

# ROBERT N. BORGHESE

Senior Quality & Compliance Advisor

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## *Overview*

Owner/President of a biopharmaceutical consulting firm after being an accomplished Director of QA/QC and Regulatory Affairs with hands-on experience with pharmaceuticals, biologics, medical devices and in-vitro diagnostic products (IVDPs). Experience includes brand and generic drugs, home use, controlled substances, and biotechnology. Excellent rapport with FDA's CDRH, CDER and CBER. Six (6) plant start-ups.

## *Certifications*

Certified ISO 9000 Lead Auditor, British Standards Institution (BSI)  
Certified GMP Auditor, Stat-A-Matrix Institute

## *Skills*

### Regulatory Affairs

- Knowledgeable of FDA, USDA, DEA, and Canadian regulations
- Successful submission of Drug Master Files, 510(k)s, PMAs, IDEs, NDAs, ANDAs, INDs and BLAs.
- Special expertise in cGMPs, ISO 9000, ISO 13485, European Medical Device Directive (MDD), CE, UL and CSA Markings
- Environmental/Safety Officer

### Quality Assurance

- Expert in adverse drug experience reporting
- Established electronic records complying with 21 CFR Part 11
- Total Quality, FMEA, validations, complaint handling, corrective/preventive action, documentation, environmental control, auditing, statistics, and new product transfer
- Experienced trainer and communicator

### Quality Control

- Managed quality control testing activities including physical/chemical, microbiological and cell culture

## *Achievements*

- Consulted for BioClinical Systems, Inc. in the landmark court case of United States vs. BioClinical Systems, Inc., 666 F. Supp. 82 (D. Md. 1987). The court held that the FDA could not impose a sterility assurance level of 0.1% on a manufacturer of plated media without going through the public review process required to establish a good manufacturing practice (GMP).
- Key player in start-up of biotechnology firms
- Outstanding regulatory compliance record, numerous FDA audits with no deficiencies
- Established QA programs in US, Europe, Japan & Puerto Rico
- Set-up purified water, water for injection (WFI), and sterilization systems
- Recommended and implemented several innovative, significant cost savings programs in QA/QC which reduced rejects, sample costs, product quarantine time, and headcount, while increasing efficiency

**Experience**

April 2001 to Present

**Borghese & Associates, Inc.** Whitehouse Station, NJ

- Owner/President of firm and consultant to the biotechnology, diagnostic, pharmaceutical and medical device industry. Major clients include Allergan, Gen-Probe, Organon-USA, and Alpharma U.S. Human Pharmaceuticals.

September 2000 to March 2001

**The MedTech Group, Inc.** S. Plainfield, NJ

- As Quality Manager was responsible for the quality program, environmental control, sterilization, depyrogenation, validations and training at this contract manufacturer of medical devices.

August 1999 to August 2000

**Glenwood-Palisades**, Piscataway, NJ

- As Senior Manager of Regulatory Affairs was responsible for the regulatory program at this manufacturer of pharmaceuticals, medical devices (including dental) and cosmetics. Commended for custom manufacturing work for Novartis and Bayer.

February 1999 to August 1999

**Borghese & Associates**, Whitehouse Station, NJ

- Consultant to the biotechnology, diagnostic, pharmaceutical and medical device industry. Consulted for Gen-Probe, the San Diego based biotechnology firm developing advanced PCR diagnostics.

1997 to February 1999

**Datascope Corporation**, Montvale, NJ

- As Manager of QA/Production Support, was key player in the start-up of the Genisphere Division that manufactures a molecular biology reagent for research use in DNA detection assays with applications in microarray technology, diagnostics and viral load quantification.
- Established written procedures, validations, microbiological monitoring, and purified water systems.
- Planned facility layout and specified/purchased all equipment and reagents in \$3M start-up investment.

1993 to 1997

**International Technidyne Corporation**, Edison, NJ

- As Director of QA/QC/RA, was responsible for the quality and regulatory program at this leading manufacturer of clinical instrumentation, diagnostic reagents, and skin incision devices. Tested and distributed pharmaceuticals used in the open-heart surgery arena.

1987 to 1993

**JRH Biosciences**, Lenexa, KS

- As Director of QA/QC/RA, was responsible for the quality and regulatory program at this leading manufacturer of cell culture media, sera, antimicrobial solutions, and enzymes. Assisted client biotechnology and pharmaceutical firms with FDA submissions and cGMP training.

1971 to 1987

**Becton Dickinson**, Cockeysville, MD

- As Quality Assurance Manager, Cockeysville, MD, 1985-1987 and Quality Assurance Manager, Cayey, Puerto Rico, 1982-1985 was responsible for the quality and regulatory program at this leading manufacturer of microbiological media and reagents, in-vitro diagnostic products and laboratory instruments.
- Prior developmental positions: Division Quality Auditor, Microbiologist, Statistician, Chem. Lab Tech and Mfg. Supervisor

***Education***

Loyola College, Balto., MD, 30 credits toward Executive MBA, 1987

University of Virginia, Charlottesville, VA, B.A., Life Sciences, 1963

Baltimore Polytechnic Institute, Balto., Maryland, Diploma, 1959

***Publications***

- "The Impact of the FDA GMP Regulation", Journal of the American College of Toxicology, Volume 9, Number 1, 1990
- "Quality Auditing as a Tool: Increase Efficiency and Reduce Costs", BioPharm, October, 1990
- "Troubleshooting Validation Failures", BioPharm, March, 1993
- "Effective Handling of Adverse Drug Event (ADE) Reports", Regulatory Affairs Focus, May, 2004

***Presentations***

- Presented seminars at professional meetings (PDA) on the subjects of making FDA submissions/getting approvals, validation, cGMPs, customer complaints

***Memberships***

- Member of Board of Directors 1991-1993, Association of Medical Diagnostics Manufacturers (AMDM)
- RAPS, ASM, ASQC, ISPE