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# Verantwortungsabgrenzungsverträge

AG 6 GMP-Gesprächskreis in Niedersachsen



# Verantwortungsabgrenzungsverträge

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## ▶ Leitung der AG 6

- ▶ Frau Pfannmüller, Med-X-Press

## ▶ Mitglieder

- ▶ Herr Dr. Piepho, NextPharma GmbH
- ▶ Herr Dr. Jahnke, Haupt Pharma Wülfig
- ▶ Herr Dr. Höfelmeier, TAD Pharma GmbH
- ▶ Frau Dr. Themann, bela-pharm GmbH & Co. KG
  - Herr Dr. Wendebourg, Gewerbeaufsichtsamt Oldenburg
  - Herr Bödecker, Gewerbeaufsichtsamt Hannover

## ▶ Treffen:

- ▶ 15. April, 8. Juni, 29. November 2010; 8. März 2011



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## ▶ 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



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



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## ▶ Appendix I „Responsible contacts“

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



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## ▶ Appendix 2 „Products of the Agreement“ / Licence

Name of product	Dosage form	Marketing Authorisation number	Batch certification



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- ▶ 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



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- ▶ 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





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- ▶ 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		



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- ▶ **Nächstes Treffen: 8.3. 2011**
  - ▶ Themen:
    - ▶ Appendix 3: Zuordnung der Verantwortlichkeiten gemäß Freigabeverantwortung
    - ▶ Ergänzende Kommentare
    - ▶ Glossar

