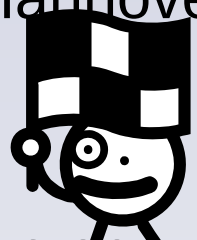
Verantwortungsabgrenzungsverträge

AG 6 GMP-Gesprächskreis in Niedersachsen

Verantwortungsabgrenzungsverträge

- Leitung der AG 6
  - Frau Pfannmüller, Med-X-Press
  - Mitglieder
  - Herr Dr. Piepho, NextPharma GmbH
  - Herr Dr. Jahnke, Haupt Pharma Wülfing
  - Herr Dr. Kotthaus TAD Pharma GmbH
  - Frau Dr. Themann, bela-pharm GmbH & Co. KG
    - Herr Dr. Wendebourg, Gewerbeaufsichtsamt Oldenburg
    - Herr Bödecker, Gewerbeaufsichtsamt Hannover
  - Treffen:
- 15. 4., 8. 6., 29. 1. 2010; 1.2. , 8. 3., 7. 6. 2011



Verantwortungsabgrenzungsverträge

- Hauptdokument

  - § 1 Basis for the Agreement
  - § 2 Object of the Agreement
  - § 3 Starting materials, semi-finished materials, bulk materials and packaging materials
  - § 4 Master manual, manufacturing instructions and manufacturing records
  - § 5 Quality control and testing records
  - § 6 Miscellaneous
  - § 7 Documentation and retained samples

Verantwortungsabgrenzungsverträge

- Hauptdokument (cont.)
  - § 8 Storage and shipment
  - § 9 Confidentiality
  - § 10 Force majeure
  - § 11 Contracting of third parties
  - § 12 Complaints and Recalls
  - § 13 Final provisions

Verantwortungsabgrenzungsverträge

- Appendix 1 „Responsible contacts“

General Manager	**Name:** **Tel: +** **Fax:** **e-Mail:**	**Date/Signature**
Qualified Person acc. to national drug law	**Name:** **Tel: +** **Fax:** **e-Mail:**	**Date/Signature**

•**List of products:**

Verantwortungsabgrenzungsverträge

- Appendix 2 „Products of the Agreement“ / Licence

Name of product	Dosage form	Marketing Authorisation number	Batch certification

Verantwortungsabgrenzungsverträge

- Appendix 3 „Division of the pharmaceutical and technical responsibilities“
  - Regulatory Aspects
  - Active ingredient(s)
  - Other Starting Materials
  - Primary Packaging Materials (foils, bottles, containers, closures)
  - Secondary Packaging Materials (cartons, leaflets, labels, measuring aids)
  - Other Packaging Materials (eg. shipping label, cartons)
  - Bulk Product
  - Finished Product

Verantwortungsabgrenzungsverträge

- Appendix 3 „Division of the pharmaceutical and technical responsibilities“ (cont.)
  - Validation
    - Process validation
    - Method validation/ method transfer
    - Product Quality Review (PQR) according to EU GMP Guideline
    - Stability Test (Ongoing stability)
    - Pharmacovigilance
    - Complaints
    - Product Recall
    - Transportation of Bulk and /or Finished Product
    - Documentation

Verantwortungsabgrenzungsverträge

- Appendix 4 „Agreed suppliers of starting materials and primary packaging materials“

Active ingredient(s)	**Manufacturer(s)/ manufacturing unit (address)**	**Supplier(s) (address)**
Other starting materials		
Primary packaging materials		

Verantwortungsabgrenzungsverträge

- Appendix 5 “Glossar”

- Alle Dokumente stehen den Kolleg(inn)en zur Verfügung
- Das Hauptdokument steht i e zur Verfügung

Dank an Frau Borstelmann, NextPharma ☺