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NOV. 28 – DEC. 2, 2022 | LAS VEGAS, NV

LFS302

Regulator and industry perspective for achieving GxP compliance on AWS

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Agenda

Introduction to AWS for Health

The future of pharma

FDA Digital Health Center of Excellence

Exploring the FDA’s new CSA guidance

Achieving GxP compliance with AWS

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Raising the bar on product quality to improve public health

is my why.

Senthil Gurumoorthi
Global HCLS Security Assurance Lead
AWS, Security Assurance-RISE

AWS for Health



Omics



Healthcare



Life sciences

Accelerating innovations from benchtop to bedside

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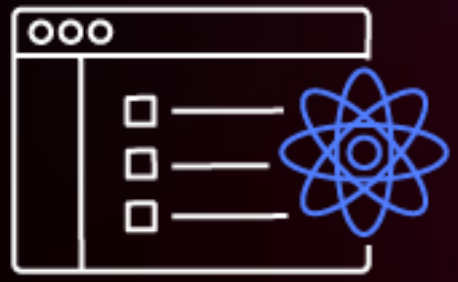
4 critical capabilities of pharma 2030



Patient centricity



Industry partnerships



Data science–driven



Risk and compliance savvy

"Advanced risk and compliance capability is likely to be critical to performance in this highly pressured environment."

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Source: Reshaping the Future of Pharma, Life Sciences, KPMG, April 2019

"The pace of the technological change and a growing need for innovative evolution, too little risk appetite is fast becoming a brick wall to real progress…Key challenge is overcoming the cultural shift and breaking down the barriers compliance teams have often placed around patients."

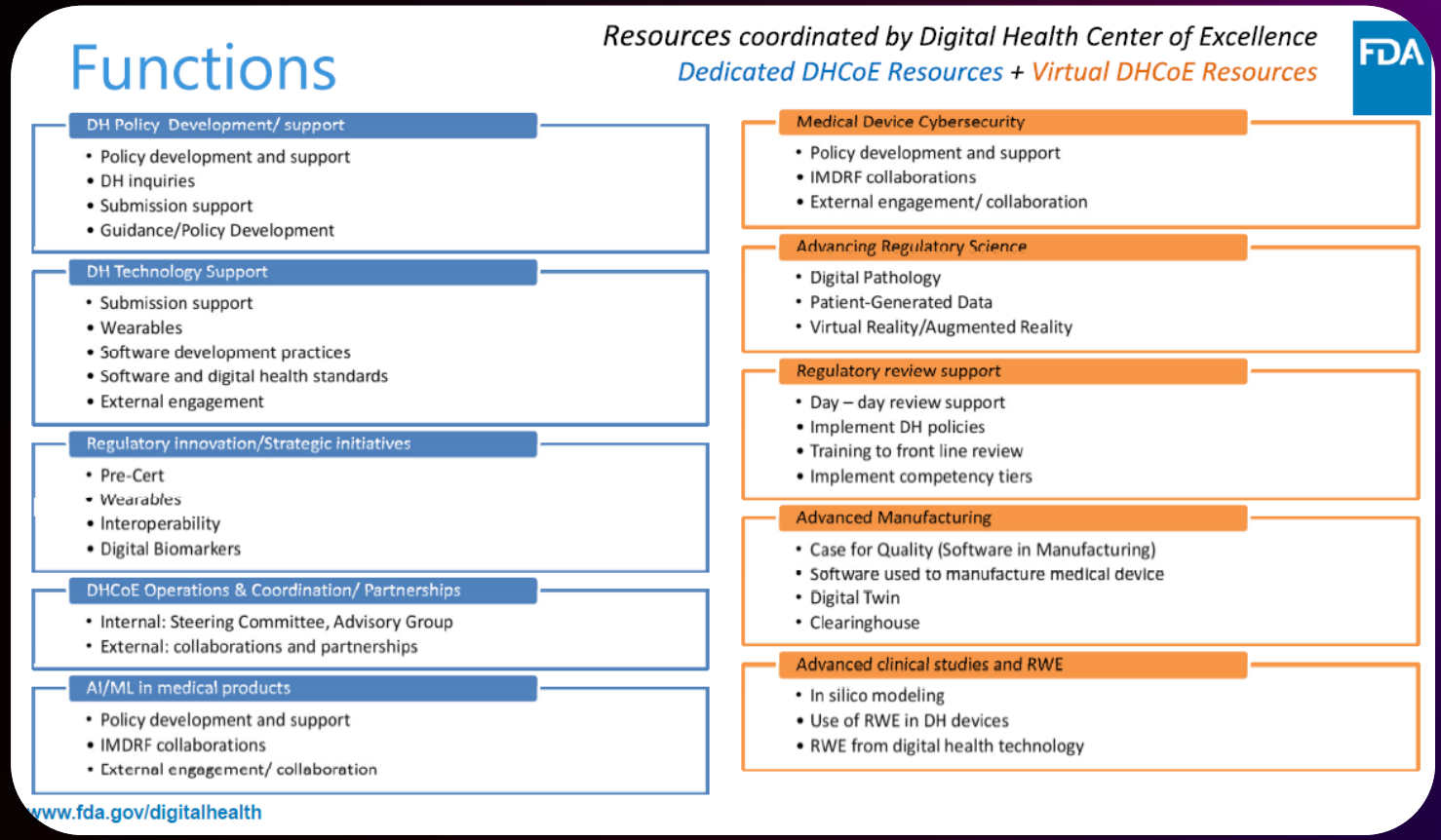
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Source: Reshaping the Future of Pharma, Life Sciences, KPMG, April 2019

FDA – Digital Health Center of Excellence

"It's more than just having the enabling technologies for us to use. It will come down to even rethinking the regulatory paradigms that we apply to more modern-day technologies."

-Dr. Jeffrey Shuren, FDA



Source: Digital Center of Excellence Listening Session by Bakul Patel, Director, CDRH, Oct. 19, 2020

Source: https://www.raps.org/news-and-articles/news-articles/2021/6/shuren-time-to-rethink-fdas-device-regulatory-fram?feed=Regulatory-Focus

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FDA’s Computer Software Assurance (CSA) – Regulator Perspective

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FDA Industry CSA Team journey

2011–2012: FDA Case for Quality begins

2015 Q2: Siemens executive exchange with FDA: CSV barrier identified

2016 Q1: Industry team formed/recommendation development begins

2017: Promote recommendations: ZOLL LifeVest + MDT examples

2018

- FDA "A List" status for CSA Draft Guidance
- More examples developed, and more manufacturers begin applying recommendations (Vericel, ICU Medical,etc.)

2019

- More industry adoption and CSA success stories (REGENXBIO, Convatec, and many others)

2020

- ISPE GAMP endorsement
- CSA Draft Guidance release targeted for 2021
- 25+ manufacturers' implementation

2021

- ISPE GAMP released two Good Practice Guides
  - Data Integrity By Design
  - Enabling Innovation
- CSA Draft Guidance release targeted for 2022
- MDIC joins FICSA team
- 50+ manufacturers' implementation

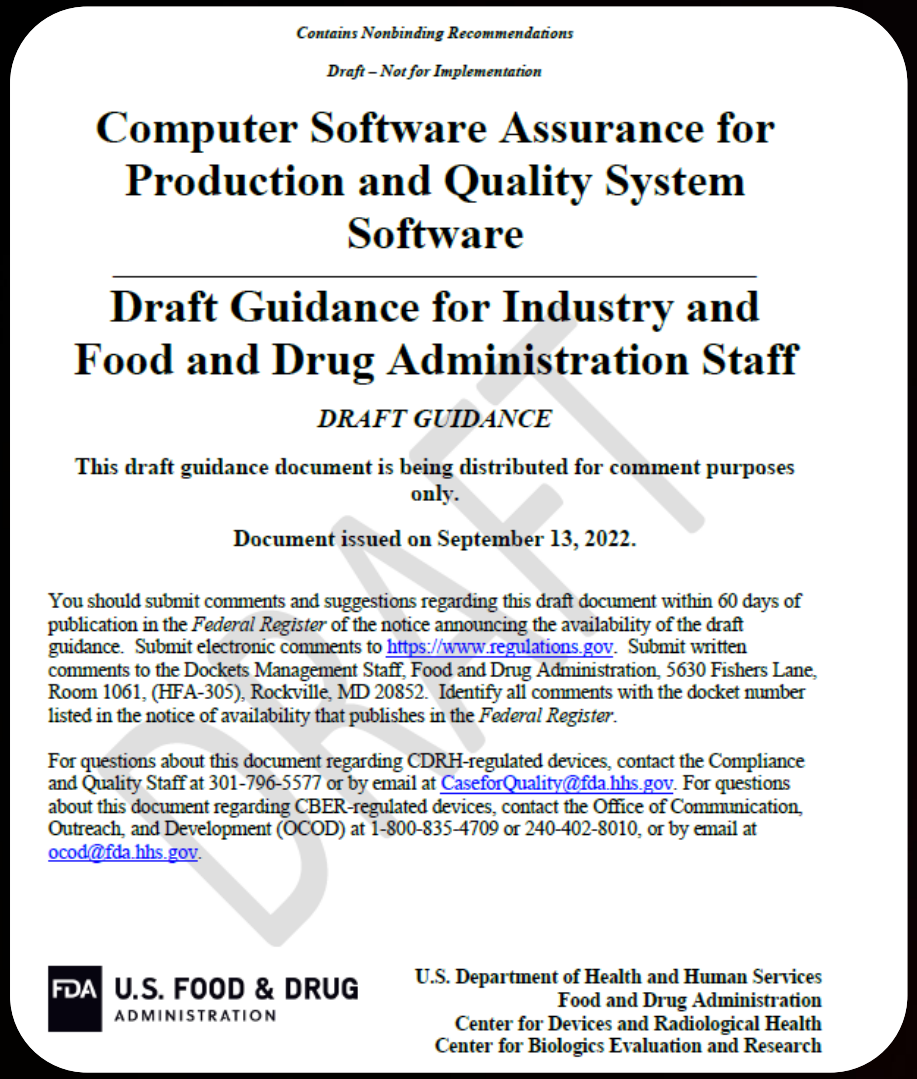
2022

- ISPE GAMP 5 Second Edition
- ***FDA CSA Draft Guidance***
- 100+ Manufacturers implementation



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CSA Draft Guidance released September 13, 2022



Contains Nonbinding Recommendations

Draft – Not for Implementation

Computer Software Assurance for Production and Quality System Software

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on September 13, 2022.

You should submit comments and suggestions regarding this draft document within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document regarding CDRH-regulated devices, contact the Compliance and Quality Staff at 301-796-5577 or by email at CaseforQuality@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

III. Scope

IV. Computer Software Assurance

V. Computer Software Assurance Risk Framework

- A. Identifying the Intended Use
- B. Determining the Risk-Based Approach
- C. Determining the Appropriate Assurance Activities
- D. Establishing the Appropriate Record

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CSA Draft Guidance Released September 13, 2022

Contains Nonbinding Recommendations

Draft – Not for Implementation

Computer Software Assurance for Production and Quality System Software

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction[1]

FDA is issuing this draft guidance to provide recommendations on computer software assurance for computers and automated data processing systems used as part of medical device production or the quality system. This draft guidance is intended to:

- Describe "computer software assurance" as a risk-based approach to establish confidence in the automation used for production or quality systems, and identify where additional rigor may be appropriate; and
- Describe various methods and testing activities that may be applied to establish computer software assurance and provide objective evidence to fulfill regulatory requirements, such as computer software validation requirements in 21 CFR part 820 (Part 820).

When final, this guidance will supplement FDA's guidance, "General Principles of Software Validation" ("Software Validation guidance")[2] except this guidance will supersede Section 6 ("Validation of Automated Process Equipment and Quality System Software") of the Software Validation guidance.

III. Scope

When final, this guidance is intended to provide recommendations regarding computer software assurance for computers or automated data processing systems used as part of production or the quality system.

This guidance is not intended to provide a complete description of all software validation principles. FDA has previously outlined principles for software validation, including managing changes as part of the software lifecycle, in FDA's Software Validation guidance. This guidance applies the risk-based approach to software validation discussed in the Software Validation guidance to production or quality system software. This guidance additionally discusses specific risk considerations, acceptable testing methods, and efficient generation of objective evidence for production or quality system software.

This guidance does not provide recommendations for the design verification or validation requirements specified in 21 CFR 820.30 when applied to software in a medical device (SiMD) or software as a medical device (SaMD). For more information regarding FDA's recommendations for design verification or validation of SiMD or SaMD, see the Software Validation guidance.

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Moving Forward

- Where else is additional clarity needed?
- Where can we benefit from increased collaboration?
- How do we continue to challenge the status quo?
- What can be done to inform and educate the industry?



Guidance is not regulation it is recommendations. Regulations are broad and flexible to maintain relevance.



Unscripted does not mean undocumented. The goal is an appropriate and efficient record of objective evidence of value to the organization.



Think critically but don't over complicate applying CSA principles. The goal is to make implementing technology easier.



Increase agility and flexibility to maintain confidence in the software throughout the lifecycle.



DOES NOT MEAN - DO NOTHING! Take credit for work done and existing process controls

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Achieving GxP compliance – Industry perspective

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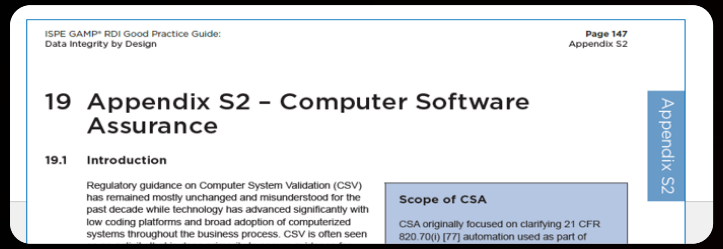
ISPE GAMP endorses CSA







Data Integrity By Design – 2020



ISPE GAMP® RDI Good Practice Guide: Data Integrity by Design — Page 147, Appendix S2

19 Appendix S2 – Computer Software Assurance

19.1 Introduction

Regulatory guidance on Computer System Validation (CSV) has remained mostly unchanged and misunderstood for the past decade while technology has advanced significantly with low coding platforms and broad adoption of computerized systems throughout the business process. CSV is often seen

Scope of CSA

CSA originally focused on clarifying 21 CFR 820.70(i) [77] automation used as part of

Appendix S2

Enabling Innovation – 2021



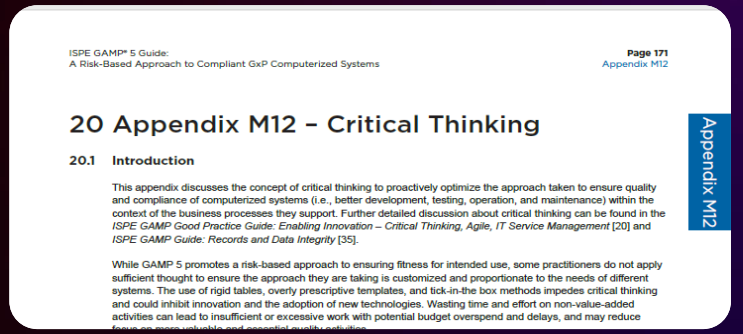
ISPE GAMP® Good Practice Guide: Enabling Innovation — Page 11

2 Critical Thinking for Computerized Systems

2.1 Introduction

Life cycle management of computerized systems in the pharmaceutical industry must ensure reliable operation and regulatory compliance while responding to the realities of maintaining and growing business profitability. While *ISPE GAMP 5* [2] presents a risk-based approach to ensuring fitness for intended use, some practitioners apply unthinking and rigid table-driven or tick-in-the box approaches not tailored or proportionate to the needs of different systems.

GAMP 5 2nd Edition, July 2022



ISPE GAMP® 5 Guide: A Risk-Based Approach to Compliant GxP Computerized Systems — Page 171, Appendix M12

20 Appendix M12 – Critical Thinking

20.1 Introduction

This appendix discusses the concept of critical thinking to proactively optimize the approach taken to ensure quality and compliance of computerized systems (i.e., better development, testing, operation, and maintenance) within the context of the business processes they support. Further detailed discussion about critical thinking can be found in the *ISPE GAMP Good Practice Guide: Enabling Innovation – Critical Thinking, Agile, IT Service Management* [20] and *ISPE GAMP Guide: Records and Data Integrity* [35].

While GAMP 5 promotes a risk-based approach to ensuring fitness for intended use, some practitioners do not apply sufficient thought to ensure the approach they are taking is customized and proportionate to the needs of different systems. The use of rigid tables, overly prescriptive templates, and tick-in-the box methods impedes critical thinking and could inhibit innovation and the adoption of new technologies. Wasting time and effort on non-value-added activities can lead to insufficient or excessive work with potential budget overspend and delays, and may reduce

Appendix M12

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Digitalization – Where is it taking us?

Industry 4.0 → IoT, cloud computing, RPA, AI/ML, digital twins, cybersecurity, edge computing, predictive analytics



Continuous verification



Data integrity by design



Preventive and predictive operational controls



Maximize time-to-value and compliance



Smart environment monitoring



Lifecycle management & planning – end-to-end seamless compliance

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Digitalization – Compliance roadmap to consider

Change management – people, process, technology

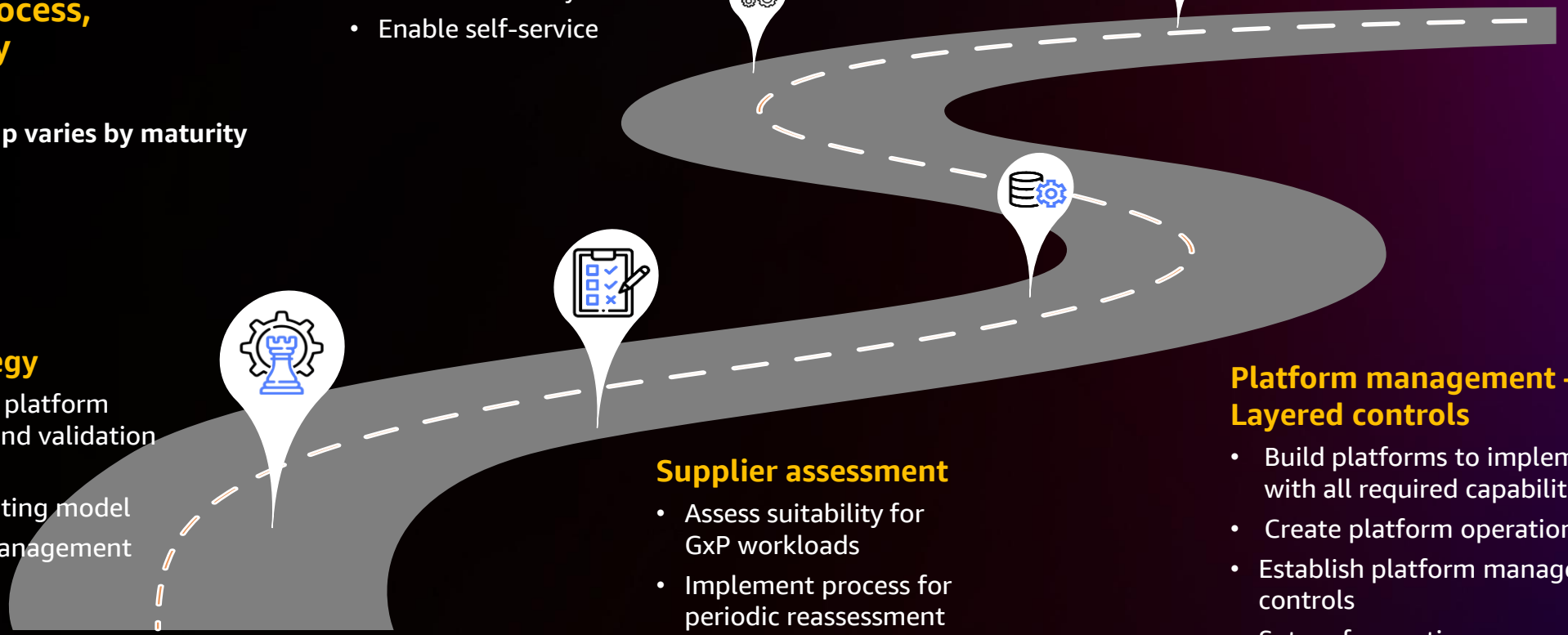
Note: Roadmap varies by maturity of the org

Enable DevSecOps/CI/CD

- Establish platform architecture guidance for application teams
- Create or modify CSV SOPs
- Enable self-service

Enable operational control

- Establish platforms controls
- Implement guardrails



Platform strategy

- Define overall platform qualification and validation strategy
- Layered operating model
- Quality risk management

Supplier assessment

- Assess suitability for GxP workloads
- Implement process for periodic reassessment
- Basic assurance (CSA)

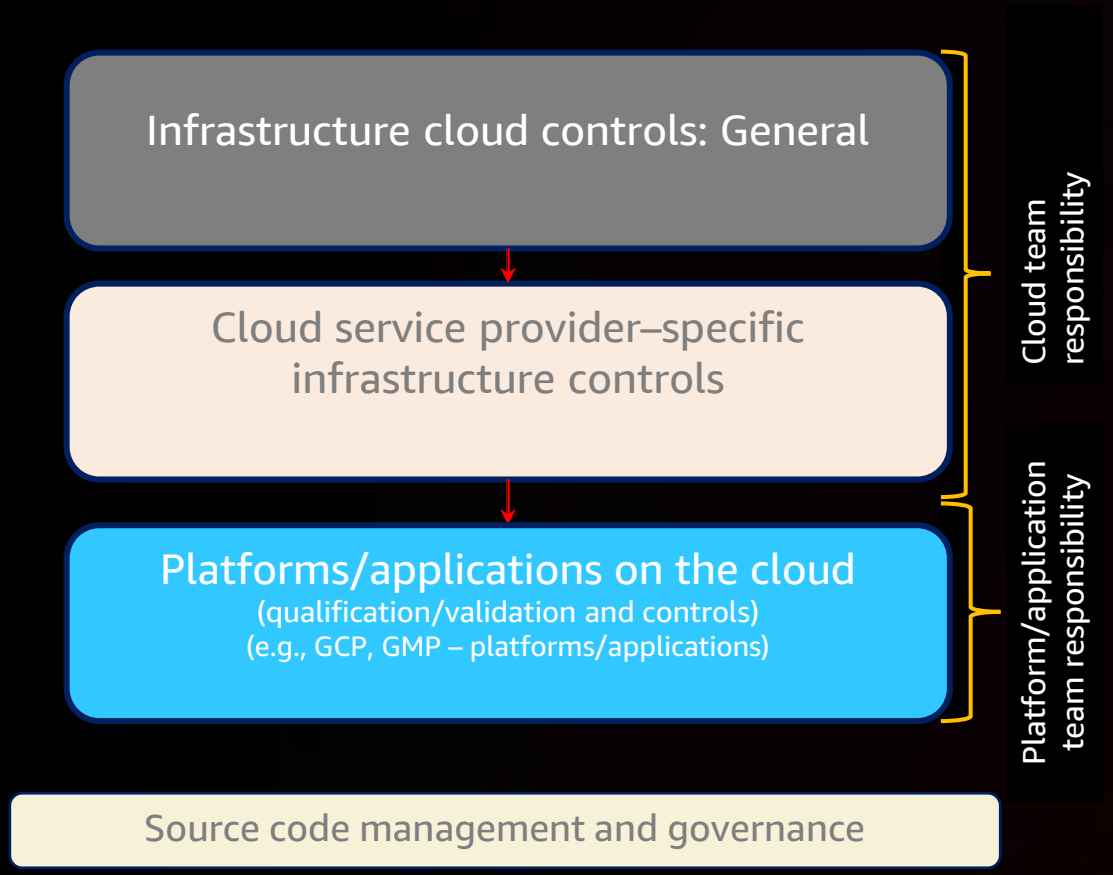
Platform management – Layered controls

- Build platforms to implement with all required capabilities
- Create platform operations SOPs
- Establish platform management controls
- Set up for continuous compliance

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Cloud quality management



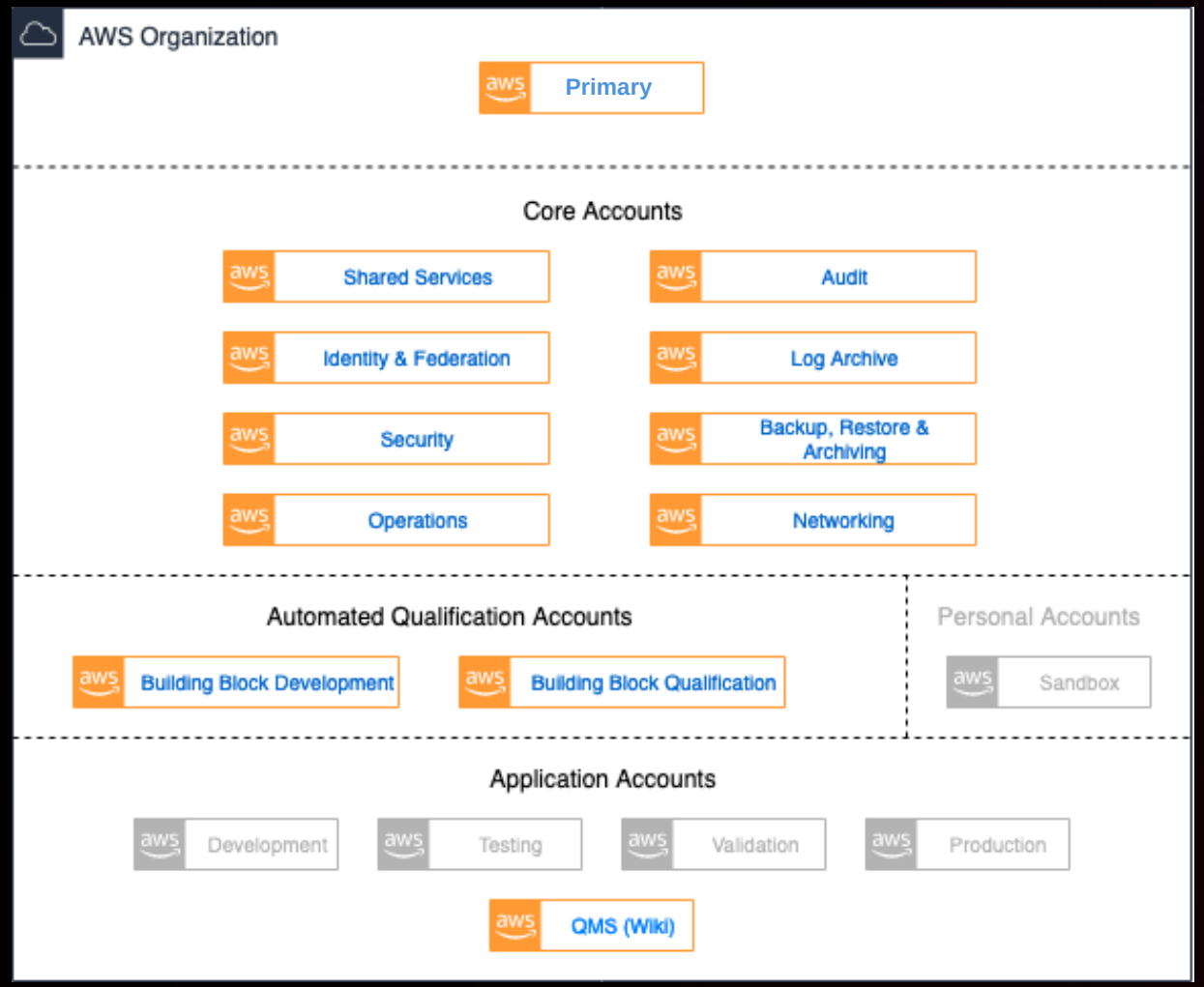
ISPE GAMP 5 Second Edition* embraces and reflects: Increased importance of service providers, which includes encouraging regulated companies to maximize supplier involvement to leverage knowledge, experience, and documentation where possible

ISPE GAMP 5 Second Edition* embraces and reflects: Evolving approaches to software development, emphasizing that the GAMP specification and verification approach is not inherently linear but also fully supports iterative and incremental methods

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*ISPE GAMP 5 Guide Second Edition, July 2022

Regulated landing zone



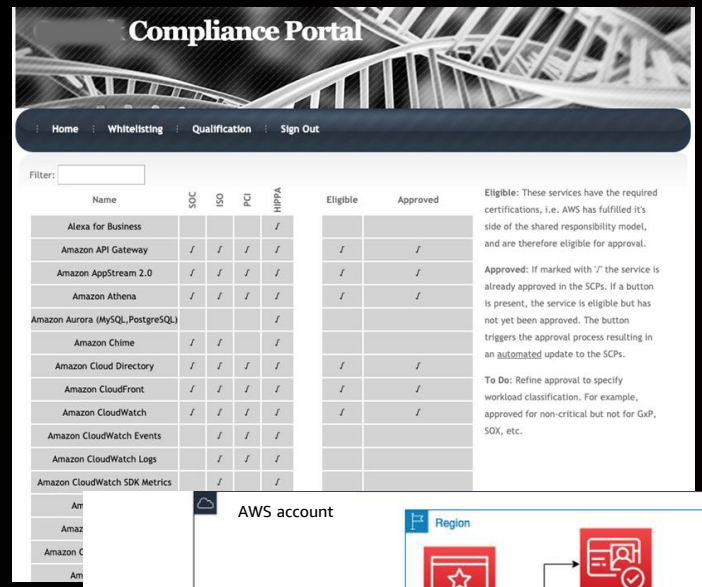
Regulated landing zone

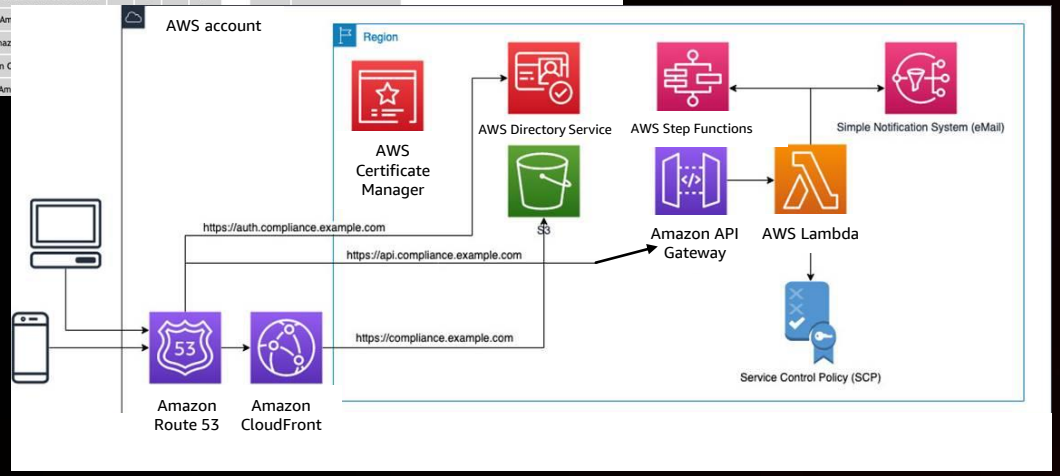
- Account provisioning
- Change management
- Configuration management
- Security management
- Server management
- Network management
- Incident management
- Backup, restore, and archiving
- Disaster recovery
- Monitoring
- Audit management
- Cost management

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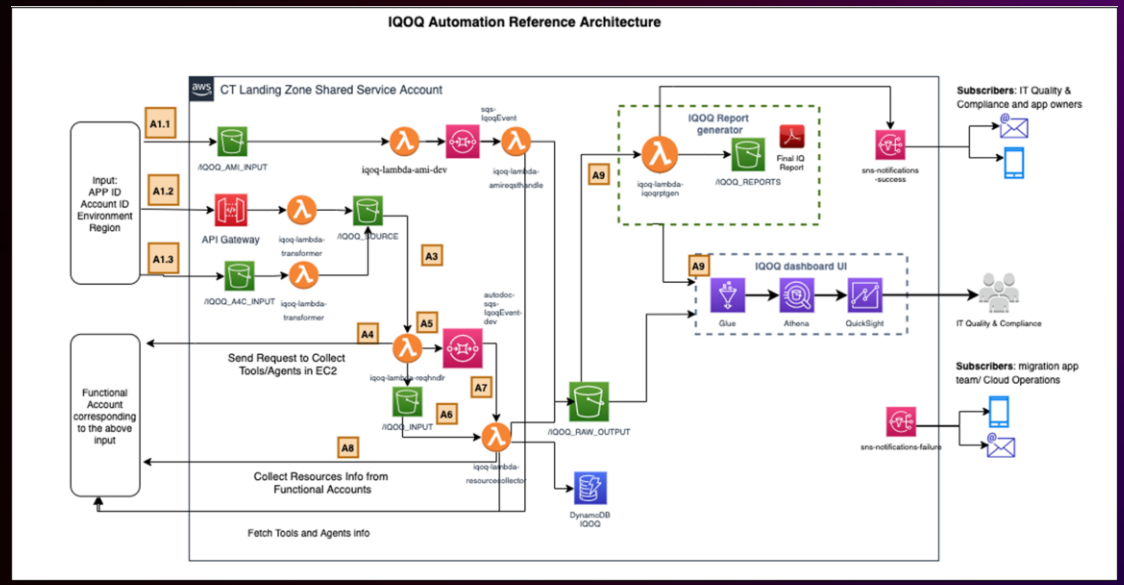
GxP accelerators

Automated service approval





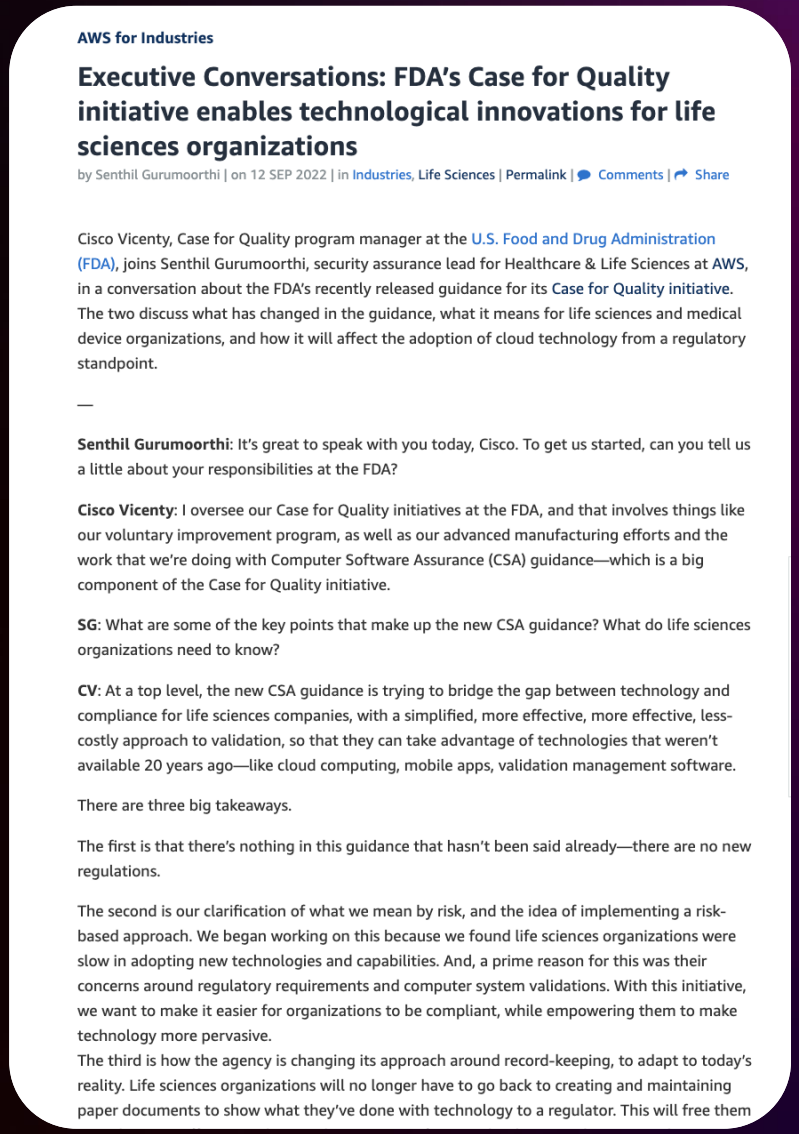
Computer systems validation
IQ automation



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AWS Executive Conversations with the FDA



AWS for Industries

Executive Conversations: FDA's Case for Quality initiative enables technological innovations for life sciences organizations

by Senthil Gurumoorthi | on 12 SEP 2022 | in Industries, Life Sciences | Permalink | Comments | Share

Cisco Vicenty, Case for Quality program manager at the U.S. Food and Drug Administration (FDA), joins Senthil Gurumoorthi, security assurance lead for Healthcare & Life Sciences at AWS, in a conversation about the FDA's recently released guidance for its Case for Quality initiative. The two discuss what has changed in the guidance, what it means for life sciences and medical device organizations, and how it will affect the adoption of cloud technology from a regulatory standpoint.

—

Senthil Gurumoorthi: It's great to speak with you today, Cisco. To get us started, can you tell us a little about your responsibilities at the FDA?

Cisco Vicenty: I oversee our Case for Quality initiatives at the FDA, and that involves things like our voluntary improvement program, as well as our advanced manufacturing efforts and the work that we're doing with Computer Software Assurance (CSA) guidance—which is a big component of the Case for Quality initiative.

SG: What are some of the key points that make up the new CSA guidance? What do life sciences organizations need to know?

CV: At a top level, the new CSA guidance is trying to bridge the gap between technology and compliance for life sciences companies, with a simplified, more effective, more effective, less-costly approach to validation, so that they can take advantage of technologies that weren't available 20 years ago—like cloud computing, mobile apps, validation management software.

There are three big takeaways.

The first is that there's nothing in this guidance that hasn't been said already—there are no new regulations.

The second is our clarification of what we mean by risk, and the idea of implementing a risk-based approach. We began working on this because we found life sciences organizations were slow in adopting new technologies and capabilities. And, a prime reason for this was their concerns around regulatory requirements and computer system validations. With this initiative, we want to make it easier for organizations to be compliant, while empowering them to make technology more pervasive.

The third is how the agency is changing its approach around record-keeping, to adapt to today's reality. Life sciences organizations will no longer have to go back to creating and maintaining paper documents to show what they've done with technology to a regulator. This will free them

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Q&A

GxP on AWS solution page:
https://aws.amazon.com/health/solutions/gxp

For more information about deploying GxP workloads on AWS, please reach out to
hcls-solution-gxp@amazon.com

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AWS Health Lounge

Connect with **AWS health experts** and other attendees in our dedicated lounge space for **informal discussions and networking.**

Explore **AWS healthcare and life sciences demos** and new additions to the AWS for Health portfolio!



Location: AWS Industries Networking Lounges; Caesars Forum Main Hall

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AWS + Children's National Hospital

Customer obsession = patient obsession

Collect pins at the AWS Health Lounge from child artists who are also patients at Children's National Hospital – learn about their inspiration and their "why"





Artwork provide by Zahara, age 13, patient with sickle cell disease

"I drew a cherry blossom because I love going to the DC Cherry Blossom Festival in the spring. The care I get at Children's National allows me to do all the things I love and have lots of fun!"

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Thank you!



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