



## Curriculum Vitae

Personal information **Peter van Venrooy-Markefka**

### Work experience

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2020/05 – present

Pharmacist / GMP/ GDP-Inspector

LaGeSo Berlin, Germany

- GMP-Inspector
- Responsible for assessing the compliance of manufacturers with EU "Good Manufacturing Practice" (GMP)
- GDP-Inspector
- Responsible for assessing the compliance of wholesale distributors and their premises with EU "Good Distribution Practice" (GDP)

2020/01 – 2020/04

Self-employed

- Self-employed as GMP consultant

2017/02 – 2019/02

Head of Production

Advance Pharma GmbH, Berlin, Germany

- Head of Production
- Contract manufacturing of solid oral dosage forms (capsules, film tablets, tablets, granulates) for diverse APIs
- Optimization of manufacturing and logistic processes
- Identification of bottleneck equipment and processes
- Role as workstream lead production for introduction of new ERP (SAP)
- Support of refurbishment project of packaging area (primary and secondary)
- Commissioning and ramp-up of packaging area
- Commissioning of high rack warehouse
- Introduction of a qualification matrix and training system for production staff
- Continuation of 5S
- Functional design of an electronic OEE-system
- Responsibility for qualification and process validation
- Due diligence projects

2016/03 – 2017/01

Head of Production / Pharmacovigilance Manager

NextPharma / PenCef Pharma GmbH, Berlin, Germany

- Head of Production
- Contract manufacturing of solid oral dosage forms (capsules, film tablets, tablets, granulates) for Beta-Lactamantibiotics
- Optimization of manufacturing and logistic processes
- Introduction of 5S
- Development and introduction of a needs-based OEE-system
- Creation and revision of manufacturing documentation
- Responsibility for qualification and process validation
- Management of preparation for FDA inspection
- Introduction of a qualification matrix for production staff
- Support of refurbishment project of packaging area (primary and secondary)
- CAPEX planning
- Pharmacovigilance manager for special customers

2012/04 – 2016/02

Head Strategic Projects / Information Officer (AMG)

B.Braun Avitum AG, Melsungen, Germany

- Head Strategic Projects
- Establishing of medical device production in Vietnam
- Lead of international teams
- Evaluation and feasibility testing for ground breaking technologies
- Planning of new production plants and -modules for international usage
- Information officer
- Ensuring compliance of all print media of medicinal products of B.Braun Avitum AG

Head of Manufacturing / Head Compliance Production

B.Braun Avitum AG, Glandorf, Germany

- Head of Manufacturing / Head Compliance Production
- Manufacturing of diverse dialysis products partly terminally sterilized (infusion and rinsing solution, powder cartridges, concentrates)
- Optimization of manufacturing and logistic processes
- Start of 5S
- Creation and revision of manufacturing documentation
- Responsibility for qualification and process validation
- Education of QV staff
- Project management for remodelling and audit findings
- Lead of BRR group
- Lead of artwork team
- Execution of international due diligence with focus on manufacturing technique

2009/01 – 2012/03

Head Technical Operations R&D / Head of Manufacturing

Dr. Gerhard Mann GmbH, Berlin, Germany

- Head of production
- Responsibility as workflow manager
- Responsibility for bulk production, aseptic and standard filling as well as tableting and packaging of all products manufactured at the site
- Manufacturing of primary packaging material in clean room by injection blow molding
- Introduction of 5S
- Implementation of rhythm wheel
- Start of implementation of an electronic MES
- Head Technical Operations
- Responsibility for product and method transfer
- Introduction of a global artwork system
- Optimization of manufacturing processes
- Revision of regulatory documents
- Responsibility for feasibility studies
- Lead of international teams

2007/07 – 2008/12

Head Galenics DPI

Aeropharm GmbH, Rudolstadt, Germany

- Head development
- Head of an analytical lab focussed on inhalation products
- Partnering with external development team
- Scale-up of formulations from lab scale to final scale in production area
- Usage of modern statistic principles as ICH Q8-Q11 and implementation of DOE
- Drafting of a generic development file to ensure global standard within the company

2005/05 – 2007/06

Pharmacist Product Development

R.P.Scherer GmbH, Eberbach, Germany

- Pharmacist Product Development
- Development of customer related formulations in the area of soft gelatin capsules
- Feasibility studies up to manufacturing of clinical trials material
- Dietary supplement to NCEs and cytostatics
- Execution of technology projects
- Development of innovative plant derived capsule shell
- SPOC for development projects

2005/01 – 2005/05

Postdoc at section „Pharmazeutische Technologie und Biopharmazie“

Christian-Albrechts-Universität, Kiel, Germany

- Execution of projects with diverse companies
- Teaching activity in course of the seminar biopharmacy

2000/05 – 2004/12

Ph.D. student at section „Pharmazeutische Technologie und Biopharmazie“

Christian-Albrechts-Universität, Kiel, Germany

- Creation of doctoral thesis
- Execution of projects with diverse companies
- Teaching activities
- Administration of the network (120 clients)

1999/10 – 2000/04

Research associate at section „Pharmazeutische Technologie“

Friedrich-Alexander-Universität, Erlangen, Germany

- Teaching activities
- Execution of third party project: Development of plant derived petroleum jelly like ointment
- Administration of the network (20 clients)

1999/01 – 1999/06

Trainee at the Russeer Apotheke

Russeer Apotheke, Kiel, Germany

1998/06 – 1998/12

Trainee at the research and development department

Astra GmbH, Wedel, Germany

## Education and training

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2004/12

Conclusion of Ph.D. Course with „*summa cum laude*“

2000/05 – 2004/12

Ph.D. position at section „Pharmazeutische Technologie und Biopharmazie“ Christian-Albrechts-Universität, Kiel, Germany

1999/09

Achievement of the license to practice as a pharmacist

1999/09

Conclusion of the pharmaceutical studies

1994 – 1998

Pharmaceutical studies at Christian-Albrechts-Universität, Kiel, Germany.

1992 – 1994

Alternative Service at "Dispensary Städtische Kliniken Frankfurt am Main"

1989 – 1992

Vocational training "Stiftung Collegium Pharmazeuticum", Frankfurt/Main, Germany.

Degree to be earned: PTA.

1980 – 1989

Grammar school "Bischof Neumann Schule", Königstein, Germany.

1976 – 1980

Primary school "Geschwister Scholl Schule", Schwalbach, Germany

## Additional information

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### Publications

#### PhD. Thesis

Peter Markefka, Surface properties of lactose as excipient in pulmonary administration, Dissertation, Christian-Albrechts-Universität zu Kiel, 2004

#### Articles

Steckel, H., Markefka, P., teWierik, H. and Kammelar, R., Effect of milling and sieving on functionality of dry powder inhalation products. *Int. J. Pharm.* 309, 1-2, 51-59, (2006); Markefka, P. and Steckel, H., Powder flowability analysis as predictor for delivered mass uniformity from dry powder inhalers. *Pharmind* 67, 7, 823-829, (2005); Steckel, H., Markefka, P., teWierik, H. and Kammelar, R., Functionality testing of inhalation grade lactose. *Eur. J. Pharm. Biopharm.* 57, 495-505, (2004)

#### Lectures / Posters

van Venrooy-Markefka, P., Case Study: Abfülllinie für sterile Augentropfen mit RABS Technologie, 5. Jahrestagung Maintenance in der Pharm. Industrie, Berlin (2011); Markefka, P., Kammelar, R., teWierik, H. and Steckel, H., The effect of lactose pretreatment on DPI functionality. *Proc. Drug Del. Lungs XV*, London (2004); Markefka, P., Kammelar, R., teWierik, H. and Steckel, H., Functionality testing of inhalation grade lactose. *Proc. International Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology*, Nuremberg, 15-18 March (2004) 745; Markefka, P., Rasenack, N., Steckel, H. and Müller, B.W., Detection and quantification of partially amorphous surfaces by DVS. *Proc. International Meeting on Pharmaceutics, Biopharmaceutics and Pharm. Technology*, Nuremberg, 15-18 March (2004) 131; Rasenack, N., Markefka, P. und Steckel, H., Disordered structures in milled drugs and their detection by dynamic vapor sorption measurement (DVS). *Abstracts zum XI. Workshop über die Charakterisierung von feinteiligen und porösen Festkörpern* (2002) 34-35.; Markefka, P., Rasenack, N. und Steckel, H., Quantification of amorphous lactose by dynamic vapour sorption and isothermal microcalorimetry. *Abstracts zum XI. Workshop über die Charakterisierung von feinteiligen und porösen Festkörpern* (2002) 32-33.; Markefka, P. and Steckel, H., Assessment of low levels of amorphous content in lactose by DVS and isothermal microcalorimetry, *Arch. Pharm. Med. Chem.* 335, Suppl. 2 (2002); Markefka, P. and Steckel, H., Evaluation of a powder rheometer as add. tool to characterize powder properties, *Proc. of the 4th World Meeting APV/APGI*, Florence (2002) 147; Markefka, P. and Steckel, H., Prediction of mass uniformity of inhalations powders by measuring powder flowability, *Proc. of the World Meeting APV/APGI*, Florence (2002) 1019; Bolzen, N., Markefka, P. and Steckel, H., Influence of amorphous content and pre-treatment of lactose on alpha- / beta-lactose ratio in recrystallized powders, *Arch. Pharm. Med. Chem.* 334, Suppl. 2 (2001) 71; Markefka, P. and Steckel, H., How to measure reliably the SSA of alpha-lactose monohydrate, *AAPS PharmSci 2000 AAPS Annual Meeting Supplement* (2000) 2 (4)

### Projects

#### Memberships

Arbeitsgemeinschaft für Pharmazeutische Verfahrenstechnik e.V. (APV), Mainz, Germany

Deutsche Pharmazeutische Gesellschaft (DPHG), Frankfurt / Main, Germany

### Other Relevant Information