CAN A PLATFORM APPROACH FOR PACKAGING OR DELIVERY BE USED AND STILL MEET REGULATORY EXPECTATIONS?

YES

Characterizing and using a packaging or delivery system platform may help to accelerate drug development programs.

- Similar branding
- Common understanding across platforms
- Fewer incoming components and suppliers to manage
- Leverage historic baseline knowledge/data

CHALLENGE

Must still prove the package/combination product system meets the specific drug/patient needs.

SOLUTION

- Acquire generic, non-molecule specific design verification testing and other supportive technical knowledge about the package and device.
- A summary of the relevant data for those aspects of the device which pertain to the "platform" should be presented. Suitability with regards to specific drug products and subsets of the target patient population should be demonstrated.*
- Develop a process for lifecycle management updates as changes to the platform occur.

LIFECYCLE MANAGEMENT

- Same drug can expand the labeling of approved medicines to new indications.
- The process to justify the new indications is established from a clinical perspective.
- For a combination product the indication is a relevant design input. An assessment of the Design History File and impact of changes and risks are to be evaluated and documented.

Simplify the Journey™ with a combination product solution.
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* Source: European Medicines Agency Guideline on the Quality Requirements for Drug-Device Combinations; Section 4.3., May 2019

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