

Use of Routine Data for Requalification & Revalidation

Risk-based continuous process verification

The lifecycle-oriented approach in a GMP-regulated environment requires continuous assessment of the qualified and validated status of plants and processes. Routine data from plant operation, process control, and quality monitoring can be used to assess the control status and derive targeted measures. To assign reliable data to the control status of systems and processes, a deep understanding of the process is required.

As a GMP service provider with many years of experience, Valicare is well-versed in this field! We support you in the collection, evaluation, and risk-based use of production data for requalification & revalidation. This enables the transition from purely time-controlled intervals to condition-based monitoring (Continuous Process Verification, CPV). This guarantees safety & quality over the entire product life cycle and full compliance with EU-GMP Annex 15.



Our Competence

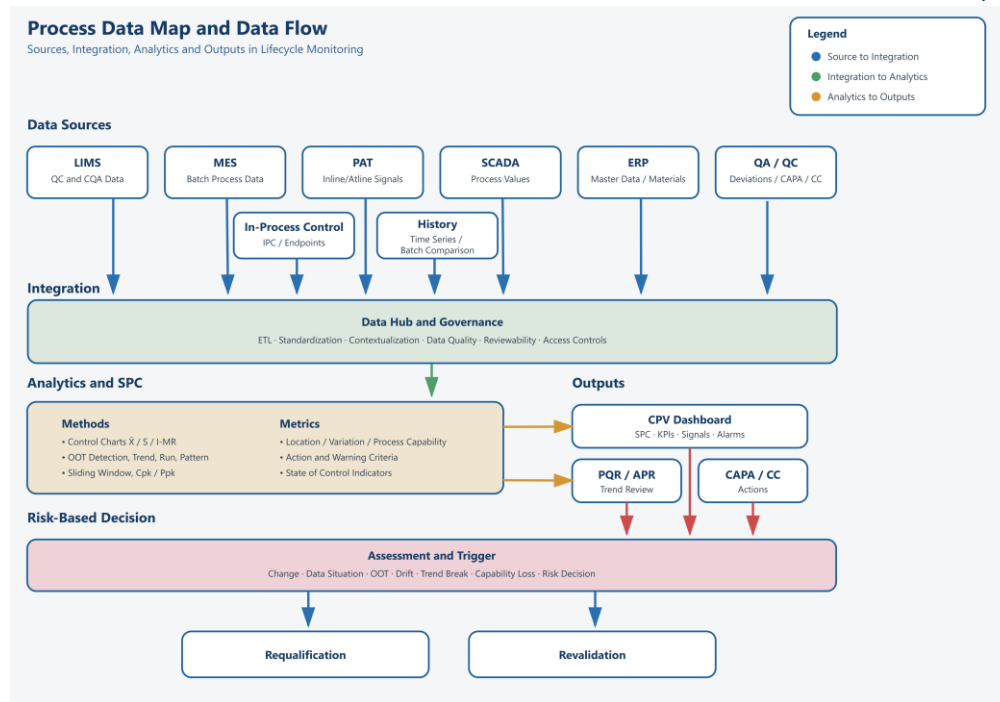
- Successful GMP service provider for over 20 years
- Multidisciplinary teams of engineers and scientists
- Technical expertise and extensive process experience
- > 5,000 GMP projects worldwide
- 150 employees in Europe

Our Services & Support

- Implementation of risk-based use of process data for enhanced system and process control
- Evaluation of trends and Statistical Process Control (SPC)
- Ensuring "Data Governance" & data integrity (ALCOA+)
- GMP-compliant project management

Your Benefits

- Action and verification basis for continuous system and process control
- Early detection of OOT/OOE
- Ensure data integrity from creation to long-term archiving
- GMP compliance & audit-ready documentation



The graph illustrates the data input, data flow and analytics required for a risk-based requalification and revalidation approach.

Valicare has a lot of experience in managing and execution of qualification and validation projects. Regardless of whether the classic, integrated, or continuous approach, we are your partner! **Unlock the potential of your existing data and contact our experts for a non-binding initial consultation. Together we are successful!**

COCREATE & COSUCCEED!



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