



DR. GRANT A. WILLIAMS

CURRICULUM VITAE

Personal details

Name: Grant A. Williams
Education: MD
Internal Medicine
Fellowship in hematology and oncology and board certified in oncology.

Professional experience

Current position:

- Member, NDA Advisory Board
- President, Williams Cancer Drug Consulting, LLC

Previous positions:

- 2006 – 2008, Executive Director, Clinical Development, GlaxoSmithKline Pharmaceuticals
- 2005 – 2006: Executive Director, Clinical Development, Novartis Pharmaceuticals
- 2002 – 2005: Deputy Director, Division of Oncology Drug Products, CDER, FDA
- 1997 – 2002: Medical Team Leader in the Division of Oncology Drug Products, FDA
- 1989 – 1996: Medical Review Officer in the Division of Oncology Drug Products, FDA
- 1988 – 1989: Private practice in medical oncology

Area of Expertise

- In-depth knowledge of medical oncology
- Detailed knowledge of the FDA approval system from Division of Oncology Drug Products point of view including requirements for US Accelerated Approval.
- Clinical documentation requirements to support Investigational New Drug (IND) and New Drug Application (NDA) applications including scientific and strategic design aspects of clinical development plans
- Pharmacogenomics, biomarkers and personalised medicines



Major projects

As Regulator:

- Review of IND and NDA submissions on a large portfolio of cancer drugs including phase 1, phase 2, and phase 3 trials.
- Participation in PreIND, End-of-Phase-2, and PreNDA meetings
- Advice on design of pivotal trials in oncology to obtain Marketing Authorisation in the US
- Author of FDA Guidance Documents, e.g.: Cancer Guidance on Clinical Data in Marketing Applications (Draft), IND Exemptions for Lawfully Marketed Cancer Drugs, Oncology General End Points Guidance .
- Member of the FDA Pharmacogenomics Working Group and Interdisciplinary Pharmacogenomics Working Group (IPRG).

In Industry:

- Member of PhRMA working group on progression free survival
- Chairman of oncology protocol review committee

Associations

Member of American Society of Clinical Oncology, American Society of Hematology and Drug Information Association

Publications

Publications and conference presentations on aspects of Regulatory and clinical aspects during development and assessment of Anticancer medicinal products.

The complete list can be provided upon request.