Dr. Markku Toivonen
CURRICULUM VITAE

Personal details

Name	Markku Toivonen
Education	MD, PhD Specialisation in Internal Medicine

Professional experience

Current position

- NDA Scientific Director
- NDA Advisory Board member

Previous positions

- 2003-2004: Head of Section, Marketing Authorisation Department, National Agency for Medicines, Finland (NAM)
- 1997 – 2004: Senior Medical Officer, NAM
- 1991-1997: External reviewer, non-clinical and clinical documentation, National Agency for Medicines, NAM
- 1986-1997: Physician, Internal Medicine, various positions

Area of Expertise

- 20 years in regulatory affairs, including assessment of non-clinical and clinical dossiers of Marketing Authorisation Applications for small chemical entities and recombinant biotherapeutics; main therapeutic areas:
    - Oncology
    - Psychiatric disorders
    - Neurology (Parkinson's disease, epilepsy, ALS, Alzheimer's Disease)
    - Cardiovascular disorders
    - Metabolic and endocrine disorders
    - Gastrointestinal disorders
    - Infectious diseases
- Detailed knowledge of the European approval system including European Medicines Agency (EMEA).
- Non-clinical and clinical documentation requirements to support European Clinical Trial Applications (CTA) and Marketing Authorisation Applications (MAA)

- Design of non-clinical and clinical development plans: Scientific and strategic aspects
- Orphan Drug Designation

Research
- Neuropharmacology, neuroendocrinology

Major projects

As Regulator
- Finnish Member of the CPMP/CHMP 1997-2004
- Rapporteur/Co-rapporteur, non-clinical and clinical assessor for NCEs and rDNA products in the Centralised Procedure
- Scientific Advice co-ordinator for CPMP Scientific Advice Review Group (SciARG) 1998-2000.
- Chair of CHMP Scientific Advice Working Party 2000-2004
- Coordinator, non-clinical and clinical reviewer of national scientific advice requests, including advanced therapies, NAM 1999-2004
- Review of non-clinical and clinical parts of MAA in national/MRP procedures 1997-2004
- Chair of the CPMP Ad hoc group on (pre-) clinical comparability of biotech products
- Member of the CPMP Blood Products Working Group

As Consultant
- Regulatory strategy for European submission of CTA and MAA for small chemical entities, biotherapeutics and advanced therapies
- Optimisation of non-clinical and clinical development plans, including risk management
- Evaluation and tackling of regulatory risks and hurdles
- Strategic and scientific/regulatory assistance in preparing Briefing documents, written responses to queries/lists of questions and meetings with Regulatory Authorities, including:
    - Scientific Advice
    - Pre-submission meetings
    - Hearings/Oral Explanation meetings with national authorities and EMEA
    - Participation in mock Oral Explanation meetings as ex-regulator
    - Review of draft response documents in MRP, DCP and CP
- Attendance as regulatory expert in medicinal product development milestone meetings and workshops
- High-level, general and focused, detailed presubmission evaluation of MAA dossiers
- Post-marketing (PM) authorisation activities including review of PMS study plans, review of PM safety experience

- Gap analyses
- Orphan Medicinal Product designation
- Paediatric Investigation Plan (PIP) review

Associations

- TOPRA
- DIA
- Finnish Pharmacological Society
- Finnish Internal Medicine Society
- Finnish Medical Association

Publications

Publications and conference presentations on all aspects of Regulatory Affairs of medicinal products. Publications in scientific journals and textbooks on drug therapy/clinical pharmacology.

The complete list can be provided upon request.