

Is your company in a state of control?

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A recent survey by international Regulatory Agencies suggests that your Company may not be. The survey indicated:

1. No significant differences in types of deficiencies across countries.
2. Companies are:
 - Over confident on current systems
 - Reactive rather than proactive
 - Operating facilities no longer 'fit for purpose'
 - Lacking focus on creating a culture of quality
 - Failing to attract or develop an appropriate level of expertise

What does this mean to you?

International regulatory agencies are sharing information with increased harmonization and significantly improving their ability to look across the full supply chain. The agencies are asking 'If companies consider themselves to be operating in a 'state of control' and applying cGMP, why are we still finding:

- The same, recurrent/repeated deficiencies over time?
- Increasing numbers of citations, warning letters, regulatory actions?
- Increasing numbers of recalls?
- Increasing cases of lack of data integrity

Why is this happening?

Fundamentally the problem is one of communication and leadership. Management does not appear to be addressing issues promptly and often fail to see the significance of what their trend data is telling them. Decisions are being made without all the necessary data, knowledge or experience that will lead to predictable outcomes.

What can your company do?

- Recognize and accept that, most likely, your company does have a problem.
- Perform a risk management assessment of your entire internal and external supply chain
- Learn from others and take action to improve.

Biography

Brian Hill is the president and senior managing partner at Brian Hill & Associates, a business and technical consultant company providing a wide range of specialized services to the Pharmaceutical and Life Science industries. He is a seasoned professional and entrepreneur with over 30 years experience in the pharmaceutical industry. Over this time he gained expert knowledge of leadership, the design of quality systems and the interdependencies of business, operations, quality and the supply chain. He has worked with many companies in US, Canada and Europe and has an excellent understanding of global cGMP requirements, current regulatory direction and trends.

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