

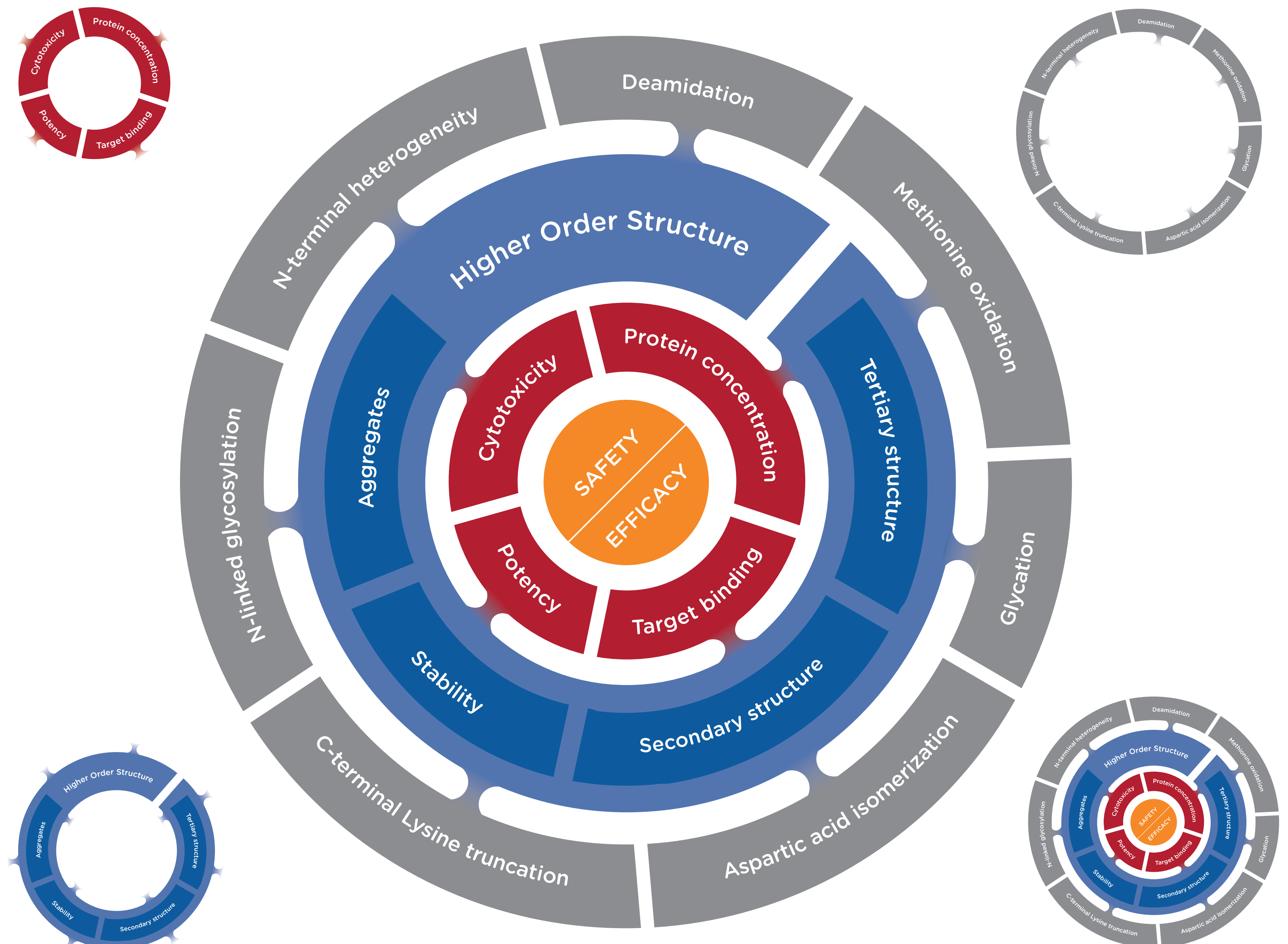
TARGETING HOS IN BIOTHERAPEUTIC DEVELOPMENT

1 Highest risk CQAs impact directly on Safety and Efficacy

- Biopharma use a standardized science-/risk-based approach to ensure product **safety** and **efficacy**.
- **Critical quality attributes** (CQAs) are product characteristics that must be controlled to ensure safety and efficacy.

2 CQAs impact on Structure and Function

- The structure-function relationship is a central concept in protein science.
- The function of a protein is a consequence of its shape or structure.
- Risks associated with CQAs are best understood when impact on both **structure** and **function** is known.



3 HOS: CQA and measure of CQAs

- CQAs relating to **higher order structure** are required because **structural changes** lead to **functional changes**.
- **Higher order structure** is also important for understanding risk associated with other CQAs. Example: risk associated with asparagine deamidation is best understood by determining impact on both **structure** and **function**.

4 Regulatory agencies demand rigorous approaches

- Regulatory agencies require use of **latest technology** and **orthogonal** approaches
- Biosimilar developers are expected to use appropriate **statistics** for objective decision making.

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Orthogonal approach: assess structure with far- and near-UV circular dichroism, absorbance and fluorescence

Walk-away time: increased productivity and flexible working

Robust decision making: precision across multiple samples and statistical validation

Compliance: stay ahead of evolving regulatory expectations

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Near-UV CD | Absorbance | Fluorescence | Protein Stability | Fast HDX | Far-UV CD

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