

# CURRICULUM VITAE OF PAUL G. KING, PHD

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An experienced professional having broad analytical, facilities and systems, current good manufacturing practice (CGMP), and management experience with a record of high-level responsibility and proven accomplishment in pharmaceuticals chemicals, and biocides. Analytical perspective and results oriented. Key strengths:

Leader and manager of people, change, organizational units and projects from inception to completion and beyond to meet customer, quality, regulatory and business expectations.

Innovative scientist who finds or invents and develops cost-effective methodologies and procedures.

Problem solver/innovator with the ability to comprehend, and to successfully interpret, the complex interrelationships among customers, quality, regulations, processes, operations, and technologies.

Analytical chemist with excellent written and verbal skills as well as in-depth understanding of chemistry, pharmaceuticals and all facets of the pharmaceutical industry [CGMP; GLP; GAMP; ISO 9000; TQM; PAT; Commissioning; Qualification; Validation; mission, vision and values statements; general policies; standard operating procedures (“SOPs”); design, development and validation of test methods, equipment, processes, and supplies; scheduling; staffing and training; materials definition; methods; and systems management].

## PROFESSIONAL EXPERIENCE:

Genetic Consultants of New Jersey, Parsippany, NJ 2009 – Date  
**DIRECTOR**

Oversee the day-to-day operation of this satellite office of ASD Centers LLC.

FAME Systems, Lake Hiawatha, NJ 2001 – Date  
**CONSULTANT**

Working with clients, including the United States Food and Drug Administration (FDA) and public advocacy groups, to:

- Provide training in, insight into, and analysis of the requirements of the drug CGMP statutes and regulations as well as their impacts and cost effective approaches to pro-active quality-based systems for compliance with said requirements. [**Note:** Areas addressed include method/process development, validation, and manufacturing, and electronic records.]
- Address public health and safety issues associated with current industry practices, FDA guidances and initiatives, and the CDC’s handling of the “mercury in medicines” issues.

In addition, currently oversee two Internet websites:

- <http://www.dr-king.com> on which my general background and other information is maintained.

- <http://www.mercury-freedrugs.org> on which pertinent advocacy-related articles are posted

Pro bono Science Advisor to CoMeD, NCOW, and other not-for-profit organizations who seek my advice.

R & D Scientific Corporation, Flanders, NJ 2000 – 2001  
**VP of QUALITY MANAGEMENT**

Spearheaded the conversion of manufacturing systems from *ad hoc* into documented systems that complied with the strictures of ISO 9001:1994.

Generated requisite policy, SOP, work instruction and tool documents for the quality management and related functions and provided quality systems guidance to the others.

Rewrote the Users Manual for their main product so that it actually matched that system's functionalities.

Paul G. King Consulting, Lake Hiawatha, NJ 1995 – 2000  
**CONSULTANT**

Worked with a variety of clients to solve their problems, develop and validate test methods and procedures, design robust processes, and improve their quality.

Audited proposals, systems, and suppliers as well as generated documents, methods, designs and systems as needed.

Nutro Laboratories, Inc., South Plainfield, NJ 1995 – 1996  
**DIRECTOR OF QUALITY**

To improve product quality, started the critical checking of data and effected production changes that upgraded product quality to meet Company and customer expectations.

Furnished the President of Nutro with detailed information on quality problems, their root causes and changes that could either eliminate the problem or reduce the risk of a recurrence.

Sidmak Laboratories, Inc., East Hanover, NJ 1992 – 1994  
**DIRECTOR OF QUALITY CONTROL**

In order to meet the expectations of the FDA, took charge of the development and validation of methods; reorganized operations; restructured lab audit and control procedures; and upgraded training and staff. [**Note:** The FDA's concerns were addressed.]

To address overcrowding and productivity, designed, equipped, and staffed two new laboratories within a \$3MM budget to meet ISO/IEC Guide 25 (now, ISO 17025) competency standards.

Implemented systems for: acquisition, evaluation and archival of all data; qualification of instruments and analysts; demonstration of analyst/equipment "suitability;" and critical evaluation of results.

Overall, lab productivity more than doubled.

Biocraft Laboratories, Inc., Fair Lawn, NJ 1986 – 1992  
**DIRECTOR LABORATORY QUALITY ASSURANCE** - 5.5+ years

Oversaw the auditing of the Laboratory and implemented a validated LIMS system.

Developed and validated stability-indicating methods for various bulk pharmaceuticals using HPLC and cleaning methods using UV spectroscopy.

To speed the registration of Cephalexin, developed and validated a sub-ppm HPLC method for detecting possible penicillin contamination that the FDA accepted by.

So that the drug product tested in a clinical trial could be produced reliably, developed a process, and the analytical controls, for the manufacture of the drug Sucralfate in China.

Biocraft Laboratories, Inc., Fair Lawn, NJ 1986 – 1992

**MANAGER OF QUALITY CONTROL LABORATORY** - 0.5 year

Developed improved HPLC, GC, and titrimetric methods for ingredient testing.  
Managed a Bulk Pharmaceutical Chemical Quality Laboratory that passed FDA Inspection and met the NJ DEP competency standards for the environmental testing it performed.

At-Sea Incineration, Parsippany, NJ 1985 – 1986

**MANAGER OF LABORATORY OPERATIONS** –

Oversaw all aspects of both the company's laboratory operations and the activities of the contract laboratories that performed testing for the company.

Berlex Laboratories, Cedar Knolls, NJ 1983 – 1984

**SENIOR SCIENTIST** –

Led the reorganization of the laboratory that increase its productivity and raised its stature.

Developed and improved analytical methods in support of Schering AG's drug discovery efforts.

Developed improved operational protocols and test procedures that improved laboratory productivity and the quality of the result values reported.

Found novel HPLC separation approaches for chiral compounds and chiral mixtures that improved component separation and quantitation.

BASF Wyandotte, Fairfield, NJ 1981 – 1983

**SENIOR RESEARCH SCIENTIST** –

Spearheaded International BASF Corporate Team that selected the Laboratory Information Management System (LIMS) vendor to be used by BASF worldwide.

Worked with German and Japanese scientists to evaluate and establish the ruggedness and utility of a key analytical method that I had developed.

Led Analytical Method Team that developed innovative methods for residue, impurity and actives for several biocides.

Designed and oversaw the installation of a state-of the-art gas distribution system for the laboratories.

Developed method for manufacturing "acetamide" HPLC columns that was critical for the analysis of the active and impurities in the herbicide POAST.

American Cyanamid, West Windsor, NJ 1976 – 1981

**RESEARCH SCIENTIST** –

Developed analytical methods and techniques for a variety of research and approved biocides.

Discovered and developed an impurity method for the analysis of N-nitroso-amine impurities in chemical compounds that allowed the approximate ppm or ppb level to be measured even where the structures of the impurities were not known.

Led team that redeveloped the process and analytical controls for a nitrated herbicide. [**Note:** This process improved process safety, throughput and costs.]

Supervised the successful overhaul of Puerto Rican laboratory operations for LEVAMISOL after the FDA had the facility “red tagged” – in less than two (2) months lab operation was brought into compliance.

Developed modernized Phase Solubility purity methodology for AVENGE.

Led corporate committee on HPLC, and oversaw the critical evaluation of laboratory equipment.

United States Army, Walter Reed General Hospital, Washington, DC 1969 – 1971  
**PHYSICAL SCIENCE ASSISTANT** – MOS: 01F20

Worked as clinical chemist and phlebotomist at the hospital.

Improved the sample handling and the precision and reliability of several continuous-flow, air-segmented automated analysis systems.

Won the Serviceman of the Quarter awards for the hospital, Walter Reed General Hospital, and the post, Walter Reed Army Medical Center.

Rose in rank from E-1 to the first in my unit to be promoted to E-5 (Specialist 5) in less than 18 months.

## **EDUCATION:**

**Postdoctoral Fellow** at THE UNIVERSITY OF GEORGIA, Athens, GA where I worked for Dr. L. B. “Buck” Rogers and helped develop an SCF system, an Enzyme Analysis System and improved the operation of a Laboratory Data Acquisition System.

**Ph.D., ANALYTICAL CHEMISTRY**, EMORY UNIVERSITY, Atlanta, GA. [In 1974, my dissertation, “The Automated Development of Analytical Methods,” won Sigma Xi award for excellence.]

**M. S., INORGANIC CHEMISTRY**, EMORY UNIVERSITY, Atlanta, GA. [My 1969 thesis dealt with the synthesis of Tantalum (V) chloro-alkoxide coordination compounds containing  $\beta$ -di-ketone ligands.]

**B.A., CHEMISTRY** (ACS Certified), VANDERBILT UNIVERSITY, Nashville, TN, 1967.

## **TECHNICAL TRAINING**

**TECHNICAL DEGREE** in “Computer Programming and Systems Analysis.” [A 1971 honor graduate from COMPUTER LEARNING CENTERS, INC., Rockville, MD.]

### **Technical Courses on:**

- ❖ Quality Management (2001),
- ❖ Aseptic Processing (2001), 21 CFR 11 (1999);
- ❖ How To Prepare For Your FDA Inspection: A Practical Approach (1999);
- ❖ FDA Global Inspections (1998);
- ❖ Current FDA Views on Pharmaceutical Laboratory Operations and CGMPs (1998);

- ❖ Computer Validation and the FDA (1997);
- ❖ Interfacing with the FDA (1997);
- ❖ Pre-Approval Inspection (1996);
- ❖ Validation and Auditing (1995);
- ❖ Software Auditing (1993); Various Aspects of the Pharmaceutical Industry (1991);
- ❖ QA for Labs (1989);
- ❖ Perkin-Elmer LIMS/CLAS System; Lab Automation and QC (1984);
- ❖ Personnel Supervision (1981); and
- ❖ Management (1978).

**CURRENT PROFESSIONAL AFFILIATIONS:**

- ❖ American Chemical Society [ACS]
- ❖ International Society for Pharmaceutical Engineering [ISPE]
- ❖ Parenteral Drug Association [PDA] [resigned at the end of 2010]

## DR. KING'S UNIVERSITY EDUCATION

- ❖ FROM September of 1974 until the end of 1975, Dr. King worked at THE UNIVERSITY OF GEORGIA in Athens, Georgia as a Graham Perdue Postdoctoral Fellow and Assistant Professor to Dr. L. B. (Buck) Rogers, Graham Perdue Professor. There he was, among other things, the System Manager, Systems Analyst, and Programmer for a Multi-User Hewlett Packard Minicomputer. Research efforts included the design and the construction of a computer-controlled system for constant-temperature ( $\pm 0.01$  °C) comparative study of enzymatic reaction rates of immobilized enzymes to the rates using the soluble enzyme.
- ❖ From mid-May of 1971 through: August of 1973, Dr. King attended EMORY UNIVERSITY in Atlanta, Georgia in a Ph.D. program under Dr. Stan Deming (who is currently at The University of Houston) that awarded him a Ph.D. in December of 1974 that was officially conferred upon him in June of 1975. Dr. King's major field of endeavor was Analytical Chemistry with minors in Inorganic Chemistry and Physical Chemistry. In Dr. King's Ph.D. program, he:
  - A. Partially designed and then constructed, installed, debugged, and validated a full bi-directional parallel multiplexed external interface to a **PDP-9** Minicomputer.
  - B. Designed, constructed, installed, debugged, and validated a remote interface to **PDP-9** for the robot, **MADAM** (**M**achine for the **A**utomated **D**evelopment of **A**nalytical **M**ethods).
  - C. Designed and constructed the power systems, controls and critical components for **MADAM**.
  - D. Debugged the operation of **MADAM** and validated that **MADAM** met or exceeded its hardware design specifications.
  - E. Working from a version of **FOCAL**<sup>™</sup> (a DEC interactive, interpretative language similar to BASIC) written for a **PDP-15 (FOCAL.LAL)**, Dr. King researched this computer's machine language; dissected the core coding needed for this project; and generated his own version of **FOCAL (FOCAL.PGK, version 1)**.
  - F. Wrote, debugged, and validated key machine-code patches to **FOCAL.PGK (Version 1A)** for the required data acquisition and control subroutines that provided real-time control and data acquisition capabilities for **MADAM**.
  - G. Generated, programmed, debugged, and verified the performance of his own "**SIMPLEX**" direct-search algorithms that were used by the robot to adaptively search for an "Optimum" as defined by Dr. King.
  - H. Selected a simple colorimetric analysis method for the determination of formaldehyde for his initial study; prepared the reagents needed by the robot, primed the eight (8) reagent delivery pumps and checked that the robot's component systems for acquisition (1) and system control (8) were operating as designed.
  - I. Generated a simple "optimum" (Absorptivity of the colored reaction product); started the robot's search for the optimum "greatest Absorptivity" using

“**EXPLEX**,” his modified **SIMPLEX** search algorithm; and monitored the performance of **MADAM** as the robot first found the region of optimum Absorptivity and then tracked it.

- J. Following mapping, he reviewed and verified all of the data and generated the appropriate reports.
  - K. Then, selected a more complicated colorimetric test having more variables and repeated steps **G** through **J**.
  - L. Finally, wrote his dissertation summarizing his research and findings, submitted the final document for review by the department, and defended his dissertation and findings in an open discussion that included faculty from all divisions of the Chemistry Department. [**Note:** In recognition of Dr. King’s contribution to science in chemistry, automation, and process control, his copyrighted dissertation, “*Automated Development of Analytical Methods*,” (ADAM) received a **SIGMA XI**’s annual award for scientific excellence.
- ❖ From September of 1971 through: April of 1969, Dr. King attended EMORY UNIVERSITY in Atlanta, Georgia in a Ph.D. program under Dr. Ronald C. Johnson that admitted him to Ph.D. candidacy and, in March 1969, awarded him an M.S. in Inorganic Chemistry. In Dr. King’s original Ph.D. program, he:
- A. Studied Inorganic, Physical, Physical and Organic Chemistry.
  - B. Prepared, characterized and studied several novel Tantalum (V) chloro-alkoxide complexes with  $\beta$ -di-ketone ligands.
  - C. Worked as a laboratory teaching assistant and tutor.
  - D. Wrote his thesis on “The Coordination Chemistry of Tantalum (V).”

In addition, Dr. King holds an ACS Certified B.A. in Chemistry with a minor in Physics from Vanderbilt University, Nashville, Tennessee (awarded in 1967).



## DR. KING'S ON-GOING TECHNICAL TRAINING

- A. Dr. King was certified as an **ASQ-Trained Quality Auditor** ([1995]), with competence certified by passing the formal ASQ written examination for Certified Quality Auditor.
- B. The numerous formal Technical Courses that Dr. King has successfully completed include:
  1. **ASQ Certified Quality Manager Course** (2001)
  2. **13<sup>th</sup> Annual ASQ Quality Management Conference** (2001) including:
    - a. Quality in a Lean Organization,
    - b. Tools of Six Sigma,
    - c. Navigating Your Organization Through the ISO 9000:2000 Transition,
    - d. Using the Theory of Constraints to Resolve the Quality Dilemma,
    - e. Using Quality Tools to Improve Performance Excellence in the Day-to-Day Operations, and
    - f. Certification: The Next Step for Quality Managers
  3. **25<sup>th</sup> International GMP Conference and Aseptic Processing Tutorial** (2001)
  4. **23<sup>rd</sup> International GMP Conference and How To Prepare For Your FDA Inspection: A Practical Approach** (1999);
  5. **FDA-sponsored training on 21 CFR 11** (1999);
  6. **FDA Global Inspections** (1998);
  7. **Current FDA Views on Pharmaceutical Laboratory Operations and CGMPs** (1998);
  8. **Computer Validation & Aspects of Process and Equipment Validation** (1997);
  9. **Interfacing with the FDA** (1997);
  10. **Pre-Approval Inspection** (1996);
  11. **Quality Auditing** (1995);
  12. **Pharmaceutical Validation** (1995);
  13. **Software Audits** (1993), "TESTING COMPUTER SYSTEMS IN PHARMACEUTICAL APPLICATIONS," given by **Confidence in Software**. The 3-day course covered:
    - a. **FDA** Requirements,
    - b. Planning Validation,
    - c. Validation Preparation,
    - d. Testing Modules,
    - e. Testing Interfaces,
    - f. Challenging Functions,
    - g. Challenging the System,
    - h. Conducting the Challenge, and
    - i. Acceptance Testing.
  14. **Various Aspects of the Pharmaceutical Industry** (1991);

15. Quality Assurance for Laboratories (1989);
16. *Perkin-Elmer LIMS/CLAS System Management and Operation* (1984) (Laboratory Information management System ["LIMS"] and Computerized Laboratory Acquisition System ["CLAS"]);
17. Laboratory Automation and Quality Control (1984);
18. Personnel Supervision (1981); and
19. General Management (1978).

C. From September 1970 through March 1971, he studied:

1. The formalized process by which software is defined, stated, written, debugged, tested and verified in a controlled documented manner,
2. Programming in several IBM System 360 languages (including Basis Assembly Language [BAL], FORTRAN 66, COBOL, and PL/1), and
3. The Fundamentals of Systems Analysis (including project planning, PERT charting, project auditing and review, and systems' standards).

In 1971, **COMPUTER LEARNING CENTERS, INC.** of Rockville, Maryland awarded him an honors diploma in "**Computer Programming and Systems Analysis.**" Dr. King went on to apply when he completed his active duty military service 1971 and returned to Emory University to successfully pursue his Ph.D.

## PUBLICATIONS BY PAUL G. KING

### 1969

1. **The Coordination Chemistry of Tantalum (V)**, 48+ pages (master's thesis) Ann Arbor Press 1969
2. Coordination Compounds of Niobium (V) and Tantalum (V) Chloroalkoxides with Ligands Related to beta-Diketones, *Journal of Less-Common Metals* (1969); **19**: 141-149, with R. C. Johnson *et al.*

### 1974

1. Computers and Experimental Optimization. *Research/Development*, 1974; **25**(5): cover and pages 22-24 & 26, with Stanley N. Deming.
2. **Automated Development of Analytical Methods**, 443+ pages (Ph.D. Dissertation that won a Sigma XI Award for Excellence) Ann Arbor Press 1974.
3. UNIPLEX: Single-Factor Optimization of Response in the Presence of Error. *Analytical Chemistry* 1974; **46** (11): 1476-1481, with Stanley N. Deming.

### 1975

1. DIFFICULTIES IN THE APPLICATION OF SIMPLEX OPTIMIZATION TO ANALYTICAL CHEMISTRY. *Analytical Letters* 1975; **8** (5): 369-376, with Stanley N. Deming and Stephen L. Morgan.

### 1984

1. Laboratory Automation and Information Management. *Analytical Instruments and Computers* 1984; **1**: 45-47.
2. Laboratory Computerization and Good Laboratory Practice Standards (GLPS). *Anal Instruments and Computers* 1984; **2**: 14-15.
3. Quality Assurance and Computerization in the Regulated Laboratory. *Computerized Applications in the Laboratory* 1984; **2**: 298-304.

### 1985

1. Intelligence in Instruments. *Instruments & Computers* 1985; **3**: 4-5.

### 1996

1. Articles in **The AOAC International's** periodical, *The Referee*, in 1996 on:
  - a. Business and the Laboratory;
  - b. Twentieth International Good manufacturing Practices Conference (in two parts);
  - c. ISO/IEC Guide 25 and Laboratory Competence;
  - d. Safe Handling of Hazardous Materials, Carcinogens and Biohazards.
2. Altered Dynamics for USP Apparatus 2. *Dissolution Technologies* 1996; **3**(3): 8-12.

### 1997

1. Bringing a Chinese Bulk Pharmaceutical Chemical Manufacturer Up to FDA Expectations. *J. cGMP Compliance* 1997 April; **1**(3): 38-43.
2. The Future of Validation A Validation "Life Cycle" Journey. *J. Validation Technology* 1997 May; **3**(3): 296-297.

3. ISO/IEC Guide 25, An International Quality System Standard, and the FDA-Regulated Laboratory. *J. cGMP Compliance* 1997 July; **1**(4): 25-35.
4. Equipment Validation A Logical Approach to the Pharmaceutical “Life Cycle” Journey - Part I of a Series -. *J. Validation Technology* 1997 August; **3**(4): 345-354.
5. Process Validation for Existing Processes A Logical Approach to the Pharmaceutical “Life Cycle” Journey - Part II of a Series -. *J. Validation Technology* 1997 November; **4**(1): 53-64.

### 1998

1. Process Validation for New Processes A Logical Approach to the Pharmaceutical “Life Cycle” Journey - Part III of a Series -. *J. Validation Technology* 1998 May; **4**(3): 234-242.
2. A Direct Approach to Determining The Valid Linear Range for A Comparative Method that Uses a Single Standard, *Scientific Computing & Automation* 1998 June: 63-64.
3. Improving cGMP Training Programs – Part One of a Two-part Series -. *J. cGMP Compliance* 1998 June; **2**(4): 56-63.
4. Improving cGMP Training Programs – Part Two of a Two-part Series -. *J. cGMP Compliance* 1998 October; **3**(1): 78-85.
5. Recommended Revisions to Several USP Standards. *Pharmaceutical Forum* 1998 November: **24**(6): 7343-7348.

### 1999

1. HPLC METHOD DEVELOPMENT AND VALIDATION: A Direct Procedure For Determining An HPLC Method's “Linear Through Zero” Range. *LC•GC* 1999 January; **17**(1): 46, 48, 50.
2. An Empirical Algorithm For Dissolution Profile Calculations. *Scientific Computing & Instrumentation*, March 1999: 76-77.
3. Process Validation – Establishing the Minimum Process Capability for a Drug-Product Manufacturing Process (Part 1 of 2: The Basics). *Pharmaceutical Engineering* 1999 November/December: **19**(6): 8-16, 74-86.

### 2000

1. Process Validation – Establishing the Minimum Process Capability for a Drug-Product Manufacturing Process (Part 2 of 2: Content Uniformity Examples and Extension to Other USP Tests). *Pharmaceutical Engineering* 2000 March/April; **20**(2): 72-88.

### 2004

1. An “American Mystery Disease”? *Medical Veritas*, 2004 November; **1**(2): 304.
2. The best medicine that money can buy? *Medical Veritas*, 2004 November; **1**(2): 305-312.

### 2005

1. Mercury Emissions, August 2005; 4 pages. <http://www.mercury-freedrugs.org>
2. Thimerosal Causes Mercury Poisoning I– A Rebuttal to Dr. Novella's Views, September 2005; 99 pages. <http://www.mercury-freedrugs.org>
3. Thimerosal Causes Mercury Poisoning III – Rebuttal To Dr. Orenstein's Views, 21 October 2005; 38 pages. <http://www.mercury-freedrugs.org>
4. Dr. King's Rebuttal to WSJ 051022 Pro Pharma Editorial for S\_1873, “Bioshield II”, 30 October 2005; 6 pages. <http://www.mercury-freedrugs.org>

5. Thimerosal Causes Mercury Poisoning II – Rebuttal To Dr. Offit's Views, November 2005; 30 pages. <http://www.mercury-freedrugs.org>
6. Thimerosal & Mercury Poisoning – Draft Review of CDC's 050922 Q&A on the Flu Vaccines, November 2005; 30 pages. <http://www.mercury-freedrugs.org>
7. Fearmongering – Flu Vaccines & Pandemic Scares – Marketing Mercury Poisoning?, November 2005; 3 pages. <http://www.mercury-freedrugs.org>
8. Critical assessment of CDC's “Questions and answers: Thimerosal-containing influenza vaccine.” *Medical Veritas*, 2005; **2**(2): 703-720.
9. Dr. King's Response To Dr Mike Fitzgerald's 051109 “When Quackery Kills,” 9 November 2005; 16 pages. <http://www.mercury-freedrugs.org>
10. Thimerosal Causes Mercury Poisoning IV – Review Of Dr Darshak Sanghavi's 051204 “The Secret Truth” Article, 6 December 2005; 34 pages. <http://www.mercury-freedrugs.org>
11. Dr. King's Review 051221 of Vaccine Liability- Congress Should Give Vaccines Shot in the Arm, 21 December 2005; 15 pages. <http://www.mercury-freedrugs.org>
12. Autism Speaks' Policy Statement On Mercury and Vaccines 051222 Draft Review, 22 December 2005; 7 pages. <http://www.mercury-freedrugs.org>

## 2006

1. Review of HR2863's Pandemic Flu Provisions & PREP\_Act, 3 January 2006; 33 pages. <http://www.mercury-freedrugs.org>
2. Thimerosal Causes Mercury Poisoning V – Review Chambers & McIntyre's “When Science Is Not Enough” Article, 15 February 2006; 82 pages. <http://www.mercury-freedrugs.org>
3. Thimerosal Causes Mercury Poisoning VI – Review Of Pro-Thimerosal Groups' Letter To Congress, 9 April 2006; 15 pages. <http://www.mercury-freedrugs.org>
4. Thimerosal Causes Mercury Poisoning VII – Rebuttal to “Beyond the Headlines: Link still claimed between thimerosal and autism” *Rev.* 3, 3 July 2006; 28 pages. <http://www.mercury-freedrugs.org>
5. Thimerosal Causes Mercury Poisoning VIII – Mercury-poisoning the Public: The case against the Thimerosal-preserved vaccines [a rebuttal to “Don't ban thimerosal ...”], 30 June 2006; 8 pages. <http://www.mercury-freedrugs.org>
6. Commentary: Thimerosal—what the Lister Hill transcript did not clearly state! *Medical Veritas*, 2006; **3**(1): 821-826.
7. Editorial – Thimerosal: Proven systemic human poison, immunogen and autoimmunogen, and suspect human, proven animal teratogen. *Medical Veritas*, 2006; **3**(1): 914-915.
8. Thimerosal Causes Mercury Poisoning IX – Immunization Issues [a rebuttal to “Arsenal of immunizations ...”] *Rev.*, 30 July 2006; 22 pages. <http://www.mercury-freedrugs.org>
9. Thimerosal Causes Mercury Poisoning X – Link Between Thimerosal and Pervasive Developmental Disorders [Draft Rebuttal to Fombonne et al.'s “Pervasive Developmental Disorders in Montreal, Quebec, Canada: Prevalence and Links With Immunizations”], 27 August 2006; 102 pages. <http://www.mercury-freedrugs.org>
10. Thimerosal Causes Mercury Poisoning XI – Draft Rebuttal to the Opinions of Peter Hotez and Rosalynn Carter in their article, “Act could turn the tide on common birth defect,” 27 August 2006; 73 pages. <http://www.mercury-freedrugs.org>
11. Geier DA, King PG, Geier MR. Influenza vaccine: Review of effectiveness of U.S. vaccination program, and policy considerations. *J Am Phys & Surg.* 2006 Fall; **11**(3): 69-74.

12. Thimerosal Causes Mercury Poisoning XII – Draft Response to the DHHS Letter Date-stamped “AUG 25 2006” – The DHHS's Response to “An Open Letter to the American Public” posted on the Internet on 9 April 2006, 9 September 2006; 60 pages. <http://www.mercury-freedrugs.org>
13. CoMeD's Petition to FDA for a STAY under 21 CFR Sec 10.35, 21 October 2006; 130 pages. FDA Docket 2004P-0349/PSA1 filed 24 October 2006 by FDA Division of Dockets Management.
14. CoMeD Response to FDA Letter Date-Stamped “DEC 21 2006,” December 24, 2006, 5 pages. <http://www.mercury-freedrugs.org>
15. CoMeD Review of NJ Dept Health & Senior Services Letter About Influenza Vaccines: Ineffective & A Mercury-poisoning Vector, 27 December 2006; 11 pages. <http://www.mercury-freedrugs.org>

## 2007

1. CoMeD's Recommendations for Changes to Revisions Proposed by the NJ Dept Health and Senior Services to N.J.A.C. 8:57-4, Immunization of Pupils in School, 24 January 2007; 14 pages. <http://www.mercury-freedrugs.org>
2. CoMeD Rebuttal to “For the Good of the Herd,” an op-ed piece by Arthur Allen published online on January 25, 2007 by the New York Times, 25 January 2007; 12 pages. <http://www.mercury-freedrugs.org>
3. Review of Kevin Leitch's Critique of “Autistic Children Clinically Proven Mercury Poisoned,” April 2007, 12 pages. <http://www.mercury-freedrugs.org>
4. Thimerosal Causes Mercury Poisoning XIII – Rebuttal to an editorial in Nature Neuroscience 2007; 10: 531, “Silencing debate over autism,” 6 May 2007; 18 pages. <http://www.mercury-freedrugs.org>
5. Thimerosal Causes Mercury Poisoning XIV – Updated Review of “Another Salvo in the Mercury/Autism Controversy” By Stephan Novella, 18 May 2007; 16 pages. <http://www.mercury-freedrugs.org>
6. The Deadly Panacea: Vaccines, Immunity & Corporate Science. *ACRES USA* May 2007; **37**(5): 56-60.
7. Critical assessment of an FDA letter concerning a Citizen Petition specifying actions against Thimerosal-containing drugs. *Medical Veritas*, 2007; **4**(1): 1282-1370.
8. Note regarding filing of 2007P-0331 – submitted for publication, 24 August 2007; 1 page. <http://www.mercury-freedrugs.org>
9. 2007P-0331 Ban Use of Mercury In Medicine, UNLESS Proven Toxicologically Safe to the CGMP Standard Sufficiently Nontoxic, 24 August 2007; “447” pages. <http://www.mercury-freedrugs.org>
  - 9.1 2007P-0331 Ban Use of Mercury In Medicine, UNLESS Proven Toxicologically Safe to the CGMP Standard Sufficiently Nontoxic: Initial remarks, signature pages, supporting organizations, outline, and references listing, 10 August 2007; 25 pages. <http://www.mercury-freedrugs.org>
  - 9.2 2007P-0331 Ban Use of Mercury In Medicine, UNLESS Proven Toxicologically Safe to the CGMP Standard Sufficiently Nontoxic: Formal Citizen Petition text, “10 August 2007”; 422 pages <http://www.mercury-freedrugs.org>
10. Instructions for Submitting Comments to FDA Docket # 2007P-0331, 30 August 2007; 2 pages. <http://www.mercury-freedrugs.org>
11. Thimerosal Causes Mercury Poisoning XV – Mercury Poisoning by Thimerosal in Vaccines – A Rebuttal to the Doublespeak in: “On Vaccines, Immune to Reason” By Paul Howard, 18 October 2007; 19 pages. <http://www.mercury-freedrugs.org>

12. Thimerosal Causes Mercury Poisoning XVI – No Proof Of Safety for Thimerosal in Vaccines – A Rebuttal to the Doublespeak in: “Suffer the Little Children” No More By Michael Fumento, 29 October 2007; 20 pages. <http://www.mercury-freedrugs.org>
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## **OTHER DOCUMENTS & COMMENTS DIRECTLY (OR INDIRECTLY, THROUGH THE FEDERAL COURTS) SUBMITTED TO THE FDA**

**By Paul G. King**

1. Formal comments on the FDA's "Current Good Manufacturing Practice; Proposed Amendment of Certain Requirements for Finished Pharmaceuticals," IN SEPTEMBER 1997.
2. "In-Process 'Powder' Blend Sampling And Evaluation (And Appropriate In-Process and Final Release Specifications)," A WHITE PAPER, JANUARY 1998. [This condensed white paper was submitted to certain key industry and FDA administrators at the 23<sup>rd</sup> International GMP Conference held in March 1999 at the University of Georgia in Athens, GA. The Agency has reviewed, commented on, and provided a formal response (late in 1999) on one of the key issues discussed (in-process mix uniformity testing).]
3. Formal comment on FDA's proposed 21 CFR 26, "Mutual Recognition of Pharmaceutical Good Manufacturing Practice Reports, Medical Device Quality System Audit Reports, And Certain Medical Device Premarket Evaluation Reports Provide By European Community Member State Regulatory Authorities And European Community Conformity Assessment Bodies" in May 1998. [Agency ignored or misrepresented comments when they responded to them.]
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15. Initial Formal Comments To Docket 03D-0061 - "Draft Guidance, Comparability Protocols - Chemistry, Manufacturing, and Controls Information," pp. 14; posted 15 May 2003"
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17. Updated Formal Comments To Docket 03D-0061 – “Draft Guidance, Comparability Protocols — Chemistry, Manufacturing, and Controls Information,” pp. 14, submitted 9 May 2003.
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 ... [Numerous additional comments to the FDA concerning the original **CoMeD** Citizen Petition and the illegal actions taken by FDA appertaining thereto; another **CoMeD** Citizen Petition and the correspondence arising there from; and numerous legal filings in 2 federal lawsuits seeking to have the U.S. Federal Courts compel the Commissioner of the FDA and the Secretary of HHS to comply with the laws governing the conduct of their reports in a manner that complies with federal statutes (42 U.S.C. § 300aa-27 and 21 U.S.C. § 351(a)(2)(B)) and the operational regulations (e.g., 21 CFR § 601.4) governing the conduct of federal administrative personnel (one of which is still being litigated) as well as contributions to other filed and/or pending federal litigation on vaccine issues.]
- ~60. Formal **CoMeD** Docket Comments' Review Comment To: FDA Docket: FDA-2010-N-0099 - [RIN 0910-AG15] "Revision of the Requirements for Constituent Materials" [FDA-2010-N-0099-0007.1.pdf] pp 10, Submitted 25 June 2010.