Overview of validation including AI enabled Computerized Systems

George Wasserman

EMEA SDE Bloemfontein

7 November 2025

Agenda Overview

Introduction to Computerized System Validation (CSV)

AI enhanced systems

Advances in validation tools

Introduction to Computerized System Validation (CSV)

DPCS
the power of sense

Layered approach to qualification and validation

Layer description	SOP Type	Description
Business Procedure**	Operational SOPs	Business processes using computerized systems
Computerized System*	SLC SOP	Documented quality for computerized system validation incl. SaaS
Software Development	SDLC SOP	Documented quality for software development
Infrastructure	IT SOPs	Servers, Network infrastructure, IaaS

Overarching QMS

DPCS the power of sense

Why do we need to perform validation?

- What is:
  - a computerized system?
  - computerized system validation (CSV)?
- When is it needed?
  - Participant safety, product quality, data integrity

Health Care Regulations:

- Title 2: Food & Drugs (FDA), Clinical Trials Regulation (EU)

Guidance:

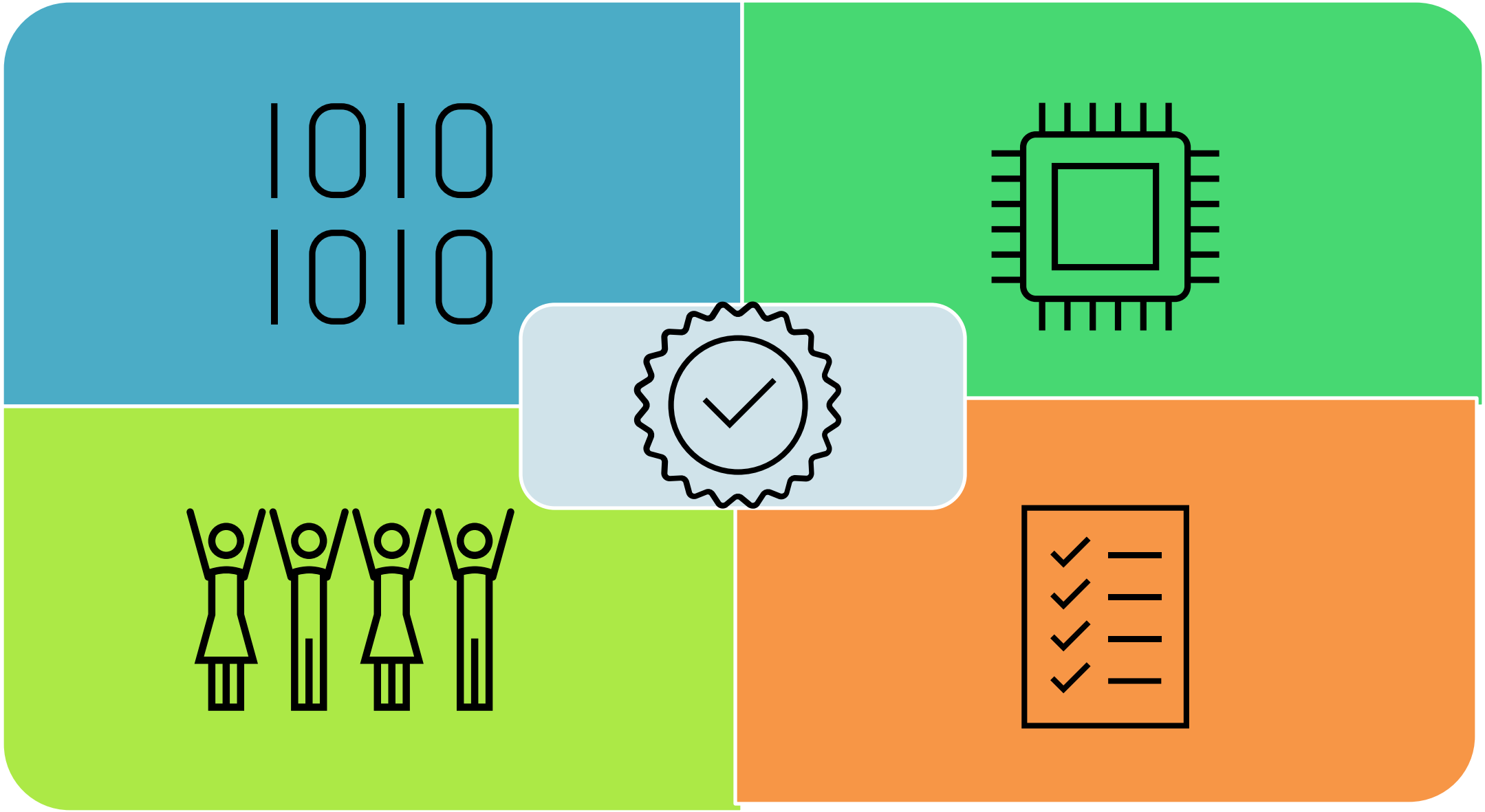
- ICH Guidelines: e.g., E6 (R3) - Good Clinical Practice
- Guidance for Industry: Computerized Systems Used in Clinical Investigations (FDA)
- Guideline on computerised systems and electronic data in clinical trials (EMA)

Healthcare Relevant Electronic Record & Electronic Signature Regulations:

- 21 CFR Part 11 (FDA), Annex 11 (EMA), and ER/ES (Japan)

DPCS
the power of sense

What is a computerized system?



Typical CSV Life Cycle

- Consists of distinct phases:
  - Initiate
  - Execute
  - Report
  - Operate
  - Retire
- Continuous process

AI enhanced Systems

DPCS
the power of sense

EU AI Act: world first comprehensive AI law

- Published June 2023
- Last updated February 2025
- Provides
  - Comprehensive framework
  - Risk-based AI classification system
  - Unacceptable Risk (prohibited)
  - **High Risk (strict obligations)**
  - Limited Risk (transparency obligations)
  - Minimal risk (voluntary code of conduct)
- Dedicated roles:
  - “Provider” is the supplier
  - “Deployer” is the regulated company
- Participants must be informed and provide approval:
  - If AI will make decisions about their health
  - If they will directly interact with an AI interface (such as part of an ePRO solution)

DPCS
the power of sense

AI technology is everywhere

Layer description	Description
Business Procedure	Use of AI to assist in creation of business procedures
Computerized System	Enhanced functionality of a system
Software Development	Programming environments and tools
Infrastructure	Embedded in firmware

DPCS
the power of sense

Responsible Company

- During risk assessment:
  - Include GxP risk level
  - Include AI risk level – this can elevate the overall risk level

- Accountable for the understanding of the AI technology used
  - Internally custom developed – provide details
  - Internally developed system using API calls – collaborate with provider
  - Use of 3rd party system – collaborate with provider – must have proper contractual clauses in place with provider.

DPCS
the power of sense

Typical model development life cycle

- Model Requirement Specification
- Model Design Specification
- Test data set creation (actual or synthetic data)
- Split data into:
  - Training data set
  - Validation data set
  - Testing validation data set

DPCS
the power of sense

Typical model development life cycle

- Model engineering using test data set
- Model evaluation
- Model selection
- Data engineering
- Validation data set is used for model evaluation (during development)
- Test data set is used for model testing on the release candidate
- After successful testing has been completed the model is
  - Integrated and deployed
  - Acceptance & model verification is completed
  - Reporting and Release

DPCS
the power of sense

Principles of Trustworthy AI

- Human autonomy and control
- Safety & Security
- Fairness & mitigation of bias
- Privacy & data protection
- Transparency
- Accountability
- Sustainability

Advances in validation tools

DPCS
the power of sense

Modernization in validation tools

- eValidation systems
- Use of AI in eValidation systems
  - Create User Requirements
  - Check regulatory compliance of validation package

DPCS
the power of sense

Thank you

DPCS
the power of sense