Immunogenicity risk of biosimilars and peptides – an industry perspective

GRx and Biosims, 27 Oct 2025

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Enabling Affordable Access to Lifesaving Biosimilars, Worldwide

Biocon Biologics has acquired the global biosimilars business of Viatris to become a unique, fully integrated, leading global biosimilars player.

Immunogenicity of biosimilars and generic peptides

Key risks and common mitigation strategies

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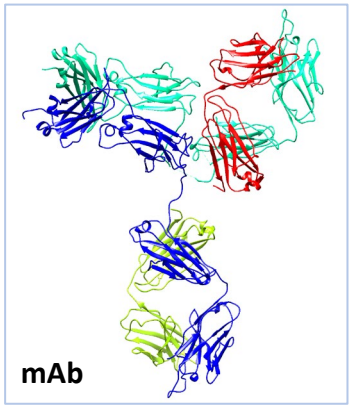
- Immunogenicity risk assessment is an inherent part of biopharmaceutical development
- For the generic/biosimilar industry, AA sequence related immunogenicity, does not exist


mAb

Biosimilars – Risks and mitigation

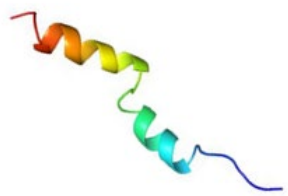
- ✓ Expression host change
- ✓ Unique manufacturing process
- ✓ Alternate formulations, new excipients
- ✓ Differences in protein aggregates and PTMs
- ✓ Host cell proteins (HCPs)

- ✓ Detailed critical risk ranking
- ✓ Extensive analytical comparability
- ✓ Science-based justification of residual uncertainty
- ✓ Head-to-head comparative clinical trials
- ✓ Sensitive bioanalytical assays for anti-drug antibodies
- ✓ Post-market safety surveillance

Generic peptides – Risks and mitigation

- ✓ Process differences
  - recombinant Vs synthetic
- ✓ Synthetic impurities during chemical synthesis

- ✓ Risk assessment of unique impurities
- ✓ Scientific/empirical justification of unique impurities
- ✓ Orthogonal non-clinical assessment
  - in-silico analysis of substitutions, truncations
  - in-vitro assays
- ✓ Model Master Files (MMF) submission to FDA


peptide

Extensive development experience and clinical history have reduced the risk of immunogenicity

Challenges and opportunities

Despite their differences, both industries face a common set of challenges

- ✓ Technical limitations – lack of universally standardized positive and negative controls and obtaining fresh, high-quality human immune cells
- ✓ Correlation of predictive tools and in-vitro assays with clinical outcomes
- ✓ Evolving regulatory landscape requires manufacturers to be flexible and adaptive, increasing the cost and timeline of development

How the CES waiver impacts immunogenicity risk

- ✓ Immunogenicity risk assessment becomes a central component of the analytical similarity with more emphasis on a science-based approach to justify residual uncertainty and process related impurities
- ✓ Highly sensitive and drug-tolerant assays to detect and characterize anti-drug antibodies (ADAs) during Phase 1 studies with continued post-marketing surveillance
- ✓ Morphing of the Phase 1 to an abbreviated Phase 3 study with the requirement of long term immunogenicity assessment and multi-dose study

Paradigm shift from requiring Phase 3 trials by default to justifying their necessity

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