

**Duane J. Bush**  
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## Summary of Qualifications and Skills

- 20+ years of research and development experience in infectious disease, food-borne pathogens, and bio-warfare agents.
- Responsible for product development of immunoassay based diagnostic tests for the detection of infectious and bio-warfare agents, from initial feasibility through transfer to manufacturing, including development of relevant documentation
- Experience in Process and Method Validations
- Experience in Accelerated and Real Time stability evaluations
- Proficient in diverse microbiological techniques for bacterial, viral, protozoan, and fungal organisms.
- Experience working in and maintenance of BSL-2/cGMP and BSL-3/cGMP environments.
- Proficient in a wide variety of protein chemistry and immunological techniques.
- Experience with and knowledge of regulated environments: QSR, cGMP, GLP, radioactive and biohazardous waste disposal, FDA 510k submissions, ISO certifications, shipping hazardous materials and OSHA compliance.
- Knowledgeable and experience in Design of Experiments methodologies.
- Experience in drafting SOP's for safety, manufacturing formulations, quality control, raw materials receiving, and shipping.

## Professional Experience

**BioMARC, Colorado State University** *contract BSL-3 cGMP* Sept 2012 - present  
*manufacturing and process development*

### **Process Development Specialist/Quality Control Specialist**

#### Responsibilities

- Responsible for maintenance of clean room control (BSL-2 and BSL-3/cGMP environments) including monitoring activities.
- Technical assistance with virus purification process development contract
- Assist Quality Control with assay evaluation and risk assessments
- Provide technical support to Quality Control
- BSL-2/cGMP and BSL-3/cGMP manufacturing

**MicroPhage, Inc.** *in vitro diagnostics manufacturing*

April 2006 – August 2012

**Product Development Scientist**

Responsibilities

- Develop Lateral Flow Immunoassay detector for bacteriophage detection
- Development of bacteriophage-based detection of bacteria and bacteriophage-based determination of bacterial antibiotic susceptibility.
- Bacteriophage discovery, manipulation, characterization studies
- Facilitate transfer of technology and techniques from R&D to GMP manufacturing
- Draft manufacturing, safety, quality control and research SOP's
- Company safety officer responsible for OSHA compliance, shipping hazardous materials, and biohazardous waste disposal.

**Inverness Medical – BioStar, Inc.** *in vitro diagnostics manufacturing* Sept. 1998 – April 2006

**Scientist**

Responsibilities

- Served as Technical Lead for development of rapid diagnostic assays on OIA platform against infectious disease agents and biowarfare agents, from feasibility through clinical trials and transfer to manufacturing group
- Organized training seminar for company on Design of Experiments methodologies.
- Member of team responsible for the development of an instrument for automation and readout of OIA assays
- Assisted in trouble-shooting efforts for manufacturing, technical services, and quality control
- Supervised biohazardous waste collection and disposal

**DDx, Inc.** *in vitro diagnostics development*

Feb. 1996 – Feb 1998

**Research Associate**

Responsibilities

- Member of team responsible for the development of a novel instrument read platform for diagnostics assays
- Develop rapid diagnostic assays for food-borne pathogens and bio-warfare agents

**Colorado State University** *Teaching, Research and Extension institute* Jan 1993 – June 1995

**Research Associate** Dept. of Microbiology

- Conducted research into cell wall synthesis in *Mycobacteria* using protein and carbohydrate chemistry techniques and radio-labeling
- Responsible for radioactive and hazardous waste disposal

**Colorado State University Teaching, Research and Extension Institute** June 1990 – Dec. 1992

**Research Associate** Dept. of Pathology

- Conducted research on the immune response of cats co-infected with *Toxoplasma gondii* and FLV
- Developed ELISA to detect *Trichostrongylus axei* in cattle
- Identified *Eimeria bovis* antigens expressed on host cell surface via immune electron microscopy.

## Related Experience

**Princeton Review test preparation institute**

Sept. 1997 – April 1999

**MCAT Instructor**

Responsibilities

- Instructed and mentored students in preparatory course for MCAT in biology, organic chemistry and verbal sections of test

**Summit Institutional Review Board independent IRB**

Jan. 1991 – June 1993

**Consultant**

Responsibilities

- Reviewed Clinical Trial Protocols and Patient Consent Forms for compliance with Good Clinical Practice (GCP) guidelines
- Researched safety claims in Clinical Trial Protocols

**Colorado State University Teaching, Research and Extension Institute** 1985, 1989 - 1990

**Graduate Teaching Assistant**

Responsibilities

- Taught laboratory for upper level Parasitology course
- Taught traditional and computer-aided freshman biology laboratory

**Peace Corps Technical and Cultural Exchange Organization**

May 1986 – July 1989

**Volunteer (Director Veterinary Diagnostic Laboratory, Ministry of Agriculture, Commonwealth of Dominica)**

## Responsibilities

- Lead Peace Corps Volunteer
- Conducted veterinary diagnostic procedures in parasitology, bacteriology, hematology, mycology, urinalysis, and serology
- Assisted with surgeries on companion animals and livestock
- Assisted with rural veterinary mobile clinics
- Member of team responsible for implementation of quarantine and eradication program for the tick *Amblyomma variagatum*
- Set up and monitored regular anthelmintic program for agricultural stations
- Maintained inventory of veterinary pharmaceutical, surgical, and other supplies for veterinary unit for Ministry of Agriculture
- Coordinated artificial insemination program for nation's dairy farmers
- Assisted with formation of two dairy cooperatives and with national rodent control program
- Assisted Dr. P.H.G. Evans (Oxford Univ) with his research on the impact of land use practices on native flora and fauna.

## **Bureau of Land Management** *federal land and natural resource management agency*

June – Aug 1979, May – Aug 1980

### **Fisheries Technician**

#### Responsibilities

- Collected base-line data for Environmental Impact Statement (EIS) including hydrology, stream channel stability, range trend analysis, wildlife use, and identification of plant, animal, fish, and aquatic invertebrate species.
- Conducted Soil-Vegetation Inventory Method (SVIM) mapping
- Engaged in fire suppression activities as needed

## **Academic Credentials**

BSc. Wildlife Biology, Colorado State University,	May 1982
BSc. Microbiology (minor Chemistry), Colorado State University	Dec. 1982
MSc. Biology (conc. Parasitology), Colorado State University	May 1990

Certificate of Completion – Bullet-Proof Manager Training, Crestcom International

April 2002

Jmp Design of Experiments Workshop, SAS

July 2003

SBIR/STTR Grant Writing Workshop, BBCetc

March 2009

IATA Dangerous Goods Shipping by Air, FedEx	July 2009
Recertification, Global Transport Training Services	April 2012
Lateral Flow Technology Workshop, BioDot	Nov. 2010
OSHA 10 hour safety course, OSHA Outreach Training	June 2011