

Risk Management and the Combination Product Testing Strategy

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Abstract

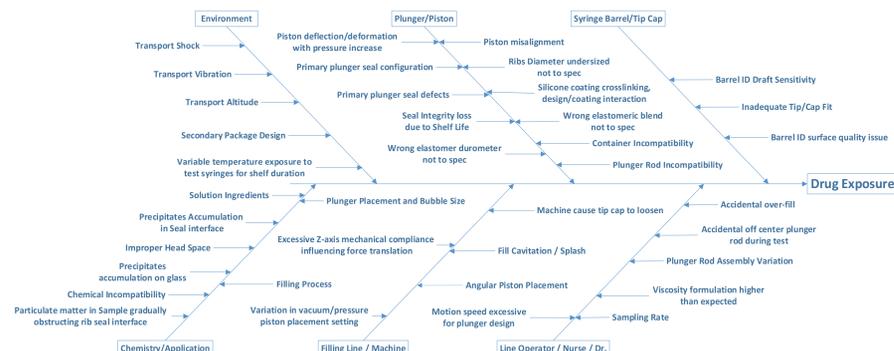
Understanding combination product risks from the start is critical. Components are often sourced at opposite ends of the globe and are proven to be robust due to investments in research, development and testing. It is essential to have an equal and complete understanding of all components where they come together at the interfaces where the risks are hidden. Understanding the essential performance of the combination product at all stages is a win-win for the patient and all stakeholders within the supply chain.

Design Feasibility Assessment Preceding Formal Development

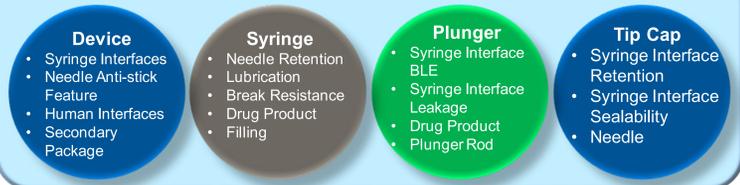
There are inherent benefits in having freedom to explore concept design feasibility prior to formal development.

- Rigorous early concept testing roots out weaknesses before design or drug formulation completion
- Project timelines are difficult to rework when problems arise
- Project budgets are fixed and leave no room for design iteration
- Molds and tooling are expensive and long lead time and rework due to issues discovered late will impact opportunity costs
- Thoroughly challenge and understand concepts to reduce time to market, reduce patient risk and reduce opportunity costs.
- The cost of a recall can harm patients, damage reputation and can permanently damage the well being of a corporation.

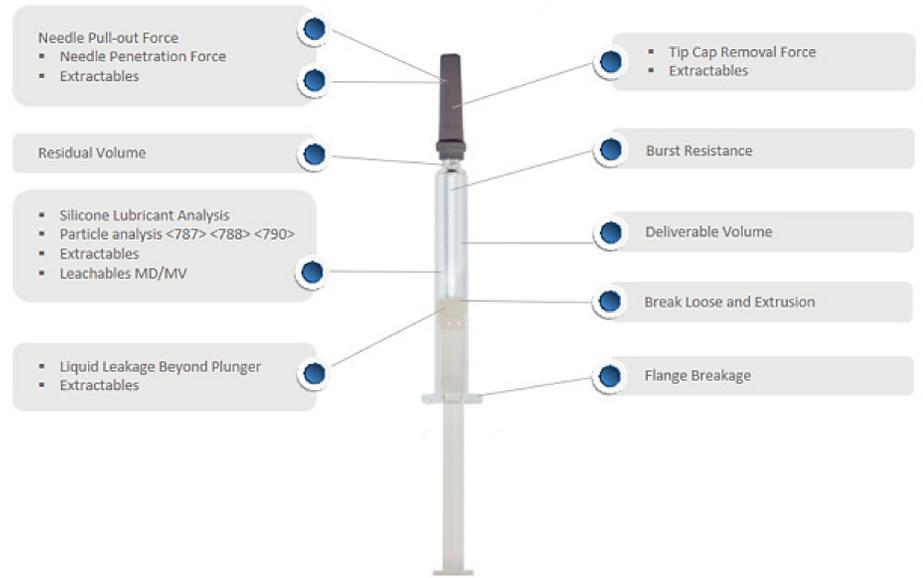
Component Interfaces Risks Mapping



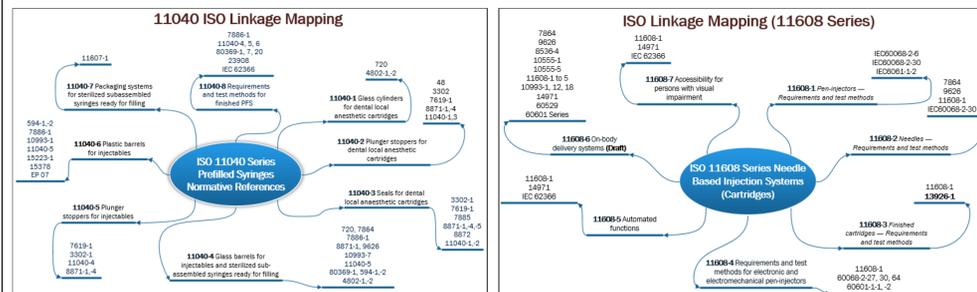
Combination Product Critical Physical Interface Considerations



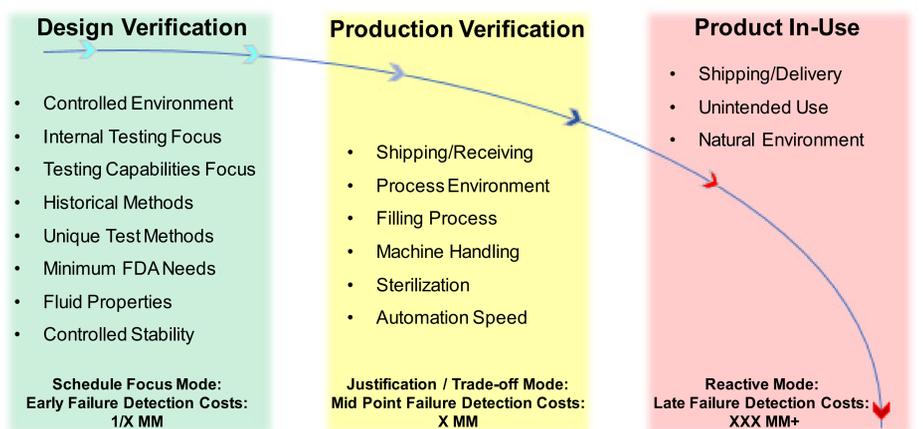
Thinking Beyond the Component



ISO Standards Mapping 11040 and 11608



Unknown Risks Performance Degradation Curve



Critical Risk Management Success Factors

- Drives design, process improvements and testing strategy
- Assessments performed very early at concept selection
- Includes higher level component interactions and simulations
- Clarifies and drives actions and design/process controls needs
- Living documents from concept through product lifecycle
- Critical input to the design verification and validation plans
- Contains past field failures lessons learned
- Gets to root-cause and is a knowledge center

For More Information, Visit: www.westpharma.com/knowledgecenter

or

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