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Driving Innovation With Validation 4.0

Presented by:

Amy Wilhite, Kneat Solutions | 11 September 2024

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For Discussion Purposes Only

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Agenda

- About Kneat
- Interactive Poll
- Featured Presentation
  - Validation 4.0 Overview and Benefits
  - Aligning Validation 4.0 With Pharma 4.0 Objectives
  - Common Implementation Challenges
  - Updates on Regulatory Standards
  - Overcoming Regulatory Implementation Challenges
- Q&A

Speaker

Amy Wilhite

Senior Process Engineer,
Kneat Solutions

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Validation, digitized

About Kneat

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About Kneat

- Global organization with operations in **Ireland, USA, France, Germany, Switzerland, Denmark,** and **Canada**
- Public company, listed on the Toronto Stock Exchange (TSX), **held to high governance standards**
- Validation platform to **8 of the top 10 life sciences companies** and **3 of 4 COVID-19 vaccine manufacturers**
- **45,000+ users** in the Kneat SaaS platform
- **100+** customers across **350+** locations
- **40+** certified global partners
- All in-house development, no outsourcing for maximum quality
- **ISO 9001:2015, ISO 27001 certified**

45,000+

Users globally

8/10

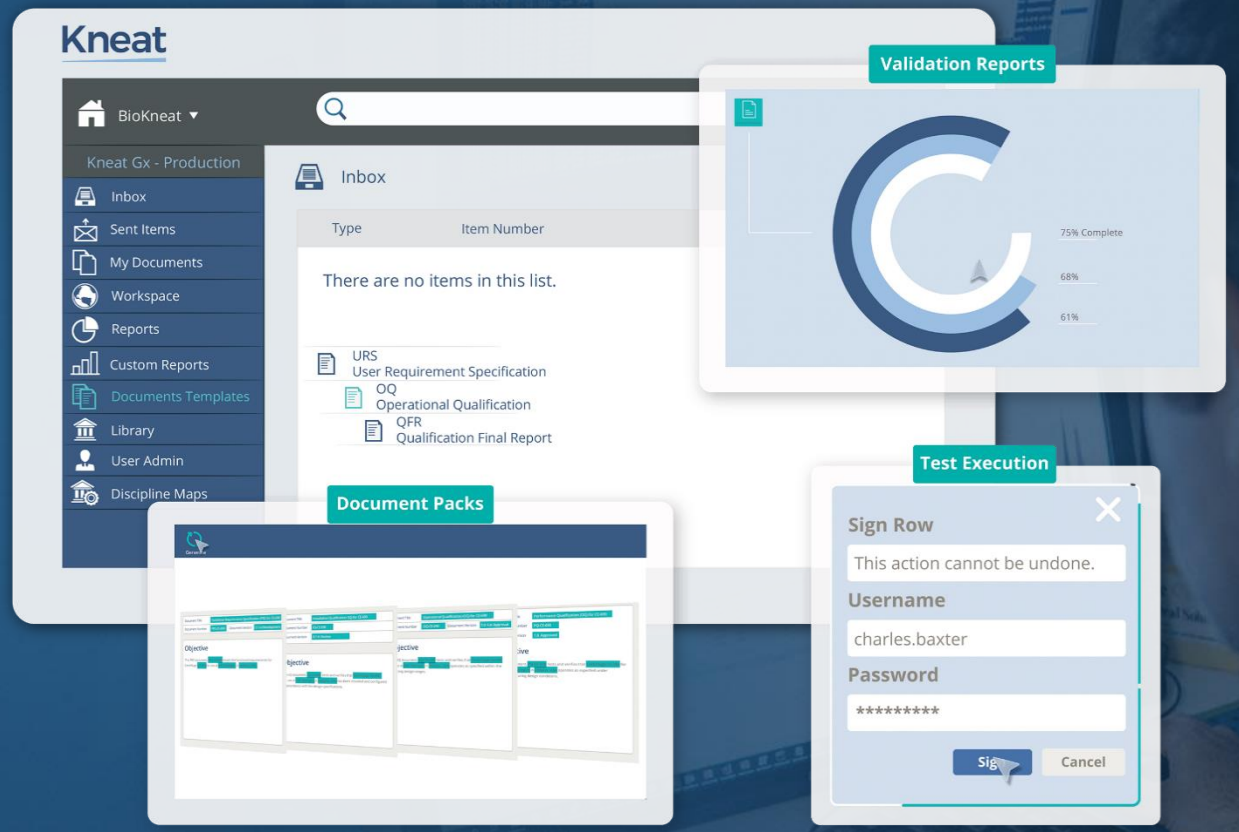
Of the world's top 10 pharma companies

1st

To fully digitalize facility, utility, and equipment C&Q for a new large facility build

What Is Kneat Gx?

Kneat Gx is a SaaS Validation Life Cycle Management Platform that digitalizes validation from end to end, enabling regulated companies to make validation easier, faster, and smarter.



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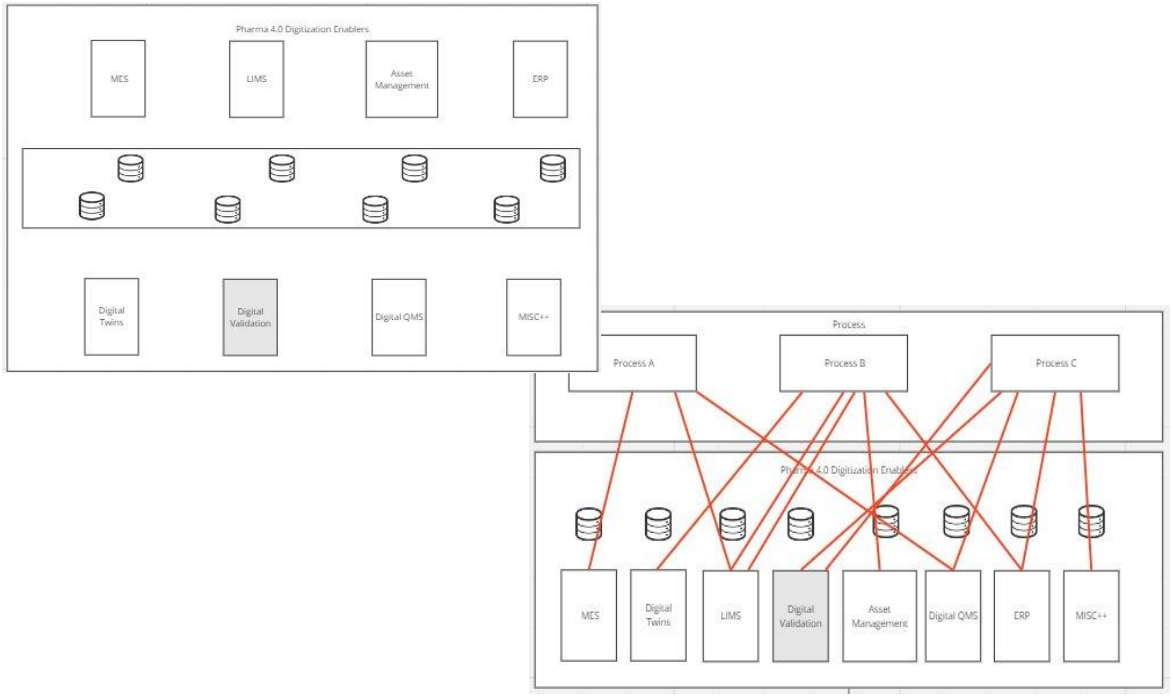
What Is Validation 4.0?

Validation 4.0 - a standalone pillar of the Pharma 4.0 evolution, underpins crucial elements of the operating model.

- A key milestone on the Digital Maturity pathway
- A critical enabler of Data Integrity by Design and
- An enabler of a holistic control strategy.



Pharma 4.0 - a representation of Industry 4.0 / 5.0 and its applied use and best practices in the regulatory world of pharmaceutical manufacturing, enabling organizations to maximize the potential of digitization, increasing speed to patient.

Enablers

- Digital Maturity
- Data Integrity by Design

Elements

- Elements
- Resources
- Information Systems
- Organizations and Process
- Culture

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Aligning Validation 4.0 With Pharma 4.0 Objectives

Interconnectivity With Processes

- Process Sync – Align validation checkpoints with production processes for efficiency

Data-Driven Decision Making

- Predictive Analysis – Identify validation failure trends to plan proactively

Continuous Improvement

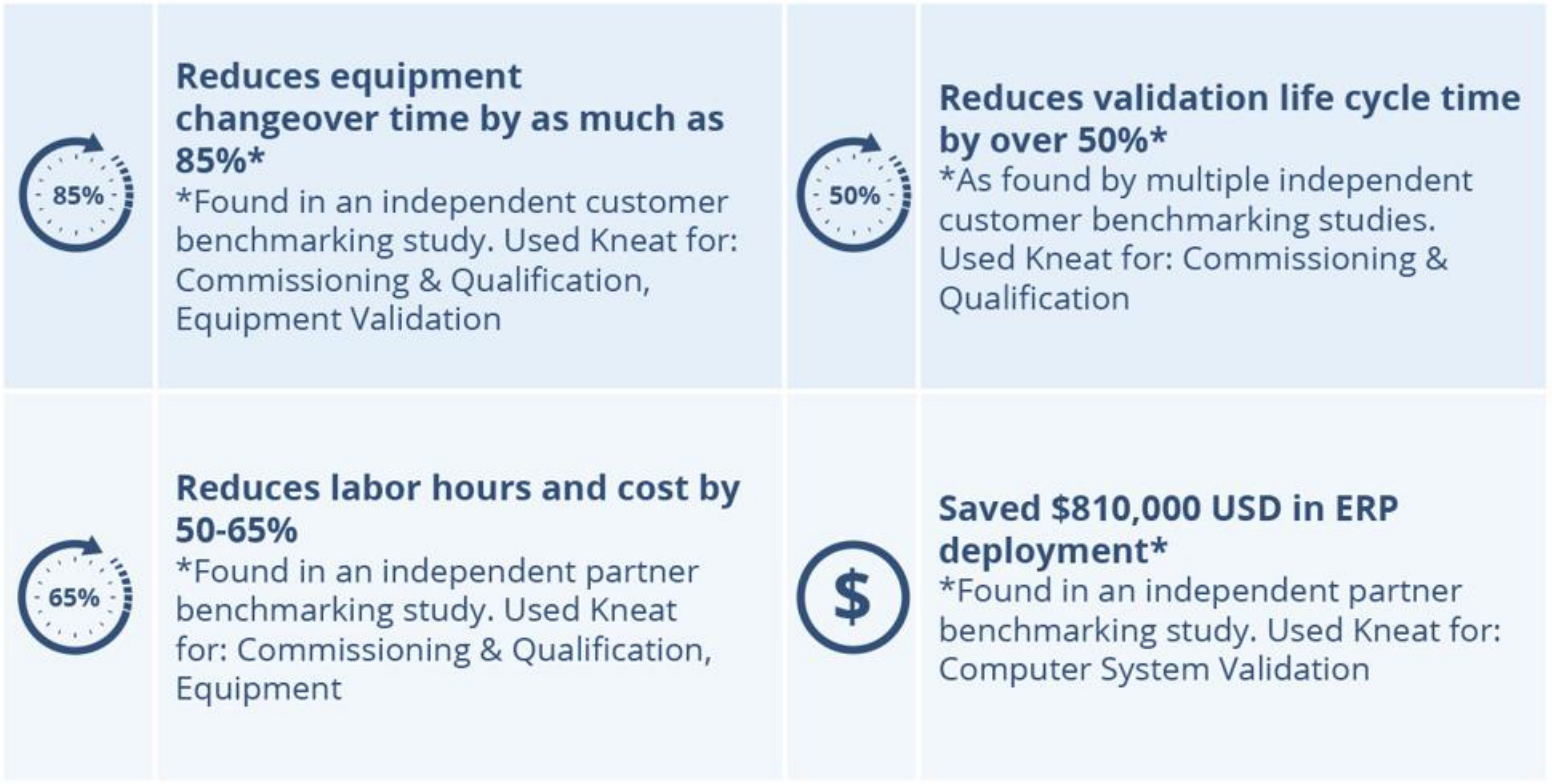
- Feedback Loops – Feed validation outcomes back into the manufacturing process

Adaptability

- Adaptive Learning – AI can be used to evolve validation strategies

Efficiency of Validation 4.0

Validation 4.0 is allowing cutting-edge digital technologies to transform traditional validation methods into agile, data-driven processes that significantly boost efficiency, compliance, and product quality.



Scalability of Validation 4.0

Validation 4.0 is harnessing cutting-edge digital technologies to adapt and scale operations to meet market demands without compromising quality or compliance.

MSD Case Study: Real-World Example of Successful, Scalable Digital Validation

Executing on its visionary Global Quality Management Systems Strategy, industry leaders Merck Sharp & Dohme Corp. (MSD), a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA selected Kneat to digitalize seven validation work processes across two divisions (Manufacturing and Research) at 27 sites around the world.

Scalability Benefits

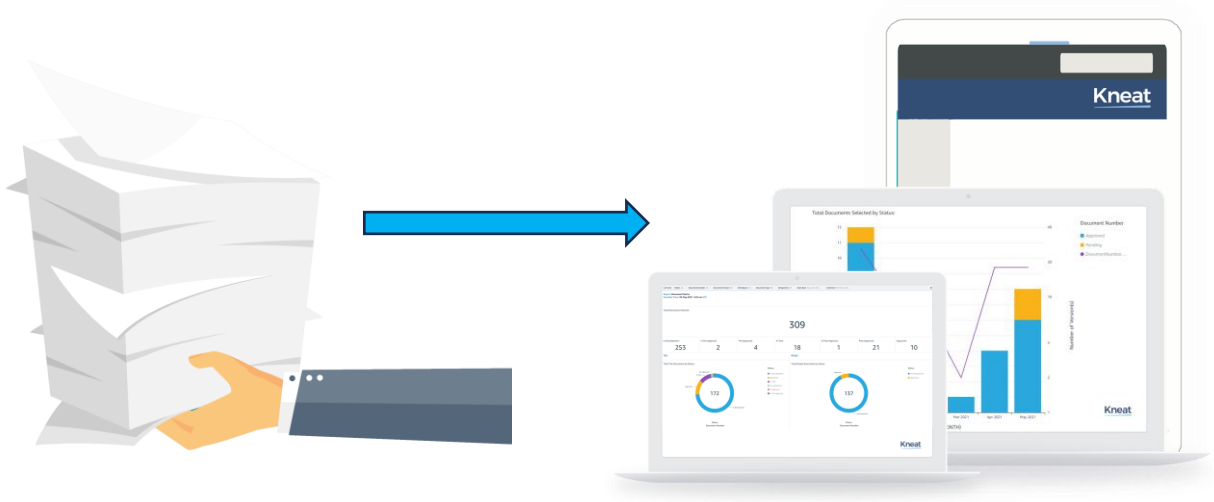
- **Rapid Scaling of Production:** Digital validation processes can be replicated and scaled up more efficiently across different locations, facilitating quick adaptation to increased production demands.
- **Flexibility in Manufacturing:** Digital technologies provide the flexibility to switch between product lines with minimal downtime and re-validation, supporting a more agile manufacturing environment.

The Foundational Pillars of Validation 4.0

Leveraging digital technologies to automate and optimize validation processes

Digitalization

Convert traditional paper-based processes into digital formats



Integration

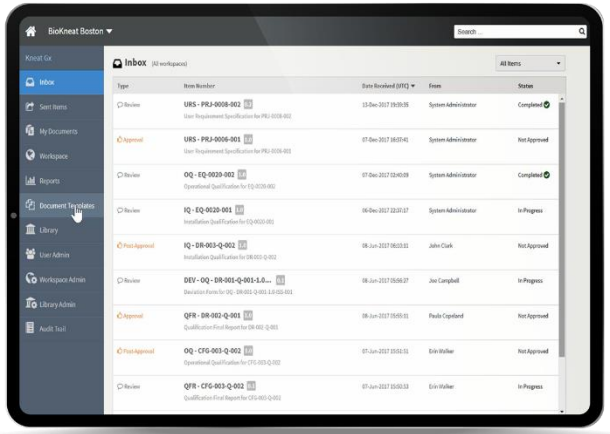
Seamless flow of information across different systems and processes

The Technological Pillars of Validation 4.0

Leveraging digital technologies to automate and optimize validation processes

Digital Validation Systems

- Data Integrity
- Real-Time Data Analysis
- Automated Smart Validation
- Online Test Execution
- Open API Integrations



Internet of Things (IoT)

- Real-Time Monitoring
- Employee Safety and Compliance

Blockchain for Data Integrity

- Traceability
- Security

Cloud Computing / Big Data

- Data Storage and Accessibility
- Analytical Processing

Common Implementation Challenges

01 Cultural Resistance (Change is Bad)

02 Training Requirements (Tech Savvy Skills)

03 Outdated CSV Strategies (Compliance Focused)

04 Compatibility Issues (Hardware and Software)

05 Data Silos (Access and Format Conflicts)

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Updates on Regulatory Standards

Five Things You Need To Know

Regulatory bodies worldwide are evolving to keep pace with the digital revolution, general current thinking puts patient safety and product quality at the heart of the risk assessment process rather than simply performing document exercises for compliance only.

1. Risk is based on the impact to patient safety and product quality measured against requirement complexity
2. ISPE's GAMP 5 guidelines recommend the preferred method of the least burdensome documentation approach
3. FDA's CFR Part 11 compliance guidelines now include expectations for electronic records and signatures
4. Agencies are allowing for adaptive regulatory pathways to accommodate iterative digital innovations such as real-time release testing
5. Several regulatory bodies recognize Sandbox environments as controlled frameworks allowing for live experiments on new technologies

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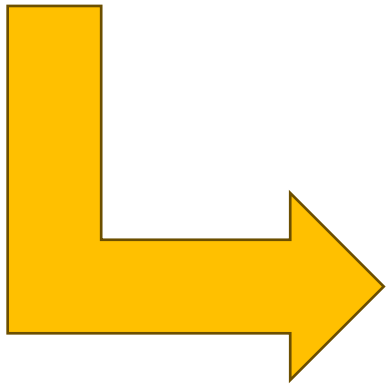
Overcoming Regulatory Implementation Challenges

03 **Outdated CSV Strategies (Compliance Focused)**



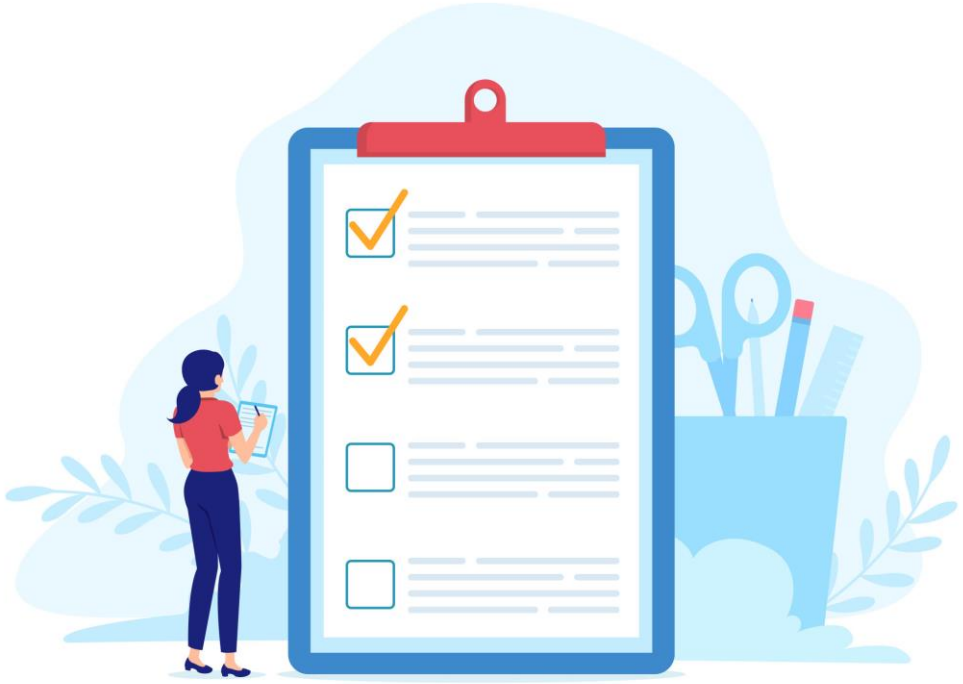
When Planning to Adopt Validation 4.0 and Implementing your Digital Validation Solution.....

- Ensure your vendor assessment process is clear so that preferred, suitable vendors can have documentation leveraged to the fullest potential.
- Should be flexible regarding acceptable format and structure so that supplier documentation can be leveraged as is based on quality and quantity.
- Don’t require rebranding or reformatting of vendor documents or duplicate them just to match internal formats.
- Leverage GAMP 5 2nd Edition principles to reduce overall documented test evidence record burden such as risk-based testing types and execution of proving steps only.
- Use critical thinking to focus on what is required for the best quality of the overall system, not what looks cleanest for an audit.

Make a Validation Plan That Includes Intent to Leverage

- **Vendor Documentation (Customer to Assess for Acceptance)**
  - Functional Specifications
  - Product Risk Assessment
  - Functional Testing
  - Trace Matrix

- **Customer Documentation**
  - User Requirements (Intent to only add specific needs)
  - Business Risk Assessment (Intent to only assess with new criteria)
  - Gap Testing (Intent to only test items not tested by the vendor)
  - Trace Matrix (Intent to only trace new requirements)



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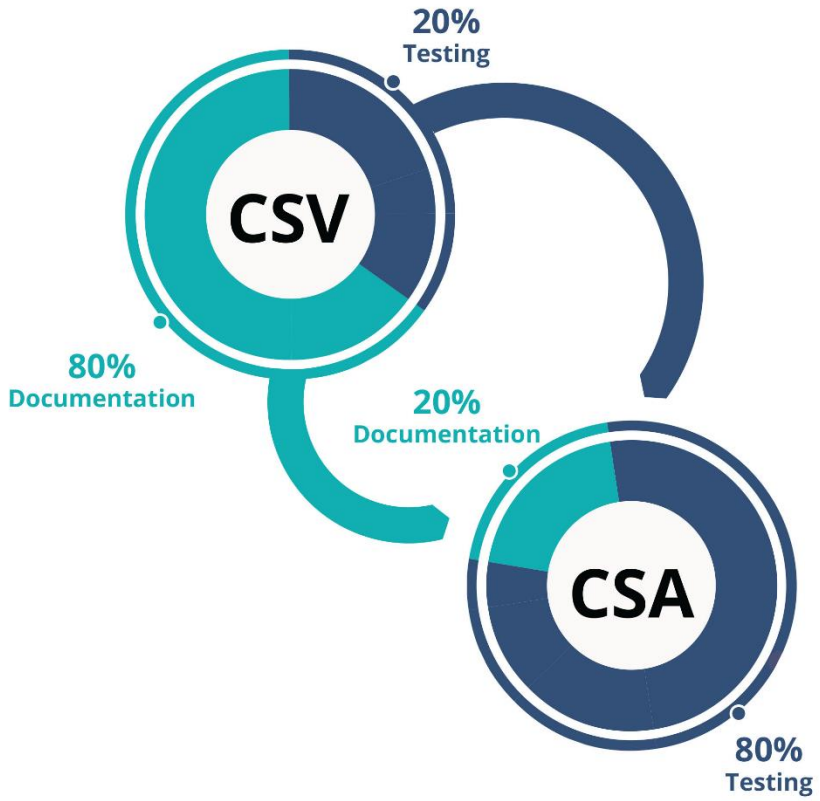
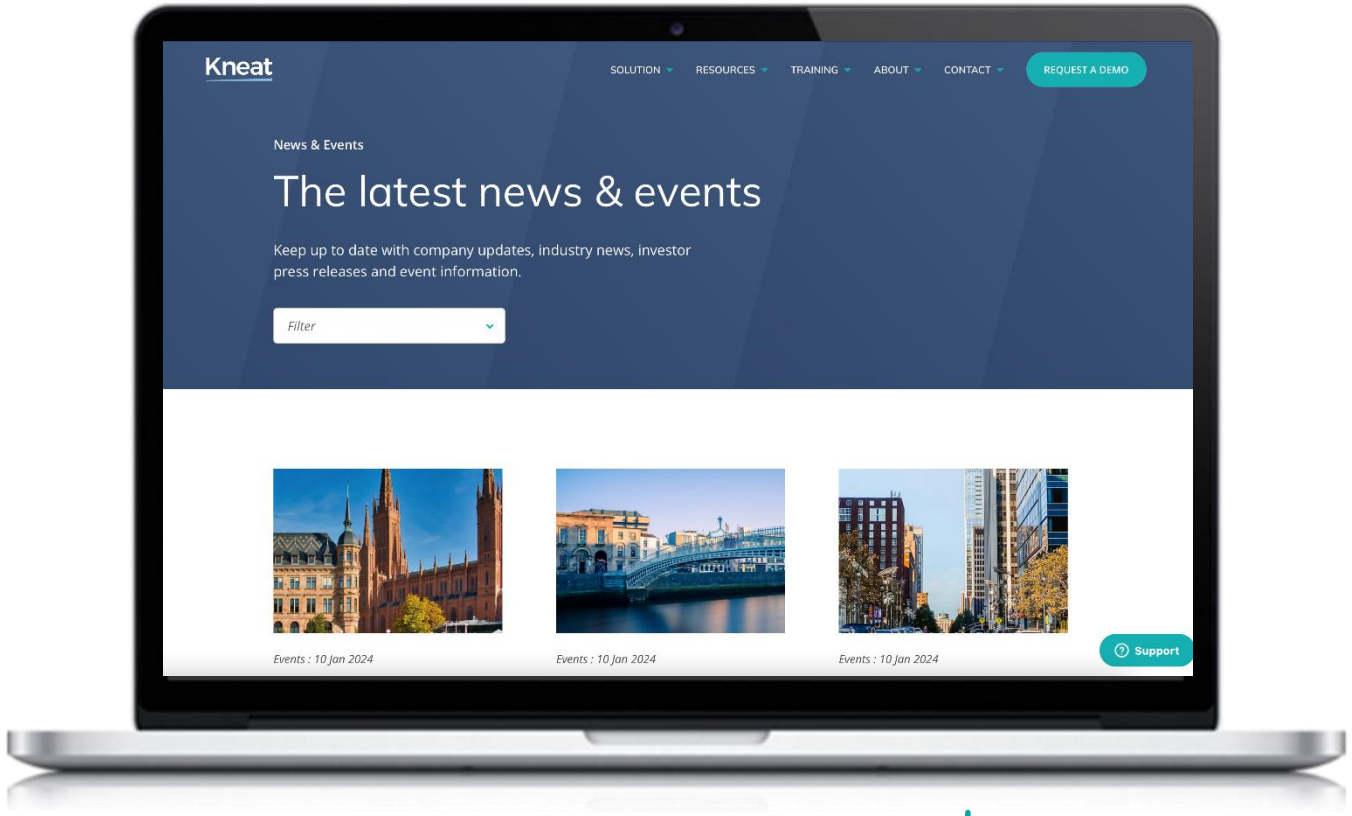
Comparing CSA and CSV

The U.S. FDA recommends Computer Software Assurance (CSA) as a commonsense approach to Computer System Validation (CSV)



CSV	CSA
Emphasizes meeting industry regulations	Emphasizes software quality & security
Validates entire computer systems, encompasses hardware, software, & processes	Assesses individual software applications, prioritizes risk-based thinking & critical analysis
Documentation-heavy process for scripted tests, use cases, & more	Reduces redundant compliance documentation, with increased focus on vendor testing, unscripted testing, & ad-hoc tests
Resource intensive	Can reduce paperwork by up to 80%

Upcoming Events



Learn more about Kneat events:
kneat.com/news-and-events

Webinars

Kneat Gx Demonstration

SEPTEMBER 25 // 11 AM ET

Conferences

ISPE Annual Meeting & Expo

OCTOBER 13 // Orlando, FL

KENX Validation & GMP University Europe

NOVEMBER 7 // Dublin, Ireland

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We Appreciate Your Feedback

Take Our Post-Webinar Survey

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