



Society of Quality Assurance

41st Annual Meeting & Quality College

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Spotlight on Quality Assurance: The Future is Bright

E-1 Using a Cloud Environment for Regulated Data

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Ricardo Torres-Rivera

Agenda

- Background
- Roundtable Challenges
- Discussion Points
- Next Steps

Opinions expressed in this roundtable are those of the individuals and not of SQA or JSQA.

Welcome

Richie Siconolfi Noriaki Katanozaka Distinguished Panel

- Vince D'Angelo
- Bill Drummond
- Chris Meister
- J. Heléne Andersson
- Joseph Franchetti
- Kevyn Matijevich
- Ricardo Torres-Rivera

● Using a Cloud Environment for Regulated Data

- A joint position paper by the Society of Quality Assurance's CVIC Specialty Section and the Japanese Society of Quality Assurance
- To be published in *Quality Matters* and JSQA Journal

- MoU (SQA, RQA, other areas (ASIA))
 - cooperates mutually to each other's general meetings, developing guidelines, and **exchanging** opinions on GxP
- PMDA concerns
 - Compliance of ALCOA+ principles
 - Dynamic Data Control
 - The reconciliation between the available sets of blank forms
 - Exit Strategy (Cloud computing)

Background

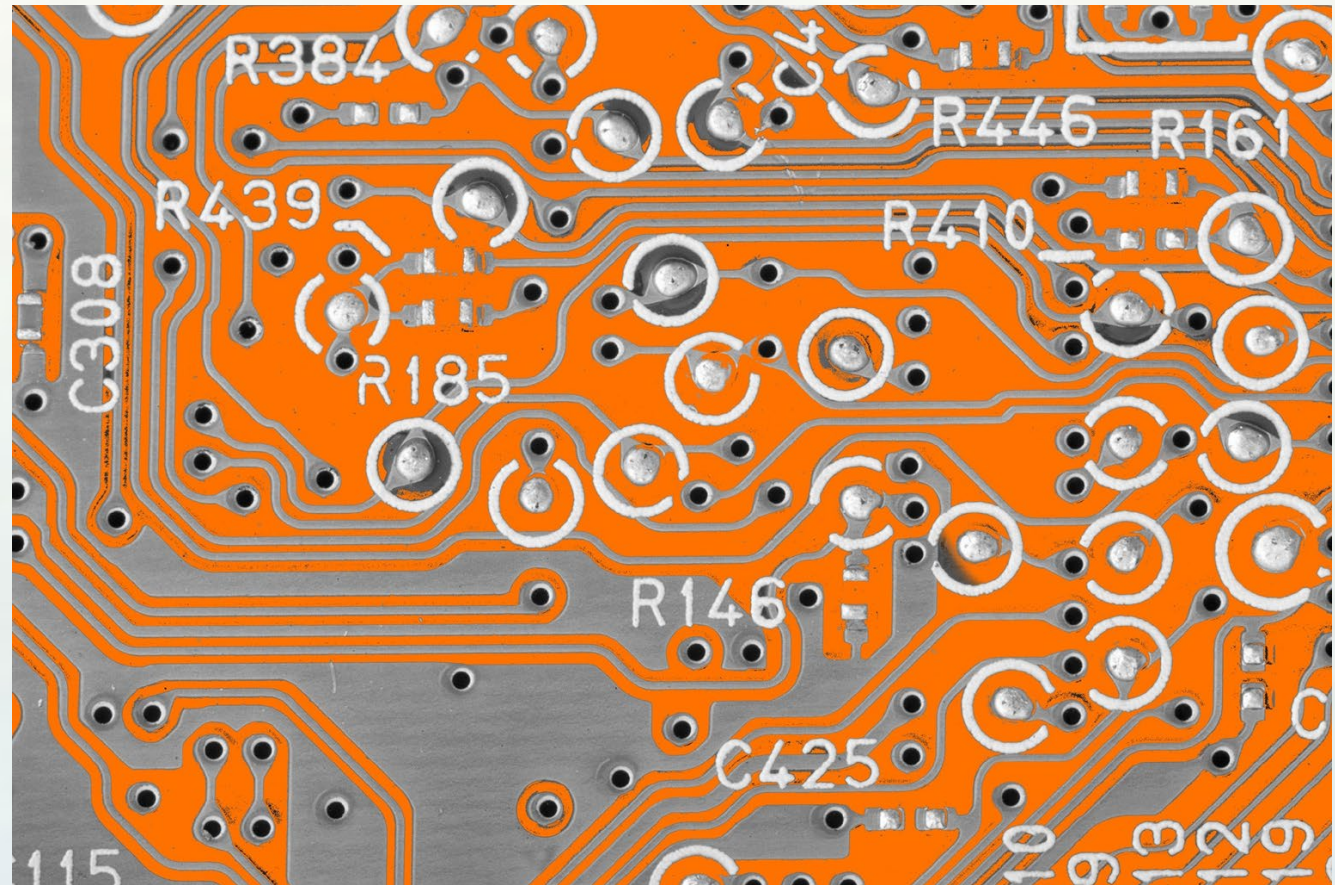
- Joint JSQA and SQA-CVIC communications initiated in 2023
- Prepare a position on data storage and data retention using Cloud Service Providers
- Key issues
 - Study Director's and TFM Responsibilities
 - Archivist responsibilities
 - Certain Regulator's concerns regarding the use Cloud Service Providers
 - Assessment, Validation, Monitoring
 - Archiving and Data locations

Guidelines, Guidance Documents, etc.

- OECD Document Number 17 on Application of GLP Principles to Computerised Systems, 2023, including supplement 1.
- OECD Document Number 15 on Establishment and Control of Archives that Operate in Compliance with the Principles of GLP, 2009
- US FDA Guidance for Industry, 21 CFR Part 11, Electronic Records; Electronic Signatures - Scope and Application, August 2003
- US FDA 21 CFR Part 11 Electronic Record; Electronic Signature, 1997
- GAMP 5, A Risk-Based Approach to Compliant GxP Computerized Systems, Second Edition, 2022

Five D's of Compliance

- Data Integrity
- Data Quality
- Data Availability
- Data Storage
- Data Archiving



Roundtable Challenge

Challenge Number 1

Security, Access, Business Continuity

- Testing Facility
- Sponsor
- Software Vendor
- Cloud Service Provider



Roundtable Challenge



Challenge Number 2

Cloud Service Provider's Assessment

- Methodology
- Frequency

Roundtable Challenge



Challenge Number 3

Service Level Agreements

Testing Facility Management, CRO,
and Sponsor

- Responsibility
- Requirements
- Monitoring

Roundtable Challenge



Challenge Number 4

Data Integrity & Data Quality

- Validation
- Change Management
- Risk Assessment
- IT & QA Oversight

Discussion Points

Number 1

Assessing Cloud Service Provider

Method

Frequency



Discussion Points

Number 2

Disaster
Recovery

Business
Continuity



Discussion Points

Number 3

Audit Team

Assessment



Discussion Points

Number 4

Release
Management &
Change Control

Data Quality
Data Integrity



Discussion Points

Number 5

Contract Exit Strategy

Think about SLA's

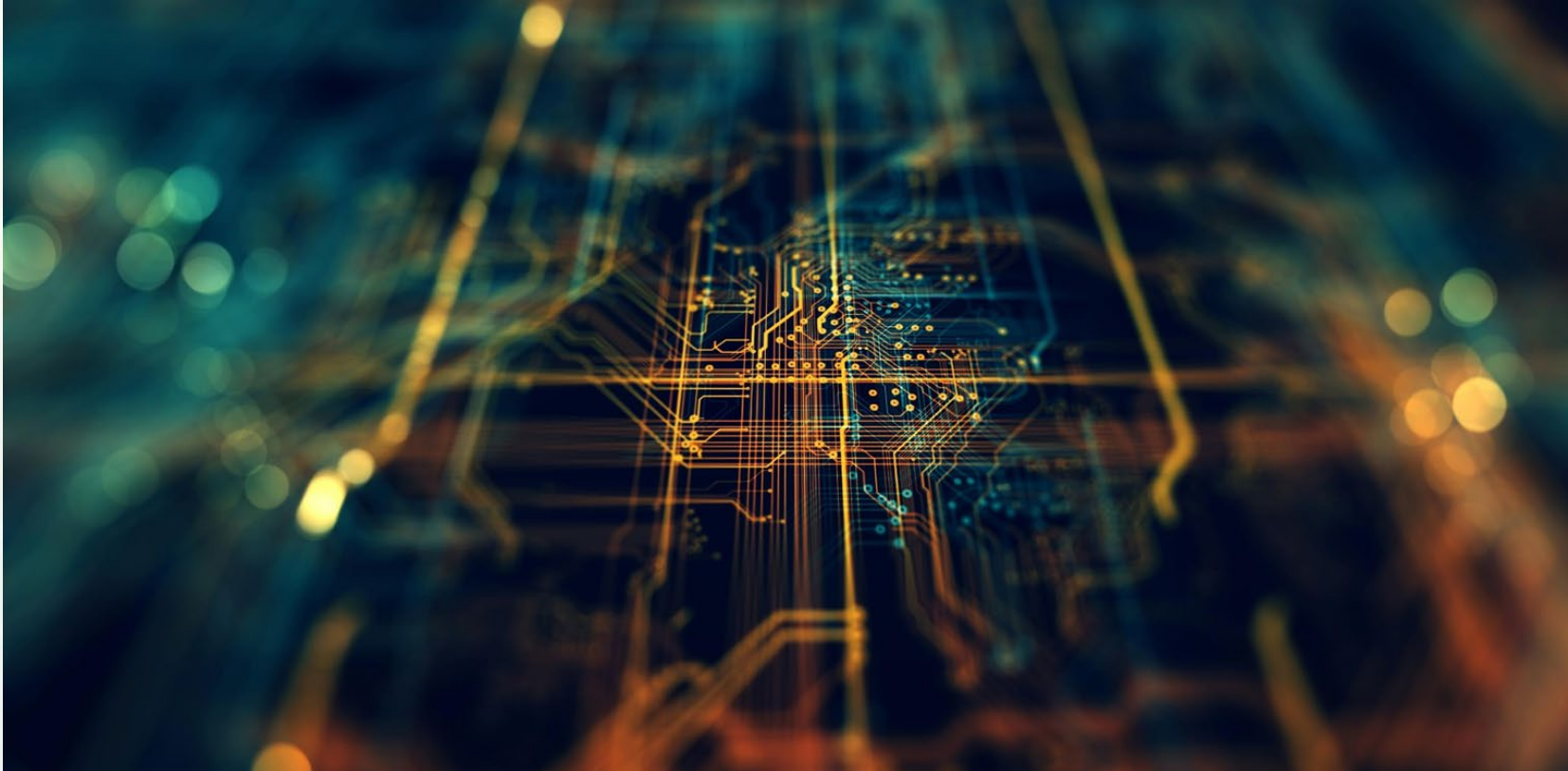


Next Steps

How will you address ...

- Assessment
- Compliance
- Data integrity & data quality
- Security
- Business continuity
- Release management & change control





Thank you

Enjoy the rest of the meeting