# David William Grob

**7302 Blazing Star Court**
**Chattanooga, TN 37363**
**845-988-7734**



***SUMMARY:*** A versatile, experienced, and action-oriented Regulatory/Scientific Affairs executive who has delivered successful strategic advice and operational/fiscal excellence in Regulatory, Scientific and Clinical Affairs, and has a solid knowledge of sNDA, 510(k), OTC monograph products and NDA OTC switch submissions. Primary liaison with Regulatory Agencies (FDA, EPA, NAD/FTC, BATF/TTB, DEA), building rapport at all levels within these agencies and professional organizations (CHPA, PCPC, ADA). Proven ability for building class-leading regulatory organizations.


## *EXPERIENCE:*

1/17 – present **Sanofi Consumer Healthcare (Chattem, Inc.), Chattanooga, TN**
***Head, CHC Regulatory Affairs, North America***
• Sucessfully led the integration teams for the Boehringer ingelheim global CHC product acquisition.

11/11-12/16 **Chattem, Inc., Chattanooga, TN (part of the Sanofi group)**
***Vice President, Regulatory Affairs***
• Responsible for all regulatory policy issues, strategic planning (global and regional), and corporate compliance management.
• Direct the daily operations of U.S. and International Regulatory departments, Clinical and Drug Safety/Medical Affairs, Consumer Affairs, Pharmacovigilance and the regulatory aspects of Product Development, Business Development and Quality Control for all OTC and NDA drugs, Medical Devices, Dietary Supplements and Cosmetics.
• Lead global consumer healthcare product life-cycle management and Rx-to-OTC switch teams to success in a complex multi-organizational matrix environment. Co- led the Regulatory Switch team for **Allegra**, **Nasacort 24HR** (1st in class Rx-to-OTC switch), **Xyzal** and the pending switch of **Cialis**.

11/05-11/11 ***Director, Regulatory Affairs and Safety***
• Responsible for all US regulatory policy issues, and corporate compliance management.
• Regulatory Team Leader for the **Allegra Allergy** Rx to OTC switch; primary contact with FDA on all switch issues leading to an on-time launch.
• Design, review, and summarize clinical studies/data for claim support.
• Compile and submit all NDA related documents (Annual Reports, CMC supplements, advertising).
• Primary contact with FDA/FTC/DEA on all issues, including site inspections, labeling negotiations and advertising challenges.
• Provide Regulatory and Scientific guidance on new product acquisitions, product development and due-diligence activities for acquisition products or development projects.

1/04-11/05 **Purdue Pharma, L. P. Stamford, CT**
***Senior Director, OTC Regulatory Affairs***
• Led the expansion of the OTC RA Department and creation of a new Scientific Affairs group within an OTC strategic business unit.
• Formed interdepartmental task forces to quickly evaluate and develop new OTC products for global launches.
• Provide strategic and tactical scientific/regulatory affairs direction to executive-management and domestic/international product development teams.
• Business Development Support: Provide regulatory support and intelligence for all acquisition and in-licensing efforts. Provide detailed regulatory evaluations and regulatory strategies for potential acquisition or line-extension products.

12/01-12/04 ***Director, OTC Regulatory Affairs and Labeling***
• Expanded the functionality of the labeling group to provide strategic regulatory oversight for all corporate labeling activities, including the development of labeling for NDA submissions and harmonized CCDS for all global drug and medical device products. Created and filed 510(k) device premarketing clearance submissions to FDA for class II devices.

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8/00-12/01 ***Associate Director, OTC Regulatory Affairs and Labeling***

Assumed responsibility for the development and implementation of Global Labeling Control Group while retaining leadership of the OTC RA function.

- Provide regulatory support to global project teams for development & registration strategies of new drugs/devices/OTCs.

12/99-7/00 ***Assistant Director, OTC Regulatory Affairs***

- Responsible for the regulatory maintenance of prescription and OTC drug products (including sterile opthalmics, hard-surface disinfectants, vaginals, topicals, orals, & otics), and NDA OTC products; including amendments, NDA Annual Reports, NDA Supplements, and Annual ADE Reports.
- Core Team Member on Global Product Development projects including medical devices (510(k) and PMA), NDA, USEPA, and OTC monograph products.
- Review and approve all labeling and advertising, including Drug Facts Box conversions.
- Establish and maintain contact with all trade associations, serving on Scientific Affairs Committee (CHPA). Primary correspondent with FDA.

**DEL Laboratories, Inc., Farmingdale, N.Y.**

6/98- 11/99 ***Director, Regulatory Affairs***

Reported to the Sr. VP Scientific Affairs and CEO. Define, develop, and implement corporate regulatory strategy, interact with industry task groups on regulatory issues, and direct overall compliance for a multi-facility/multi-site company producing drugs (topical, oral, optical, otic, hard-surface disinfectants) and cosmetics. Direct daily activities of three Regulatory Affairs Associates, one Senior Associate/Manager and six Consumer Relations Representatives. Acted as internal regulatory consultant on executive level issues of pharmaceutical product development, review of product concepts, and provided counsel to Project Teams on regulatory issues. Generated and implemented departmental budget.

4/96-6/98 ***Manager, Regulatory Affairs***

- Manage daily activities of two Regulatory Affairs Associates, and direct the Consumer Relations Department Adverse Reaction reporting, tracking, and investigation functions.
- Primary correspondent with FDA and Primary contact with FDA during inspections. Prepare draft responses to FDA 483's and inquiries.

6/95-4/96 ***Regulatory Affairs Associate***

- Responsible for FDA compliance of all pharmaceuticals, setup of safety studies and claim substantiation clinical trials, and compliance with monograph status and FD&C Act.
- Pesticide registrations with State and Federal EPA, filings with Bureau of A.T.F, and registrations with the State Board of Pharmacy. Assist the Legal Department with lawsuit investigations.
- Development of new/revised labeling and coordination of all typesetting and art requirements for all drugs and cosmetics. Initiated claim substantiation review system.
- Responsible for International registrations and compliance issues, including Canadian DIN and GP, EEU and Japan.

**Applied Genetics, Inc., Freeport, N.Y.**

9/93-6/95 ***Manager/Senior Scientist***, Quality Control and Process Development

- Responsible for the setup of a Quality Control department and preparation of Standard Operating Procedures and validations under cGMP/cGLP for FDA licensed production facility. Organized operational systems to lead the QC and Production departments from the startup/IND stage to full scale production. Trained and supervised three QC technicians.
- Involved in preparation of IND submissions to FDA for drug with Orphan Drug Status.
- Advanced the research and development of novel liposome encapsulated biological agents and cosmetic ingredients. Increased encapsulation efficiencies of small biological molecules.

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***EXPERIENCE: continued***

3/93-9/93 ***Associate Scientist,*** Immunohistochemistry

- Responsible for the development and optimization of immunohistochemical cancer diagnostics using monoclonal antibody production and computerized/CCD image analysis.
- Initiated genetic engineering strategies and process optimization of bacterial fermentations for recombinantly produced proteins in the Production department. Increased product yield 55% and decreased the use of inducing agents.

***EDUCATION:***

- M.S. Biology- Adelphi University, Garden City, N.Y.
- B.S. Biotechnology- Rochester Institute of Technology, Rochester, N.Y. (Concentration: Economics)

***PUBLICATIONS:***

- D.W. Grob, et.al. "Lymphoid Tissue Source of Autotumorlytic Factor(ATF)", FASEB, 7:3, A730, 1993.
- M. Belanich, T. Ayi, B. Li, J.T. Kibitel, D. W. Grob, T. Randall, A. White, M. Citron, D. Yarosh. "Analysis of $O^6$-methylguanine-DNA Methyltransferase in Individual Human Cells by Quantitative Immunofluorescence Microscopy", Oncology Research, Vol. 6, No. 3, pp. 129-137, 1994.
- Grob, D. W., et. al. "$O^6$-methyltransferase measured in single human cells by quantitative immunofluorescence and its application to standard pathology specimens from cancer." AACR, #2352, Experimental Therapeutics, 1994.
- Grob, D., et. al. " Reduction of Endotoxin in a Protein Mixture Using Strong Anion-Exchange Absorption". Pharmaceutical Technology, Vol. 20, No. 3, 1996.

***CERTIFICATIONS:***

- Regulatory Affairs Professional Society: Regulatory Affairs Certified (RAC) 1996

***PROFESSIONAL SOCIETIES:***

- Regulatory Affairs Professional Society
- Drug Information Association

***TRADE ASSOCIATION PARTICIPATION***:

- Consumer Healthcare Product Association:
  Scientific Affairs Committee, Label Coordinators Committee, Prop 65 Task Force, Laxative Task Force, Dietary Supplement Task Force, External Analgesic Task Force
- Personal Care Products Association (formerly CTFA)
- Invited speaker by CHPA and DIA on OTC monographs, advertising regulation and Rx-to-OTC switch