

## novel analytical approaches to characterize particles in biopharmaceuticals

Grabarek, A.D.

## Citation

Grabarek, A. D. (2021, October 21). *novel analytical approaches to characterize particles in biopharmaceuticals*. Retrieved from https://hdl.handle.net/1887/3217865

Version:	Publisher's Version
License:	<u>Licence agreement concerning inclusion of doctoral</u> <u>thesis in the Institutional Repository of the University</u> <u>of Leiden</u>
Downloaded from:	https://hdl.handle.net/1887/3217865

**Note:** To cite this publication please use the final published version (if applicable).

- 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