



“Data Integrity is a key requirement for the regulated health sector, as product quality decisions and prerequisites, as well as compliance with applicable regulatory requirements, are made on the basis of data.”

(Istitute of Validation Technology)

DATA WITHOUT INTEGRITY is just numbers

PTM Consulting developed a methodology to support companies to build appropriate Data Integrity strategies, with a new approach, integrated to the company Quality System and based on sound risk analysis and management, according to the principles of the ICH Q9.

Systematic and versatile, the methodology can be used during the design phase of a Data Management process as well as during the analysis and reengineering of existing processes.



System Compliance Strategy & Remediation according to Data Integrity

Software Selection
in Quality by Design



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SYSTEMS COMPLIANCE STRATEGIES under Data Integrity

PTM Consulting operates within Risk Management frame with a Quality-By-Design approach. Mapping of the operating flow and data provided by Cymapp, the proprietary software developed by PTM, is the basis of this system compliance service; thanks to a continuous focus on **Integrated Quality Risk Management (IQRM)**, Cymapp ensures a specific **Risk Analysis** to keep data validation process constant and continuous in compliance with the reference

standards. Starting from the mapping activity, PTM supports the customer to develop a **Data Integrity** strategy where data is managed accordingly to **ALCOA** starting from **Intended Use**.

The innovation of this approach is in evaluating Intended Use for which the data is generated, within the operational framework of a global process analysis.

CYMAPP

Cymapp, an innovative software - based on the IDEF0 methodology and entirely developed by PTM - allows you to perform functional mappings of processes, products, and projects, and to gather crucial information according to QbD development in an organized database. Cymapp, in addition to allowing extraction and data management, provides a fundamentally innovative database visualization and updating suite.

QbD

Quality by Design is defined as a systematic approach to system development that begins with predefined goals and emphasizes understanding of products and processes by defining mathematical models and risk management.

IQRM

PTM approach to Risk Management is holistic. For every aspect (quality, development, production, etc.) a risk management strategy is formulated including all the different levels of the company. With systemic methodologies, PTM helps companies define and share key risk management information across the entire product life cycle from Research & Development to Production.

ALCOA

According to the Data Integrity approach in a process, the data must be:

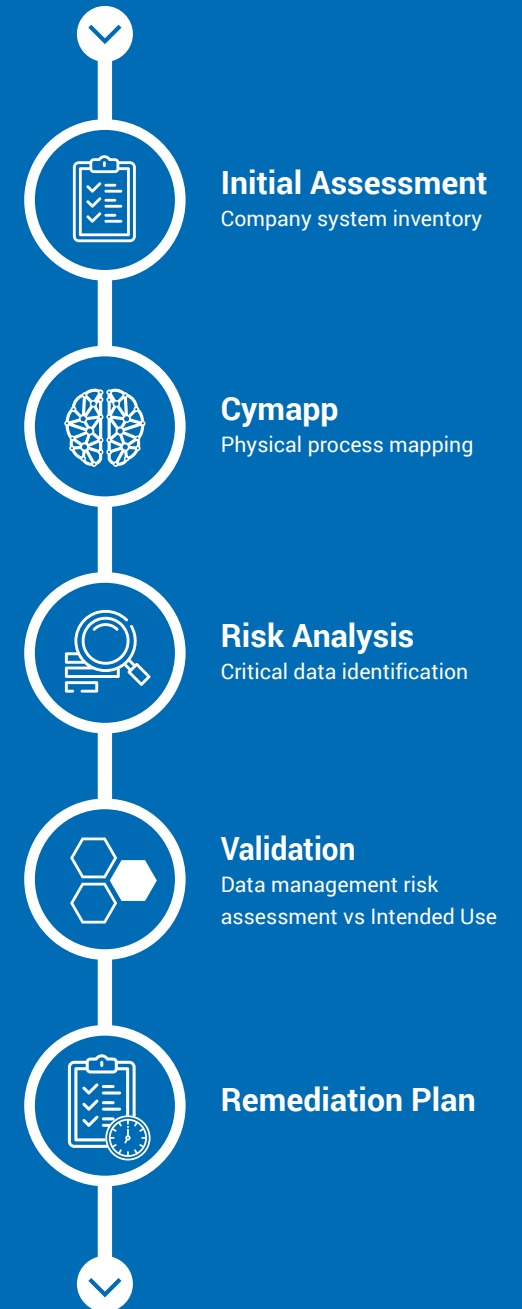
- A** Attributable
- I** Legible
- C** Contemporaneous
- O** Original
- A** Accurate



REMEDICATION TO SYSTEM VALIDATION according to Data Integrity

In Health Care companies, Data Integrity has become a mandatory requirement under current regulation. About information systems, **Good Manufacturing Practices** establishes the need for validation, both at software and documentation level, as well as at a system installation and performance level. Having an updated **Data Integrity** system means minimizing errors and having a low risk

of vulnerability, ensuring product identity, patient safety, and thus generating greater value for business and brand reputation. The rationale provided to adapt the data management process to current regulations for **Data Governance** (Data Quality and Integrity) is robust, scientific, measurable and so compelling and ready to read and handle during inspections.





SOFTWARE SELECTION IN QbD

Software System Identification and set up

In the widest context of Quality by Design, PTM developed a new service of **Software Selection** to support the customers in the critical analysis of the process considering operational aspects as well as strategic and organizational aspects.

A Software Selection project is based on a deep knowledge of process itself: so the first step is always to make a **mapping through Cymapp**. Where areas of optimization or critical issues are highlighted in software, PTM can intervene by providing the customer with:

1. the **correct choice** of the software to use;
2. **system set up** parameters identification.

