DR. MARGARET MITRANE
CURRICULUM VITAE

Personal details

Name:	Margaret Mitrane
Education:	MD
	Internal Medicine
	Rheumatic Diseases and Immunology expert

Professional experience

Current position:

- Member, NDA Advisory Board
- President, Manhattan BioPharm Consultants

Previous positions:

- 1998 – 1999: Medical Director , Celebrex Global Development Team, Pfizer Inc
- 1997 – 1998: Director, Clinical Research, Transplantation/ Immunology, Novartis Pharmaceuticals Corp.
- 1994 – 1997: Deputy Director, Division of Vaccines and Related Product Applications, CBER, FDA
- 1993 – 1994: Medical Officer, Division of Vaccines and Related Product Applications, CBER, FDA
- 1989 – 1993: Medical Officer, Division of Biological IND's , CBER, FDA
- 1988 – 1989: Associate Director, Clinical Research, Oncology, American Cyanamid Corporation - Medical Research Division - Lederle Laboratories
- 1986 – 1988: Assistant Professor of Medicine, Division of Rheumatic Diseases & Immunology, New York Medical College
- 1983 – 1995: Rheumatology Fellow, UMDNJ - Robert Wood Johnson Medical School
- 1982 – 1983: Internal Medicine Attending Physician, East Orange Veterans Administration Hospital

Area of Expertise

- Clinical background in general internal medicine and rheumatology
- In-depth knowledge of the development of medicinal products and therapeutic proteins for the treatment of autoimmune and inflammatory diseases, including knowledge of

clinical program and study design, relevant endpoints, safety considerations, and current regulatory and commercial landscape

- Detailed knowledge of the FDA approval process from Center for Drug Evaluation and Research point of view
- Clinical documentation requirements to support Investigational New Drug (IND), Biologic License (BLA) and New Drug (NDA) applications
- Development of medicinal products and therapeutic proteins for Orphan Diseases
- Preparation of pediatric investigational plans for submission to FDA and European Medicines Agency (EMA) pediatric committees.

Major projects

As Regulator:

- Review of IND, BLA and NDA submissions on a portfolio of therapeutic proteins (e.g. monoclonal antibodies, and cytokine inhibitors for treatment of autoimmune diseases such as rheumatoid arthritis and multiple sclerosis, coronary artery disease, sepsis, solid tumors, and hematological malignancies) and vaccines (e.g. hepatitis B, hepatitis A and Lyme disease)
- Participation in Pre-IND, End-of-Phase-2, and Pre-BLA meetings
- Establishing CBERs policy on clinical development of Lyme disease vaccines.
- Representing the FDA as a biologics expert on the ACR committee on design and outcomes in clinical trials in systemic sclerosis.
- Biologics expert on the FDA Rheumatology Working Group establishing guidance policy on the clinical development of products for rheumatic diseases.
- CBER representative on the Good Review Practices Track IV Committee providing guidance to FDA physicians on how to review an IND.

In Industry:

- Chair of the Arthritis Clinical Subgroup providing input to the strategic and clinical planning for anti-inflammatory and immunosuppressive agents in development.
- Preparation of clinical documents in CTD format for marketing authorization applications of biopharmaceuticals submitted to FDA and EMA, for various indications including rheumatoid arthritis, psoriatic arthritis, psoriasis, multiple sclerosis, Crohn’s disease and ulcerative colitis

Associations

Member of American College of Physicians and American College of Rheumatology

Publications

Publications and conference presentations on aspects of Rheumatology and Vaccine development.
The complete list can be provided upon request.