DIANE K. BLOOMER, MPH, RAC, MRSC
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Senior Regulatory expert with more than 18 years industry experience including extensive CMC, International and Biologics experience. Created and established relationships with US Department of Defense (DOD), US Food and Drug Administration (FDA), US Department of Commerce (DOC) and International agencies including PEI (Germany) and DCGI (India). Regulatory, compliance, training, auditing and quality assurance in the pharmaceuticals, biologics and medical device industries specialist. Real world manufacturing facility experience (medical devices, biologic vaccines and pharmaceuticals). Project lead for domestic and international submissions including initial licensing submissions; changes to licensed product; standardized product protocols and authorizations and initial license applications. Lead liaison with regulatory agencies including US FDA.

THERAPEUTIC AREAS AND PHASES
Vaccine (biologic): Biodefense (Anthrax); Commercial BLA and Franchise Expansion
Vaccine: Allergenic Extracts; Commercial BLA
Large Molecule: Oncology Orphan; MAA (EU)
Small Molecule: Oncology Orphan; Phase III IND/CTA and NDA
Biologic (x2): Oncology; Phase I IND/CTA
Blood Products (x2): Hemophilia; Phase III IND and BLA
Medical Device (multiple): Sterile Disposable Labware (Class III); Commercial

EXPERIENCE:

ARRAY BIOPHARMA – CAMBRIDGE, MA
Regulatory CMC ***October 2016 to Present***
Create & execute CMC submission strategy for investigational new drug (IND) submissions, clinical trial applications (CTA) & IND CMC updates, including section edits.
Create and execute End of Phase II (EOPII) CMC meeting strategy, including meeting request, questions and briefing package.

TESARO, INC. - Waltham, MA
Regulatory CMC ***January 2015 TO JUNE 2016***
Created & executed submission strategy for investigational new drug (IND) submissions, clinical trial applications (CTA) & IND CMC updates, including section edits. Authored quality overview summary (QOS).
Created & executed common technical document (CTD) creation strategy for FDA new drug application (NDA) & European Union (EU) marketing authorization application (MAA)
Change control & system review.
Creation of style guides and document author/reviewer and approver matrix and timeline.

Validant Consulting
Regulatory CMC Consultant ***2014 to 2015***
- Biologics
  - Biologics Manufacturer Client
    - Review of historic product records (pre-FDA and FDA) and create chronology.
    - Identify and assign appropriate eCTD section for chronology records.

- Review created sections.

DKB Consulting
Regulatory, Compliance, Project Management, Auditing and Quality Assurance 2009 to 2014

- Created multiple CMC sections for a variety of products including biologics, blood products, large molecules, small molecules, and orphan drugs.
- Created submissions for US, Indian and EU regulatory agencies.
- Change control system.
- Performed compliance audit and created device master file for medical device supplier
- Critical review of systems and SOPs

BioPort Corporation – Lansing, MI (2007 Name Change to Emergent BioDefense Operations Lansing Inc.) Regulatory & Compliance December 2001 to January 2009

- Responsible for regulatory activities and submissions at Lansing facility. Primary regulatory and quality representative to non-US regulatory agencies. Primary regulatory representative to FDA, DOD and DOC for projects, including CMC, comparability, labeling, etc.
- Led team in the licensing of a biologic vaccine (Anthrax Vaccine Absorbed) in India and Europe (Germany). Collaborated with team regarding distribution and sales in international markets.
  - Met with international regulatory agencies in Germany (PEI) and India (DCGI). Presented regulatory strategy for licensure of historic biologic product (pre-marketing application [PMA] meetings). Presented CMC and technical material.
  - CMC and regulatory technical expert and company representative to DOC regarding export technology requirements.
  - Led project team in the creation of hybrid CTD for license submission to Germany (National procedure). Reviewed CTD, including pre-clinical, clinical, CMC and labeling, for sufficiency.
  - Drafted product and patient leaflet for use in German market.
  - Created Summary Document and other required documents for submission to India (paper submission).
- FDA interaction including, but not limited to:
  - Facility and process changes discussions to determine appropriate course of action.
  - Requested, facilitated and participated in Type A, B and C meetings.
  - Meeting facilitation between DOD, FDA, Strategic National Stockpile and other agencies regarding destruction of product.
  - Creation of reconditioning plan which met FDA and customer requirements.
  - Removed NOIR from Lansing facility.
  - Destroyed "Cache" lots of product with consent from DOD and FDA.
- Primary liaison to DOD for post-exposure use IND amendments, including technical meetings.
- Created scale-up strategy (with team) for vaccine, including regulatory and process strategy and comparability.
- Created Quality Policy Manual in alignment with FDA Quality Systems guidance with multi-functional team.
- Sold Pertussis Adjuvant (technology & pre-cursors) to third party. Technical and regulatory expert. Participation and leadership was critical to the successful sale.
- Other experience including, but not limited to:

  - License amendment supplement (CMC) for WFI critical utility creation. Accepted as a CBE-30 instead of a PAS.
  - Created and reviewed BLA CMC amendment supplements for the facility and product (e.g., facility or process improvements, product changes, etc.).
  - Team member charged to demonstrate comparability for biologic product manufactured using scaled-up process.
  - Regulatory and compliance lead on CMC project teams for redundant capabilities; critical utilities (upgrades and installation); equipment validation and process improvement.
  - Developed CMC regulatory strategies with supporting rationale for projects and process improvements for presentation to the FDA.
  - Performed domestic and international vendor qualification audits.
  - Drafted and reviewed Quality Agreements.
  - Reviewed and signed standardized product protocols submitted to the FDA.
- Maintained good working relationship with regulatory agencies.
- Authorized Official with the FDA for Lansing, MI facility.
- Alternate Responsible Official for transport of Select Agent.

ALK-Abelló, Inc. – Round Rock, TX
Regulatory, Quality & Compliance ***September 1998 to December 2001***

- Sole Regulatory representative for North American operations. Primary contact to US regulatory agencies (CMC, compliance, labeling, etc.).
- Supported facilities in the US and Europe as member of Global Quality Assurance Team.
- FDA interaction, including but not limited to:
  - Standardized product protocols to the FDA CBER (vaccine - biologic allergenic extracts),
  - Biological product deviation reports (BPDR) and adverse event reports (MedWatch; AVERs).
  - Lead contact for inspections, compliance, products and facility, and
  - Facility compliance improvement plan presentation to FDA.
- Additional experience, including but not limited to:
  - Created CMC BLA license amendments for facility and product (e.g., facility expansion, facility or process changes and improvements, product transfer, vendor additions, etc.).
  - Created BLA license amendments for label and labeling changes.
  - Performed and documented internal audits with CAPA recommendations.
  - Reviewed and approved all procedures used at the manufacturing facility.
  - Member of CMC compliance improvement initiative team.
  - Authorized official with the FDA for the Round Rock, TX facility.
- Created and submitted license application to USDA (US Department of Agriculture).
- Management oversight of complaint handling and subsequent submissions required by the FDA regarding patient reactions and product recall from market.
- Created and implemented customer complaint tracking system for facility to address reporting requirements to agencies, trending and oversight.
- Facilitated and trained the Safety Task Force regarding safety requirements.
- Prepared and conducted internal training courses on team work, basic statistics and use of the MIL STD (statistical sampling by attributes).

Nalge Nunc International Incorporated North American Operations (NNI-NAO) – Naperville, IL Regulatory Affairs & Quality Assurance June 1993 to July 1998

- Sole regulatory representative for Nunc NAO (medical devices). Primary regulatory Nunc representative to US regulatory agencies, including CMC, compliance, labeling, etc. Responsible for products imported into the US from Denmark.
- ISO Core Team Leader of ISO 9001 certification effort for Naperville facility. Achieved certification on first attempt. ISO Deputy for NNI-NAO.
- Quality System Regulatory (QSR) compliance responsibility at manufacturing facilities (domestic and international). Corporate auditor for NNI facilities, including NNI-Penfield and NNI-Denmark.
- Product development project team leader including process validation, technology transfer, sterilization, etc.
- Maintained product and facility listing with the FDA.
- Responsible for facility as regulated by the US EPA and State environmental agencies with regard to CAAA, TSCA, SARA, etc.
- Removed company from the FDA Reference List. Established a better relationship with FDA. Identified and implemented system and cultural changes to bring company from product seizure to a general inspection with zero FDA Form 483 observations.
- Reviewed and approved all SOPs prior to implementation.
- Reviewed and approved externally distributed literature and material, including technical (scientific) presentations, TechNotes, Bulletins, advertisements, labels, inserts, etc.
- Lead Internal Auditor of processes and departments (cGMP, QSR and ISO compliance.)
- Lead External Vendor Auditor of contractors, including processing, sterilization, raw materials and products (CMO) with regard to cGMP, QSR and ISO compliance.
- Certified Medical Device Lead Auditor. Trained audit team members for both internal and external audits.
- Management oversight responsibilities for technical service and customer service with regard to complaint handling.
- Management oversight responsibilities for the quality assurance and quality control group at the domestic facility.

WW Engineering & Science, Inc. – Livonia, MI Toxicologist 1992 to 1993

- Reviewed hazardous waste site work. Submitted site critique and future work recommendations.
- Developed and executed strategies and work plans for site investigations and remediation.
- Created templates to streamline report generation.
- Reduced cost and time by benchmarking internal Phase I and Phase II reports for corporate-wide use.
- Compiled and interpreted data in accordance with the Michigan Environmental Response Act (MERA). Developed and presented seminar on the implications of MERA. Updated staff on MERA requirements and interpretations.
- Served as risk assessment and compliance resource to other branch offices.

ChemRisk – Cleveland, OH Toxicologist 1991 to 1992

- Project manager for human health risk assessment. Projects included: development of health based clean-up levels (remediation efforts) and developed sampling plans to for Phase I investigation and risk assessment.
- Co-authored proposals for remediation work using a template approach.
- Developed qualitative risk analysis statements and reports for manufacturing facilities.

- Performed detailed toxicological evaluations on chemicals involved in human health risk assessment. Investigated topics including chromium excretion in urine, chlorination of water and probability density functions (Monte Carlo Analysis).
- Assisted in the preparation of health and safety documents.

Michigan Dept. of Public Health – Lansing, MI Chemist 1984 to 1988

- Extracted, prepared & analyzed water samples for volatile and non-volatile organic contaminant analysis by gas chromatography and purge/trap and direct injection and other detectors.

Coulter Immunology – Hialeah, FL Senior Technician 1982 to 1984

- Developed protocol for production extraction, purification and conjugation of phycoerythrin dye to monoclonal antibodies.
- Developed production protocols for purification and conjugation of monoclonal antibodies, including packaging and labeling of final product.

Additional Experience

DKB Consulting *1996 to 2009*

- Trained scientists (in Moscow, Russia) to perform internal and vendor audits for US regulatory compliance (cGMP).
- Presented GMP Principles (RAPS GMP101) (Dallas, TX).
- Performed Annual cGMP audit for Class II medical device (Chicago, IL).

Austin Community College – Austin, TX Adjunct Professor 2000 to 2001

- Developed and instructed Introduction to Quality Assurance (QA) in Biotechnology, including ALK-Abello' on-site instruction.
- Presented overview to community college professors at Bio-Link Summer Fellows Forum.

Washtenaw County Dept. of Public Works & Environmental Services – Ann Arbor, MI
Intern *1989 to 1991*

- Assisted in preparation of Michigan P.A. 641 Solid Waste Management Plan for Washtenaw County Update of 1989. Drafted new solid waste facility siting process for Plan.
- Provided written and verbal responses to public and elected officials regarding environmental and household toxicology and hazardous waste. Composed resolutions for committee appointments, group and individual recognition, policy adoption by county or community and resource allocations.

Warner-Lambert/Parke-Davis – Ann Arbor, MI Temporary Technician 1989

- Performed drug-screening assay using rat cortex and radiolabel to monitor the inhibitory effect of the drugs on calcium channels.

Michigan State University – East Lansing, MI Research Assistant August 1979 to March 1982
Independent Research January to July, 1981

- Synthesized, purified and identified alpha-F-palmitate. Utilized gas chromatography, fractionating columns, and TLC.

Michigan State Police Crime Lab – East Lansing, MI Research Assistant 1981

- Developed and perfected a new analytical technique for detection of arson accelerant using extraction techniques and gas chromatography.

EDUCATION:

M.P.H., Toxicology, University of Michigan
B.A., Chemistry, Michigan State University
A.S., Chemistry, Lansing Community College

CERTIFICATION:
M.R.S.C, Member of the Royal Society of Chemists, 2013, maintained
R.A.C., Regulatory Affairs Professional Society, 1997, maintained
Lead Auditor for Medical Devices & Health Care Sector, 1998

Professional Development
Workshops and seminars including Basic GMP Workshop (August 1993); Skills for GMP Auditors Workshop (April 1994); CE Marking Seminar (May 1996); FDA Grass Roots Seminar (July 1996); MD&M Seminars (June 1997); Error & Accident Workshop (March 2000); Aluminum in Vaccines Workshop (June 2000); Promotion of Off-Label Uses (June 2001); Regulatory Strategy for Pharmaceuticals Workshop (2013).

Conferences including RAPS Annual Conference (1997 – 2013); GMP by the Sea (1998); PDA Conference 2004; 2015); Assorted DSMA conferences; Global Awareness – Canada (July 2001).

Training including Environment, Safety & Health Auditor Training Course (Sybron Corporate) (1996); Lead Auditor for Medical Devices & Health Care Sector training course (1998)

Other development including BioPort /Emergent Management Training (2002 - 2009) Peer Coaching (2006 – 2009); Non-Management Coaching (2007 – 2009); OTJ cGMP training Maintains RAC certification.

Publications:
"D, L-alpha-Fluoropalmitic Acid Inhibits Sphingosine Base Formation and Accumulates in Membrane Lipids in Cultured Mammalian Cells," R.M. Soltysiak, F. Matsuura, D. Bloomer and C.C. Sweeley; Biochimica et Biophysica Acta, 792(1984)214-225.

Professional Organizations:
Parenteral Drug Association (PDA)
Regulatory Affairs Professionals (RAPS)
TOPRA (International Group for Regulatory Affairs Professionals)
Royal Society of Chemistry (MRSC)