MARK GOLDBERGER MD MPH
CURRICULUM VITAE

Personal details

Name: Mark Goldberger MD MPH
Education:

- George Washington University – Washington D.C.: Master of Public Health (Concentration in Health Administration), September 1989 – June 1991
- Colombia University College of Physicians and Surgeons – New York, N.Y.; Doctor of Medicine, September 1969 – May 1973
- Johns Hopkins University - Baltimore, MD; Undergraduate Education, September 1966 - June 1969.

Professional experience

Current position:

- Member, NDA Advisory Board
- Mark Goldberger MD MPH LLC, Founder, (September 2014 – Present)

Previous positions:

- AbbVie, Vice President / Strategic Advisor Regulatory Affairs, (January 2013 – August 2014)
- Abbot Laboratories / AbbVie, Divisional Vice President for Regulatory Intelligence and FDA Liaison Issues, (October 2007 – December 2012)
- Food and Drug Administration, Medical Director for Emerging and Pandemic Threat Preparedness, (August 2006 – September 2007)
- Food and Drug Administration, Director & Acting Director, Centre for Drug Evaluation and Research, Office of Antimicrobial Products (October 2001 – August 2006)

Area of Expertise

- Clinical medicine & clinical development
- Regulatory strategy
- Anti-infectives

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- FDA policies and procedures & interpretation of FDA actions in other therapeutic areas
- Quality Assurance
- Product development in multiple therapeutic areas

Major projects

- With AbbVie: Provided expertise on development program and regulatory strategy for several programs in HCV, Crohn's disease, Parkinson's disease
- With Abbot:
    - Provided insight on major regulatory initiatives at the FDA and EMEA including FDASIA, pediatrics and biosimilars.
    - Provided heightening awareness and understanding of FDA's perspective in a number of product development areas and provided advice on how to best engage to address differences between Abbot and FDA.
    - Provided regulatory and technical advice to development teams in multiple therapeutic areas including metabolic, pain, immunologic and antiviral therapies.
- With the FDA:
    - Acted as a focal point and scientific resource within CBER for activities related to pandemic influenza and emerging infections
    - Overall administrative responsibility of the Office of Antimicrobial Products
    - Provided providing broad scientific and policy leadership and direction to staff within the Office.
    - Served as the Director of the Division of Special Pathogens and Transplant Drug Products

Scientific Activities

- Member Scientific Advisory Board Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (Carb-X)
- Member Scientific Advisory Group Global Antibiotic Research and Development Partnership (GARDP)
- Member Scientific Advisory board TB Alliance 2102-2017
- Ad hoc Reviewer:
    - New England Journal of Medicine
    - American Journal of Respiratory and Critical Care Medicine
    - International Journal of Tuberculosis and Lung Disease