

Keep the Faith – Ageing Plant Compliance

Overview

- The advantages associated with legacy systems and equipment
- Using 'single source' quality management systems information to drive the system lifecycle

Overview

Can this...

do what this does...?



Biotherapies for Life™ **CSL Behring**

Audience poll

- Of your primary manufacturing systems, what is their approximate age?
 - a) Less than 7 years
 - b) 7 to 10 years
 - c) 10 to 15 years
 - d) 15 years plus

Quality Risk Management (QRM) and Lifecycle

- The application of effective QRM throughout the lifecycle of a system will drive effective strategies for managing the system
 - Leveraging initial QRM efforts to shape your preventative action tasks
 - Maintaining QRMs as systems change must be formalised

The advantages of legacy systems

Use the Validation and verification platform to...

...drive your maintenance and calibration priorities and works

...ensure the Continuous Process Verification (CPV) strategy is targeted and based on 'routine' business operations

Use mature QRM to...

...review (or establish) what's critical, providing the opportunity to formalise knowledge within your QMS

... review (or establish) CQAs and CPPs and the inherent system knowledge

With an array of data sources, legacy systems should be the best managed systems

The advantages of legacy systems

- Controlling variability should be associated with legacy systems
 - A longer inspection history will be apparent
- System simplicity
 - Less likely to have data integrity and computerised systems 'issues'
 - Increased prevalence of pneumatics

The disadvantages of legacy systems

The disadvantages of legacy systems include...

Suppliers that may no longer exist

Replacement parts and equipment procurement may require ingenuity and not always fully meet expectations

Unplanned breakdowns

An inability to synchronise with up/downstream equipment

Reduced capacity

Complacency (“we’ve always done it that way”...) and outdated equipment leading to potential increases in human error

The disadvantages of legacy systems

- Changes in regulatory expectations and mandates could expose vulnerabilities in legacy systems
- Any system must be built to comply and to fulfil its intended purpose
 - Cannot validate or risk assess a system into compliance

Managing legacy systems

Stronger reliance on people

For routine operators, detailed training plans and assessment strategies need to be developed using observed examples

For maintenance personnel, change overs may be a challenge, however there is extensive literature on applying lean methodologies to change overs

Formalising knowledge will provide opportunities to use technology, for example filming critical operations to supplement training

Maintaining regulatory requirements

This is a challenge to any type of system and the proposed updates to Annex 1 will demand more QRM efforts

What is the tipping point regarding the viability of legacy systems?

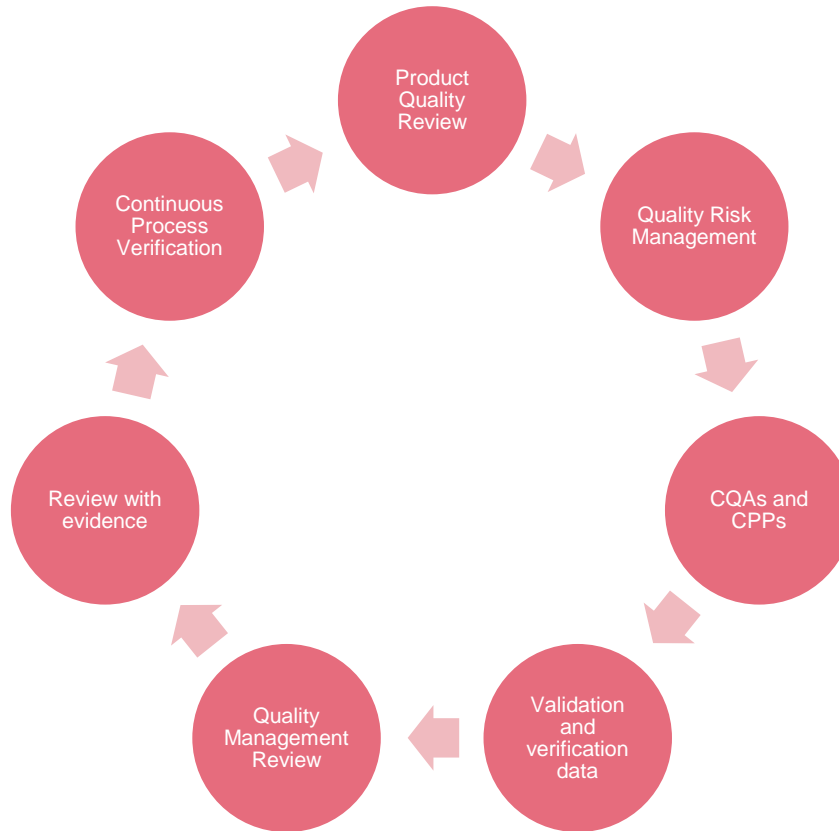
Audience poll

- By dollar value, how much do you anticipate spending to replace major infrastructure within manufacturing facilities?
 - a) Less than \$1M
 - b) \$1M to \$5M
 - c) Greater than \$5M

The springboard to the next generation

- Experience can be a powerful ‘teacher’ and motivator
 - Reviews with evidence can play a significant part in the planning phase for your next project, while potentially fulfilling an existing compliance requirement
- Consider different ways to learn and acquire knowledge

Using quality metrics and data to maximum effect



Conclusion

- With so many competing forces and instability in world economies, maximising the value from any manufacturing system is critical
- Quality and manufacturing metrics, already established in your business, can serve multiple purposes and provide comprehensive multivariate analysis of legacy systems

Thank you for listening and contributing

John Montalto

Director Quality Management Systems, CSL Behring

John.montalto@cslbehring.com.au