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Austrian Qualified Person Association

Mutual Recognition Agreement on GMP inspections EU and USA

May 2017

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MRA EU/USA

C(2017) 1323 final

Effective date: 01 March, 2017

Definitions:

- „… „capable“ does not require that the authority maintain procedures… that are identical to FDA‘s procedures.“
- „… „equivalency“ does not require … identical procedures.“

Scope:

- Post-approval inspections
- Pre-approval inspection: upon request; if recognized authority does not conduct inspection, requesting authority has the right to conduct ist own inspection (review of experience no later than 15 July 2019 to decide)
- „… may accept official GMP documents … of the other party for … facilities located outside the territory of the issuing authority.“

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Product coverage:

- Marketed finished pharmaceuticals for human or animal use
- Intermediates and in-process materials
- 15 July 2019: consider veterinary products
- 15 July 2022: consider vaccines for human use and plasma derived pharmaceuticals:
  - option of joint inspections
- Human blood, plasma, tissues and organs, and veterinary immunologicals excluded
- Full list: Appendix 3

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Assessments:

- Assessment of authorities listed (Appendix 2)
- Criteria and procedure specified in Appendix 4
- EU shall complete assessment of the FDA no later than 1 July 2017
- FDA shall complete assessment of each EU Member State authority (Appendix 2):
  - Nov 1, 2017: 8 (Plan: Spain, UK, France, Italy, Sweden, Croatia, Greece, Austria)
  - March 1, 2018: +4 (expected next countries to follow: Germany, Denmark, Ireland, Estonia, Czech Republic and Hungary)
  - June 1, 2018: +2
  - Dec 1, 2018: +6
  - July 15, 2019: +8
- If by Nov 1, 2017, FDA has not completed assessment of at least 8 Member States … shall be postponed to the date on which FDA has completed assessments of at least 8 such authorities
- MRA shall terminate on 15 July 2019 if FDA has not completed assessment of each EU Member State authority

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Recognition of Inspections:

- A Party shall recognize and accept, except:
  - Specific circumstances, e.g.
    - Material inconsistencies or inadequacies in an inspection report
    - Quality defects identified in post-market surveillance
    - Other specific evidence of serious concern in relation to product quality or consumer safety
  - Party shall notify the other Party and the relevant authority of reasons:
    - Clarification in a timely manner
- Each Party may determine terms and conditions to accept GMP documents

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Batch testing:

- QP will be relieved of carrying out the controls (Art. 51 § 1 of 2001/83/EC) provided:
  - Controls carried out in the USA
  - Product manufactured in the USA
  - Each batch/lot is accompanied by a batch certificate (WHO scheme) certifying that product complies with requirements of the MA and signed by person responsible for releasing the batch/lot
- Shall not apply until the date on which **all** EU member state authorities have been recognized by the FDA (July 15, 2019)

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Alert System:

- The other Party to be made aware proactively and with appropriate speed:
  - Quality defect
  - Recalls
  - Counterfeit or falsified product
  - Potential serious shortages
  - Other problems concerning quality or non-compliance with GMP which could necessitate additional controls or suspension of distribution of affected products