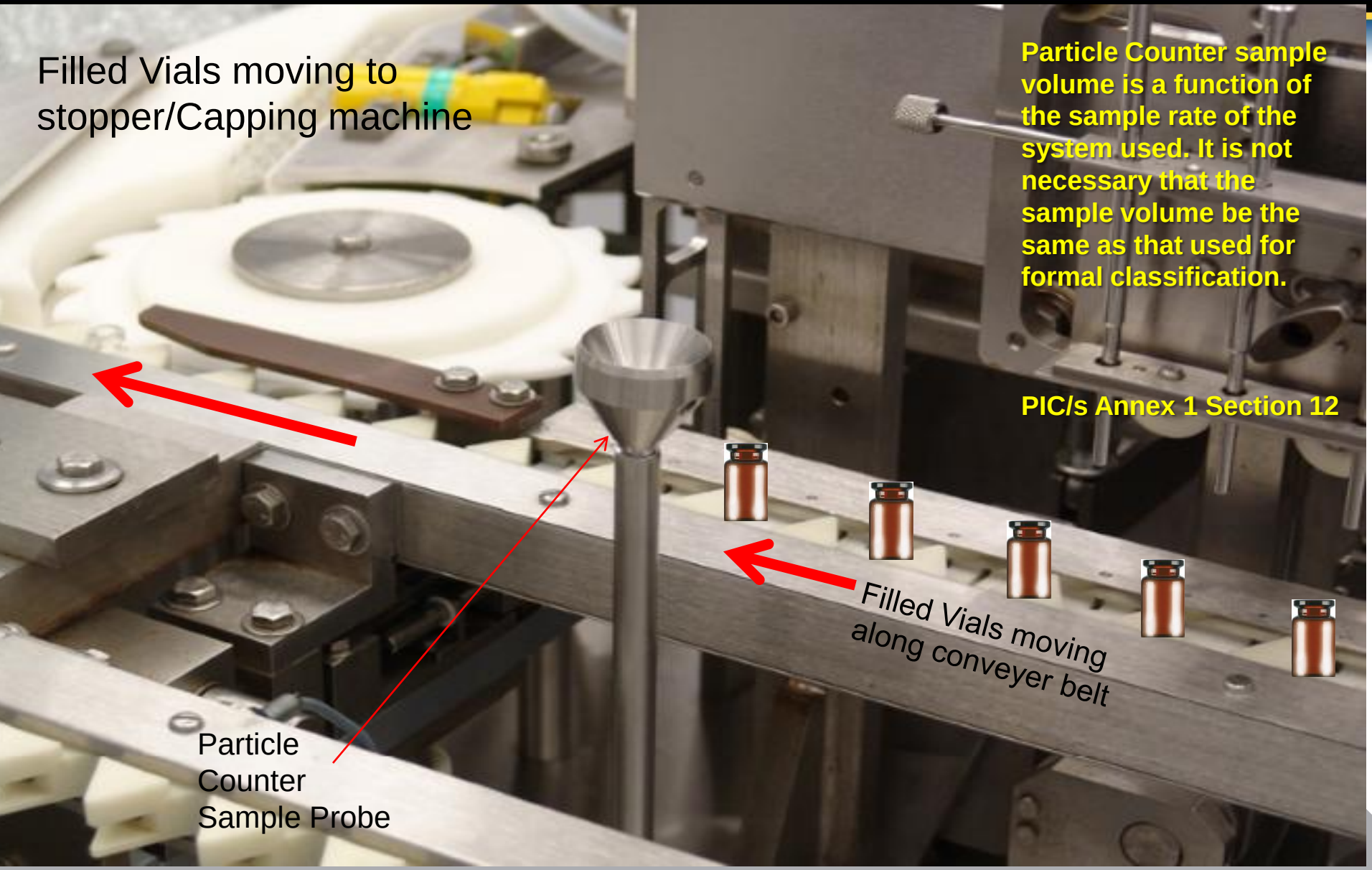


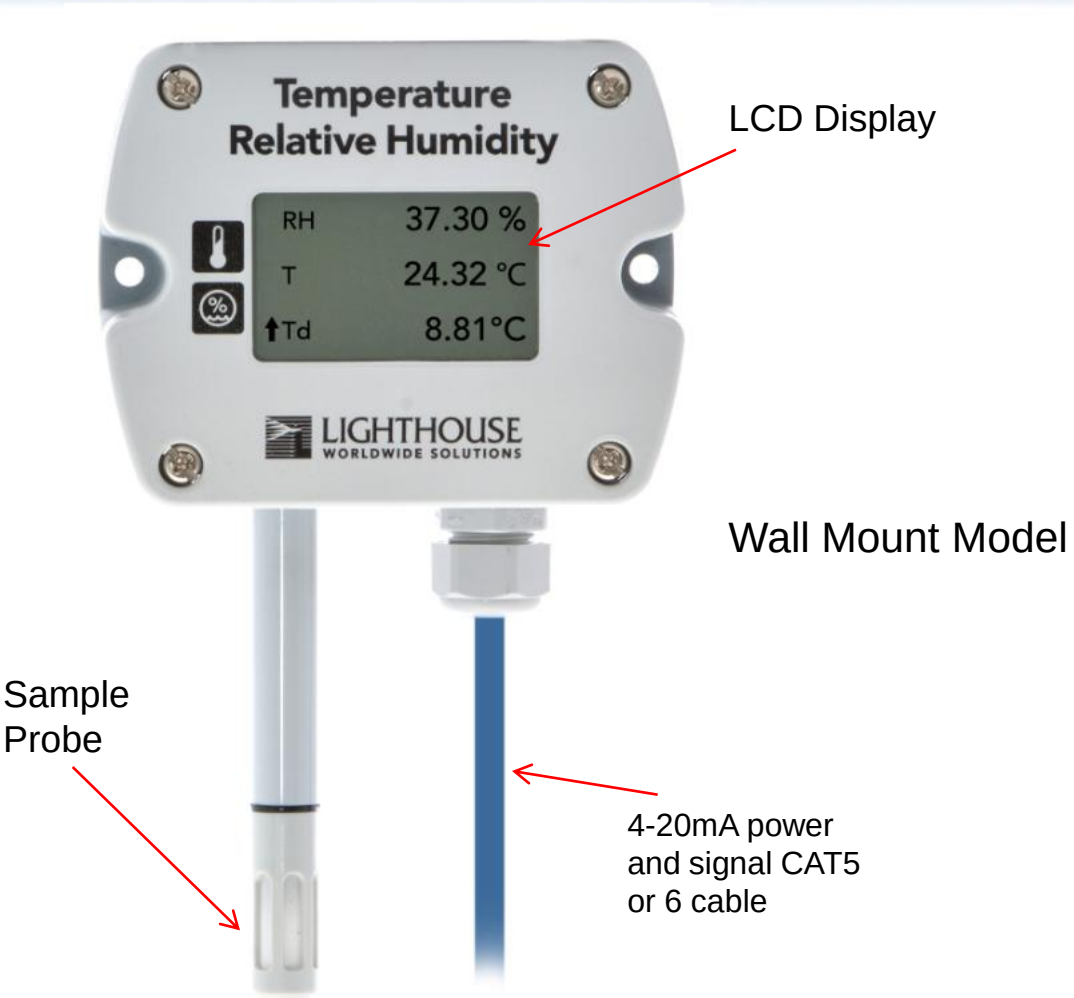
# EMS
# Particle Counter sample location



# EMS
# Particle Counter sample location



# EMS Sensors
# Temperature & Humidity Sensor




- Combined Sensor
- Monitors Room Environment
  (ºC or ºF & % RH)
- External power 24VDC
- Transmits data using 4-20mA signals (preferred method)
- Loop powered from a 24VDC supply source
- Location needs to be considered carefully
- Return air ducts are a good location (average room sample)

# EMS Sensor
# Differential Pressure Sensor


LCD Display

Wall Mount Model

Sample Inlets
(+) and (-)

4-20mA power
and signal CAT5
or 6 cable

- Monitors Room Environment
  (Pascal's Pa or Water Column WC")
- External power 24VDC
- Transmits data using 4-20mA signals (preferred method)
- Is loop powered from a 24VDC supply

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# PART 4

# EMS System Design and Validation

## Following the ISPE GAMP Process

## Environmental Monitoring System

# What is ISPE?

## Connecting Pharmaceutical Knowledge

ISPE, is the **I**nternational **S**ociety for **P**harmaceutical **E**ngineering

ISPE's Core Members are pharmaceutical professionals who use expert knowledge to create high-quality, cost-effective GMP solutions.

**Our Purpose:** ISPE delivers technical and operational solutions to support our Members across the global pharmaceutical and biopharmaceutical industry in the manufacture of quality medicines for patients.

EMS are designed based on ISPE's **G**ood **A**utomated **M**anufacturing **P**ractices (Known as GAMP Guidelines).

The GAMP "V" model is widely used.

Website is www.ispe.org for more information

# DESIGNING A MONITORING SYSTEM

## How is it validated – Validation Lifecycle?

Design and Validation of an Environmental Monitoring System is a systematic process that starts from a Customer developed Risk Assessment Which is the basis for the URS, which in turn determines how the system is designed; (FDS) tested (FAT) installed (SAT) and the actual validation (IQ/OQ) proving that the designed and installed system actually meet the URS and is ready to be handed over to the end user. The end user then performs a PQ to determine the performance of the installed EMS based on their process. Mitigating any observed risks to product quality and safety.

# Sample URS



## Revision History

| Revision | Date | Author | Details |
|---|---|---|---|
| | (DATE) | (NAME) | First Draft |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

(CUSTOMER NAME)

USER REQUIREMENT SPECIFICATION

(CUSTOMER) SYSTEM ID:
AT
(CUSTOMER LOCATION)





LIGHTHOUSE WORLDWIDE SOLUTIONS | USER REQUIREMENT SPECIFICATION (URS) | Page 3 of 17
Document Title: User Requirement Specification | LWS Document Number: LMS-URS-001
Customer: (Customer Name and Address) | (Customer) Document #:
Project: Lighthouse Monitoring System
Prepared by: (Insert Name) | Department:

## Table of Contents



922234823-1 R1

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# Sample URS

LIGHTHOUSE WORLDWIDE SOLUTIONS

| LIGHTHOUSE WORLDWIDE SOLUTIONS | USER REQUIREMENT SPECIFICATION (URS) | Page 8 of 17 |
|---|---|---|
| Document Title: User Requirement Specification | LWS Document Number: LMS-URS-001 | |
| Customer: (Customer Name and Address) | (Customer) Document #: | |
| Project: Lighthouse Monitoring System | | |

Customer User Requirement ID number

Description of URS for Particle Counters

Business Essential Attribute and/or Quality Control Attribute

Where Vendor documents the design and testing to meet URS

**7.1 Hardware and Monitoring Requirements**

| URS Designation | Particle Counters - Description | Requirement Type | FDS Section | IQ/OQ Section |
|---|---|---|---|---|
| 7.1 URS-1 | The system must be capable of collecting data from a minimum of (#) (particle counter type) particle counters. | BEA/QCA | ✖ | ✖ |
| 7.1 URS-2 | The (particle counter type) particle counters must be able to sample when required from a series of rooms or during (example: Aseptic fill operations). | BEA/QCA | | |
| 7.1 URS-3 | If the air flow through the particle counter is not within the specification during the sampling period, an alarm will be generated and logged, an audible / visible alarm will alert user.<br>Flow detection accuracy must be +/-5% as per ISO 21501-4. | BEA/QCA | ✖ | ✖ |

This Section is the traceability and validated documentation to prove regulatory compliance

# URS Compliance Matrix

LIGHTHOUSE WORLDWIDE SOLUTIONS

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | LIGHTHOUSE WORLDWIDE SOLUTIONS | | Date: 6/17/15 | Completed by : | Brandon Amador | | Software Engineer | |
| | | | | | Lawrence Ashton | | Software Manager | |
| | | | | Reviewed by : | Jason Kelly | | Director of Systems | |
| | **Particle Monitoring Computer system** | | **Compliance Matrix** | **Proposed Software Solution:** | **LMS Pharma** | | | |
| | Title: Particle Monitoring System User Requirements Specification | | | | | | | |
| | This Compliance Matrix has been developed based on [redacted] submission "Particle Monitoring System User Requirement Speci | | | | | | | |
| | The table below indicates the URS requirements along with LWS response co | | | | | | | |
| | **Note :** For regulated customers who manufacture regulated products LW | | | | | | | |
| | as an indication to auditors as to where the LWS Particle Monitoring system a | | | | | | | |
| | Items that need clarification shall be highlighted by an orange cell | | | | | | | |
| | **Compliance** at this stage is **97.6%** depending on items highlighted "TBC" bein | | | | | | | |
| | Operatio | | | | | | | |

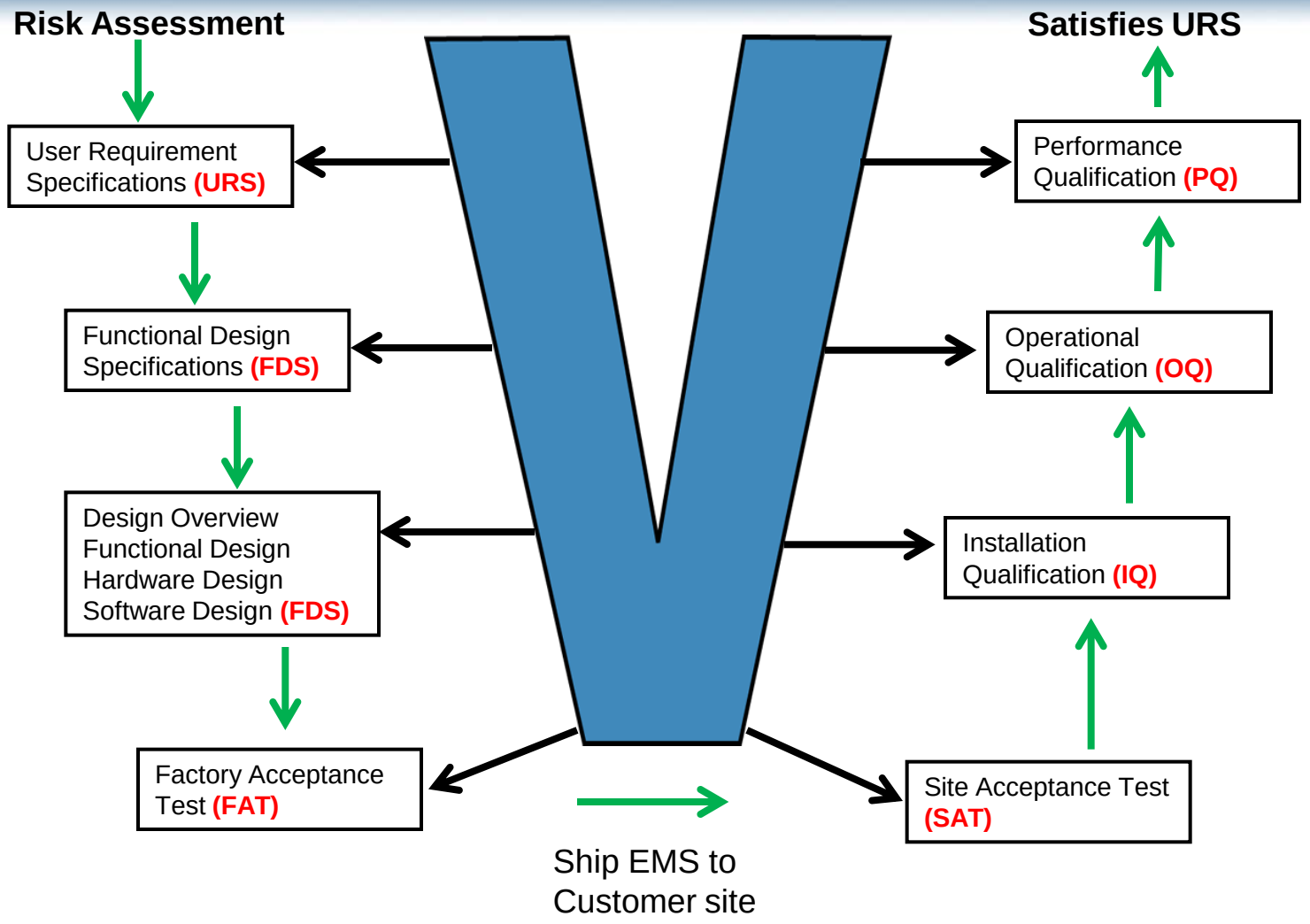
**Vendors response to meeting Customer URS**

**Vendors Compliance Rate (%) based on meeting Customers URS**

**Customer User Requirements**

| URS No. | R | LWS Response | Compliance 97.6% | Traceability FDS | SDS | OQ | Additional Comments |
|---|---|---|---|---|---|---|---|
| 3.1 | Functions | | | | | | |
| 3.1.1 | | | | | | | |
| 3.1.1.1 | Define multiple role levels including the following (at minimum) | | | | | | |
| 3.1.1.1.1 | View-Only (user with ability to only view select screens) | We need "selected screens" to be defined but LWS does not see an issue with this requirement | TBC | X | X | X | LWS requests that Baxter provide more details on this requirement |
| 3.1.1.1.2 | Operator (user with ability to view most screens and print reports) | Can be configurable to meet this requirement | Yes | X | X | X | |
| 3.1.1.1.3 | Supervisor (user with ability to view raw data as well as Operator-level privileges) | Can be configurable to meet this requirement | Yes | X | X | X | LMS Pharma has 3 user levels as standard |
| 3.1.1.1.4 | Administrator (user with configuration abilities as well as Supervisor-level privileges) | Can be configurable to meet this requirement | Yes | X | X | X | |
| 3.1.1.2 | Count ≥ 0.5 µm and ≥ 5.0 µm air particulates in the ISO-5/4.8 areas of aseptic filling, formulation, and lyophilization areas continuously throughout manufacturing operations. | We recommend using LWS APEXR5 particle counters to meet this requirement | Yes | X | X | X | LMS Pharma using ApexR5 particle counters meets this requirement |

# ISPE GAMP "V" Model Overview



## DESIGNING A MONITORING SYSTEM

### EMS Process Overview

# PROCESS FLOW

# Procurement and Implementation

## ISPE GAMP Process – Monitoring System

# ISPE GAMP Process Monitoring System

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| EMS PROCESS FLOW – EMS Design and Implementation | | | |
|---|---|---|---|
| | | Short Description | Responsible |
| Risk Assessment | Develop Risk Assessment | A formal risk assessment is developed based On the guidelines of EUGMP Annex 20 or ICHQ9 | CUSTOMER |
| URS | Develop URS | A URS is developed by all Company stakeholders, the URS outlines the EMS requirements based on the findings of the Risk Assessment | CUSTOMER |
| Quote | Submit Quote | The EMS Supplier develops a Quote based on the URS | EMS SUPPLIER |
| Audit EMS Supplier | Supplier Audit | Customer conducts site audit of EMS Supplier QMS and Software development process and service support (EUGMP Annex 11 Computerized Systems) | CUSTOMER |

# ISPE GAMP Process Monitoring System

LIGHTHOUSE WORLDWIDE SOLUTIONS

| | | | |
|---|---|---|---|
| Select EMS Supplier | Select EMS Supplier | Based on Risk Assessment the Customer selects a Primary EMS supplier with a secondary backup supplier once a P.O. is provided the project commences. | CUSTOMER |
| Start of System Project Management | Kick Off Meeting | The kick Off Project Management meeting is critical to confirm the project schedule, introduce the key Managers and set the objectives and goals of the project. A Gantt Chart is typically used by the Project Manager to Schedule and track the project. Good communication is critical throughout the project and weekly project meetings Keep the project on track as well as daily site updates. | CUSTOMER<br>EMS SUPPLIER |
| EMS Quality Plan | Quality Plan | The quality plan is a document, that specifies quality standards, practices, resources, specifications, and the sequence of activities relevant to a particular product, service, project, or contract. The Customer must review and sign off the Quality Plan. | EMS SUPPLIER |
| Functional Design Specification | FDS | A Functional Design Specification (FDS) is a document used by companies in a pre-development phase to translate all notes, concepts, and scope into a complete requirements document. The document can include anything from flowcharts, screenshots, and wiring diagrams to describe the functionality of the system. It is always best practice to develop the FDS using the URS as the main driver. The Customer must review and sign off the FDS. | EMS SUPPLIER |

# ISPE GAMP Process Monitoring System

LIGHTHOUSE WORLDWIDE SOLUTIONS

| | | | |
|---|---|---|---|
| Design Review | Design Review | The design review is a milestone within a product development process whereby a design is evaluated against its requirements in order to verify the outcomes of previous activities and identify issues before committing to - and if need to be reprioritized further work. The ultimate design review, if successful, therefore triggers the system build. | CUSTOMER<br>EMS SUPPLIER |
| System Build and Test | Build & Test | The Build and test stage of the EMS lifecycle is where The EMS software is configured and the hardware is connect. Once connected the system is tested for functionality and connectivity. After build and test is completed the system is then ready for a formal FAT. | EMS SUPPLIER |
| Factory Acceptance Test | FAT | The factory acceptance test (FAT) is a test conducted at the EMS suppliers premises to verify that the system operates accordingly to the specifications of the FDS. The Customer must review and sign off the FAT. | CUSTOMER<br>EMS SUPPLIER |
| System Delivery | System Delivery | After successful FAT the system is securely packaged and shipped to site. | EMS SUPPLIER |
| Site Acceptance Test | SAT | A formal site acceptance test occurs once the system is unpacked to verify connectivity and functionality on-site. The SAT is typically completed so the system is ready for and IQ/OQ<br>The Customer must review and sign off the SAT | CUSTOMER<br>EMS SUPPLIER |

# ISPE GAMP Process Monitoring System

LIGHTHOUSE WORLDWIDE SOLUTIONS

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| Installation Qualification | IQ | The IQ is completed after the monitoring system has been fully tested during the site acceptance testing. A successful SAT paves the way for a successful IQ. The IQ should be traced back to the URS. Meaning the protocol IQ tests should indicate the critical attributes in the URS have been formally tested in the IQ<br>The Customer must review and sign off the IQ and witness the testing | CUSTOMER<br>EMS SUPPLIER |
| Operation Qualification | OQ | The OQ is completed after the IQ has been signed off. The OQ should be traced back to the URS. Meaning the protocol OQ tests should indicate the critical attributes in the URS have been formally tested in the OQ and the system proves operational functionality. It is recommended a 24-48hr dry run is performed to validate the Monitoring system can run without any issues prior to handover<br>The Customer must review and sign off the IQ and witness the testing | CUSTOMER<br>EMS SUPPLIER |
| System Training | Training | Sufficient training needs to be provided and this is a critical step in the handover process. Training needs to be measurable and the operator and/or administrator needs to show repeatability. The training should have a formal exam based on witnessed and successful end user performances. The training provided should be well developed so the end user can perform their PQ without vendor assistance | EMS SUPPLIER |
| Performance Qualification | PQ | The Customer should perform a live PQ once the monitoring system has been handed over. This PQ should be based on a live process run and scenario. It is at this stage that final configurations and any alarm adjustments are made and captured with Change Control. SOPs should be executed and well understood especially with 21CFR11 requirements and what the procedure is when an Alert or Action Alarm is triggered. Any intuitive Auditor will look for these SOPs in place and been used | CUSTOMER |

# EMS Lifecycle Summary

- Customer develops a Risk Assessment
- Customer develops a URS based off of the Risk Assessment
- Customer chooses a qualified supplier based on a supplier audit
- Supplier designs the EMS design based off of the URS and follows GAMP guidelines
- Customer approves the Design
- Supplier Builds and tests the EMS prior to delivery
- Supplier installs and tests the EMS prior to qualification
- Supplier and Customer perform IQ & OQ
- Customer performs PQ and confirms EMS meets their requirements

## QUESTIONS ?

# Your Presenter

**Biography – Jason Kelly Director of Systems – Lighthouse Worldwide Solutions**

20 Years Management positions in Environmental Monitoring Systems Service, Design, Installation, Validation and ongoing support. Has worked on many Projects for top Life-Science companies assisting in procurement, delivery and compliance to ensure regulatory acceptance. Worked across the World on many projects in the UK, Ireland, Europe, Australia and now resides in Oregon USA. He can be contacted by email on jasonk@golighthouse.com or on LinkedIn and always welcomes queries and questions on Monitoring Systems connected to particle counters or environmental sensors.


If you have any more queries on Environmental Systems and want to contact Jason Kelly directly then send him an email on

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