

Pharmaceutical aspects of subvisible particles in protein formulations Weinbuch, D.

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Propositions

accompanying the PhD thesis:

Pharmaceutical Aspects of Subvisible Particles in Protein Formulations

Daniel Weinbuch

- 1. When a measurement system detects no subvisible particles, this does not mean that they are not there. (this thesis)
- 2. Systems that measure particles in the same size range, even when using the same measurement principle, do not necessarily deliver the same results. (this thesis)
- 3. Signals larger than the monomeric protein detected by light scattering based-techniques are not necessarily caused by protein aggregates. (this thesis)
- 4. Impurities in stabilizing excipients can have destabilizing effects on a therapeutic protein. (this thesis)
- 5. The density of subvisible protein particles is lower than previously estimated and more affected by the type of protein than by the stress condition. (Folzer et al. J Pharm Sci 2015, 104(12))
- 6. Interfaces, rather than shear forces, promote the formation of subvisible protein particles during mechanical stress. (Sediq et al. J Pharm Sci 2016, 105(2))
- Subvisible particles detected by flow-imaging microscopy that show a protein particlelike morphology are not necessarily proteinaceous. (Siska et al. J Pharm Sci 2015, 104(2))
- 8. Our lack of understanding the influence of certain aggregate/particle properties on immunogenicity is largely due to limited analytical capabilities. (Moussa et al. J Pharm Sci 2016, 105(2))
- 9. The difference between a master and a beginner is that the master has failed more often. (Stephen McCranie)
- Write down notes for yourself just as you would write them down for someone else.
 (Sarah Zölls)
- 11. A Frisbee is the evolution of the ball.
- 12. The real voyage of discovery consists not in seeking new landscapes, but in having new eyes. (Marcel Proust)