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# Integrating Risk Management into Computer System Validation

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The last decade has brought about a number of changes to how pharmaceutical companies address validation. These changes have been brought about primarily by regulatory changes and the economy. Rather than focusing on the "documented evidence" aspect of validation, companies and regulators are switching the focus to "where is the biggest risk" and managing thusly. In 2005, the International Conference on Harmonization (ICH) issued ICH Q9 *Quality Risk Management* and followed it up with ICH Q10 *Quality Management Systems* (2). These two documents along with ICH Q8 *Pharmaceutical Development* set the stage for using a risk-based approach to validation. In 2011, the European Commission revised Annex 11 to the European Union (EU) Good Manufacturing Practices (GMPs) to increase the focus on risk. The shift in focus to use of a risk-based approach and management responsibility should result in more appropriate validation efforts rather than "paperwork."

GXP: Maintaining the Validated State in Computer Systems
VIDEO: Periodic Review of Validated Systems