FIVE VALIDATION

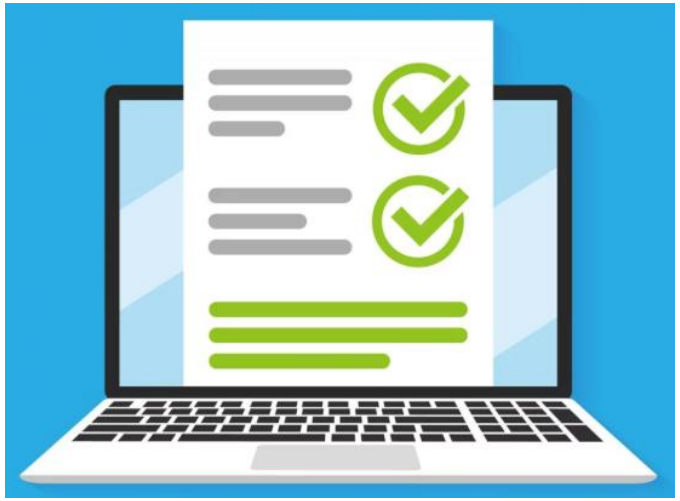
Introduction to Computer System Validation (CSV)

Ensuring Trust in Digital Systems in Regulated Industries

Silvia Martins· 12/JUN/2025

What is CSV

- Definition: CSV ensures that computerized systems do what they’re supposed to do.
- Focus: Data integrity, patient safety, product quality



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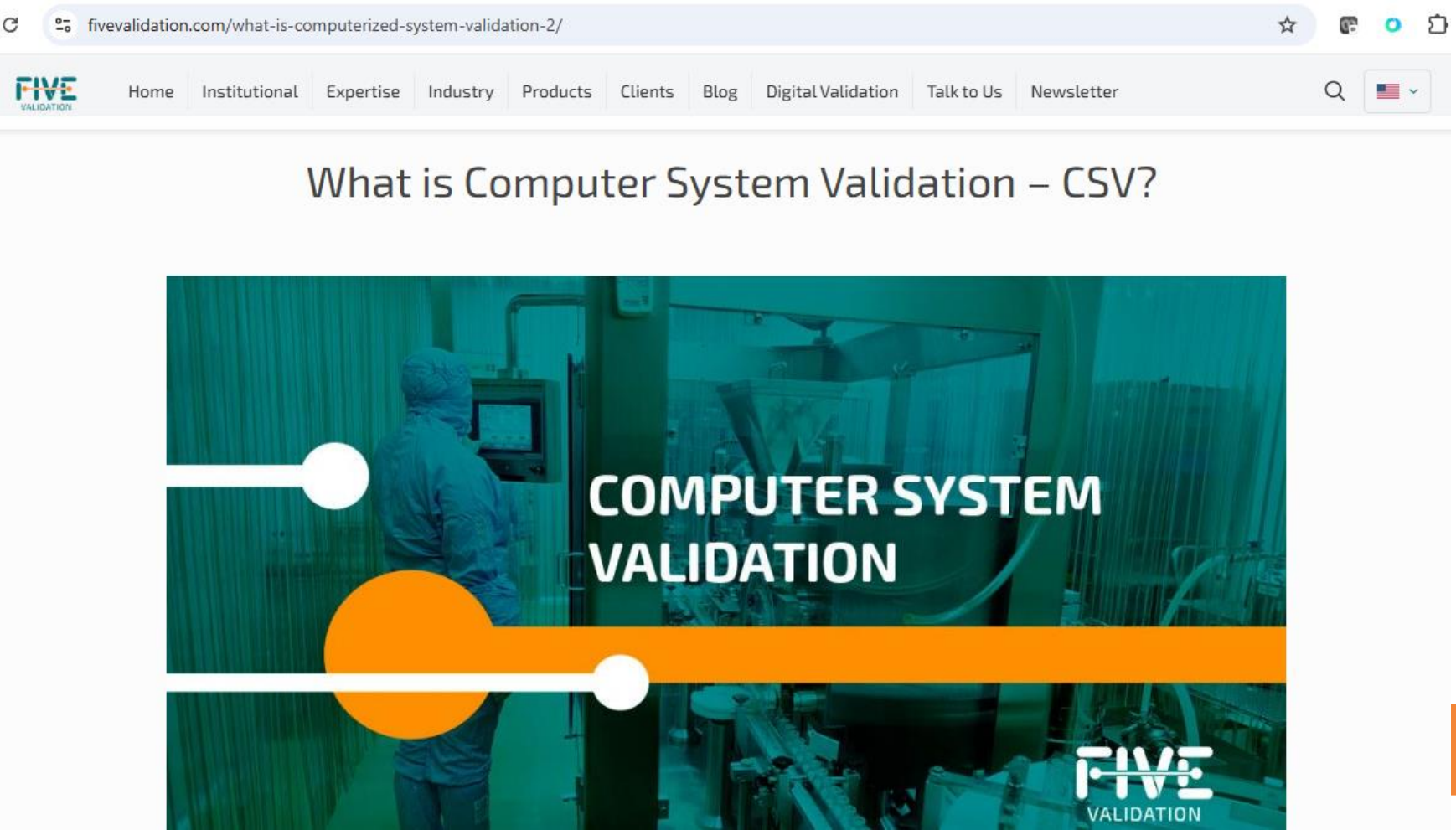
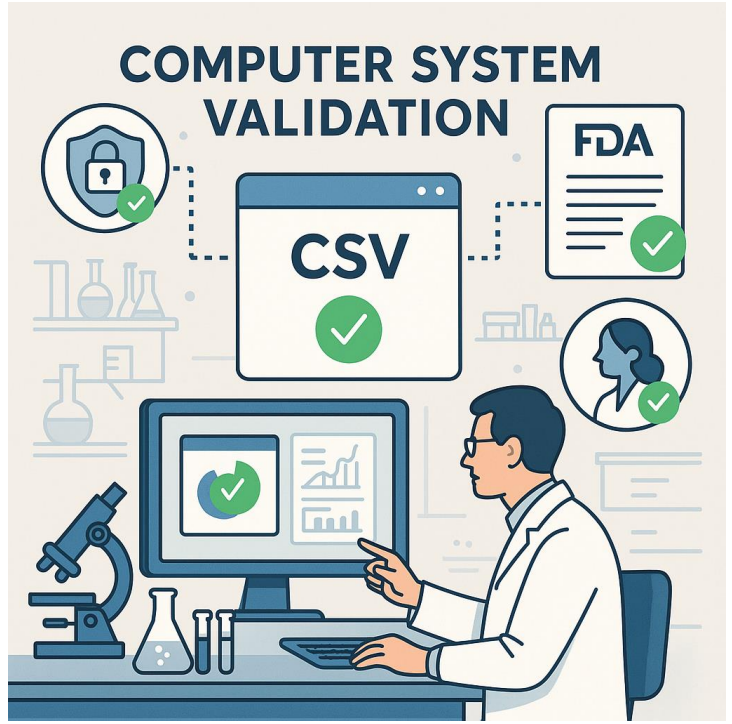
Homework: Blog – What is Computer System Validation



https://fivevalidation.com/what-is-computerized-system-validation-2/

Why is CSV Important?

- Used in pharma, biotech, and medical devices
- Regulatory requirement (FDA, EMA, ANVISA)
- Helps prevent errors or compliance issues



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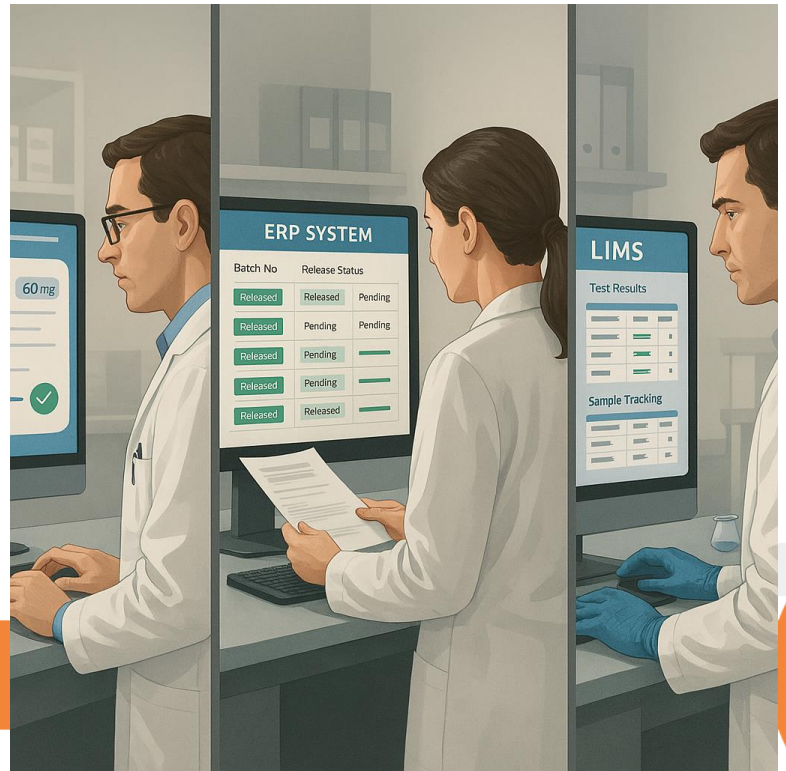
Real-Life Examples

- Validating a system that controls medicine recipes
- Tracking drug batch release in ERP
- Managing lab data (LIMS)



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Key Terms to Know

- **GxP**: Guidelines that ensure products are safe and meet quality standards in regulated industries.
- **Audit Trail**: A record showing who did what and when in a system.
- **ALCOA+**: A principle that says data should be Attributable, Legible, Contemporaneous, Original, Accurate, plus Complete, Consistent, Enduring, and Available.
- **Validation vs. Verification**: Validation proves the system works as intended in the real world; verification checks if each part meets its specific requirements.

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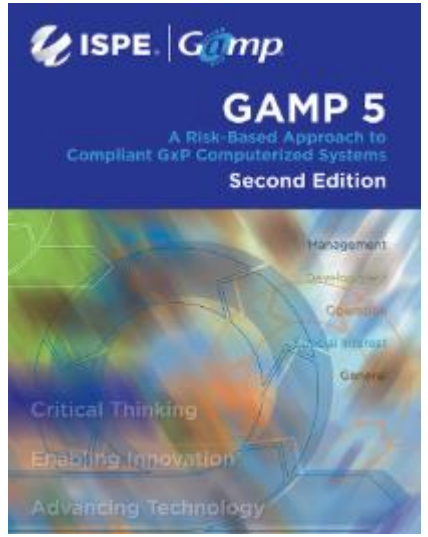
Regulatory Background

FDA
21 CFR Part 11

EU GMP
Annex 11



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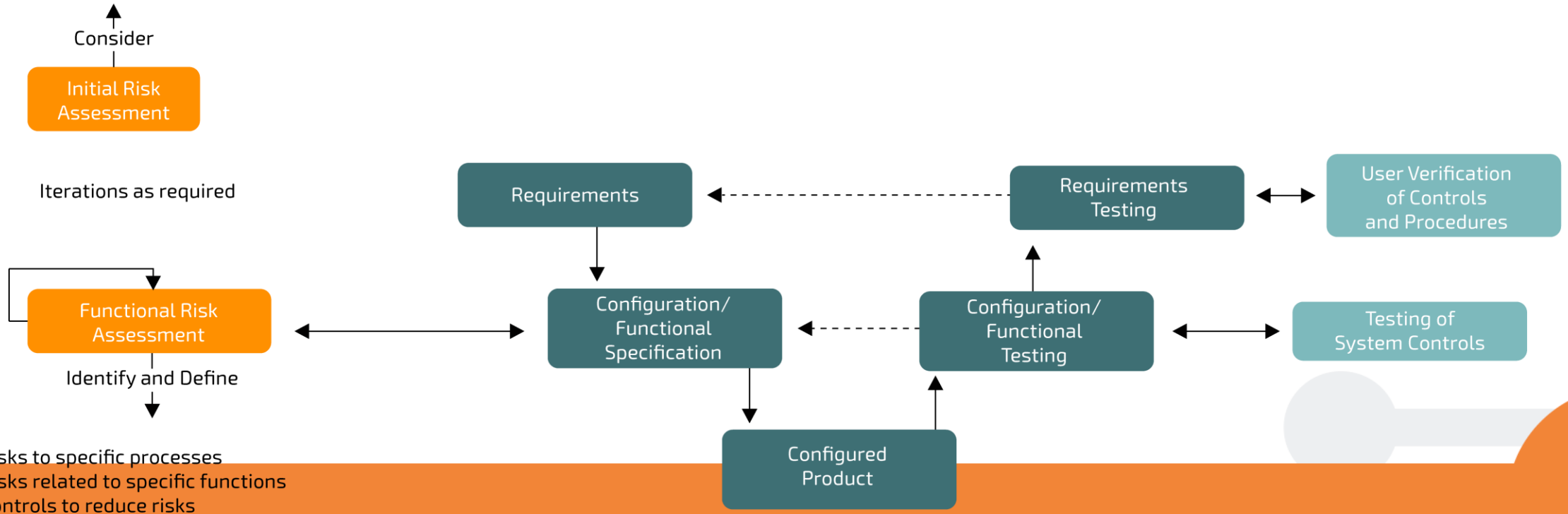
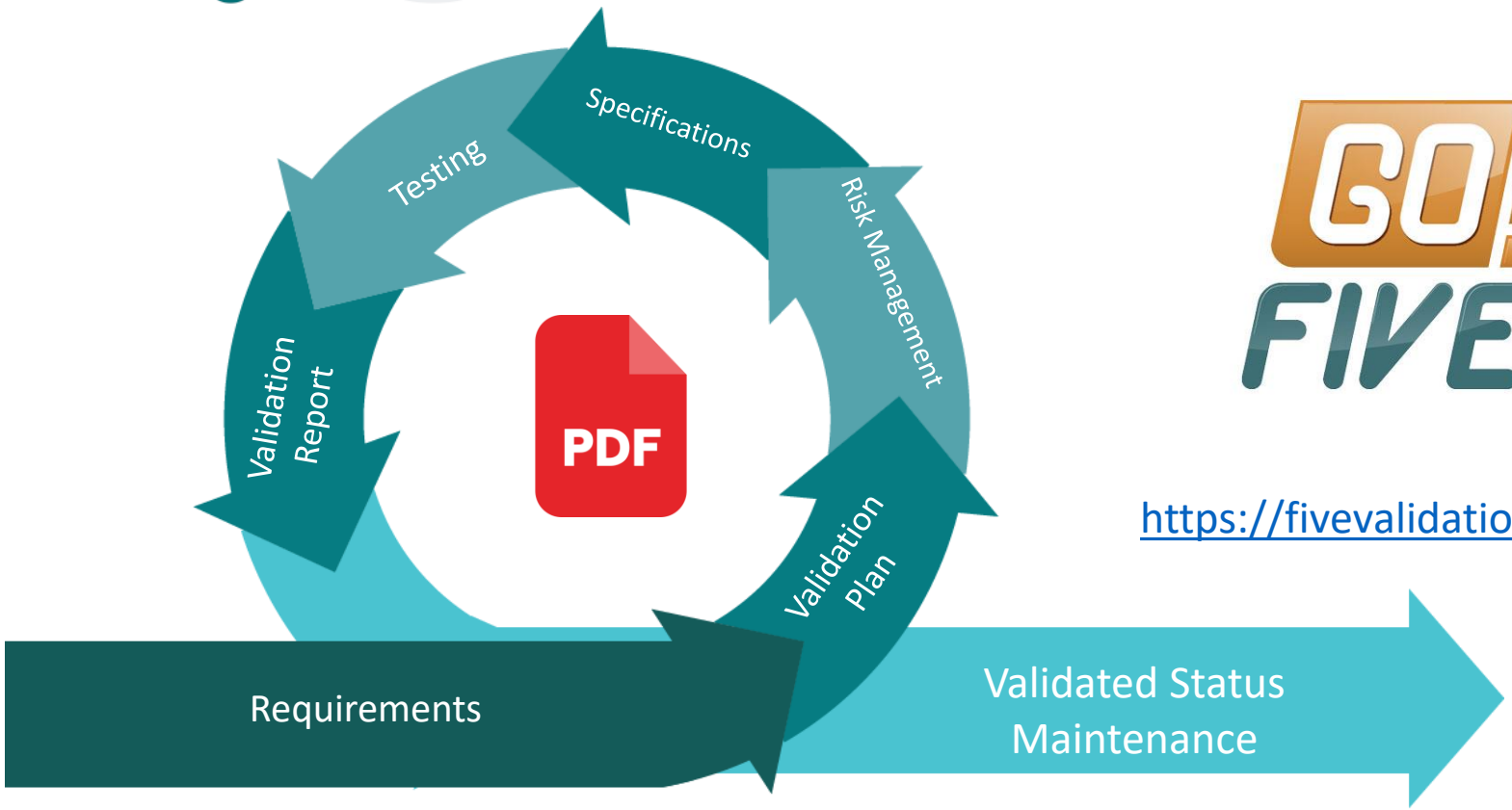
The CSV Lifecycle

- Overall risks to the business?
- Gxp determination?
- Overall system impact?
- Are more detailed assessments needed?



- Risks to specific processes
- Risks related to specific functions
- Controls to reduce risks

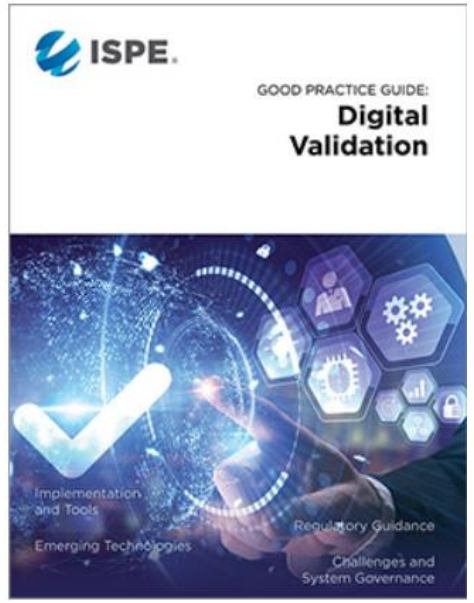
Agile Validation



https://fivevalidation.com/paperless-validation/

ISPE® Digital Validation Tool Guide

The ISPE Guide: Digital Transformation of Validation provides key insights for transitioning from traditional to digital validation.



What it covers:

- Benefits of digital validation tools
- Criteria for selecting a digital validation platform
- Integration with existing QMS and IT systems
- Risk-based approach in a digital context
- Data integrity and regulatory alignment (e.g., ALCOA++, GxP)

Key takeaway:

ISPE encourages Life Sciences companies to adopt digital validation tools to improve efficiency, traceability, and regulatory readiness.

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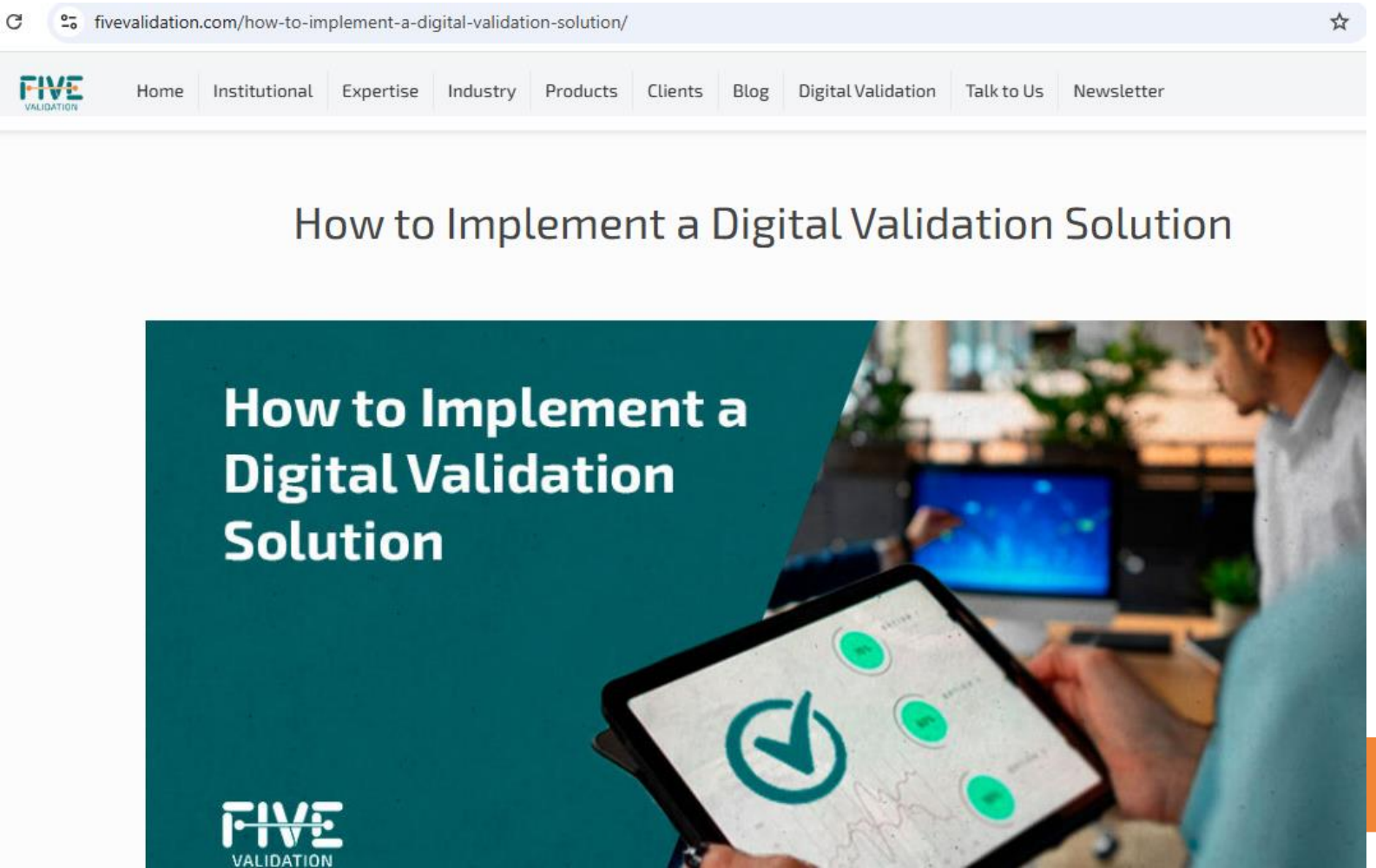
Digital Validation – Present and Future

Digital validation is no longer just a future trend; it’s already a reality for many companies.
Tools like GO!FIVE® is helping organizations move from paper-based processes to faster, more compliant digital systems.
While not all companies have adopted it yet, digital validation is transforming how we plan, test, approve, and maintain validated systems.

- 7x faster
- More traceable
- Easier to maintain
- Aligned with modern regulatory expectations

Homework: Blog – Implementing Digital Validation



https://fivevalidation.com/how-to-implement-a-digital-validation-solution/

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Validation Plan

What is it?

- A Validation Plan is a document that outlines how a computerized system will be validated and ensures the process is organized, traceable, and compliant with regulations.

Why was it created?

- It provides a clear roadmap for validation activities, defines roles and responsibilities, and helps demonstrate to regulators that the validation is planned and risk-based.

What's typically included?

- Scope of the system
- Responsibilities (who does what)
- Validation strategy and approach
- Risk assessment method
- Deliverables and timeline

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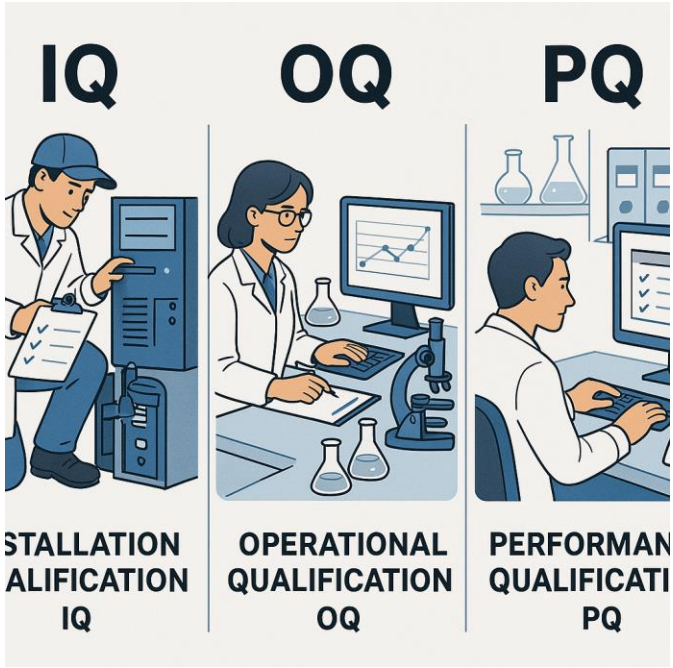
Testing Activities

- **Installation Qualification (IQ) or Configuration Testing –** Verifies that the system is installed correctly
- **Operational Qualification (OQ) or Functional Testing –** Tests system functions under various conditions
- **Performance Qualification (PQ) or Assisted Operation –** Confirms the system performs as intended in a real-use environment before issuing the Final Validation Report.



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Common CSV Mistakes

- No risk-based approach
- Missing traceability
- Poor documentation

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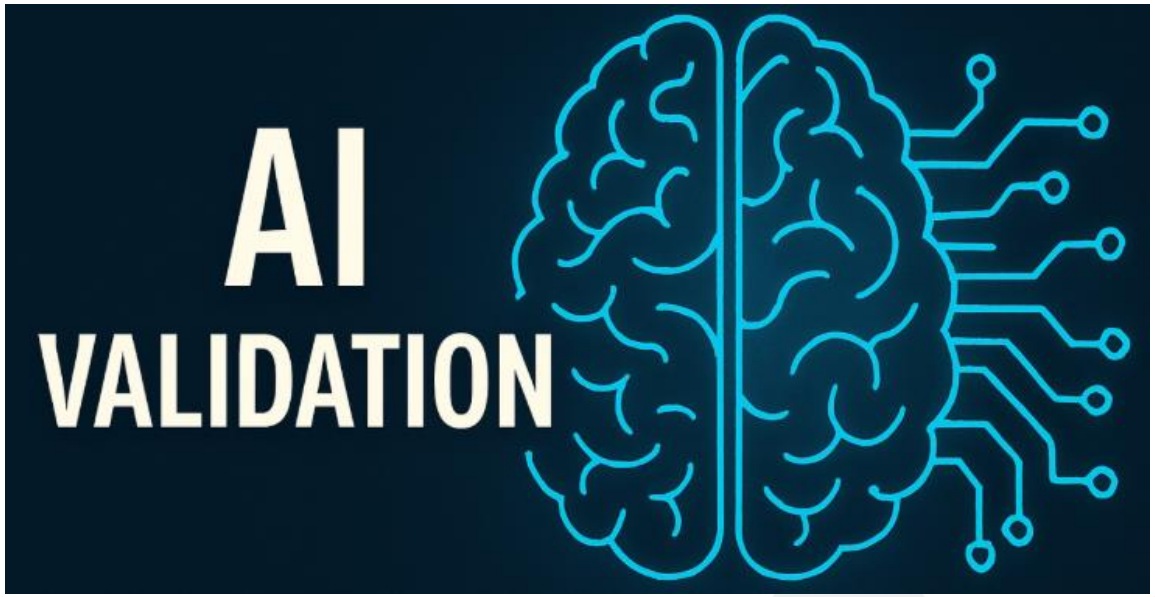
Validating AI in Life Sciences

AI ≠ Traditional Software
It learns and evolves, so validation should go beyond fixed rules.

Key Points:

- Define intended use
- Validate with real data
- Monitor performance over time
- Ensure traceability & transparency



Goal:
Keep AI systems compliant, reliable, and under control.

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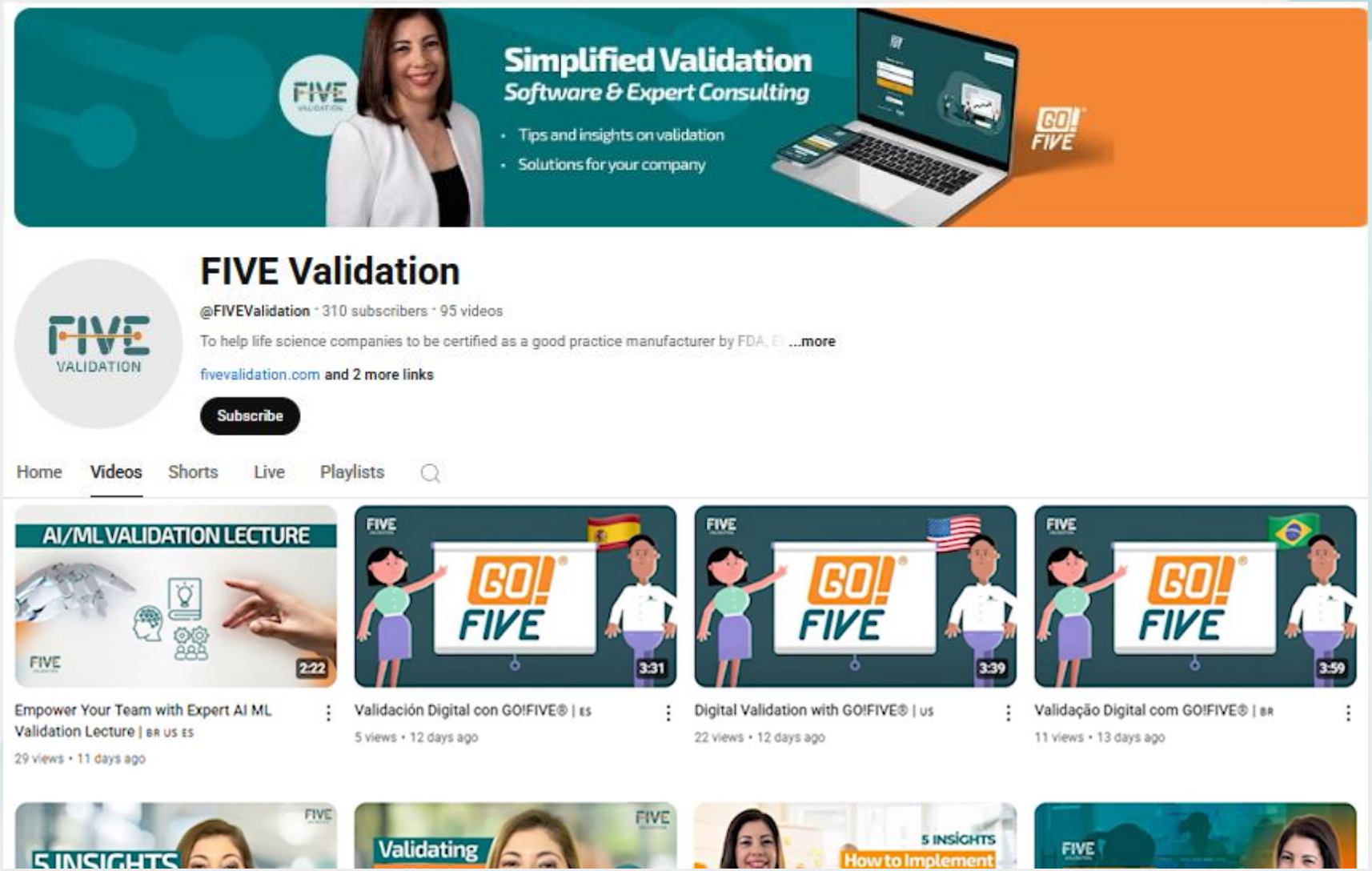
YouTube Channel has a lot of content about AI validation

https://www.youtube.com/@FIVEValidation



Building Smart Factories Through Integration and Validation

Without integration, AI doesn’t work.
Most pharma companies still rely on:

- Paper forms
- Unconnected systems
- Manual reviews

Digital validation is the foundation for:

- Reliable data
- Smarter decisions
- Regulatory compliance

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Thank you!

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