QA- Agreement

Tasks and the Division of Pharmaceutical Responsibilities in Contract Manufacturing and Testing

§ 1 Basis for the Agreement

Manufacture of medicinal products
EU- GMP
National drug law
CA holds a manufacturing authorization
Make available all necessary excerpts from the registration documents:

- technical pharmaceutical matters
- HSE requirements
- MSDS

Notice of any changes
Key personnel
Inspections of the production and control facilities
Declaration for the marketing of the products

§ 2 Object of the Agreement

Manufacture the products itemized in Appendix

§ 3 Starting materials, semi-finished materials, bulk materials and packaging materials

Quality of the starting materials: specification agreed by CG
Starting materials, packaging materials, semi-finished materials and bulk materials provided by CG are considered to be of the requisite quality, which is to be proved by a test certificate or release certificate.

QP muss sich überzeugen, dass die Lieferantenqualifizierung ordnungsgemäß durchgeführt wird (Vorlage Auditbericht oder QP-Erklärung); QP muss das QS-System des CG akzeptieren

Suppliers are listed in Appendix
Responsibilities defined in Appendix:

- Test requirements
- Qualification of suppliers

Packaging materials

§ 4 Master manual, manufacturing instructions and manufacturing records

Manufacture in accordance with the marketing authorization
Validation of manufacturing procedure
Agreed batch sizes
Manufacturing instructions (Marketing Authorisation).

Problematisch bei Marktfreigabe durch CA (§16 Abs. 2 Nr. 4 AMWHV)!
Wie stellt die QP sicher, dass der CG über ein funktionierendes Dokumentenmanagement und CC-Verfahren verfügt? Zulassungskonformität der Kennzeichnung fällt in die Verantwortung des CG (in D Informationsbeauftragter gem. § 74a AMG) und der freigebenden QP gem. § 16 Abs. 2 Nr. 4 AMWHV
Bei Freigabe durch CA ist die Verantwortung der QP zu beachten.

Wording of labels and leaflets with the marketing authorization registration file.

Freigebende QP muss sich davon überzeugen (z.B. durch Abgleich mit der Zulassungsdokumentation), dass der CG die entsprechende Verantwortung auch übernimmt,

§ 5 Quality control and testing records

Carry out the tests in accordance with the testing instructions
Testing instructions that in compliance with the registration documents
Testing procedures validated resp. transferred

§ 6 Miscellaneous

Change Control
Deviation management
Out of Specification (OOS) management
Reprocessing / Reworking
Product Quality Review (PQR): definition of review periods and reporting times
Ongoing Stability

§ 7 Documentation and retained samples

Storage of documents
Retained samples

§ 8 Storage and shipment

Conditions for starting materials and the manufactured products
Shipment of the products
Shipment under quarantine

Das Inverkehrbringen nicht freigegebener Arzneimittel verstößt grundsätzlich gegen § 17 AMWHV!

Responsibility for transportation
Shipped based on CoC the release status of the batch will labeled as "Awaiting QP- release"

§ 9 Confidentiality

§ 10 Force majeure

§ 11 Contracting of third parties

Third party manufacturing and testing laboratories

§ 12 Complaints and Recalls

Complaints
Recall decisions

Bei Markfreigabe durch QP des CA ist die QP über jede Beanstandung und jeden Rückruf zu informieren (8.1 GMP-Leitfaden).

§ 13 Final provisions

Signature
termination and review

Appendices

- 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**

- Appendix 2 „Products of the Agreement“ / Licence

Name of product	**Dosage form**	**Marketing Authorisation number**	**Batch certification**

- Appendix 3 „Division of the pharmaceutical/technical responsibilities“

- 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		