

French National Agency for Medicines and Health Products Safety

Innovation Office

François Cuenot

Coordinator for Scientific Activities: Innovation and Research Projects

Division for Strategy and International Affairs

26 April 2013

EMA – SMEs workshop - London

The Innovation Office

- ◆ Focuses on early development of health products (medicines, ATMP, medical devices) by:
 - SMEs and start-ups
 - Academic research units, hospital units
 - ◆ In order to:
 - Avoid inappropriate development
 - Identify regulatory issues
 - Anticipate evaluation difficulties due to the innovation
 - Accelerate access to patients
 - ◆ Complementary to Scientific Advices during development and pre-submission for clinical trials
- The aim is not to promote/support research on new therapeutic and diagnostic approaches.

What we propose

- ◆ Direct answers to project managers or identification of the right contact person at ANSM;
- ◆ Meetings at ANSM for most innovative projects;
- ◆ Organization each year of information days at ANSM on regulatory/scientific issues;
- ◆ Orientation towards French organizations promoting innovation (Ministries, Funding agencies, Technology transfer companies...);

Figures and facts

- ◆ Innovation Office implemented in 2008
- ◆ Free of charges
- ◆ 150 requests/35 meetings in 2012
- ◆ Example of projects:
 - Advanced Therapy Medicinal Products
 - Nanoparticles in health products
 - Implantable Medical Devices

Contact, procedure, request form

ANSM

Division for Strategy and International Affairs

François Cuenot

143 - 147 Boulevard Anatole France

93285 Saint Denis Cedex - France

innovation@ansm.sante.fr

<http://ansm.sante.fr/L-ANSM2/Accompagnement-de-l-innovation>

Avertissement

- Lien d'intérêt : personnel salarié de l'ANSM (opérateur de l'Etat).
- La présente intervention s'inscrit dans un strict respect d'indépendance et d'impartialité de l'ANSM vis-à-vis des autres intervenants.
- Toute utilisation du matériel présenté, doit être soumise à l'approbation préalable de l'ANSM.

Warning

- Link of interest: employee of ANSM (State operator).
- This speech is made under strict compliance with the independence and impartiality of ANSM as regards other speakers.
- Any further use of this material must be submitted to ANSM prior approval.