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Is your company in a state of control?

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Abstract

Recent trend data collected by Regulatory Agencies of various countries suggests that *your* Company may not be. In a survey performed by international regulatory agencies as members of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) findings were indicating that many 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
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Quality Systems along with *Operations* took the #1 and #2 spots for the most severe deficiencies. Whilst, Design and maintenance of facilities ranked #3

The PIC/S survey concluded that there was:

1. A correlation between the most frequent GMP deficiency classes and the most severe GMP deficiencies within those classes.
2. No significant differences in the types of deficiencies cited among member country regions.
3. Based on the agency findings, having good procedures and a Quality System by themselves does not appear to be enough. It is clear that companies must also have a culture of quality that demonstrates an ability to apply cGMP on a continual basis.