

### Problem

#### Nowadays we have two conflicting IT Systems

- Validated GxP Programs – Set in stone
- The cloud – Constantly being updated



#### The Challenge

- One system is resistant to change
- The other system changes constantly



#### Your Problem

- Your SAS environment is moving to the cloud
- You have to keep things validated, 24/7
- You do not have the same change control
- Traditional validation will not work
- You have no extra budget or resources



#### Some Terminology:

**Cloud Computing:** Delivering IT Services over a network

**CI/CD:** Continuous innovation/Continuous development, constant system change

**CP:** Cloud provider – The people providing you with a cloud environment

**GxP:** Good {clinical/laboratory/manufacturing/etc} practice

**Qualification:** Assuring compliance with conditions / standards / requirements

**IQ/OQ/PQ:** Installation/operational/performance qualification.  
PQ is often referred to as user acceptance testing

**O/S:** The computers operating system

**On-Premises/IaaS/PaaS/SaaS:** Different levels of cloud computing solutions

**Risk:** The probability of something going wrong, it is something you want to minimise

**Risk Transfer:** Have someone else to take responsibility and manage the risk

**SLA:** Service level agreement, the committed standard of service supplied;

**SCE:** SAS computing environment

**SOPs:** Standard operating procedures, the defined processes showing how things should be done;

**Validation:** Collaborating something (your SCE) on a sound authoritative basis;

**Verification:** Establishing the reality or truth of something – what actually happens;



### Solution

#### Risk Transfer

- Let the cloud provider (CP) change control and validate the things they look after
- So things such as O/S patches, backups, security, etcetera are transferred to the CP
- These become SEP (someone else's problem)
- Get copies of their SLAs, SOPs, etc and refer to these in your validation plans and documents



#### Continuous Validation

- Automate as much as possible
- Automatically run verification scripts, processing known inputs, for all parts of your system
- Have your tests set things up and then run an actual job (or part of a job) from your **real** SCE system
- Cover everything: initializations, the inputs, file access, DB access, all intermediates stages, the results, the reports, tidying up
- Make these low volume and fast – seconds or minutes rather than hours
- Do this to a schedule  
(Every day? Every week? First thing every weekday? On platform power up? Your decision)
- Tests must verify/qualify themselves by auto-checking the results are as expected – compare today's result with what the results should be
- This also ensures your CI/CD pipeline is reliable and delivering quality functionality
- Get a simple pass or fail result and display in your dashboard
- If all results are as expected then you have:  
(re-)verified, (re-)qualified and (re-)validated your system.



#### Reality & Expectations

- In the real world there is no single “best answer” to this
- Every site and every instance will have some variation that raises challenges
- Plan your way to an acceptable solution



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