

Curriculum Vitae

Ellen Raaf

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Senior Consultant

Biologics Consulting Group, Inc.

Sanford, NC

SUMMARY OF EXPERTISE

- Quality Assurance professional with over 20 years in the vaccine and biopharmaceutical arena; 10+ years each in management, R&D and Quality.
- Strengths include optimizing Quality Systems, Stability, Analytical Chemistry and Microbiology, assay and equipment validation, process development and technology transfer.
- Strong knowledge base of GMP, GLP, ICH guidelines.
- Trackwise Coordinator, Configuration, and Utilities certifications.

EDUCATION

B.S. *Microbiology*, The Pennsylvania State University (1985)

B.S. *Medical Technology*, Lankenau School of Medical Technology, ASCP registry (1985)

EXPERIENCE

Biologics Consulting Group, Inc., Senior Consultant

Sanford, NC (Nov. 2007 - present)

Biolex, Inc. Manager, Quality Assurance

Pittsboro, NC (2006 – Oct. 2007)

- Provided oversight and improvements of the quality systems for a 2-product facility.
- Tracked nonconformances and trends, deviations, investigations, CAPA, and Change Control.
- Oversaw the administration and review of documents to include: Batch records, SOPs, protocols, and other technical documents.
- Responsible for batch release and issuance of certificates of compliance by accurate and timely review of all batch records, solution records, in-process data, release data and certificates of analysis.
- Mentored and coached systems administrators and quality specialists.

Embrex Poultry Health, LLC, Senior Manager, Quality Assurance and Control

Laurinburg, NC (2004 – 2006)

- From start-up to pilot licensing serials, established in less than 6 months a staffed and trained QA/QC Department for a start-up poultry vaccine facility.
- Developed and implemented Quality Assurance and biosecurity programs, strategies and processes to ensure product safety and biological containment.
- In accordance with 7 CFR and 9 CFR established QC procedures to ensure accurate and valid data for purity, safety, efficacy and potency tests.



- Ensured manufacturing procedures and documentation were in compliance with regulatory requirements. As Head Government Liaison maintained timely correspondence and accurate regulatory documentation.
- Designed and participated in Research & Development animal protocols and laboratory experiments for Field Safety submissions.

Bayer Corporation, *Quality Manager, Systems Administration*
Clayton, NC (2003 - 2004)

- Directed a department staff of 30+ personnel, managed \$4 million budget, and served as Subject Matter Expert for several disciplines within the department.
 - Managed the Stability Department to support clinical trial material, and 12 commercial products, which included 1000+ active stability programs.
 - Managed the Standards and Controls program to qualify and provide expiry dating for product in order to assure test methods were properly validated and maintained a state of control.

Bayer Corporation, *Project Manager, Quality Assurance Release and Compliance Systems*
Clayton, NC (2001 - 2003)

- Provided Quality Assurance and Technical Oversight for the Animal Facility, Quality Control and Analytical Support
 - Managed and reviewed Change Control systems, Discrepancy and Failure Investigations, and Corrective Actions in order to assess batch disposition and product impact.
 - Reviewed Technical Registration Documents, assay development, and assay and equipment validation documents.
 - Served as a site 'super-user' and trainer for Trackwise.
- Enforced Site Compliance and Supported Product Release
 - Trained the laboratories on pertinent Quality procedures in order to stay current with FDA and industry practices.
 - Supported CQA, internal audits, and GCA, FDA, and PAI inspections and commitments.
 - Ensured monthly product release schedule was maintained.

AlphaVax, *Manager, BioAnalytical Methods Development and Quality Control Laboratories*
Durham, NC (2000 – 2001)

- Established Quality Control and Development laboratories
 - Developed and optimized viral test methods from Research & Discovery to Development & QC.
 - Ensured timely testing of stability, clinical trial intermediates and final dosage material.
- Established a Quality Function for a start-up biotechnology company specializing in HIV, and cancer vaccines
 - Implemented Standard Operating Procedures, Standard Test Methods, Cell Bank and Batch Productions Records, and Product Specifications.
 - Served as compliance oversight for the release testing laboratories.
- Performed Regulatory oversight



- Provided technical documentation for the CMC sections of IND/CTX, NIH grants, Investigator Brochures.
- Educated and trained Research & Discovery on cGMPs, USP, ICH, and FDA guidance for Contract Services to include: animal testing, contract manufacturing, and product

Wyeth-Lederle Vaccines and Pediatrics, QC Senior Supervisor, Microbiology

Sanford, NC (1996 – 1999)

- Managed and mentored ~10 laboratory staff
 - Responsible for \$6.2 million budget expansion of new 10,000 sq. ft. laboratory, equipment purchases, labor cost forecasts, and hiring of personnel to support new vaccine launches.
 - Responsible for release of commercial product, bulk intermediate, and clinical trial material.
- Improved Analytical and Microbiological laboratory compliance
 - Provided technical support to Product Development and Technical Services, participated in PAI submissions, FDA and other international inspections

Wyeth-Lederle Vaccines and Pediatrics, Research Associate II, Bacterial Vaccine Development

Sanford, NC (1992 – 1996)

- Developed, and validated assay methods for bacterial vaccine candidates
 - Provided data, statistical analyses, and reports on analytical development to support new vaccine candidates and patents.
 - Analytical expertise: Chromatography: HPLC and GC, atomic absorption spectroscopy, proton NMR, UV/VIS, electrophoresis, wet chemical, and enzymatic assays.
 - Microbiological expertise: cell culture, ELISA, western and slot blot, and cell toxicity assays.
- Recipient of the American Cyanamid Special Achievement Award

Wyeth-Lederle Vaccines and Pediatrics, Research Associate I, Process Chemistry Development Sanford, NC (1991 - 1992)

- Developed processes to prepare and purify vaccine candidates for Haemophilus influenzae type b and Streptococcus pneumoniae (7 serotypes)
 - Responsible for preparation of clinical trial material in accordance with cGMPs, and provided process improvements to support manufacturing.



SmithKline & French R&D, *Medical Technologist/Biochemist*
Philadelphia, PA (1985 – 1991)

- Key member of the Pathology/Toxicology drug team
 - Performed animal venipuncture, dosing and testing to screen pre-clinical drug candidates.
 - Conversant with GLPs.
- Performed cell culture, hybridoma selection, and mAb purification
 - Developed ELISAs to detect presence of pesticides for FDA.
 - Developed reverse phase methods for drug metabolites, and performed pharmacokinetic animal studies.

US Army Reserves, *Laboratory Officer/Medical Technologist*
(1984 – 1998)

- Received ROTC commission as a 2LT
 - Graduated Army's Basic Airborne School, Fort Bragg, NC.
 - Graduated Medical Service Corp, Officer's Basic Course, Fort Sam Houston, TX.
- Officer In-Charge (OIC), 361st EVAC Hospital, Philadelphia, PA
 - Performed STAT testing, crossmatches, antibody screenings and atypical antibody problem solving for the immuno-hematology laboratory.
 - Responsible for personnel and laboratory readiness during peacetime and at war.
- Individual Ready Reserves