FRESENIUS KABI

Post Approval Changes for Peptides

Regulatory expectations and lifecycle management

Chaoju Xiao, Ph.D.,

Director, Formulation

Research &Development, Fresenius Kabi USA

The views expressed in this discussion should not be interpreted as unique or specific to Fresenius Kabi.

© 2026 by Fresenius Kabi USA, LLC



Overview

01 Common Post-approval Changes

02 Scientific and Regulatory Challenges

03 Lifecycle management Considerations

Common Post Approval Changes

- Specification update
- Analytical test method change
- Alternate API source
- Container/Closure System or supplier change
- Product manufacturing process change
- Product manufacturing site transfer

© 2026 by Fresenius Kabi USA, LLC

Scientific and Regulatory Challenges

- Addressing gaps when applying general post-approval framework for peptides with complex structural and functional attributes.
- Selecting the appropriate filing category.
- Defining a science- and risk-based scope for comparative re-characterization or In vitro release test (IVRT) in case of oral dosage.
- Establishing how many batches to assess for each product or strength.
- Integrating the peptide specific requirements into efficient, robust lifecycle management.

© 2026 by Fresenius Kabi USA, LLC

Peptide Lifecycle Management Considerations

- Review/update product specifications of the approved peptide products to align with the updated PSG for a more robust product quality control.
- Identify critical peptide attributes potentially impacted by the post approval changes through a science-based risk assessment:

  e.g. Higher order structure, Aggregation, Bioactivity.
- Tailor comparative re-characterization to the attributes at risk.
- Seek FDA advice early on proposed changes and the supporting rationale.

© 2026 by Fresenius Kabi USA, LLC

THANK YOU!

- Special Thanks to my colleague

  Deepali Vartak

- Fresenius Kabi R&D and US colleagues
- Members in the breakout session discussions

© 2026 by Fresenius Kabi USA, LLC