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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))

7. Subvisible particles detected by flow-imaging microscopy that show a protein particle-like 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)

10. 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)