What are the barriers/challenges?

Ensuring adequate performance. The inherent limitations of the Internet apply to cloud computing. These performance limitations can take the form of delays caused by demand and traffic spikes, slowdowns caused by malicious traffic/attacks, and last mile performance issues, among others.

Ensuring adequate security. Most cloud-based applications involve confidential data and personal information. Therefore, one of the key challenges cloud providers have had to overcome is the perception that cloud-based services are less secure than desktop-based or in-house based services.

Ensuring basic mind-set and understanding of terminology. The cloud as a term is often understood as web-applications. It is important to appreciate that cloud computing is a model for enabling 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.

Ensuring diversified controls, roles and responsibilities. It is critical that organizations working on cloud solutions understand what their responsibilities are within each service model - client, supplier, sub-suppliers; also called the “IT Supply Chain.”

Ensuring a Quality Management System is fit for purpose. Each organization in the IT Supply Chain must have a QMS that reflects its regulatory responsibilities and the technology solutions’ capabilities.

The initial validation ensures that the solution is fit for intended use (and “inspection ready”)

- After that, both the consumer and the supplier(s)/providers must sustain this fitness for use and inspection readiness.
- The ongoing operation and maintenance of a cloud solution requires that:
  - Documentation is always up to date.
  - Roles and responsibilities maintained.
  - Agreements with suppliers/providers maintained - down the supply chain.
  - Operational controls are maintained by parties in the supply chain - and:
    - Incident and problem management.
    - Change management and change control.
    - IT quality risk management.
    - Security management.
    - Business continuity.
    - Disaster recovery management.
  - Configuration management and related configuration review.
  - Document management.
  - Supplier/provider due diligence.

Overall Regulatory Expectations

- Agencies will exercise enforcement discretion in regard to cosmetic regulations - e.g., 21 CFR Part 11.

- Agencies will continue to enforce all pre-clinical requirements, including requirements for microdropping.

- Requirements for validation:
  - Design and development reviews.
  - CHANGE MANAGEMENT.
  - Quality Assurance.
  - Change control.
  - Training.

Design and Validation of the solution:

- Supplier(s) must design and validate [their pieces of the solution] based on good engineering practices.
- The accountable consumer must validate the entire solution for its intended use.
- A risk-based approach should be used throughout the lifecycle – right along the supply chain.

Output from the working group

Ongoing development and refinement of framework

"Continuous publication"

Adopting industry practice and experience

Emerging guidelines from regulated agencies