Dr. Mary Teeling
CURRICULUM VITAE

Professional experience

Current position

- NDA Advisory Board member.
- Lecturer in Pharmacology, Trinity College, Dublin.
- Medical Advisor, National Medicines Information Centre, Dublin.

Previous positions

- 1995-2000, Medical Director, Irish Medicines Board

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
- Detailed knowledge of the European approval system including European Medicines Agency (EMA).
- Clinical documentation requirements to support European Clinical Trial Applications (CTA) and Marketing Authorisation Applications (MAA)
- Design of clinical development plans: Scientific and strategic aspects
- Orphan Drug Designation

Scientific speciality

- Pharmacology, clinical pharmacology, clinical oncology, Pharmacoepidemiology.

Major projects

As Regulator

- Irish member and Vice-chairperson of the CPMP .
- Chair-person of the CPMP Scientific Advice Review Group
- Chair-person of the CPMP Ad Hoc Committee on Anti-Cancer Agents.
- EU member of the Steering Committee on ICH.

As Consultant

- Regulatory strategy for European submission of CTA and MAA for small chemical entities, biotherapeutics and advanced therapies
- Optimisation of 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 Other
- Consultant on signal analysis review panel, WHO-UMC, Uppsala.
- Founder director of postgraduate diploma/MSc in Pharmaceutical Medicine, Trinity College Dublin.
- Principal author of reviews on use of buprenorphine, lofexidine and naloxone in opiate dependence for governmental agency (www.nacd.ie).

Associations

- Association of Pharmaceutical Physicians in Ireland.
- Fellow of the Royal Academy of Medicine in Ireland.
- International Society of Pharmacoepidemiology.
- British Pharmacological Society.

Publications

Pharmacology, pharmacoepidemiology, clinical pharmacology, oncology, tumor markers, drug regulation. The complete list can be provided upon request.