Federal agency for medicines and health products

3rd Joint Conference of European Human Pharmacological Societies

Jean-Luc GOLNEZ-21st and 22nd of may 2015

Background in Belgium

- **National publication of the Circular 567 (regulatory background : Annexe 13 of Eudralex Vol 4), laying down requirements for manufacturing, distribution and holding of IMP. This led to a voluntary round of inspections of declared early phase units. Sites were visited in 2011-2012.**
- **Follow up with Circular 596 in 2013**

Formulations encountered

- **Non sterile, oral forms : capsules, oral solutions**
- **Sterile : iv perfusion, im vaccines**
- **Radiopharmaceuticals : radiolabeled imp**
- **ATMP**

Deficiencies encountered

- **IMP release :**
  - **Lack of sufficient QC release/testing (for starting material and finished products). Adherence to IMPD is required.**
  - **QP release process not robust enough (release register, SOP, presence of QP)**
- **Equipment/process validation :**
  - **Especially important for sterile manufacture (autoclaves, BSC, aseptic process)**
- **Reference and retention samples**

Conclusion

- **Acceptable CAPA have been set up**
- **Most sites have received appropriate autorisations (GMP/GDP)**
- **Standards have been met**
- **GMP certificate renewal process to begin soon (2 years validity)**

Contact

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