Immunogenicity Risk Factors:

- Immune competency
- Underlying disease/s
- Concurrent medication

- Dose
- Route
- Regimen

- Age
- Gender
- Race
- Genetics (MHC)

- Homology to self/sequence
- Concentration of endogenous protein
- Post-translational modifications
- Product related impurities

- Degree of existing tolerance

- Product & process related factors
  - Aggregates
  - Process related impurities
  - Contaminants
  - Excipients
  - Leachables

- Adjuvants

- Product-specific activity
  - Products that are immune modulatory

- Immune status

- Treatment related

- Patient & treatment related factors

- Patient