novel analytical approaches to characterize particles in biopharmaceuticals

Grabarek, A.D.

1. *Whether an analytical technique is suitable depends on the specifics of the application.*
   - Chapter 2
2. *The type of protein and the nature of the stress will impact the formation of aggregates, which in turn will affect their immunogenicity profile.*
   - Chapter 4
3. *The most frequent factor impacting protein stability during processing, transportation and handling is mechanical stress.*
   - Chapter 7
4. *Cell-based medicinal products comprise living particles, which are much more vulnerable to stress compared to other active pharmaceutical ingredients.*
   - Chapter 7
5. *Quality of pharmaceutical products should be achieved through thoughtful design rather than by trial and error.*
   - Adapted from ICH guideline Q8 (R2) on pharmaceutical development
6. *Development of biologics should move from a step by step approach to a comprehensive design process uniting multiple product characteristics.*
   - Adapted from Narayanan et al., 2021
7. *Understanding the discrepancies between orthogonal measurement outcomes will allow for better product characterization.*
   - Adapted from Cavicchi et al., 2020
8. *Advanced therapeutic medicinal products are a "mixed bag" of novel biologics, in contrast to the well-defined therapeutic proteins.*
   - Adapted from Crommelin et al., 2019
9. *The development process is of more value than the end result.*
   - Adapted from Michelangelo Buonarroti
10. *We learn by listening.*
    - Adapted from Epictetus
11. Question everything, but dose well to which extend or degree you question it.
    - Georg Schuster