



TT03: An Update from the PhUSE Working Group on Cloud Adoption in the Regulated Life Science Industry

Presentation at PhUSE Annual Conference, Barcelona

October 2016

Agenda

- Our Working Group
- Key aspects of the Framework
- Recommendations
- Q&A



Our working group – History and Highlights

- Formed in 2013 via PRISME to PhUSE
- Operating within the PhUSE/FDA Computational Sciences Symposium's Emerging Trends/Technologies Stream
- 2013/2014: Team formation, brainstorming, case-studies -> framework concept; **engagement with FDA**
- Q1-2014: Test concept; CSS in MD
- 2014/2015: Team consolidation, framework content refinement
- Q4-2015: New “published” framework¹; **engagement with EMA**
- >2015: More iterative refinement. Alignment with NIST² and ISO³

1. <https://s3-us-west-2.amazonaws.com/phuse/public/PhUSE+Cloud+Doc+13-Nov-2015.pdf>
2. http://www.iso.org/iso/catalogue_detail?csnumber=60544 and http://www.iso.org/iso/catalogue_detail?csnumber=60545
3. <http://nvlpubs.nist.gov/nistpubs/Legacy/SP/nistspecialpublication800-145.pdf>

Issues (?) identified

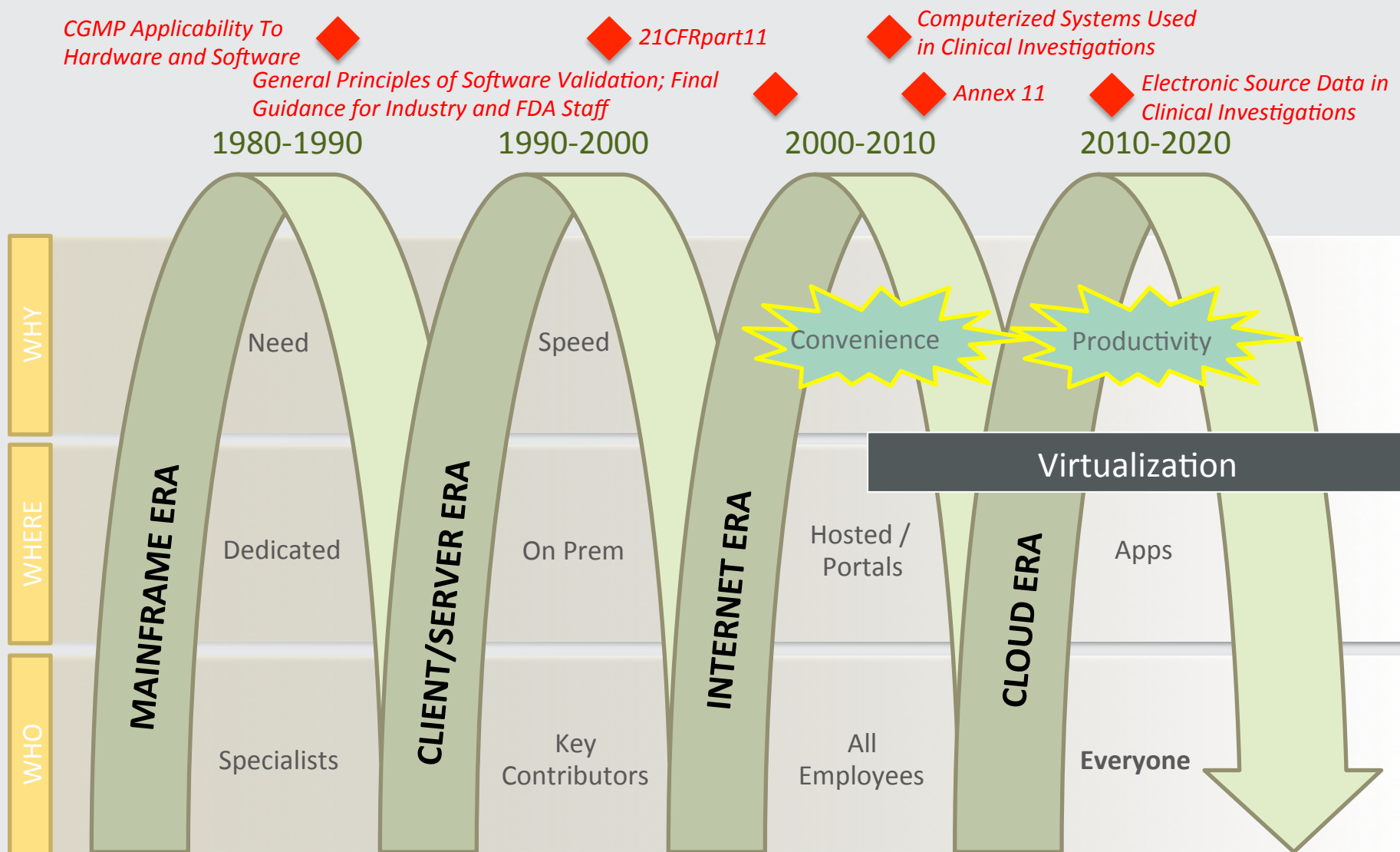
- NOT technology
- **Evolution of approaches, terminology, understanding, jargon; What the heck is [a] cloud?**
- **Conservatism**
- **A perception of diversified controls, roles and responsibilities – client, supplier, sub-suppliers → more complex “IT supply chains”**
- Absence of standards [applicable for GxP]
- SIMT apps
- **QMS fitness for purpose**
- Brings long-standing issues to the fore...privacy, legacy architectures, [truly] internationalized solutions

Park these thoughts.....

Potential Benefits of Cloud

To “IT”	To “Business”
Scalability	Scalability
On-demand usage - >	Consumption-based model - fixed cost reduction
Distributed fault tolerance Real-time maintenance	High availability
Focus on business and apps – not tech	Invisible, commoditized lower tech stack
Commoditized lower tech infrastructure	Focus on business and apps – not tech
Speed (of deployment)	Agility

Background – Technology Evolution



Framework Tenets

- Living framework document – wiki-like
- Technology has – and will – change rapidly; Life Science companies changing too; synergy!
- Bake in flexibility and technology-neutrality to processes – get things right at policy level
- Leverage NIST¹ and ISO/IEC 17788² and 17789³ – no need to reinvent
- Embrace cloud to stay/become innovative in use of technology – but, “stay in control” as per predicate rules

¹ <http://nvlpubs.nist.gov/nistpubs/Legacy/SP/nistspecialpublication800-145.pdf>

² http://www.iso.org/iso/catalogue_detail?csnumber=60544

³ http://www.iso.org/iso/catalogue_detail?csnumber=60545

Stylized EDC/CTMS (etc) Cloud setup

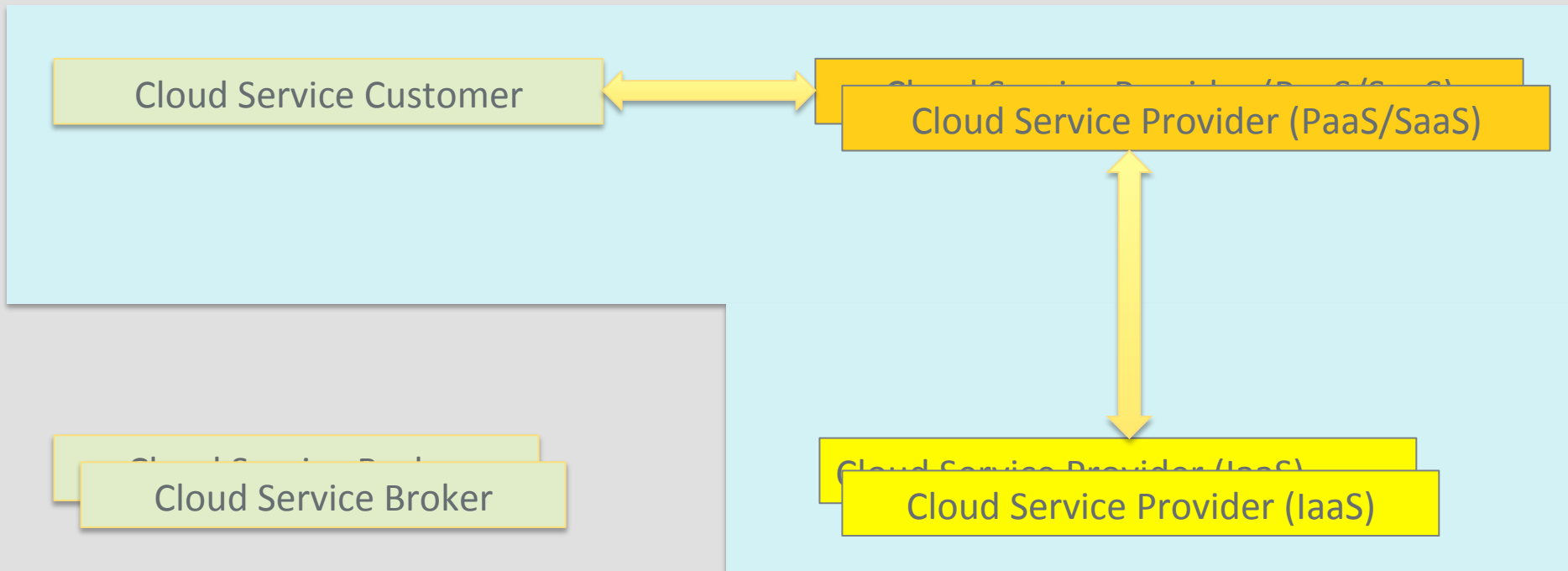


SaaS – Web Apps	G4/5	Various apps of various architecture	SaaS & PaaS
Solution Stack	G1/3	SaaS/PaaS – configurable recipes	
OS's	G1	PaaS – standardized/programmable	
Hypervisor - V	G1/5	IaaS – standardized/programmable	IaaS
Compute & Data Storage	G1	IaaS – commoditized	
Networks	G1	IaaS – commoditized	
Facilities		Multiple, connected, resilient	

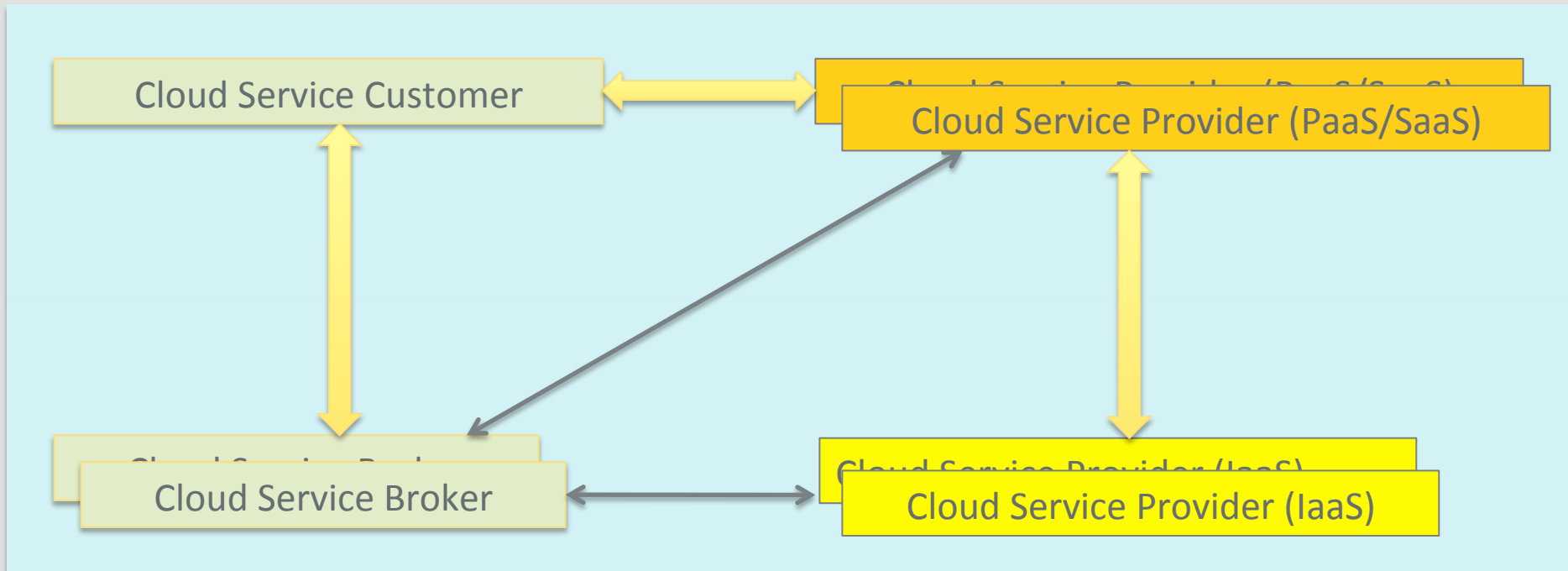
4 Key Roles (q.v. ISO 17788/ISO 17789)

- **Cloud Service Customer:** In the context of GxP, these are generally the organizations or entities that purchase/use the cloud services to support their GxP-regulated activities. They are generally billed for the cloud services they consume, and depending on the services requested (IaaS, PaaS, SaaS), their activities, use cases and GxP requirements may vary.
- **Cloud Service Provider:** Organizations or entities responsible for providing cloud services to customers. The activities that the cloud providers perform will vary depending on their particular service offerings and can include building, deploying, operating and maintaining the cloud apps, infrastructure and associated service layers.
- **Cloud Service Broker:** These are the organizations or entities that manage the configuration, delivery and use of cloud services on behalf of the cloud customer. For example, cloud managers may perform infrastructure change control activities on the infrastructure built using general purpose, commercial cloud services.
- **Cloud Auditor:** A cloud auditor is a party that is qualified to conduct assessments of the cloud provider and the cloud infrastructure underlying the IaaS, PaaS, SaaS services. The auditor may be an independent third party such as a third party assessment organization (3PAO) or can also be a member of the consumer, provider or manager organization.

Cloud “Supply Chains” – Example 1

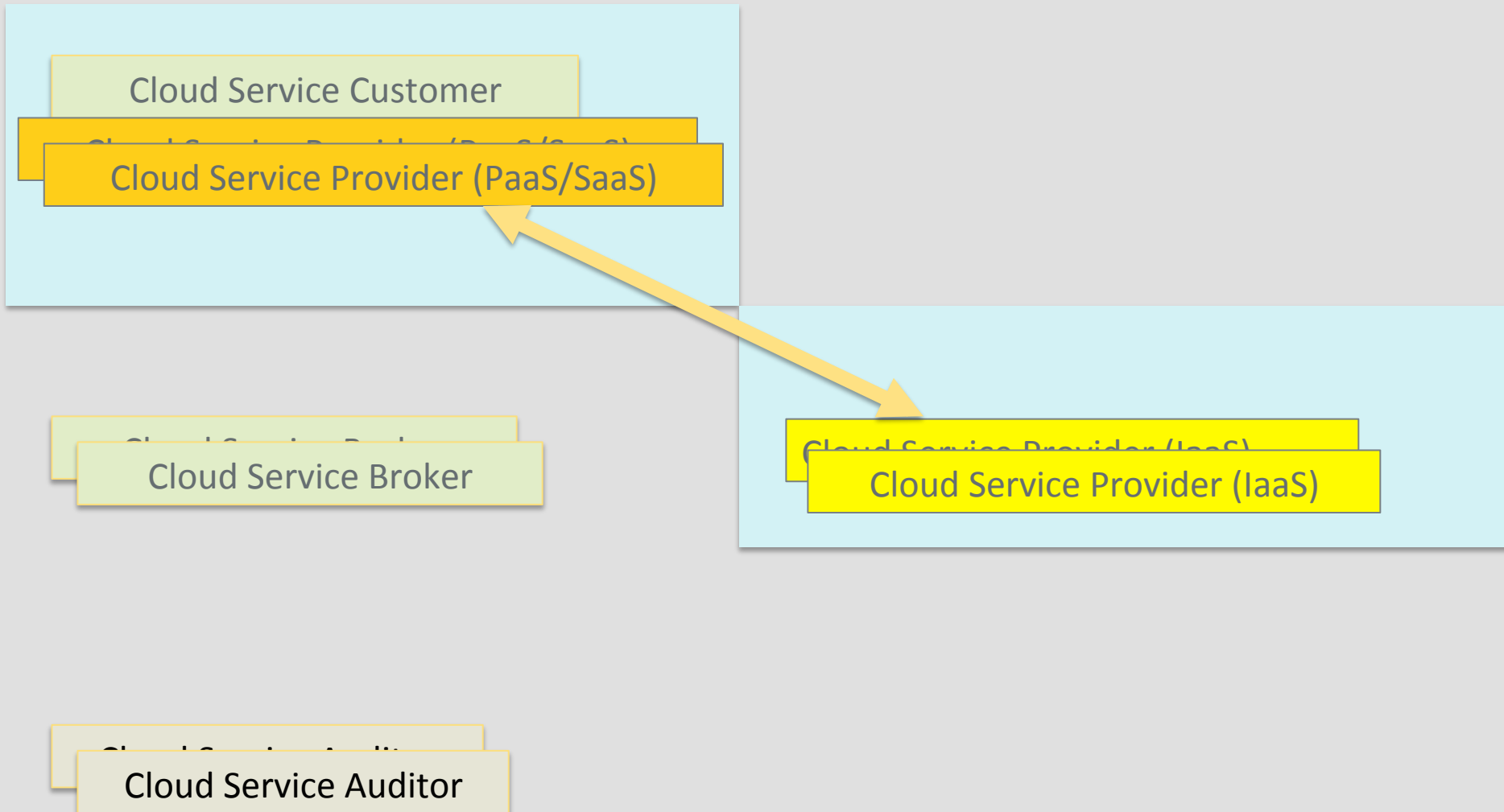


Cloud “Supply Chains” – Example 2



Cloud Service Auditor

Cloud “Supply Chains” – Example 3



Recommendations!

- Understand *Cloud*; it can be complex!
- Understand options and limitations
- Understand own processes – and be open to change to optimize and manage risks
- Examine your QS and understand its limitations – and what may need to change
 - Adequacy/appropriateness of policies and procedures
 - Qualification/validation
 - Supplier management
- Embrace automation
 - In the management of the tech stacks
 - Within the “QA functions”



Many thanks for your attendance and engagement