ISPE Pharma Best Practices Webinar Series

Quality Culture Matters: Key to Unlocking the Digital Validation Power

14 January 2025
11:00 – 12:00 EST

Dori Gonzalez-Acevedo
CEO and Co-Founder
ProcellaRX

Amy Kuntzman
Principal Consultant
CAI

Khaled Moussally
Executive Vice President Corporate Development & Operations
Compliance Group Inc

George Brunner
Chief Data Scientist
Acumen Analytics, Inc.

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Speakers

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Dori Gonzalez-Acevedo is the Co-Founder and CEO of ProcellaRX, as well as the host of both the Software Quality Today and Women Leading Validation podcasts. She has over 20 years' experience in the life sciences industry, specializing in regulatory compliance strategy and computer systems validation. She started her pharmaceutical career developing FDA-approved manufacturing processes and later built on that experience to establish risk-based quality systems for operations quality groups in biotechnology firms. After making the transition to software quality as a consultant at Genilogix, Dori continued her emphasis on risk-based strategy and compliance which continued to evolve through to her role as Director of Quality Systems for Healthcare and Life Sciences at Avnet / Tech Data. Prior to forming ProcellaRX, Dori was the VP of Strategic Solutions at Tx3 Services, where she expanded Tx3's delivery capabilities with a focus on increasing technology adoption and advancing client understanding of compliance, automation, testing, and digital validation.

Amy Kuntzman is a Principal Consultant with CAI and member of the ISPE Paperless Validation Subcommittee, with over 20 years of pharmaceutical and biotechnology experience in the fields of Quality and Project Management. For the last several years she has concentrated on digital transformation, specifically the implementation and enhancement of integrated GxP systems to support large-scale manufacturing of pharmaceutical products. Amy has managed multiple successful cross-functional teams both as a Project Manager and as a Functional Manager, most recently focusing on helping clients implement digital validation tools at the network level and expand their existing instance to support additional sites and validation programs.

Khaled Moussally, a seasoned Quality & Compliance executive, boasts over 27 years of experience in IT, manufacturing, operation and quality within the Life Sciences industry's corporate sector. His transition from corporate roles to consulting positions aims to revolutionize Quality & Compliance through collaboration with regulatory bodies. Khaled actively contributes to the MDIC's 'Case for Quality Initiatives' and plays a pivotal role in shaping the FDA's draft guidance on 'Computer Software Assurance (CSA) for Manufacturing, Operations, and Quality System Software.' As a member of the 'FDA – Industry CSA team,' he is recognized for collaborative presentations at industry conferences. He also serves on the "ISPE GAMP America Steering Committee" and is a contributor to several ISPE Good Practice Guides (GPGs), including GAMP 5 2nd Edition. Khaled's forward-thinking mindset positions him as a thought leader, he encourages innovative approaches, bridging the gap between compliance requirements and technological advancements applying the CSA concept to shorten CSV cycle times and enhance overall quality. Khaled earned a bachelor's degree in mechanical engineering from Florida International University (FIU), he resides in Chicago, Illinois.

George Brunner, Chief Digital Officer at Acumen Analytics. Acumen Analytics, based outside of Philadelphia and founded in 2004, is an award winning WBE technology solution provider for the pharmaceutical, biotech, manufacturing, and technology industries. Acumen team members combine decades of Life Science experience with intelligent, resilient, future forward technology solutions, data, and a passion for possibilities. He has worked in Life Sciences companies for over 20 years, starting with Nanosystems, Inc a subsidiary of Kodak Sterling, Elan Corporation a pharmaceutical and drug delivery company headquartered in Dublin, Ireland and Johnson and Johnson in its Consumer Products OTC Drug division where he headed up the Laboratory Computing Group which provided IT, Analytics and Validation services to both R&D and Quality Labs in the US and Puerto Rico. He holds a Bachelor degree in Mathematics from Temple University and an MBA from Villanova University. He has taught Operations Mgt, Advanced Analytics, Six Sigma and Contemporary IT Mgt courses at both Villanova and St. Joseph's Universities.

Introduction and Opening Remarks

Dori Gonzalez-Acevedo

POLL #1

How familiar are you with digital validation practices?

- ❑ Very familiar
- ❑ Somewhat familiar
- ❑ Not familiar at all

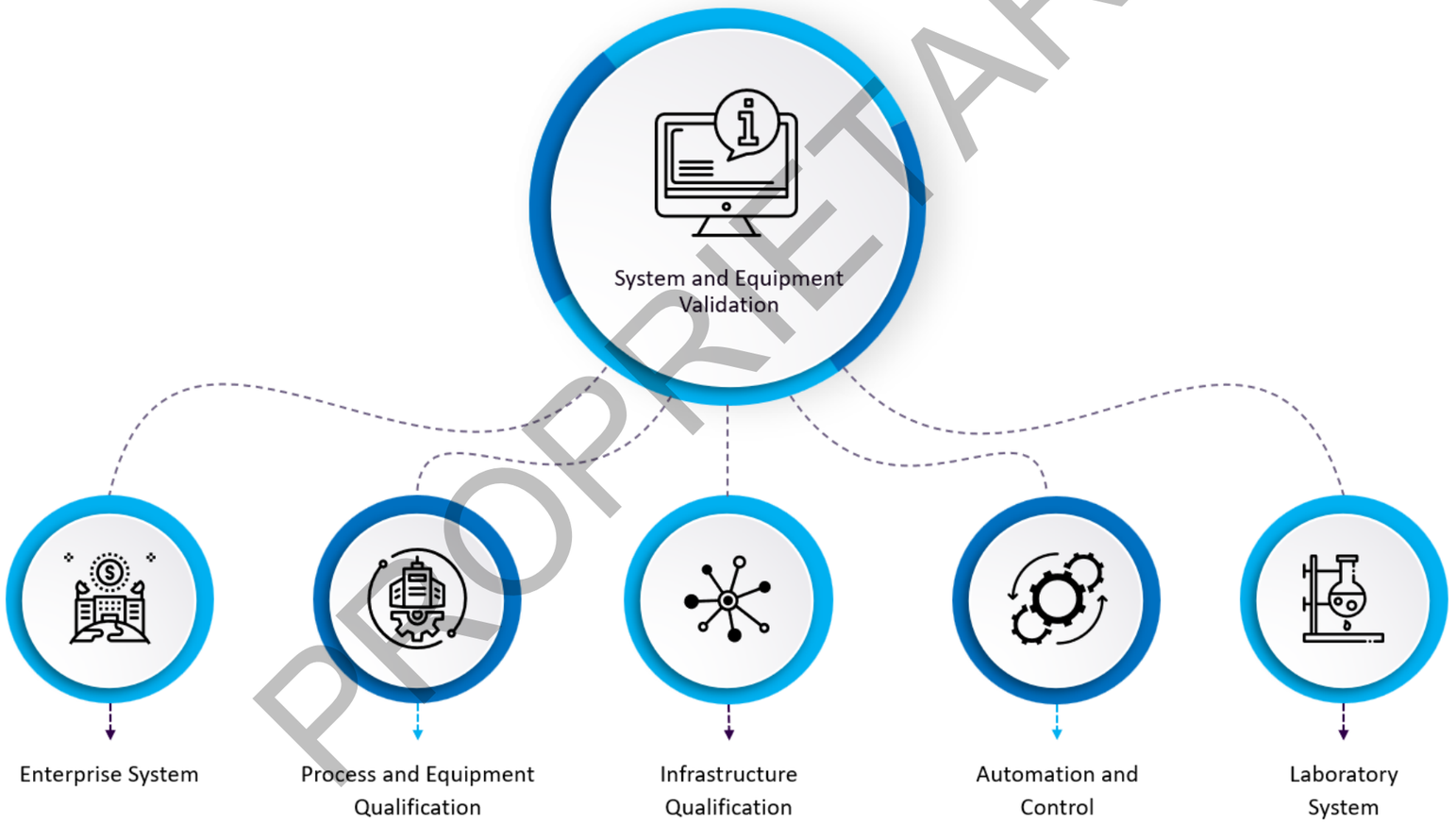
The Future is Here – Are You Ready to Lead?

From Innovation to Implementation

- Artificial Intelligence (AI) and Machine Learning Models
- Real-Time Monitoring Systems
- Blockchain for Data Integrity
- Personalized Medicine Platforms
- Augmented and Virtual Reality (AR/VR)
- IoT-Enabled Smart Devices
- Continuous Manufacturing Systems
- Genomics and Bioinformatics Tools
- Wearables and Digital Health Technologies

What is Digital Validation?

A framework or methodology in life sciences and regulated industries that utilizes advanced digital tools and systems to ensure compliance, quality, and efficiency in validation processes.



Defining Digital Validation Tools (DVTs)

Digital Validation Tools (DVTs) are comprehensive, data-centric system(s) or technologies designed to enable true digital transformation by creating interconnected, informative, and searchable ecosystems that enhance efficiency, accuracy, and scalability while ensuring regulatory compliance, audit readiness and operational excellence.

Overview of the ISPE GPG Digital Validation

Amy Kuntzman

POLL #2

Where does your organization stand regarding implementation of a DVT?

- ❑ Implemented and planning to expand
- ❑ Implemented and in steady state
- ❑ Initial implementation is on-going
- ❑ A DVT is on the roadmap
- ❑ Someday, we hope...

Coming Soon – GPG Digital Validation

The GPG presents a compliant approach to use of digital validation tools based on current technologies and industry use cases

- Digital Validation Concepts
- Crafting a Compelling Business Case for Digital Validation
- Digital Validation System Implementation
- Digital Validation System Governance
- Regulatory Considerations and Impact
- Future advancements in Digital Validation Tools

Publication expected in Q2 2025!!

Importance of Quality Culture

Khaled Moussally

Importance of Quality Culture

- Leadership Commitment
- Consistency and Reliability
- Breaking Down The Silos
- Encourages Proactive Problem Solving
- Foundation for Successful Implementation - Organizational Change Management

Importance of Quality Culture

Leadership Commitment

- Strong leadership commitment fosters a robust quality culture, driving consistent and exceptional results.
- When leaders prioritize quality, it cultivates a culture that ensures superior outcomes and leads to measurable success and continuous improvement.
- Creates an environment where excellence becomes the standard result.

Consistency and Reliability

- Quality culture promotes standardized practices and accountability, critical for consistent data input, analysis, and reporting in digital tools. This reduces variability and enhances the reliability of outcomes.

Breaking Down the Silos

- A collaborative quality culture dismantles departmental silos, enabling cross-functional teams (e.g., IT, Quality Assurance, and Operations) to work cohesively.

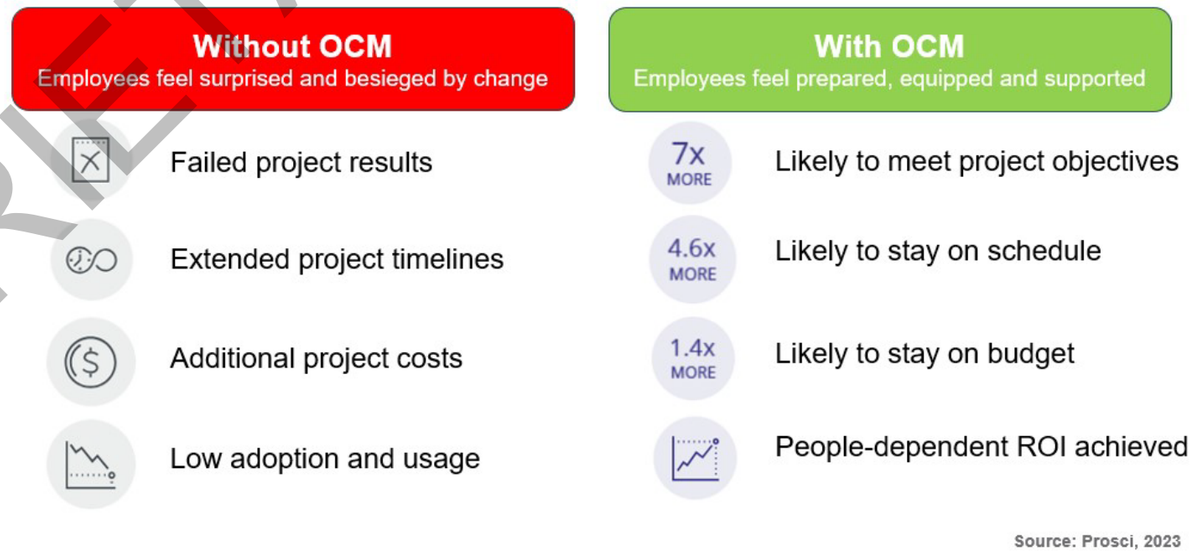
Encouraging Proactive Problem-Solving

- Organizations with a strong quality culture prioritize identifying and addressing issues early. This proactive mindset ensures smoother validation processes and minimizes disruptions during tool deployment.

Foundation for Successful Implementation is Organizational Change Management (OCM)

Transitioning to digital validation tools often requires significant change. A robust quality culture ensures the seamless adoption of digital validation tools by aligning teams around shared quality objectives. Without a strong culture of quality, even the best tools can face resistance, misuse, or underutilization.

- Implementing a digital validation tool requires careful organizational change management to ensure smooth adoption and effective utilization. Here are the key steps:
  - Define Objectives and Assess Readiness
  - Develop a Comprehensive Change Management
  - Engage & Train Stakeholders
  - Pilot & Gather Feedback
  - Full Deployment & Support
  - Sustain Change & Drive Continuous Improvement

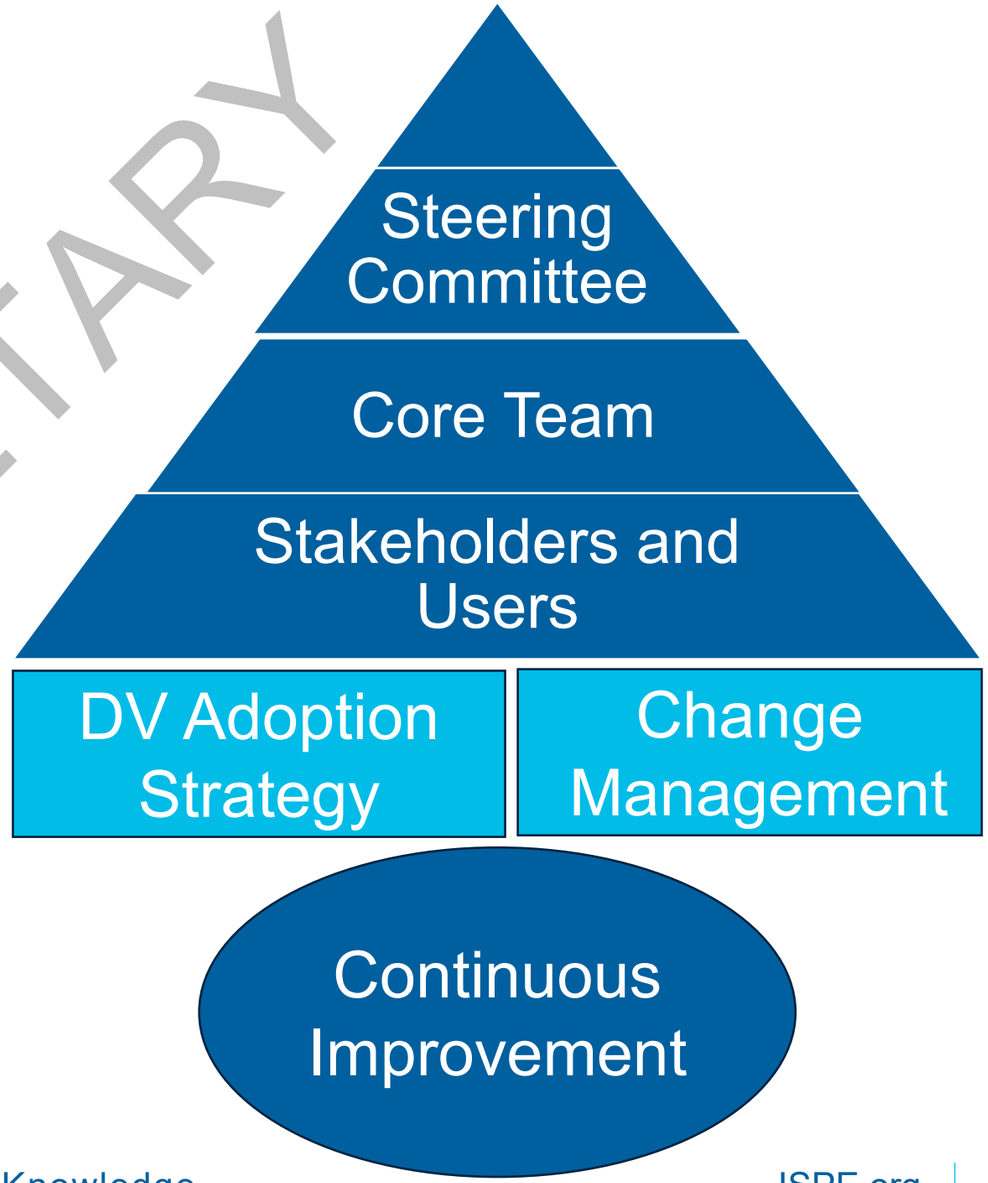


Governance and Change Management

George Brunner

Governance & Best Practices in Digital Validation

- Governance Framework
- Digital Validation Adoption Strategy
- Enterprise Steering Committee
- Change Management
- Continuous Improvement



Risk Management and Continuous Improvement

Panel Discussion

POLL #3

What topics from the Good Practice Guide would you like to see addressed in future webinars?

- ❑ Developing a Business Case for Digital Validation
- ❑ Digital Validation System Implementation
- ❑ Digital Validation System Governance
- ❑ Regulatory Considerations and Impact
- ❑ Future advancements in Digital Validation Tools

Questions and Discussion

Contact Information

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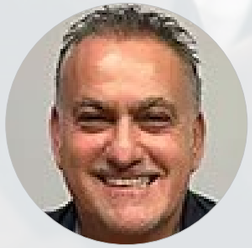

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Upcoming Webinars

- **Purified Water Microbial Testing: False OOS Due to TNTC vs Filtration Volume**
  Wednesday, 22 January
- **Improved Data Integrity via Digitization of Environmental Monitoring**
  Tuesday, 4 February
- **Actively Identifying Limiting Factors in Speed to Launch Drug Products**
  Thursday, 13 February
- **CSV vs CSA: GAMP 5's Actionable Steps to Transitioning Your Validation**
  Wednesday, 19 February

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Topic Ideas or Feedback?

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