Hypersensitivity risks in biopharmaceutical development

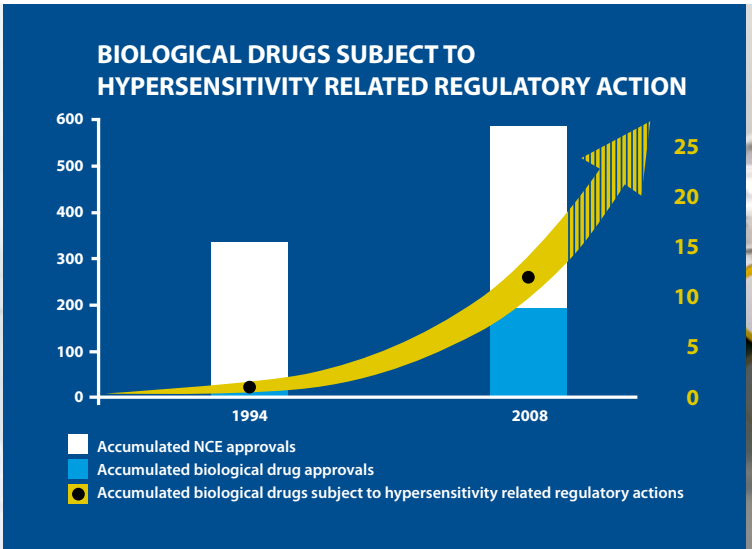
Phadia
Setting the Standard

All proteins are potentially immunogenic

The growing number of biological drugs in clinical development is presenting new testing challenges for their manufacturers. As all proteins are potentially immunogenic, the risk that they may induce an unwanted product-related immune response is ever present. The most severe immune response, acute anaphylactic reaction, may be fatal to the patient. What's more, patient and disease-related factors plus process-related impurities also increase the risk of a serious adverse reaction.

Need for better monitoring

The potential severity of the medical consequences, plus the biological complexity of the immunogenic risk, has prompted regulatory authorities to act. They now issue recommendations for performing a systematic immunogenicity assessment from a marketing authorization perspective. Assessing hypersensitivity is thus an increasingly important factor when seeking regulatory approval for a new biologic.



Key questions about the risks of hypersensitivity

Developers of new biologics need to address a number of important questions relating to hypersensitivity and the risk factors that accompany it.
These questions include:

- **How do I know that this protein is not allergenic?**
- **How do I test for allergenicity during a clinical trial?**
- **How do I ensure that this drug will not cause allergic reactions post-market?**

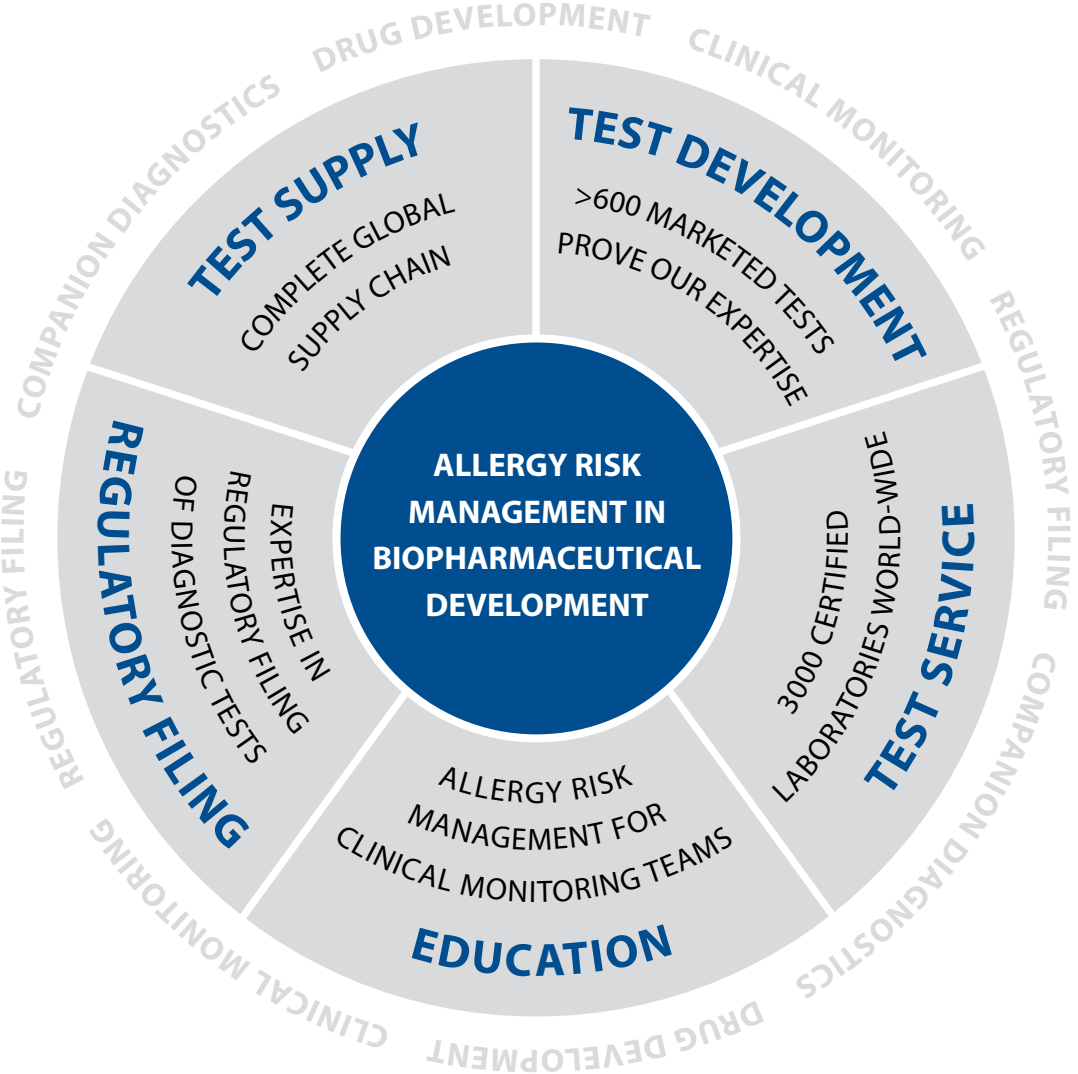
Great performance and risk management go hand in hand

Sensitive *in vitro* IgE tests will assess IgE levels before allergenic reactions occur, alerting developers to potential risks and thereby helping manage them. Phadia is the world-leader in allergy testing with a 75 % market share. Our allergy tests are the most sensitive on the market and our experience is unrivalled. With more than 40 years of R&D in allergy pathology and assay development combined with manufacturing and a complete supply chain, Phadia is your ideal partner during drug development.

Challenges

- Must distinguish between an infusion reaction and anaphylaxis due to the very different clinical consequences
- Pre-sensitization caused by previous exposure to similar or related proteins
- Therapeutic proteins used for long-term, intermittent treatment
- Therapeutic proteins used for substitution of an endogenous protein
- Product-related factors influence immunogenicity
- Process-related impurities present





Your partner in allergy risk management and immunogenicity testing

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