Cloud Framework, Terminology

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Contents

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This document has been developed by the Pharmaceutical User Software Exchange (PHUSE) Working Group on Cloud Adoption and is subject to ongoing consultation and feedback from all relevant stakeholders.

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1. Executive Summary

In adopting cloud-based solutions for GxP workloads, understanding the essential characteristics of cloud services and solutions is important for determining the applicability of GxP requirements to specific Cloud Service Providers and/ or cloud-based solution models.

This document provides terminology supporting entry into the world of cloud. It is one of three supplements to the "Cloud Services – Pre-Amble" ref 1 which all together form the "Framework for Adoption of Cloud Services in the Regulated Life Science Industry" from the Pharmaceutical User Software Exchange (PHUSE).

2. Terminology

Looking at good engineering practices, there have over time been many different terms related to Cloud services.
As such, the cloud, simply, refers to software and various IT services in one or across many data centers/facilities. Cloud computing is an evolution of online services and IT deployment models that leverages existing technologies like the Internet, service oriented architecture, virtualization, relational and non-relational databases, deployment and test automation, identity and access management, and so on.

The use of cloud services is having far-reaching effects on organizations in academia, industry, and government, and the cloud services industry is evolving and changing rapidly in terms of technological innovation as well as how various stakeholders are deploying and leveraging cloud services for the benefit of their own organizations and business models.

Owing to the rapidly evolving cloud service industry, the term "cloud" is essentially jargon and is open to many different interpretations depending on knowledge, experience and perspective. Within the PHUSE working group, we have resisted the temptation to formulate new definitions, and instead, have built our thinking - and this framework – on real life examples and case studies, identifying success, failures, benefits, and pitfalls along the way.

Having acknowledged that a common starting point for understanding cloud is needed, we have leveraged the most frequently cited definition published in September 2011 by NIST ref 3, the National Institute of Standards and Technology, a federal agency within the United States Department of Commerce.

"Cloud computing is a model for enabling ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources (e.g., networks, servers, storage, applications, and services) that can be rapidly provisioned and released with minimal management effort or service provider interaction. This cloud model is composed of five essential characteristics, three service models, and four deployment models."

The bulk of this document explains these elements of the cloud model, and the relevance to the GxPs where applicable.

2.1. Essential Characteristics of Cloud Services

Below is an interpretation of the five essential characteristics of cloud models defined by NIST ref 3.

- On-demand self-service: The ability to provision IT resources (in the form of application, platform or infrastructure capacities) without requiring human interaction is a fundamentally new paradigm for life science organizations. Traditionally, GxP system provisioning has required engagement from internal departments and/or external suppliers in order to deploy computing, storage, network, and software resources. Often, these resources were manually provisioned and tested on a case-by-case basis, requiring considerable effort and coordination across multiple stakeholders while delivery of the system often lagged behind demand. In contrast, cloud-based systems can provide the capability to signup, build, test, operate, and decommission their IT resources on demand – and, often, automatically (see rapid elasticity below). In the cloud industry today, the cloud self-service model is increasingly augmented with managed services in which the cloud provider, or a third party manager (aka, a "broker"), performs GxP activities on behalf of the consumer. In summary, this attribute allows for a Cloud Service Customer organization to operate in a more consumption-based cost model – and, in so doing, reduce its fixed costs.
- Broad network access. Although GxP systems have a history of being accessible from a variety of platforms and client types, cloud services are greatly expanding the accessibility of GxP systems by inherently supporting the use of networks, including the Internet, and standard mechanisms to promote heterogeneous use on thin and thick clients (e.g. mobile phones, tablets, laptops, workstations). For example, adding cross-platform support to a GxP file sharing application has traditionally required specialized and often redundant effort for each platform, yet now, with cloud services that use common web services and APIs across platforms, the level of effort to achieve these cross-platform capabilities can be significantly reduced.
- Resource pooling. Perhaps no other characteristic of cloud services has as much impact to interpreting GxP requirements as resource pooling. In the past, GxP users have had to purchase, commission, and manage every aspect of their IT resources, and there is a long-standing industry tradition of segregating GxP assets from non-GxP assets. Through this segregation, a lack of recognized GxP-equivalent IT standards and other factors, a paradigm has evolved where GxP practices and good IT practices are not always aligned and thus the idea of pooling and sharing IT resources across GxP and non GxP users represents new territory both from a quality assurance and compliance perspective.
- Rapid elasticity. In addition to the characteristic of being on-demand self-service, cloud services can also provide GxP users with new capabilities to dynamically provision and scale resources according to demand. Once the demand no longer requires a specific resource, users, automation, or a combination of the two can release and terminate the resource until they are required again. This form of rapid commissioning and decommissioning of resources affords reduction in the variability and level of effort in qualification/validation provided the GxP consumer has established the appropriate controls.
- Managed and measured services. Within GxP organizations today, IT resources are usually procured/managed as disparate

services in which utilization is estimated or unmonitored altogether. With cloud services, the monitoring, control, and reporting capabilities (often via contracted, external parties) can provide increased transparency, auditability, and cost controls.

2.2. Service Models

In good Laboratory, Clinical, Manufacturing and Distribution practices (GxP), a computerized system [traditionally] refers to the "..combination of [computer] hardware, infrastructure software, software applications, and associated documents (e.g. user manuals and standard operation procedures) that create, modify, maintain, archive, retrieve, or transmit digital information related to the conduct of GxP operations" ref 4.

The following graphic depicts the basic elements of an overall virtualized computer system in a "total stack" format geared toward GxP and its high-level aspects that are dealt with in this document.

	GxP Requirements
GxP Organization	IT Policies & Standards
GxP Intended Use	GxP SOPs Process Validation
COTS/Custom Software	Software Operations Software Validation Software Purchasing/ Development Supplier Assessment
OS/Application Framework/ Database Engines/Storage	Infrastructure Maintenance Infrastructure Qualification Infrastructure Purchasing
Virtual Hardware	
Hypervisor	
Physical Hardware/Networking	

Figure 1: Elements of a Virtualized GxP System

This trend toward virtualization combined with other technologies such as web services and deployment/test automation to deliver new capabilities and service models are nowadays recognized as cloud computing. With cloud-based infrastructure, this combination of technologies and cloud characteristics are used to abstract resources and controls between the self-service cloud resources (IaaS, PaaS, SaaS) and the underlying physical resources (hardware and facility).

2.2.1. Infrastructure as a Service (IaaS)

IaaS refers to infrastructure resources being provided as a cloud service model. This includes virtualized servers and network devices with scalable processing capacity and reserved bandwidth for storage and Internet access, ref 3. When IaaS is incorporated into GxP computerized systems, Cloud Service Customers retain a number of GxP responsibilities ensuring the qualification status of this infrastructure.

Cloud Service Customer	Cloud Service Provider
GXP Application	
Infrastructure Software	
Virtual Hardware	
	Infrastructure Services
	Physical Hardware
	Facility

Figure 2: Example of IaaS Responsibilities

2.2.2. Platform as a Service (PaaS)

PaaS is similar to IaaS but also includes the required services for a particular application to work. In other words, PaaS is IaaS with runtime management and software components required for a given application to work on the IaaS. In PaaS, Cloud Service Brokers and Cloud Service Providers manage the IaaS responsibilities and the virtual infrastructure, and Cloud Service Customers manage the platform and application responsibilities.

Cloud Service Customer	Cloud Service Provider
GXP Application	
Infrastructure Software	
	Virtual Hardware
	Infrastructure Services
	Physical Hardware
	Facility

Figure 3: Example of PaaS Responsibilities

2.2.3. Software as a Service (SaaS)

SaaS includes complete software applications provided as a cloud service. SaaS systems are typically accessed via a web browser and/or installed client applications. The application(s) run (and associated data is stored/processed) on PaaS/IaaS, responsibility for which shall likely rest with the SaaS Cloud Service Provider's organization (but, which, may be contracted by the SaaS Cloud Service Provider to one or more PaaS and/ or IaaS Cloud Service Brokers and/or Cloud Service Providers). SaaS Cloud Service Providers sometimes provide – in whole or in part – their own PaaS/IaaS.

Cloud Service Customer	Cloud Service Provider
GXP Application	
	Infrastructure Software
	Virtual Hardware
	Infrastructure Services
	Physical Hardware
	Facility

Figure 4: Example of SaaS Responsibilities

2.3. Deployment Models

The cloud deployment models available allow Cloud Service Customers to access the benefits of cloud computing while ensuring that it's working within the security and risk levels of the Cloud Service Customers requirements. Below is an interpretation of the four deployment models cloud defined by NIST ref 3.

2.3.1. Public Cloud

A public cloud is a publicly accessible cloud environment owned by a third-party Cloud Service Provider. The Cloud Service is provisioned for open use by the general public; many Cloud Service Customers.

Note: For GxP environments special attention should be given to 21 CFR part 11 and terms like "open" and "closed" system.

The following controls should be taken into considerations (non comprehensive list):

- Access control
  - Limiting system access
  - Authority check
  - Password controls
  - Electronic signature control
- Records
  - Accurate and complete copies of records
  - Protection of records
  - Integrity of (electronic) records
  - Electronic signature control

Since the Cloud Service Provider is responsible for the operation and maintenance of the public cloud it's essential to have appropriate insight into the architecture in the Cloud Service, to take security, data integrity and general GxP compliance issues into considerations.

2.3.2. Community Cloud

A Community cloud is a Cloud Service provisioned for exclusive use by a specific community of Cloud service Customers from organizations that have shared concerns (e.g., mission, security requirements, policy, and compliance considerations). It may be owned, managed, and operated by one or more of the Cloud Service Customers in the community, a third party, or some combination of them, and it may exist on or off premises.
As for public cloud it's essential to have appropriate insight into the architecture in the Cloud Service, to take security, data integrity and general GxP compliance issues into considerations.

2.3.3. Private Cloud

A private cloud is a Cloud Service provisioned for exclusive used by the Cloud Service Customer comprising multiple consumers (e.g., business units). It may be owned, managed, and operated by the Cloud Service Customer, a third party, or some combination of them, and it may exist on or off premises.
Many controls for computerized systems used to create, transmit or retrieve data will be possible to have under control by the Cloud Service Customer themselves.

2.3.4. Hybrid Cloud

A hybrid cloud is a Cloud Service as a composition of two or more distinct cloud deployment models (private, community, or public) that remain unique entities, but are bound together by standardized or proprietary technology that enables data and application portability.

3. Glossary

See Glossary in PHUSE, Cloud Services - A Framework for Adoption in the Regulated Life Sciences Industry, Pre Amble, Edition 4, April, 2019.

4. References

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