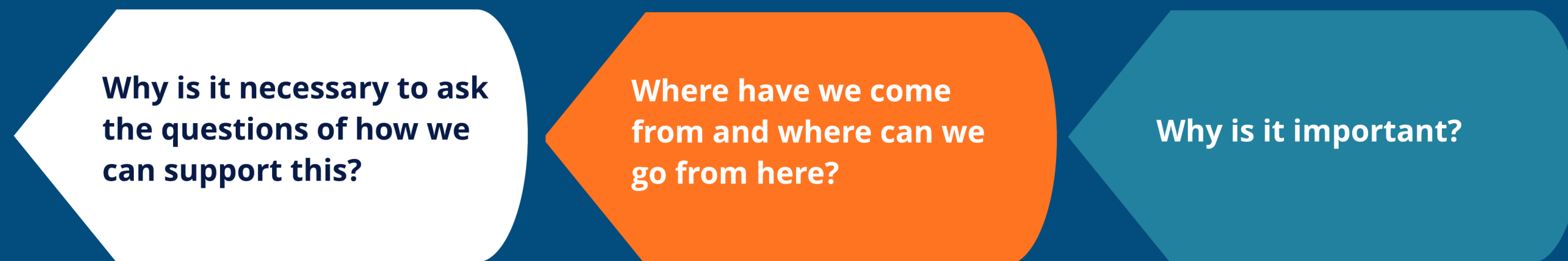


The Role of Continuous Improvement in Quality & Compliance

By Shona Ross, Head of Quality Assurance

Quality has an important role to play in the in-life and post activity assurance of compliance but how can we balance independence and the important supporting role QA can play in delivering continuous improvement to the business?



PUSH TO DEMONSTRATE CONTINUOUS IMPROVEMENT IN ALL QUALITY SYSTEMS

Many people believe it's not required for GLP...

The purpose of these Principles of Good Laboratory Practice is to promote the development of quality test data (OECD Principles of GLP - 1998)

One of the fundamental purposes of the Principles of Good Laboratory Practice (GLP) is to ensure the quality and integrity of test data related to non-clinical safety studies (Doc 22 - 2021)

If we're not keeping on top of improvements, how can we say we are following GLP?

The Past

What used to be the approach to Quality and Compliance

Historical Remediation - SD

Fix that one problem

Access impact on study

No specific requirement to learn

Resolve and move on

Issue Orientated

Fix that one problem

Separate process for corrective and preventative actions

Major problems

Effectiveness checks not called out

Repeats picked up in trending

The Present

Where are we now - what role can QA play



CCAPA - CI

Correction

- Remit of responsible person to decide
 - Do QA have to accept / agree / review
 - Is there an option for discussion
 - Is there a review of action completion

Corrective Actions

- Who decides if required
 - Who decides what's appropriate
 - Do QA have to accept / agree / review
 - Is there an option for discussion
 - Is there a review of action completion

Preventive Actions

- If it's a near miss or an extrapolation
- Who identifies the necessary stakeholders

Effectiveness checks

- Who decides what this looks like
- Who decides when to check
- Who decides who checks and where this is recorded
 - Do QA check, do QA check the check is done

The Future

Where are we headed

QA can add value to all CCAPA steps

Does this compromise our independence?

Can we afford to separate out audit from improvement?

If we separate, do we lose some of that experience?

Either way, can we afford not to support remediation and improvement

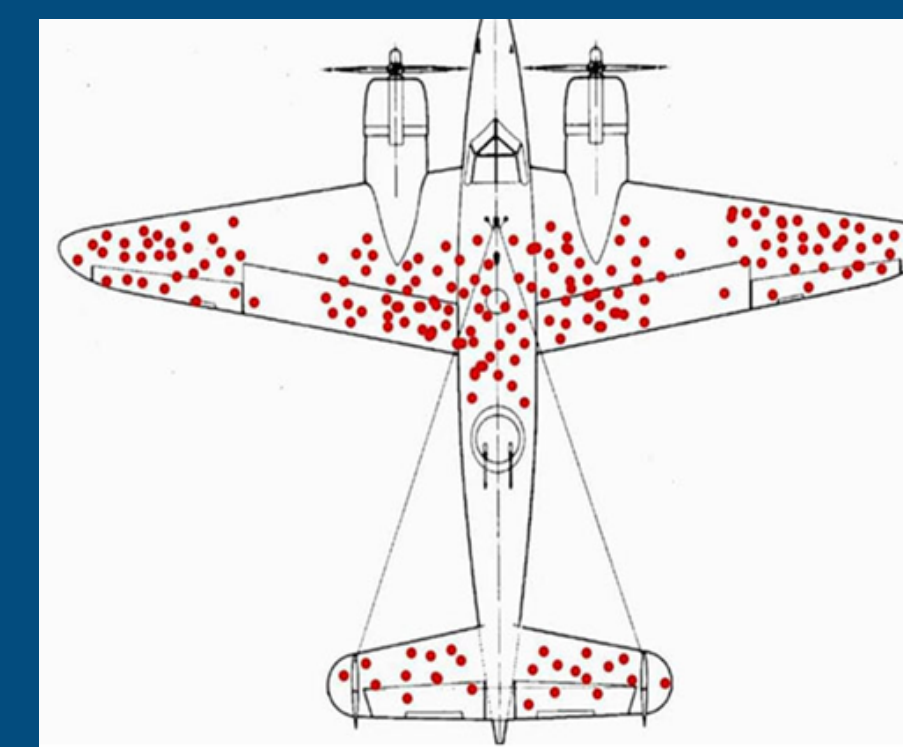
What can QA bring?

Leverage:

- Wide range of experience
- Exposure to client and regulatory
- Pool knowledge of issues, and success (or lack of success) of solutions
- Different approaches for resolution

Be careful

- Too many cooks spoil the broth
- Identifying true root cause
- Tunnel vision



FINAL THOUGHTS...

Why are external views important?

Map of bullet holes on returned WWII planes
Proposal 1; reinforce those areas marked as clearly targeted

Proposal 2; reinforce those areas not marked as those planes did not return...