

Identification of Positions with High Particle Concentrations

A service for verification of particle probe positions in isolation systems and RABS with unidirectional airflow

By checking the design documents, the respective space within the machine is divided into sectors.

In a risk-based approach positions of potentially high particle concentrations are identified and points for particle measurements are defined.

Particle measurements are executed at the defined positions under production conditions and additional distribution measurements are performed.

The results are merged and depicted graphically to evaluate the particle burden within the sectors for easy recognition of critical areas.

Valicare provides the necessary GMP compliant documentation, like protocols, test documentation and reports.



Our Services & Support

- Check of design documents
- Risk-based determination of potential high particle positions.
- Particle measurements at defined positions + distribution measurements
- Graphic presentation and evaluation of results
- Measurement with calibrated equipment
- Creation of GMP compliant documents (protocols, test sheets, reports)

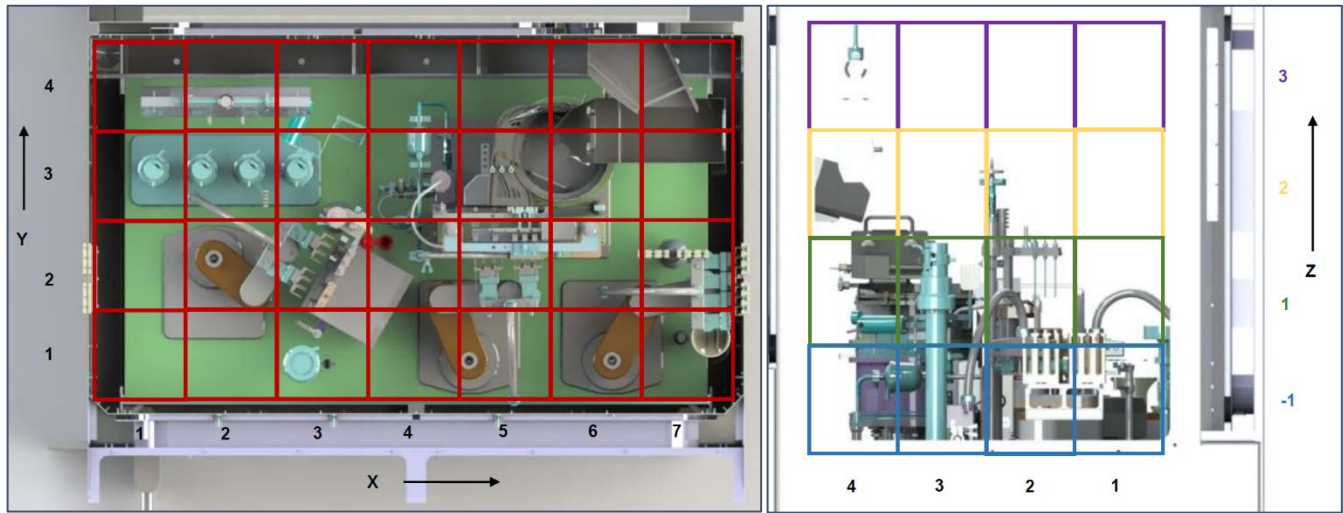
Our Competence

- More than 20 years of experience in execution of risk analyses and particle measurements
- Over 15 years' experience with isolators
- Engineers of various disciplines with technical expertise

Your Benefits

- Reasonable risk-based assignment of measuring positions usable as a basis for the positioning of particle monitoring probes
- Consideration of the whole relevant space and volume
- Clear and understandable presentation of results.

Level 2							
4	0	0	0	n.a.	0	15	0
3	n.a.	1	0	n.a.	n.a.	0	0
2	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
1	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
	1	2	3	4	5	6	7



Sector division of an isolator chamber for particle measurement
(Graphics: © Syntegon Technology GmbH)

Contact us if you are planning tests for identification of positions with high particle concentrations. We will support you!



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