

WHY AUTOMATED UAT'S?

Reproducible

 Repeat what was done at any future time point

Traceable

 Map tests to requirements via functional spec using risk

Evidenced

 Fit for purpose by developer and user testing

MHRA / GCP

- Appropriate controls of the system are in place throughout the systems lifetime
- The <u>system is fit for purpose and performs reliably and consistently as intended</u>
- Computer Systems should be periodically evaluations to confirm that they remain in a valid state and are compliant. This should include:
 - current range of functionality
 - deviations records
 - incidents
 - problems
 - upgrade history
 - performance
 - reliability
 - security
 - validation

[14.5.1 Validation Principles. MHRA Grey Guide]

[EudraLex The Rules Governing Medicinal Products in the European Union Volume 4 Good Manufacturing Practice Medicinal Products for Human and Veterinary Use Annex 11: Computerised Systems – Equivalent to FDA 21CFR11]

TESTING



ARRANGE (SETUP)



ACT
(PERFORM ACTIONS)



ASSERT (CHECK EXPECTED RESULT)

TESTING WORKFLOW



User Requirements Specification



Functional Spec (Implementation + Risk)



Test Scripts based on risk (Collaborative)

