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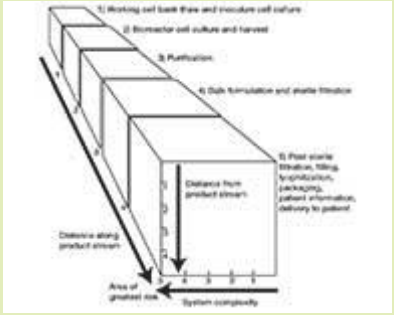
Risk Management for Aseptic Processing

By **Ed White May 21, 2013 2:11 pm EDT**



The following key points are discussed in this article:

- Aseptic processing is inherently risky. An effective risk management program can help to reduce risk while reducing wasted effort.
- Aseptic processing involves manipulation of sterile components in a carefully controlled environment using careful techniques to produce a sterile product
- Aseptic processing presents a high risk because the lack of post-processing sterilization increases the risk of non-sterility, and because the severity of the lack of sterility in a parenteral product is extremely high
- The quality risk management process is defined by the International Conference on Harmonisation's (ICH) *Q9*. It can be divided into four steps: Risk assessment, risk control, risk communication, and risk review.
- Risk assessment should be performed by a team of qualified experts
- Some of the more popular methods of risk assessment include failure mode and effects analysis (FMEA), fault tree analysis, and hazard analysis and critical control points (HACCP)
- Risk control consists of reducing risk or accepting risk. A formal risk control plan may be the output of a risk control plan as part of risk communication.
- Risk review should be performed on a periodic basis as part of the quality management process
- Risk assessment is used in processing to determine project activities to reduce the risk level. If reduction is not possible, there should be additional in-process controls, additional testing, and additional training to mitigate risk.
- Risk assessment is used in validation to determine high-risk processes. There should be proportionately increased sampling, testing, or more rigorous acceptance criteria to provide greater assurance of process acceptability.