

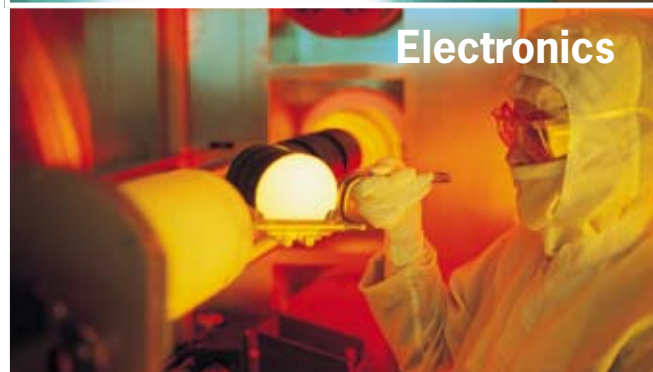


**BROOKHAVEN
INSTRUMENTS**

Contamination Control and Environmental Monitoring Systems

Brookhaven Instruments deliver, install and validate particle counters, Microbial Air Samplers and Monitoring Systems for clean rooms and other GMP critical areas. Our systems can monitor particle, microbial, differential pressure, temperature, humidity and other critical parameters.

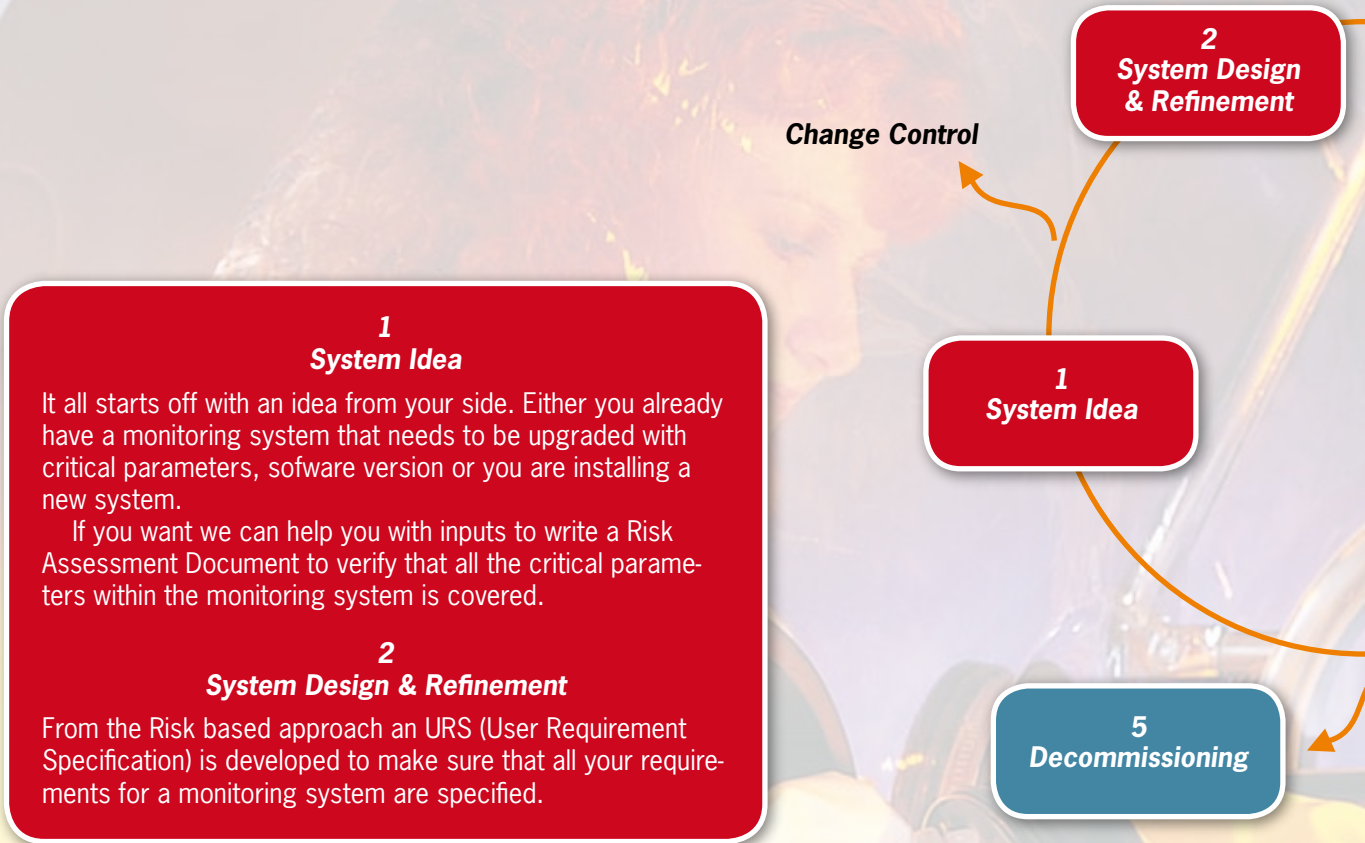
You request - we design!



Project Life Cycle

Brookhaven Instruments offer full validation of the monitoring system including life cycle documentation according to GAMP5 and VPCS from ISPE.

We also supply complete software design & validation documentation.



1 System Idea

It all starts off with an idea from your side. Either you already have a monitoring system that needs to be upgraded with critical parameters, software version or you are installing a new system.

If you want we can help you with inputs to write a Risk Assessment Document to verify that all the critical parameters within the monitoring system is covered.

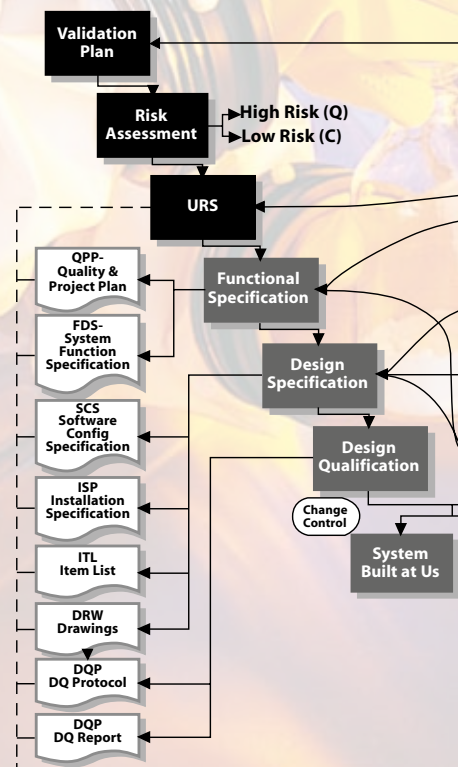
2 System Design & Refinement

From the Risk based approach an URS (User Requirement Specification) is developed to make sure that all your requirements for a monitoring system are specified.

5 Decommissioning

When your system or parts of the system comes to the end of the lifecycle we can help you with executing a controlled decommissioning. This could include:

- Final backup of data
- Final calibration of sensors
- Final tests to verify that the system were in a validated state
- Decommissioning Report



**3
System
Implementation**

**3
System Implementation**

We offer an comprehensive validation package to make sure you are in compliance with the regulatory demands. Since we have extensive experience from working with the Pharmaceutical Industry we write our own documentation. We implement our systems according to our own GAMP5 V modell.

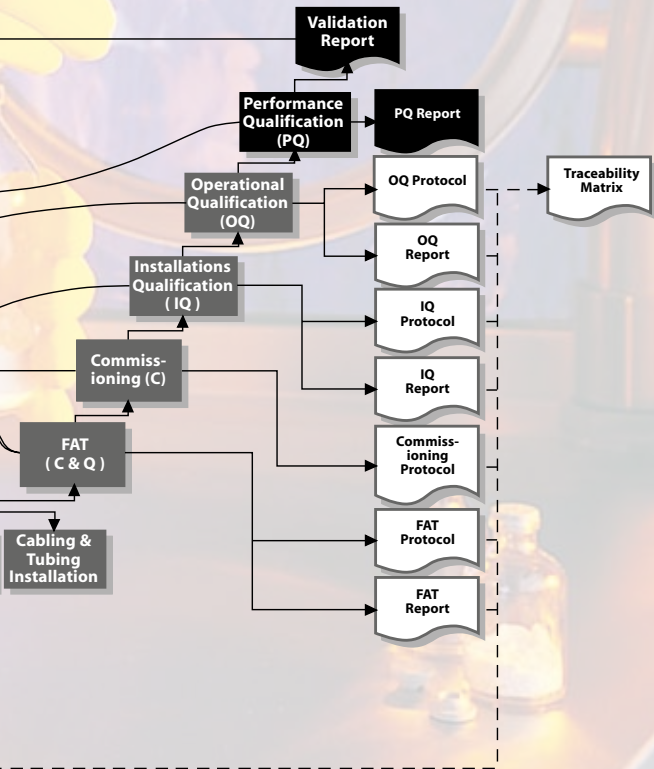
**4
Maintenance**

**4
Maintenance & Service**

When you have made an investment in a monitoring system or instrument you want to make sure that it will be in good condition and running for as long as possible without any major failures. We offer many levels of service agreements such as:

- Calibration on particle, microbial and environmental sensors at our calibration laboratory or on site with our specially designed calibration bus.
- Extended warranty on system parts or the complete system including travel & labor costs.
- Yearly re-qualification of the system to maintain the validated state.

**Brookhaven Instruments
GAMP5 V Model Interpretation**



Monitoring Architecture

We shall relieve our customers of compliance

When you invest in a monitoring system from us, you can be sure that you will be in compliance from the start. Our requirements from FDA, EC-GMP & ISO. Through all phases from design & installation through to operation according to the GAMP5 guidelines for GxP.

Environmental Monitoring

In a clean room there are many parameters to monitor to make sure that the room stays in a controlled condition. Some of the most common parameters that are monitored includes:

- Room Temperature
- Room Humidity
- Room Differential Pressure



Particle Monitoring

When your need for continuous particle counting is established we have many different particle sensors to choose from for integration into a monitoring system.

Maybe you have a need for a VHP resistant particle sensor or with a built in pump, we know what is best for your application. We can offer data communication via 4-20mA, RS-485 or TCP/IP.

We also design our own solutions for installation of the particle sensor like a stainless steel box with inspection window and an isokinetic sampling probe with a unique lid that can be fitted on top when cleaning is performed.



Communication Cabinet

The communication cabinet is the central part of the monitoring system. All communication with surrounding input & output parameters is routed through the cabinet. In the cabinet we mount devices like:



Automated Microbial Sampling

We can deliver a fully automated microbial sampling solution. It means that for your most critical areas in a grade A & B environment where you would monitor for microorganisms on a day to day basis we can simplify that work for you.

A microbial sampling head is installed at a fixed location at your critical points. The sampling head can be controlled via an operator panel where start & stop is executed. Within the monitoring software the measuring point name, start & stop time, who started the measurement and any potential flow failure is recorded.

This can later be printed together with your batch report. You can also if wanted record your microbial data after incubation. The head is compatible with 55 mm contact plates or 90 mm petri dishes.



Monitoring Software

In our system we use a software that is developed for one purpose only, to monitor critical parameters like particles, microorganisms, differential pressure, temperature and humidity etc.

It is a GAMP5 category 4 software (configurable software). It is fully validated and comes delivered with a complete lifecycle documentation. It uses a modern database like MS SQL database which ensures a flexible and stable data collection and storage.

The software is supported by all the Nordic languages and it can be used together with touch panels, SMS and E-mail services. It is also compatible with OPC server solutions.

g System ure

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om Brookhaven Instruments you can
n the beginning. Our system will meet the
his is possible since all our project
ualification & handover are executed
P Computerized Systems.

- Analog Input
- Digital I/O
- Relay Output
- RS-485 to TCP/IP
- Network Switch
- 24V Power Supply
- UPS
- SMS Modem

Monitoring Computer

- Server
- Redundant Server (Buddy)
- Network Clients

Software Data Output

- Reports
- PDF
 - CSV

Local Area Network

- Building Management Systems
- Data Backup
- Network Clients
- Printers



Equipment Monitoring

Any equipment that is critical for your process we can monitor. The equipment may have a built in sensors that supplies a 4-20mA or 0-10V signal or we install a sensor for it. Examples of critical parameters are:

- Incubators
- Refrigerators & Freezers
- Ultra Low Temperature Freezers
- Air Flow
- Gases
- TOC & Conductivity



Alarms & Human Machine Interface

The monitored process parameters and alarms might need to be displayed for the operator or supervisors. We offer several solutions like:

- Clean Room Operator Panel
- Alarm Beacon
- SMS
- E-mail
- VPN-Client
- Security Call Center



Control & Automation

There might be processes that you would like to automate or control. Examples of those are:

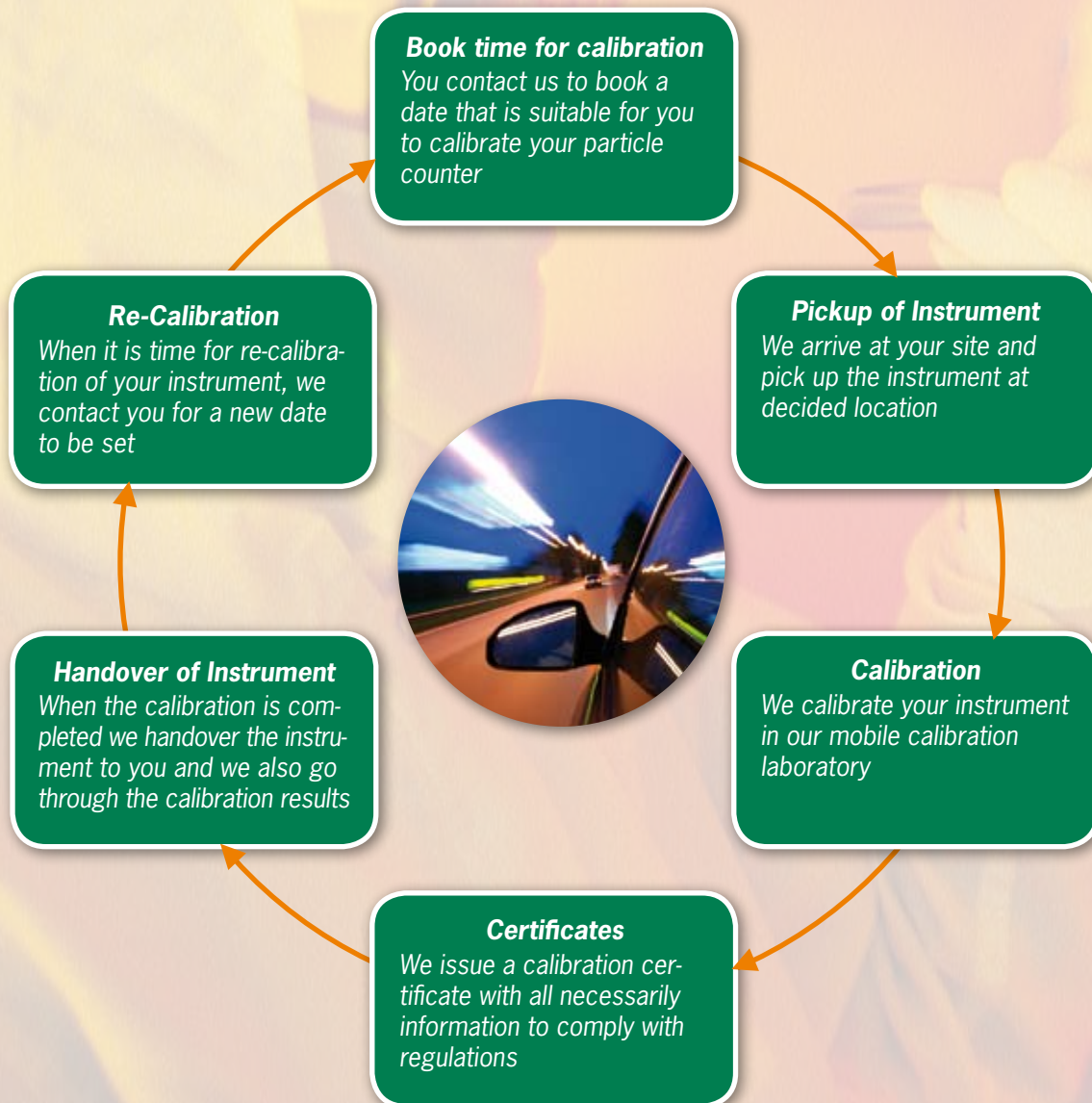
- Digital signals to & from process equipment
- Controlled changes of alarm limits
- Changes in ventilation speed
- Switching of valves
- Web Camera Monitoring



Calibration of Particle Counters and Microbial Air Samplers

We have a state of the art mobile calibration laboratory equipped with all necessarily instruments to perform calibration of almost any brand of Aerosol Particle Counters. We can also perform calibration of microbial air samplers.

Calibration of Aerosol Particle counters can be calibrated according to existing standards or the new ISO 21501-4 standard.



Particle Counters and Microbial Air Samplers

Portable Airborne Particle Counters

Our Portable Particle Counters are the ones we recommend for clean room certification according to ISO 14644-1 & EC-GMP Annex 1. They use a higher air flow and the graphical interface is more user friendly. Pre set programs and alpha numeric locations can be saved in the memory.

Data download to external software is possible where you create your own report according to ISO 14644-1 or EC GMP Annex 1.

The instruments comes with the following standard features:

- Airflow 28,3, 50 or 100 l/min
- 6 channels of particle data
- 0,3-25 µm particle size
- Software for data download to computer
- Transport Case
- Isokinetic Sample Probe
- Tripod
- Sample Tube
- IQ/OQ Document



Handheld Airborne Particle Counters

Our Handheld Particle Counters can be used for spot checks of particle concentrations in normal environments like office areas, hospitals or any other non clean room area where particles are of interest. Particle leakage in filters & general particle classification in clean rooms is also possible.

The instruments come with the following standard features:

- Airflow 0,1 CFM (2,83 l/min)
- 3 or 6 channels of particle data
- 0,3-5 µm or 0,3-25 µm
- Particle concentration from 2.000.000 counts/ft³
- Software for data download to computer



Liquid Particle Counters

Brookhaven Instrument supply liquid particle counters for the Life Science, Electronic and Chemical industry. We have both laboratory and On-line instruments.

With our laboratory liquid particle counter you can perform QC-control for injectable solutions according to USP 788 and EP-2.9.19 or sample ultra pure water down to nm particle size.

Our On-line liquid particle sensors can be used for quantifying particle concentration in high purity water systems or Parts Cleanliness Testing. The sensors sensitivity starts at nm up to µm particle sizes dependent on your needs. Communication is done via 4-20mA or RS-232 or RS-485 Modbus.



Microbial Air Samplers and Culture Media

Brookhaven Instruments is in close cooperation with Miclev AB. Miclev is one of the leading suppliers in the Nordic region on Microbial Air Samplers, and PPM - pre prepared culture media and contamination control products. Together, we can offer our customers solutions for a wide spectra of different sampling methods like handheld sampling, remote sampling for Isolators, pressurized air sampling etc.



Miclev

Design

We design and deliver your system according to your specifications. The system can be integrated into existing technology or new. If you wish we can help you with producing a User Requirement Specification (URS) that is based on our many years of experience.

Installation

We build & test the system in our dedicated production area before delivery to customer site. We can take care of the whole installation since we have our own installation personnel. We also have a wide knowledge about what components that can be used.

Validation

To secure that the system is built according to your specification we offer validation service through all the design steps. We work according to GAMP5/M6 and GAMP Good Practice Guide: Validation of Process Control Systems in all our projects for monitoring systems. We have knowledge about writing everything from Validation Master Plans to SOP's.

Service & Support

We offer calibration in our own calibration laboratory and on site with our special designed calibration bus. We offer several levels of service agreements to secure the functionality of your critical system for many years ahead.

References

We have satisfied customers within many different industries. We are happy to provide you with a reference that is working within your industry area.

Brookhaven Instruments

We have the greatest experience of Monitoring Systems for Clean Rooms within the Nordic countries.



**BROOKHAVEN
INSTRUMENTS**

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"We shall relieve our customers from the burden of compliance"