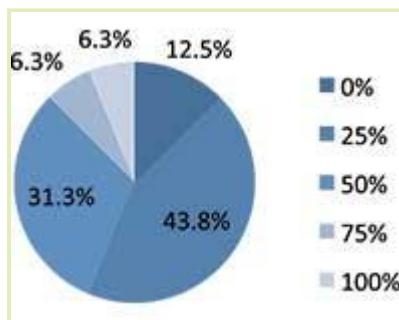


Improved Utilization of Self-Inspection Programs within the GMP Environment—A Quality Risk Management Approach

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An interview with a senior GMP inspector at the Irish Medicines Board (IMB) published in the *Journal of GXP Compliance* (3) identifies some of the issues with current self-inspection programs of pharmaceutical manufacturing companies. A major issue discussed was that significant and critical deficiencies observed during regulatory inspections were not identified and corrected by the companies themselves via their own self-inspection programs. This could be due to the fact that for many companies self-inspection comprises little more than a review of compliance with current standard operating...

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