Curriculum Vitae
Alfred V. Del Grosso, Ph.D.
July 2021

A. **Education:**

University	Degree	Year	Major	Minor
The American Univ., Washington, D.C.	Ph.D.	1991	Analytical Chemistry	Organic Chemistry
Univ. of Maryland, College Park	B.S.	1976	Chemistry	Zoology

B. **Positions**

Employer	Time Period	Position
FDA/CBER/OCBQ/Division of Biological Standards and Quality Control/Laboratory of Chemistry And Blood Related Products	2011-2018	Chemist-Team Leader (GS-14)
FDA/CBER/OVRR/Division of Product Quality/Product Testing Laboratory	2006-2011	Chemist-Team Leader (GS-14)
FDA/CBER/OVRR/IOD	2003-2006	Chemist (GS-14)
FDA/CBER/Office of Vaccines/IOD	2002-2003	Chemist (GS-13)
FDA/CBER/Division of Manufacturing and Product Quality	1998-2002	Chemist (GS-13)
FDA/CBER/Division of Product Quality Control	1992-1998	Chemist (GS-13)
FDA/CBER/Division of Biochemistry and Biophysics	1980-1992	Chemist (GS-9 to GS-13)
The American University/ Dept. of Chemistry	1984	Instructor, General Chemistry
FDA/Bureau of Biologics / Division of Control Activities	1976-1980	Chemist (GS-5 to GS-9)
Univ. of Maryland, Dept. of Chem.	1975-1976	Research Assistant
U.S. Bureau of Mines, College Park Metallurgy Research Center	1975-1976	Physical Science Aide

C. **Additional Training**

ISO Guide 34:2009 General Requirements for Competence of Reference Material Producers	2014
DoE Basics for Validation by Design	2012
LC/MS-MS for Chromatographers	2011
Waters Associates – Synapt G2 Biomolecule	2011
CMC Review: Methods Development and Validation I & II	2009
FDA Supervisory Potential Training	2006
Good Review Management Principles (GRMP)	2005
Lab Quality System – Documentation System Training	2004
CDER/CBER Joint PDUFA III Training	2003
ISO 17025 Compliance – Uncertainty Management	2003
SAS JMP Basic / Advanced	2003
American Society for Quality, Introduction to Quality Management	2002
American Society for Quality, Implementing and Auditing an ISO 9000 Quality System	2002
American Society for Quality, Audit Fundamentals	2002
Agilent Technologies – Advanced Chemstation	2002
FDA/CBER Case Study Seminar Series: Specifications, Stability and Statistics	2002
Agilent Technologies – LC/MS Iontrap Use and Maintenance	2001
AOAC - Auditing ISO Management Systems	2001
QMSLA – ISO Management Systems for the Laboratory, ISO/IEC 17025	2001
Agilent Technologies – Basic HPLC Chemstation	2001
Introductory Food and Drug Law	1998
Biologics Inspectors Training – Therapeutic and Biotechnology Derived Products and Allergenic Products	1998
Workshop on TSE Risks in Relation to Source Materials, Processing, and End-Product Use	1998
Pall Corporation - Advances in Filtration Technologies	1997
CBER Reviewer Training Program	1997
Pall Co., Advances in Filtration and Bioseparation	1997
Hewlett Packard HPLC System 1050 Maintenance	1995
CBER Workshop for Certified Inspectors	1995
CBER Inspections Training Sequence, Modules I - VI	1994
FDA/CDER - Topics in Applied Statistics, the Future of Expiration Dating	1992
Univ. of VA - Sequencing of Polypeptides by Mass Spectrometry	1991

D. **Honors and Awards**

FDA Recognition Award – Test Methods Review Course	2018
40 Year Service Award: FDA	2016
FDA Group Recognition (Cross Cutting) Analytical Procedures Guidance Doc.	2014
CBER Group Award, Flublok-Influenza Review	2014
CBER Group Award, Menhibrix Licensure	2013
CBER Center Directors Distinguished Service Award	2012

Commissioner's Special Citation, CBER Laboratory Quality System	2011
Public Health Achievement, Hiberix and Ixiaro Licensing Team	2010
Commissioner's Special Citation, FDA Response to 2009 H1N1	2010
CBER Group Award – Laboratory Quality Development	2009
CBER Group Award, Alfuria Influenza Vaccine Licensure	2008
CBER Group Award, FluLaval Influenza Vaccine Licensure	2007
DHHS Secretary's Award for Distinguished Service, Influenza Review Team	2006
30 Year Service Award; FDA	2006
DHHS Secretary's Award for Distinguished Service, Prussian Blue Team	2004
Alpha Chi Sigma, Washington Professional Service Award	2003
FDA Performance Award / Lab. Accreditation Activities	2002
Certificate of Appreciation: CBER Training Initatives	2002
Anti-Hemophilic Factor, ReFacto Group Award	2000
Certificate of Appreciation: Team Biologics Core Instruction	2000
Group Recognition Award: Team Biologics	2000
Allergenic Extract Standardization Group Award	1993
Acellular Pertussis Vaccine Characterization Group Award	1992
Allergenic Extract Standardization Group Award	1991

E. Attendance at National and International Scientific Meetings

FDA Science Forum, 2003 - 2006

American Chemical Society, 1983, 1988, 1990, 1998. 2001, 2003, 2008

International Ion Chromatography Symposium, 2002

WCBP, Interface of Analytical and Regulatory Science for Biotechnology Products, 2001, 2002, 2005, 2009 - 2017

International Conference on Column Liquid Chromatography, 1988, 1990, 1994, 2018

International Workshop on Freeze Drying and Formulation, Bethesda, MD, Oct. 24-26, 1990

AOAC International, 1984, 1995. 2000, 2003

Pittsburgh Conference for Analytical Chemistry and Applied Spectroscopy, 1984, 1985, 1987, 1991, 1993, 1999, 2012

Food and Drug Law Institute, Annual Educational Conference, 1979, 1984, 1990

F. Publications:

1. H. Wang, M. Levi, A. Del Grosso, W. McCormick, L. Bhattacharyya; An improved size exclusion-HPLC method for molecular size distribution analysis of immunoglobulin G using sodium perchlorate in the eluent, J. Pharm. Biomed. Analysis 138, 330-343 (2017)

2. Applications of Ion Chromatography in Biological Product Analyses, Chapter 22 in Applications of Ion Chromatography for Pharmaceutical and Biological Products, J. Wiley and Sons, 2012, L. Bhattacharyya and J. Rohrer Eds.

3. Y. Yang, C. Brownell, N. Sadrieh, J. May, A. Del Grosso, R. Lyon, P. Faustino; Validation of an in vitro method for the determination of cyanide release from ferric-hexacyanoferrate: Prussian Blue; J. Pharm and Biomedical Analysis 43, 1358-1363 (2007)

4. H. Wang, A. Del Grosso, J. May; HPLC Determination of Benzethonium Chloride in Anthrax Vaccine Adsorbed; Biologicals (2006)

5. J. Cieslak , C. Ausin, M. Chmieleski, J. Kauffman, J. Snyder, A. Del Grosso, S. Beaucage; 31P NMR study of the desulfurization of oligonucleoside-phosphorothioates effected by “aged” trichloroacetic acid solutions; J. Org. Chem. 70(8), 3303-6, (2005)

6. Y. Yang, P. Faustino, P.S. Pine, H. Davis, N. Grunberg, J. Phillips, R.C. Lyon, L.X. Yu, A. Ciavarella, A. Del Grosso, J. Hanig; Determination of plasma and brain levels of isotretinoin in mice following single oral dose by high-performance liquid chromatography; J. Pharm. Biomed. Analysis 37, 157-163, (2005)

7. J.C. May, A. Del Grosso, R. Wheeler, N. Etz; TGA/MS Capillary Interface, Applications to determination of residual moisture in BCG vaccine and other freeze-dried biological products; J. Thermal Analysis, 49, 929-936, (1997)

8. J.C. May, R.M. Wheeler, N. Etz, A. Del Grosso; Measurement of Final Container Residual Moisture in Freeze-Dried Biological Products; Develop. Biol. Standard., 74, 153-164, (1991)

9. A. Del Grosso. Doctoral Dissertation, "Metal Interaction Chromatography of Sulfonamides" - The American University, Washington, D.C, August (1991).

10. J.C. May, R. Wheeler, A. Del Grosso; Compositional Analysis of Drugs and Injectable Biological Products by Thermogravimetry; American Society for Testing and Materials Special Publication 997, 48-55 (1988).

11. J.C. May, A. Del Grosso; TG/MS Interface: Applications to the Determination of Moisture in Polysaccharides and Freeze-Dried Biological Products; Thermochimica Acta, 115 (1987) 289-29

12. A. Del Grosso, J.C. May; Gas Chromatographic, Liquid Chromatographic and Titrimetric Procedures for Determination of Glycerin in Allergenic Extracts and Diagnostic Antigens: Comparative Study; J. Assoc. Off. Anal. Chem. (1987) 70, 825-828.

13. J.C. May, A. Del Grosso, R. Barron; Determination of Phenol in Injectable Biological Products by Gas Chromatography; J. Biol. Standardization 8 (1980) 209-218.

G. Published Abstracts:

1. Ciavarella, A. Del Grosso, ICH Validation and Application of a Method for Analysis of 2-Phenoxyethanol in Biological Products with Robustness Testing Using Experimental Design, American Chemical Society National Meeting, 2009
2.
3. A. Del Grosso, J. May, GC/MS Determination of Tetrachloroethylene in Allergenic Extract Pollen Source Materials AOAC International, Atlanta GA, September, 2003

4. A. Del Grosso, "An FDA Regulatory Perspective on Analytical Procedures", Invited Speaker, 20th Annual Triangle Chromatography Meeting, Raleigh NC May, 2003

5. A. Del Grosso, J. May, GC/MS Determination of Tetrachloroethylene in Allergenic Extract Pollen Source Materials FDA Science Forum, Washington, D.C., April 2003

6. A. Del Grosso, J. May, H. Wang, Analytical Methods Development at FDA CBER, Laboratory of Analytical Chemistry Office of Vaccines Research and Review – Invited Speaker, American Chemical Society National Meeting, FDA Regulatory Science Symposium, New Orleans, LA, March 2003

7. Wang, A. Del Grosso, J. May, HPLC Determination of Benzethonium Chloride in Anthrax Vaccine, WCBP 2002 (Interface of Analytical and Regulatory Science for Biotechnology Products)

8. A. Del Grosso, HPLC Determination of Glutaraldehyde in Vaccine Products by Pre-Column Derivatization with p-Nitrobenzyloxyamine, International Symposium on Column Liquid Chromatography, Minneapolis, MN, 1994

9. A. Del Grosso, J. Girard, Metal Interaction Chromatography of Sulfonamides, International Symposium on Column Liquid Chromatography, Boston, MA, 1990

10. A. Del Grosso, J.C. May, Reversed-Phase Ion-Pair HPLC Procedure for Determination of Histamine in Allergenic Skin Test Control Solutions, 195th National ACS Meeting, Toronto, Canada, June, 1988

11. J.C. May, A. Del Grosso, R. Wheeler, A New TG/MS Interface: Applications to the Determination of Moisture in Polysaccharides and Freeze-Dried Biological Products, 15th North American Thermal Analysis Society Conference, Cincinnati, OH, Sept. 1986

12. A. Del Grosso, J. Progar, J. May, High Performance Liquid Chromatographic Determination of Formaldehyde in Vaccines, Toxoids, Formaldehyde Modified Allergenic Extracts and Other Biological Products. International Mtg. of the Association of Official Analytical Chemists, Washington, D.C., 1984

13. A. Del Grosso, J. May, Comparative Study: Liquid Chromatographic, Gas Chromatographic and Titrimetric Procedures for the Determination of Glycerol in Biological Products, 186th National ACS Mtg., Washington D.C., 1983

H. Oral Presentations and Workshops:

"Lifecycle Management Concepts to Analytical Procedures: FDA Guidance and USP <1220>, Kenx-Analytical Procedures and Methods Validation June 2019, Philadelphia, PA

"Regulatory Considerations for Analytical Procedures in Product Development" – Invited Speaker at "Well Characterized Biologicals Conference", IBC Life Sciences October 2018, Rockville, MD

Continued Performance Monitoring for Biological Products, June 2019 CBER/FDA: a) Information and History, b) Method Verification and Transfer, c) Method Replacement and Comparability

"Phase Appropriate Method Validation Strategies", Session Co-chair at CASSS CMC Strategy Forum, Washington, D.C. 2018

"Analytical Methods Transfer – Considerations for Biological Products", CASSS CMC Strategy Forum, ashington, D.C. 2017

"Exploring the July 2015 CDER/CBER Guidance on Analytical Procedures and Methods Validation for Drugs and Biologics" – Invited Speaker "Informa Life Sciences 6th Annual Analytical Method Development, Validation and Transfer, Sept. 2016, Berlin, Germany (by teleconference)

"Ten Key Considerations for Analytical Procedures and Validations in IND and BLA Submissions" – Invited Speaker "Informa Life Sciences 4th Annual Analytical Method Development, Validation and Transfer, Sept. 2014, Berlin, Germany

"Bridging Analytical Methods for Release and Stability Testing: Technical, Quality and Regulatory Considerations", Session Co-chair at CASSS CMC Strategy Forum, Washington, D.C. 2014

"Analytical Lifecycle Management", Workshop co-host at WCBP 2014, Washington, D.C.

"Top Ten List of Analytical Inadequacies in IND or BLA Submissions" – Invited Speaker "Well Characterized Biologicals Conference", IBC Life Sciences October 2013, Washington D.C.

"Applications of Ion Chromatography in Vaccine Characterization" Pittcon 2013, Philadelphia, PA

"Specification Setting Strategies" Workshop co-host at WCBP 2013, Washington, D.C.

"Current Issues in Analytical and Process Validations" 18th Annual Validations Week, Institute for Validation Technology, October 2012, Philadelphia, PA

"Assay Lifecycle: How, What, When and Why", Workshop co-host at WCBP 2012, San Francisco, CA

"Analytical Procedures – Key Parameters that Require Validation",Invited Keynote Speaker "Institute for Validation Technology, August 2011, Philadelphia, PA

"Analytical Procedures – Key Parameters that Require Validation",Invited Keynote Speaker "Institute for Validation Technology, July 2010, San Francisco, CA

"Methods for the Analysis of Residual Moisture in Biological Products", CBER Analytical Technology Series December 2009.

"Physico-Chemical Test Methods", CBER/ ORA Team Biologics Training, October 2009

"FDA Requirements for Analytical Procedures and Methods Validation", Invited Speaker, Washington Chromatographic Discussion Group, March 2005, Germantown, MD

"No Job is Finished Until the Paperwork is Done: GLP vs. GMP Practices", Workshop Session 1, WCBP 2005, January 2005, Washington, D.C., with S. Kuwahara (consultant)

"An FDA Perspective on Analytical Procedures", Invited Speaker, Chromatography Forum of the Delaware Valley, January 2004, Claymont, DE

"An FDA Regulatory Perspective on Analytical Procedures", Invited Speaker, 20th Annual Triangle Chromatography Meeting, Raleigh NC, May, 2003

"FDA's Center for Biologics - Origins, History and Current Challenges" – Alpha Chi Sigma Professional Service Award Recipient Address, Washington, D.C., May 2003

"Analytical Methods Development at FDA CBER, Laboratory of Analytical Chemistry Office of Vaccines Research and Review" – Invited Speaker at American Chemical Society National Meeting, FDA Regulatory Science Symposium, New Orleans, LA, March 2003

"Transfer of Analytical Procedures – Over the Wall, Across the Hall and Across the Ocean" – Workshop co-host at WCBP 2002, January, 2002

"Validation of Chromatographic Methods", CBER Workshop on Validation of Analytical Procedures, December, 2001

"Transfer of Analytical Methods to Quality Control" – Workshop co-host at WCBP 2001 (Interface of Analytical and Regulatory Science for Biotechnology Products), January, 2001

"Procedures for the Determination of Total Protein", FDA Team Biologics Core Team Training Course, April, 2000

"Allergen Patch Tests – Analytical Procedures and Technical Issues", CBER Inspectors Training for Biotechnology Derived Products and Allergenic Extracts, July, 1998

"Allergenic Extracts – Chemical Component Assays", CBER Inspectors Training for Biotechnology Derived Products and Allergenic Extracts, July, 1998

"The Chemistry of Poison Ivy", Washington Professional Chapter, Alpha Chi Sigma, February, 1995

"Current Status of Poison Ivy/Poison Oak Extracts", Food and Drug Administration, Allergy Products Advisory Committee Mtg., October, 1991

"Technical Issues in FDA Review of Allergen Patch Tests", Food and Drug Administration, Allergy Products Advisory Committee Mtg., October, 1990

"Immobilized Bioluminescent Enzymes, Applications in Continuous Flow Analyses", The American University, Chem. Dept. Seminar, March, 1985

"Separation, Identification and Quantitation of Contact Dermatitis Agents in Poison Ivy and Other Plants of the Genus Toxicodendron", The American University, Chem. Dept. Seminar, Oct., 1984

"Progress in the Development of Analytical Methodology: Chemical Constituents of Biological Products", Division of Biochemistry and Biophysics Seminar, Feb., 1984

"Application of Macroporous PSDVB Resins as Stationary Phases for High Performance Liquid Chromatography", The American University, Special Topics in Analytical Chemistry Seminar, October, 1982

"Review of the Status of Formaldehyde and Formaldehyde Testing at the Bureau of Biologics", Division of Biochemistry and Biophysics Seminar, April, 1981

FDA Committee Memberships

CBER CMC Coordinating Committee DBSQC Representative 2009 - 2018

CBER Laboratory Safety Committee, 2008 – 2018, Chair 2012 – 2018

CDER/CBER Guidance Document Development Committee – "Analytical Procedures and Methods Validation" - CBER representative, 2000 – 2006, 2012 – 2015

CDER Analytical Methods Technical Committee – CBER representative, 2000 -2006

FDA Import Strategic Policy Committee – Applied Science Subcommittee – CBER co-representative, 2002

CBER Laboratory Accreditation Committee – 2002 – 2009

CBER Laboratory Accreditation- Software Committee – 2002 - 2007

Inspections of CBER Licensed Establishments (since 1992)

Participated as product specialist inspector in 15 FDA inspections of licensed biological product manufacturers of allergenic extracts, allergenic source materials and allergen patch tests (diagnosis of allergenic contact dermatitits).

J. **Professional Societies:**

American Chemical Society	1976- present
Chemical Society of Washington	1979- present
Alpha Chi Sigma	1975- present
AOAC International	1984- 2005
Washington Chromatographic Discussion Group	1976-1989, 2003-present

K. **CBER Licensing Committees (since 1992)**

Member or consultant for over 300 reviews of biological product license applications or license supplements for vaccines, hematologic and allergenic products.

Review activities have been primarily in the areas of chemical CMC issues and analytical procedures for drug substance and drug product components, impurities, potency and consistency.

L. **Significant Accomplishments:**

Transferred, Modified and Verified USP <341> Antimicrobials gas chromatographic procedures for phenol, benzyl alcohol and parabens.

Developed GC method for 2-phenoxyethanol in vaccines based on USP <341> procedures. Procedure has been adopted as an industry standard.

Developed and validated HPLC, titrimetric and GC methods for glycerin in allergenic extracts. These procedures have been adopted as industry standards.

Developed gas chromatographic method for urushiol in poison ivy and poison oak extracts. Method was adopted by manufacturer.

Developed pre-column derivatization HPLC method for glutaraldehyde in combined vaccine products. Method has been adopted by two manufacturers.

Developed ion-pair RPLC method for histamine in positive skin test control. Method adopted by manufacturer.

Served as expert witness in criminal trial and conviction of Dr. Gonsalves, Providence Rhode Island. Testimony was presented on 2/27/04. Provided evidence based on HPLC, Ion Chromatography and GC/MS analyses of vaccine components to support charge of vaccine adulteration in clinical practice.

Tested numerous other vaccine and other biological product samples for evidence of adulteration and/or dilution. Prepared reports for use in criminal trials by state and federal agencies.

Served as CBER expert in analytical methods validation issues including development of CBER/CDER guidance document "Analytical Procedures and Methods Validation". Current revision published as Draft for Comment.

Served as expert in analytical methods validation issues on CBER Laboratory Accreditation Committee.

Served as CBER expert on analytical methods technology on FDA Import Strategic Plan – Applied Science and Technology Subcommittee.

Drafted CBER ISO 17025 compliant Procedural Documents for:

- Internal Auditing Procedures
- Validation of Analytical Procedures
- Estimation of Measurement Uncertainty
- Reporting of Results

Served on software evaluation subcommittee of CBER Laboratory Accreditation Committee. Evaluated several integrated quality management systems for suitability with respect to CBER laboratory management requirements. Recommended system and wrote justification for purchase.

Trained CBER staff in analytical procedure requirements for chromatographic, spectroscopic and total protein methods.

Trained CBER staff in requirements for validation of analytical methods.

Adopted and verified manufacturer's methods for:

Polyribosyl-ribitol-phosphate (PRP) in combined DTP–Haemophilus B Vaccine by gas chromatography.

Benzethonium chloride in anthrax vaccine by titrimetry.

Histamine in positive skin test control by pre-column fluorescamine derivatization and HPLC with UV detection.

Ethylene glycol in solvent treated pooled plasma by capillary gas chromatography.

Ethyleneiimine dimer (Inactine) in immune globulin products by cation exchange chromatography with post-column derivatization.

Developed the following methods for CBER use:

HPLC method for dihydroxyphenylalanine (L-DOPA) to measure of tyrosine hydroxylase activity in PC-12 cell cultures. Potential marker for TSE infectivity. Implemented acetylcholinesterase and total protein determinations in support of the same project. Work in progress.

HPLC method for anti-microbial preservative benzethonium chloride. Developed initial method for analyte; guided post-doctoral fellow in validation of method and application to anthrax vaccine.

Buffer anions and cations by high performance ion chromatography. Determinations of chloride, phosphate, acetate and sodium were used to support the reviews of several license applications. Determination of potassium was used to establish probable source of contamination of a tuberculin purified protein derivative (PPD) complaint sample.

HPLC method for determination of thimerosal and degradation products thiosalicylic acid and di-thiosalicylic acid in vaccines and immune globulin products.

HPLC pre-column derivatization (3,5 dinitrobenzoyl deriv.) method for azide in purified tuberculin antigen and latex antigen reference material.

HPLC pre-column derivatization method for formaldehyde in vaccines.

GC procedures for methanol, ethanol, acetone and ethyleneglycol in vaccines, hematologic and therapeutics.

GC procedure for m-Cresol in Equine Antivenins

Dynamic headspace (purge and trap) gas chromatographic procedure for residual tetrachloroethylene in allergenic extracts produced from pollen source materials.

Liquid solvent extraction GC/MS procedure for residual tetrachloroethylene in allergenic extract source pollens.

Dynamic headspace (purge and trap) gas chromatographic procedure for residual chloroform in Hepatitis A vaccine.

GC and GC/MS procedures for squalene as an alleged adulterant in Anthrax Vaccine Adsorbed.