Fimea's Annual Seminar for GLP-Test Facilities and Applicants

10 Years of GLP Supervision in Fimea Jubilee Seminar

11.12.2019 Seminar opening

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Welcome – Tervetuloa – Välkommen – желанный – Velkommen - Teretulnud !

https://www.youtube.com/watch?v=0LC0KTxRDgA

Good Laboratory Practice – why?

→ harmonized quality system intended to assure the quality and integrity of non-clinical laboratory studies that demonstrate safety for medicines and chemicals

-OECD Mutual Acceptance of Data (MAD) system: “tested once, accepted for assessment everywhere”

a safety test carried out in accordance with the OECD Test Guidelines and Principles of Good Laboratory Practice in one OECD country *must* be accepted by other OECD countries for assessment purposes

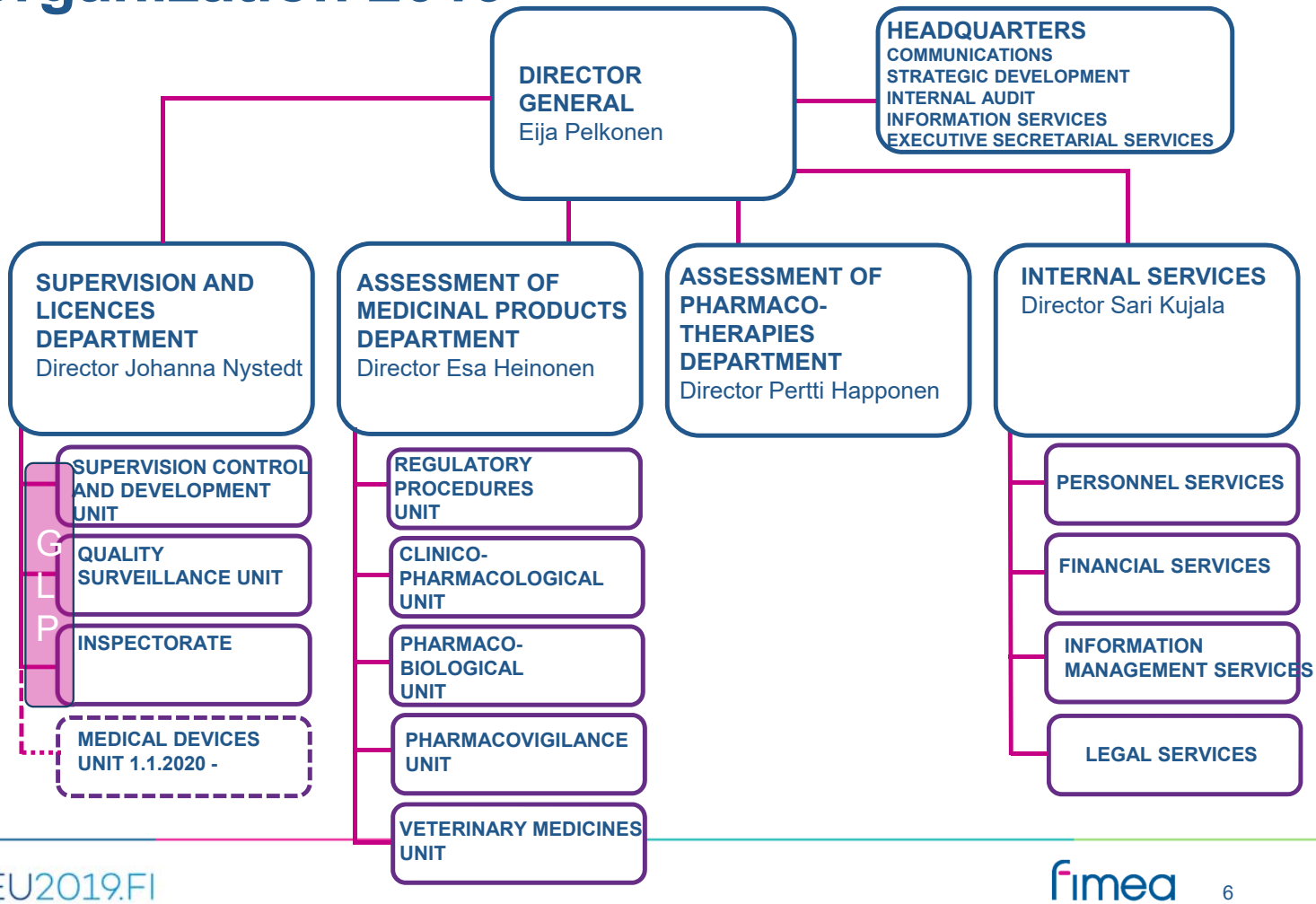
Fimea started its operations 10 years ago - and became the GLP monitoring authority

- The Finnish Medicines Agency Fimea started its operations 1.11.2009 when its predecessor, the National Agency for Medicines (Lääkelaitos), was closed down
- Simultaneously, Fimea became the sole national GLP authority
  - previously: shared responsibility between two competent authorities
- Finland joined the OECD in 1969
- OECD will evaluate Fimea's GLP program the next time in 2021 (on-site-evaluation)

Fimea: who we are and what we do

- Fimea supervises and develops the pharmaceutical, blood and tissue sectors and promotes the sensible use of pharmaceuticals in order to enhance the health of the population
  - *2020: supervision of medical devices, biobanks, GMO*
- operating under the Ministry of Social Affairs and Health
- Fimea is part of the European Medicines Regulatory network
- "Multi-office" agency (Kuopio, Helsinki, Turku, Tampere)
  - 1/2020: Helsinki office will move to Mannerheimintie 166
- Financing: about 80% from license fees, 20% budget funding

Fimea: organization 2019



GLP activities at Fimea

	2014	2015	2016	2017	2018
GLP inspections	6 (18)	3 (10)	9 (24)	7 (23)	7 (24)
GLP decisions	3	2	4	1	5
Inspections all	170 (465)	193 (558)	168 (451)	172 (528)	215 (655)
Licenses all	2242	2407	2350	2291	2406

Fimea's GLP team members:

Pirkko Puranen (co-ordinator)

Mirka Laavola (deputy)

Paula Korhola

Erik Peltomaa (in training)

Mervi Saukkosaari, Head of Section GxP

Eeva Leinonen, Head of Inspectorate

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GLP: on-going, regulatory challenges

New technologies and complex products:

- advanced therapy medicinal products (ATMPs)
- nanotechnology
- combined products: medicines – medical devices – tissues
- complicated chemicals

- How to assess toxicology?
  - Traditional toxicological methods as such might not be suitable
  - Outsourced GLP testing might not be a feasible option:
    - selection of methods usually limited to traditional methods
    - customization not possible
  - How to validate new methods? Who should do it?
  - Are there criteria we are willing to stretch without jeopardizing the purpose of GLP → reliability of non-clinical safety data
  - How to educate about GLP?
- How will a regulatory authority respond to the challenges posed by the new innovations?

GLP: on-going, regulatory challenges

- quantitative structure – activity relationship models (QSAR):
  - optional approach to assess safety by structure modelling
  - can/should GLP be applied or adapted to a QSAR approach?
- the increased awareness of the environmental impact of medicines and chemicals
  - increased need of ecotoxicological safety testing → increased need of GLP testing facilities?
  - increased need of new methods


Thank you for you attention
and
Have a great seminar!
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