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

Tutkimuslääkkeiden GMP

Fimea 17.1.2017

Pirjo Hänninen

Kliinisiä lääketutkimuksia koskeva EU:n asetus Regulation (EU) No 536/2014

- Hyväksytty 16.4.2014 (voimaan 28.5. 2016)
- Kumoaa nykyisen lääketutkimusdirektiivin (2001/20/EY)

- Aiheuttaa muutoksia IMP GMP:hen
  - Eriytetään GMP-direktiivistä 2003/94/EC
- Delegated 22 Act article 63(1) määrittää IMP valmistuksen
  => seurauksena on laadittu komission ohjeen mukaan luonnos *Good Manufacturing Practice for Investigational Medicinal Products for human use* Annex 13:a mukaillen

Guideline on GMP for IMPs

- Drafting group began work in April 2015
  - Members included experts from UK (rapporteur), Finland, Germany, Ireland, GCP IWG
- Scope of work was revision of Annex 13
  - Existing text generally seen as well-functioning
  - Convert existing text into a new guideline for GMP for IMPs
  - Take into consideration recent changes in GMP Chapters and Annexes and other relevant guidance documents
- Update was required due to legislative change following publication of European Clinical Trial Regulation No. 536/2014
- A public consultation took place from 28 August to 24 November 2015. 24 responses were received .
- http://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-203309_en

Key changes compared to Annex 13

- Introduction & Scope
  - Guideline will become stand alone document
  - Important to retain cross links to Eudralex Volume 4
- Pharmaceutical Quality System
  - Introduction of quality risk management principles by reference to Chapter 1 of Eudralex Volume 4
- Documentation
  - Retention period depending on type of record
  - Records and retention arrangements required for sponsor's clinical trial master file to be defined in an agreement with manufacturer
- Product Specification File
  - Additional examples of documents to be included
  - Details of supply chain (consistent with updated Annex 16)
  - Details of reference and retention sample plans

Key changes compared to Annex 13

- Production
  - Clarification of premises and equipment qualification and process validated expectations (consistent with updated Annex 15)
- Packaging & Labelling
  - Confirmation re-packaging and re-labelling may be performed under Article 61(5) exemption and does not require QP certification
- Quality Control
  - Reference and retention sample definitions updated
- Release of batches
  - Clause related to imported comparator products removed. If QP cannot obtain adequate assurance of equivalent GMP, then product cannot be used
  - Additional references to Annex 16 principles added including verification of supply chain
- *Shipping*
  - *Section removed at request of Commission*

Key changes compared to Annex 13

- Outsourcing
  - New section introduced with reference to Chapter 7
- Glossary
  - Updated
- Tables
  - Table 1 – Summary of labelling detail removed as labelling requirements detailed in Annex VI of EU Regulation No. 536/2014
  - Table 2 – Batch release of products removed at Commission's request
  - Table 3 – Content of the Batch Certificate removed at Commission's request.

Key areas for questions/discussion

- GMP-G*CP interface; 2-stage release process*
- *Shipping*
- Comparator modification

Up date 17.1.2017

- Expected date for adoption by European Commission – Huhtikuu 2017

Sponsorin vastuut

- Eu komissio pyytänyt GMDP IWG ja GCP IWG – ryhmiä tekemään ”stand-alone” dokumentin koskien sponsoria koskevia GMP aktiviteetteja. Dokumentti julkaistaan Eudralec Vol 10:ssä.
- Alustava draft dokumentin aikataulu Huhti kuu 2017

Kiitos!!