

July 2024

# List of Publications

PD Dr. phil. nat. Andrea Allmendinger

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## Research Articles (peer-reviewed) \* *corresponding author*

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- 1 Antiprotozoal, antimycobacterial and cytotoxic potential of twenty-three British and Irish red algae.  
**Allmendinger A**, Spavieri J, Kaiser M, Casey R, Hingley-Wilson S, Lalvani A, Guiry M, Blunden G, Tasdemir D.  
Phytother Res. **2010** Jul;24(7):1099-103. doi: 10.1002/ptr.3094. [PMID:20077438](#)
- 2 Antimycobacterial, antiprotozoal and cytotoxic potential of twenty-one brown algae (Phaeophyceae) from British and Irish waters.  
Spavieri J, **Allmendinger A**, Kaiser M, Casey R, Hingley-Wilson S, Lalvani A, Guiry MD, Blunden G, Tasdemir D.  
Phytother Res. **2010** Nov;24(11):1724-9. doi: 10.1002/ptr.3208. [PMID:20564461](#)
- 3 Antiprotozoal, antitubercular and cytotoxic potential of cyanobacterial (blue-green algal) extracts from Ireland.  
Broniatowska B, **Allmendinger A**, Kaiser M, Montamat-Sicotte D, Hingley-Wilson S, Lalvani A, Guiry M, Blunden G, Tasdemir D.  
Nat Prod Commun. **2011** May;6(5):689-94. [PMID:21615033](#)
- 4 Assessment of dual life stage antiplasmodial activity of british seaweeds.  
Spavieri J, **Allmendinger A**, Kaiser M, Itoe MA, Blunden G, Mota MM, Tasdemir D.  
Mar Drugs. **2013** Oct;11(10):4019-34. doi: 10.3390/md11104019. [PMID:24152562](#)
- 5 Rheological characterization and injection forces of concentrated protein formulations: an alternative predictive model for non-Newtonian solutions.  
**Allmendinger A**, Fischer S, Huwyler J, Mahler HC, Schwarb E, Zarraga IE, Mueller R.  
Eur J Pharm Biopharm. **2014** Jul;87(2):318-28. doi: 10.1016/j.ejpb.2014.01.009. [PMID:24560966](#)
- 6 High-throughput viscosity measurement using capillary electrophoresis instrumentation and its application to protein formulation.  
**Allmendinger A**, Dieu LH, Fischer S, Mueller R, Mahler HC, Huwyler J.  
J Pharm Biomed Anal. **2014** Oct;99:51-8. doi: 10.1016/j.jpba.2014.07.005. [PMID:25077704](#)
- 7 Measuring tissue back-pressure – in vivo injection forces during subcutaneous injection.  
**Allmendinger A**, Mueller R, Schwarb E, Chipperfield M, Huwyler J, Mahler HC, Fischer S.  
Pharm Res. **2015** Jul;32(7):2229-40. doi: 10.1007/s11095-014-1611-0. [PMID:25537343](#)
- 8 Sterile Filtration of Highly Concentrated Protein Formulations: Impact of Protein Concentration, Formulation Composition, and Filter Material.  
**Allmendinger A**, Mueller R, Huwyler J, Mahler HC, Fischer S.  
J Pharm Sci. **2015** Oct;104(10):3319-29. doi: 10.1002/jps.24561. [PMID:26149748](#)

- 9 Solid-State Hydrogen-Deuterium Exchange Mass Spectrometry: Correlation of Deuterium Uptake and Long-Term Stability of Lyophilized Monoclonal Antibody Formulations. Moorthy BS, Zarraga IE, Kumar L, Walters BT, Goldbach P, Topp EM, **Allmendinger A\***. *Mol Pharm*. 2018 Jan;15(1):1-11. doi: 10.1021/acs.molpharmaceut.7b00504. [PMID:29182876](#)
- 10 Evaluation of Glass Delamination Risk in Pharmaceutical 10 mL/10R Vials. Ditter D, Nieto A, Mahler HC, Roehl H, Wahl M, Huwyler J, **Allmendinger A\***. *J Pharm Sci*. 2018 Feb;107(2):624-637. doi: 10.1016/j.xphs.2017.09.016. [PMID:28989023](#)
- 11 Characterization of surface properties of glass vials used as primary packaging material for parenterals. Ditter D, Mahler HC, Roehl H, Wahl M, Huwyler J, Nieto A, **Allmendinger A\***. *Eur J Pharm Biopharm*. 2018 Apr;125:58-67. doi: 10.1016/j.ejpb.2017.12.018. [PMID:29331438](#)
- 12 Impact of Vial Washing and Depyrogenation on Surface Properties and Delamination Risk of Glass Vials. Ditter D, Mahler HC, Gohlke L, Nieto A, Roehl H, Huwyler J, Wahl M, **Allmendinger A\***. *Pharm Res*. 2018 May;35(7):146. doi: 10.1007/s11095-018-2421-6. [PMID:29796727](#)
- 13 Imaging Techniques to Characterize Cake Appearance of Freeze-Dried Products. Haeuser C, Goldbach P, Huwyler J, Friess W, **Allmendinger A\***. *J Pharm Sci*. 2018 Nov;107(11):2810-2822. doi: 10.1016/j.xphs.2018.06.025. [PMID: 30005985](#)
- 14 Be Aggressive! Amorphous Excipients Enabling Single-Step Freeze-Drying of Monoclonal Antibody Formulations. Haeuser C, Goldbach P, Huwyler J, Friess W, **Allmendinger A\***. *Pharmaceutics*. 2019 Nov;11(11):616. doi: 10.3390/pharmaceutics11110616. [PMID: 31744221](#)
- 15 Optimizing the Formulation and Lyophilization Process for a Fragment Antigen Binding (Fab) Protein Using Solid-State Hydrogen-Deuterium Exchange Mass Spectrometry. Kumar L, Chandrababu KB, Balakrishnan SM, **Allmendinger A**, Walters B, Zarraga IE, Chang DP, Nayak P, Topp EM\*. *Mol Pharm*. 2019 Nov;16(11):4485-4495. doi: 10.1021/acs.molpharmaceut.9b00614. [PMID: 31568722](#)
- 16 Near-Infrared Spectroscopy to Determine Residual Moisture in Freeze-Dried Products: Model Generation by Statistical Design of Experiments. Clavaud M, Lema-Martinez C, Roggo Y, Bigalke M, Guillemain A, Hubert P, Ziemons E, **Allmendinger A\***. *J Pharm Sci*. 2020 Jan;109(1):719-729. doi: 10.1016/j.xphs.2019.08.028. [PMID: 31499067](#)
- 17 Excipients for Room Temperature Stable Freeze-Dried Monoclonal Antibody Formulations. Haeuser C, Goldbach P, Huwyler J, Friess W, **Allmendinger A\***. *J Pharm Sci*. 2020 Jan;109(1):807-817. doi: 10.1016/j.xphs.2019.10.016. [PMID: 31622600](#)
- 18 Impact of dextran on thermal properties, product quality attributes, and monoclonal antibody stability in freeze-dried formulations. Haeuser C, Goldbach P, Huwyler J, Friess W, **Allmendinger A\***. *Eur J Pharm Biopharm*. 2020 Feb;147:45-56. doi: 10.1016/j.ejpb.2019.12.010. [PMID: 31866444](#)
- 19 Tissue Resistance during Large-Volume Injections in Subcutaneous Tissue of Minipigs. **Allmendinger A\***, Fischer S. *Pharm Res*. 2020 Sept;37(10):184. doi: 10.1007/s11095-020-02906-9. [PMID: 32888065](#)

- 20 Comparison of Techniques to Control Ice Nucleation during Lyophilization. Luoma J, Ingham E, Lema Martinez C, **Allmendinger A\***. Processes. 2020 Nov; 8(11), 1439; doi:[10.3390/pr8111439](https://doi.org/10.3390/pr8111439).
- 21 Glass leachables as a nucleation factor for free fatty acid particle formation in biopharmaceutical formulations. **Allmendinger A\***, Lebouc V, Bonati L, Woehr A, Kishore RSK, Abstiens K. J Pharm Sci. 2021 Oct;110(2):785-795. doi: 10.1016/j.xphs.2020.09.050. [PMID: 33035535](https://pubmed.ncbi.nlm.nih.gov/33035535/)
- 22 Filling of highly concentrated protein therapeutics: Impact of droplet drying and nozzle clogging on product quality. **Allmendinger A\***, Ni Y, Bernhard A, Nalenz H. PDA Journal of Pharmaceutical Science and Technology. 2021, 76(1):52-64. doi: 10.5731/pdajpst.2020.012492. [PMID: 34282036](https://pubmed.ncbi.nlm.nih.gov/34282036/)
- 23 Intraocular Pressure and Injection Forces during intravitreal injection into enucleated porcine eyes. **Allmendinger A\***, Butt YL, Mueller C. Eur J Pharm Biopharm. 2021, 166:87-93. doi: 10.1016/j.ejpb.2021.06.001. [PMID: 34102300](https://pubmed.ncbi.nlm.nih.gov/34102300/)
- 24 Liquid crystal phase formation and non-Newtonian behavior of oligonucleotide formulations. Farzan M, Ross A, Müller C, **Allmendinger A\***. Eur J Pharm Biopharm. 2022, 181:270-281. doi: 10.1016/j.ejpb.2022.11.021. [PMID: 36435312](https://pubmed.ncbi.nlm.nih.gov/36435312/)
- 25 Metal-Induced Fatty Acid Particle Formation Resulting from Hydrolytic Polysorbate Degradation. Gregoritza K, Cai SK, Siketanc M, Woehr A, Lebouc V, Kishore RS, Nicoulin V, Bleher S, **Allmendinger A**. J Pharm Sci . 2022, 111(3):743-751. doi: 10.1016/j.xphs.2021.09.044. [PMID: 34600939](https://pubmed.ncbi.nlm.nih.gov/34600939/)
- 26 Characterization of Freezing Processes in Drug Substance Bottles by Ice Core Sampling. Peláez SS, Mahler HC, Vila PR, Huwyler J, **Allmendinger A\***. AAPS PharmSciTech. 2024, 25(5):102. doi: 10.1208/s12249-024-02818-6. [PMID: 38714592](https://pubmed.ncbi.nlm.nih.gov/38714592/)
- 27 Directional freezing and thawing of biologics in drug substance bottles. Peláez SS, Mahler HC, Huwyler J, **Allmendinger A\***. *In revision* at Eur J Pharm Biopharm, 2024.
- 28 Formulation screening of lyophilized mRNA-lipid nanoparticles. Ruppl A, Kiesewetter D, Köll-Weber R, Lemazurier T, Süß R, **Allmendinger A\***. *Submitted* to J Control Release, 2024.

#### **Application Notes (peer-reviewed)**

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- 29 Don't shake it! Mechanical stress testing of mRNA-lipid nanoparticles. Ruppl A, Kiesewetter D, Strütt F, Köll-Weber R, Süß R, **Allmendinger A\***. Eur J Pharm Biopharm. 2024, 198:114265. doi: 10.1016/j.ejpb.2024.114265. [PMID: 38492867](https://pubmed.ncbi.nlm.nih.gov/38492867/)
- 30 Optimization of methodologies to study freeze/thaw processes in drug substance bottles. Peláez SS, Mahler HC, Huwyler J, **Allmendinger A\***. *In revision* at Eur J Pharm Biopharm. 2024.

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**Reviews (peer-reviewed)**


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- 31 Filling unit operation for biological drug products: Challenges and considerations. Adler A, **Allmendinger A\***. J Pharm Sci, 2023, In press. doi: [10.1016/j.xphs.2023.11.017](https://doi.org/10.1016/j.xphs.2023.11.017).

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**Communications (peer-reviewed)**


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- 32 Controlling Ice Nucleation during Lyophilization: Process Optimization of Vacuum-Induced Surface Freezing. **Allmendinger A\***, Butt YL, Mitzner R, Schmidt F, Luemkemann J, Lema Martinez C. Processes 2020, 8(10), 1263. doi: [10.3390/pr8101263](https://doi.org/10.3390/pr8101263).

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**Perspectives (peer-reviewed)**


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- 33 Pharmaceutical Development of Biopharmaceutical Drug Products: A changing landscape. **Allmendinger A\***. Pharmaceutical Research. 2021; In Press. doi: 10.1007/s11095-021-03037-5. [PMID: 33903976](https://pubmed.ncbi.nlm.nih.gov/33903976/)

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**Book Chapter**


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- 34 Hanns-Christian Mahler and **Andrea Allmendinger**. Stability, Formulation, and Delivery of Biopharmaceuticals. In: Tristan Vaughan, Jane Osbourn, Bahija Jallal (Eds.), Protein Therapeutics. Methods and Principles in Medicinal Chemistry, Wiley-VCH Verlag GmbH & Co. KGaA, 2017. 469-49. Print ISBN:9783527340866. Online ISBN:9783527699124. doi: [10.1002/9783527699124](https://doi.org/10.1002/9783527699124)
- 35 **Andrea Allmendinger**, Stefan Fischer, Robert Mueller. Analytical characterization and predictive tools for highly concentrated protein formulations. In: Nicholas W. Warne, Hanns-Christian Mahler (Eds.), AAPS Advances in Pharmaceutical Sciences Series 38. Challenges in Protein Product Development. Springer International Publishing AG, 2017. [ISBN10: 3319906011. ISBN13: 9783319906010](https://doi.org/10.1007/978-3-031-12634-5_5).
- 36 **Andrea Allmendinger**, Christina Häuser, Lokesh Kumar, Ilona Vollrath. Formulation Design for Freeze-Drying: Case Studies of Stabilization of Proteins. In: Jameel, F. (eds) Principles and Practices of Lyophilization in Product Development and Manufacturing. AAPS Advances in the Pharmaceutical Sciences Series, vol 59. 2023. Springer, Cham. doi: [10.1007/978-3-031-12634-5\\_5](https://doi.org/10.1007/978-3-031-12634-5_5)
- 37 **Andrea Allmendinger**, Alissa Monk, Hanns-Christian Mahler, Jack Dunkley, William Morris. The New Paradigm - Customer-centric, Sustainable Product Design. In: Mathaes, Mahler, Shi (Eds.), Combination Products for Biotech Injectables. Springer International Publishing AG, 2024. *In review*.
- 38 **Andrea Allmendinger**, Hanns-Christian Mahler. Trends in Formulation and Drug Delivery for Antibodies. In: Gottschalk U. (Ed.), Process Scale Purification of Antibodies. John Wiley&Sons Inc., 2024. *In revision*.

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**Editorial**


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- 39 Dawn of a new beginning. **Allmendinger, A**. AAPS Open 7, 1 (2021). doi: [10.1186/s41120-021-00035-0](https://doi.org/10.1186/s41120-021-00035-0)

## Research Disclosures

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- 40 **Andrea Allmendinger**, Gerhard Schilder, Raphael Mietzner, Yuen Li Butt, Joerg Lümkemann, Carmen Lema Martínez.  
Controlled nucleation during freeze drying using vacuum-induced surface freezing. Defensive publication in **Research Disclosure** journal. Nov 2016.  
<https://rd.orbit.com/OrderForm/PublicationPreview.aspx?disNum=633018>

## Expert opinion

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- 41 **Andrea Allmendinger**, Hanns-Christian Mahler, Helge Leibfritz.  
Addressing the Challenges of Developing Large Volume Drug/Device Combination Products for Parenteral SC Delivery.  
ContractPharma. [online](#) 04. April 2022. Rodman Media.
- 42 **Andrea Allmendinger** and Hanns-Christian Mahler.  
How ten23 health is meeting development challenges for intravitreal products.  
[ONdrugDelivery](#), Issue 130, March 2022, pp. 43-49. Frederick Furness Publishing Ltd.
- 43 **Andrea Allmendinger** and Hanns-Christian Mahler.  
Anticipating and Mitigating Challenges in the Commercialisation of Prefilled Syringes & Injection Devices – a Technical Drug Product Perspective.  
[ONdrugDelivery](#), Issue 142, Feb 2023, pp. 24–26. Frederick Furness Publishing Ltd.
- 44 **Andrea Allmendinger** and Hanns-Christian Mahler.  
Vakzine aus pharmazeutisch-technologischer Sicht.  
Pharmakon. Vol 11(2), March 2023, pp. 105-115. Avoxa - Mediengruppe Deutscher Apotheker GmbH. doi:[10.1691/pn.20230009](https://doi.org/10.1691/pn.20230009)
- 45 **Andrea Allmendinger** and Hanns-Christian Mahler.  
Intravitreal injections – more than meets the eye: a technical view of product use.  
[ONdrugDelivery](#), Issue 143, March 2023, pp 38–42. Frederick Furness Publishing Ltd.
- 46 **Andrea Allmendinger**, Michael Adler, Hanns-Christian Mahler.  
Integrated drug product development.  
[ONdrugDelivery](#), Issue 147, May 2023, pp. 44-51. Frederick Furness Publishing Ltd.
- 47 **Andrea Allmendinger**, Hanns-Christian Mahler .  
Managing the Complexity of Modern Sterile Product Developments.  
[PharmTech](#) e-book: Pharmaceutical Technology, Bio/Pharma Outsourcing Innovation, Issue 2, Feb 2024, pp. 4-8. MJH Life Sciences™ and Pharmaceutical Technology.
- 48 **Andrea Allmendinger**, Hanns-Christian Mahler, Philipp Behrendt.  
Addressing Intravitreal Product Manufacturing and Development Challenges.  
[ONdrugDelivery](#), Issue 157, May 2024, pp. 29-32. Frederick Furness Publishing Ltd.
- 49 Michael Adler, Venkata Appa Reddy Goli, **Andrea Allmendinger**, Hanns-Christian Mahler.  
Transitioning from Vial to Subcutaneous Injection Devices for Biological Drug Products.  
[ONdrugDelivery](#), Issue 160, May 2024, pp. 8–14. Frederick Furness Publishing Ltd.

### Supervision of Thesis

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- \* YuenLi Butt (**Msc, 2017**) Controlled Nucleation during Lyophilisation of Protein Formulations
  - \* Dominique Ditter (**PhD, 2018**) Interaction of Parenteral Drug Products with Surfaces of Glass Vials – Studies of Glass Delamination
  - \* Christina Häuser (**PhD, 2020**) Investigation of lyophilized antibody formulations to enable short freeze-drying cycles and storage at room temperature
  - \* Beatrice Drayer (**Bsc, 2023**) Gefriertrocknung von Poly-A Lipid Nanopartikeln: Einfluss verschiedener Lyoprotektoren & Evaluierung der Robustheit des Herstellungsprozesses
  - \* Dilara Ali (**Msc, 2023**) Impact of tubing material and properties used during the aseptic fill-finish process of biopharmaceutical drug products on VHP uptake
  - \* Franziska Stütt (**Msc, 2023**) Stress testing of Poly(A)-Lipid nanoparticles
  - \* Denis Kieseletter (**Msc, 2023**) Shaking and freeze/thaw stress studies of mRNA-lipid nanoparticles
  - \* Corinna Perez (**Msc, 2024**) Establishment of methodologies to study ready-to-use primary packaging material
  - \* Sarah Pelaez (**PhD, ongoing**) Evaluation of freeze/thaw equipment in biopharmaceutical drug product manufacturing
  - \* Anna Ruppl (**PhD, ongoing**) Formulation and process development of freeze-dried mRNA-lipid nanoparticles
  - \* Dilara Ali (**PhD, ongoing**) Characterization of disposable consumables in biopharmaceutical drug product manufacturing
  - \* Jari Acocella (**Msc, ongoing**) Characterization of Ready-To-Use Syringes for Intravitreal Administration
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