Lääkealan turvallisuus- ja kehittämiskeskus | Säkerhets- och utvecklingscentret för läkemedelsområdet | Finnish Medicines Agency

Ajankohtaista GMP:stä

Anne Junttonen
Fimea
17.1.2017

GMP-uudistukset/muutokset valmiina

EU GMP-opas http://ec.europa.eu/health/documents/eudralex/vol-4

- **Annex 16 Certification by a Qualified Person and Batch Release** voimaan 15.4.2016

- Ristikontaminaatioriskin hallitsemiseksi
  Chapter 3 *Premises and Equipment* ja Chapter 5 *Production*:
  Toxicological evaluation voimaan 31.5.2016
  Q&A kuulemisella ad 30.4.2017
  http://www.ema.europa.eu/docs/en_GB/document_library/Other/2017/01/WC500219500.pdf

/

GMP-uudistuksia/muutoksia tulossa

- **Eläinlääkkeet** – uusi Asetus => vet GMP/GDP?
  Asetusluonnos 10.9.2014
  http://ec.europa.eu/health/veterinary-use/rev_frame_index_en.htm

- **Tutkimuslääkkeiden** (hum) **GMP**

- **ATMP-lääkkeet ja -tutkimuslääkkeet**
- *consultation on the draft Guidelines on Good Manufacturing Practice for Advanced Therapy Medicinal Products* - päättynyt *2*6.9.2016
- Kommentit ja niiden yhteenveto julkaistu
  http://ec.europa.eu/health/human-use/advanced-therapies/developments_en
  tavoite 2017

GMP-uudistuksia/muutoksia tulossa

Annex 1 Manufacturing of sterile medicinal products

tavoite kuulemiselle 2Q/2017

Yhteistyönä EMAn IWG GMDP ja PIC/S

Q&A WFI kuuleminen päättyi 4.11.2016;
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2016/08/WC500211657.pdf

GMP-uudistuksia/muutoksia tulossa

Annex 17 Real time release testing

Ollut kuulemisella;

Tavoite 2017

Annex 21 Importation of medicinal products

Tavoite kuulemiselle 2017

Concept paper kuultu 2015

Intended to clarify expectations for importers given that existing guidance is mostly aimed at conventional manufacturing activities and leads to differing expectations in the context of importation

Reflection paper on GMP and MAHs

EU Guide to GMP refers in several places to Marketing Authorisation Holder (MAH) companies and their responsibilities in relation to GMP ensuring that the manufacturing authorisation holder can comply with GMP.

…a lack of clarity and awareness among MAHs as to the various responsibilities that relate to them, as stated in the current EC Guide to GMP and in related legislation, enabling compliance of the manufacturing authorisation holder with GMP…

=> *MAHs (and manufacturers) to have increased clarity as to what their respective responsibilities are.*

- Concept Paper kuuleminen päättynyt 30.11.2016

http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2016/10/WC500213610.pdf

a voluntary basis? H+V July 2006

3. When a new application is submitted in the EEA and a GMP inspection is deemed necessary, which competent authority carries out the inspection? H+V July 2006

Data integrity (NEW August 2016)

Back to top

Expand all items in this list

- Data integrity
- 1. How can data risk be assessed?
- 2. How can data criticality be assessed?
- 3. What does 'Data Lifecycle' refer to?
- 4. Why is 'Data lifecycle' management important to ensure effective data integrity measures?
- 5. What should be considered when reviewing the 'Data lifecycle'?
- 6. 'Data lifecycle': What risks should be considered when assessing the generating and recording of data?
- 7. 'Data lifecycle': What risks should be considered when assessing the processing data into usable information?
- 8. 'Data lifecycle': What risks should be considered when checking the completeness and accuracy of reported data and processed information?
- 9. 'Data lifecycle': What risks should be considered when data (or results) are used to make a decision?
- 10. 'Data lifecycle': What risks should be considered when retaining and retrieving data to protect it from loss or unauthorised amendment?
- 11. 'Data lifecycle': What risks should be considered when retiring or disposal of data in a controlled manner at the end of its life?
- 12. Is it required by the EU GMP to implement a specific procedure for data integrity?

PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

PI 041-1 (Draft 2)
10 August 2016

DRAFT PIC/S GUIDANCE

GOOD PRACTICES FOR DATA MANAGEMENT AND INTEGRITY IN REGULATED GMP/GDP ENVIRONMENTS

DRAFT

MRA USA-EU

- TTIP (Transatlantic Trade and Investment Partnership) – sopimusneuvotteluiden yhteydessä pyrkimys Mutual Recognition Agreement -sopimukseen GMP -tarkastuksissa
- Tavoitteena allekirjoittaa 20.1.2017 mennessä ja voimaan 2017
- Kattaisi alkuun laajasti ihmisille tarkoitettuja lääkkeitä, ja mahdollistaisi myöhemmin laajentamisen.