

Robert J. Serra

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QUALITY ASSURANCE/PRODUCT & PROCESS DEVELOPMENT

Extensive Pharmaceutical (Drugs & Biologics) and Medical Device experience with Schering Plough, Johnson & Johnson, Novartis and MBH. Well versed in the total product development cycle from Clinical through scale-up and commercialization for sterile products which also include combination products of Pharmaceuticals or Biologics and Devices. Strong scientific and technical expertise focused on Technical Operations, Validation, Compliance, and Quality Assurance. Specific expertise in:

- **Process Development/Validation**
- **Process Scale-Up/Pilot Operations**
- **Aseptic Processing**
- **Process Excellence**
- **GLP, GCP and cGMP Audits**
- **Military Laboratory Projects**
- **Technology Process Transfer**
- **Due Diligence**
- **Terminal Sterilization**
- **Development of Drug/Device Products**
- **LVP and SVP sterile products**

PROFESSIONAL EXPERIENCE

QbD Auditing, Inc.

July 2009 - Present

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Cofounder – Principal Consultant

This is a newly formed company which is actively working with regulated industries to provide technical assessments and c’GMP audits of their operation with recommendations for migration of risk

Biopharma Consulting, Inc.

May 2008 - Present

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Principal Consultant – Consult on Sterile Pharmaceutical, Biologic and Medical Devices for start-up operations

This company was formed from **Biopharma Consulting LLC** which is still in existence.

- Provide technical support to regulated companies for start-up operations in a global market
- Conduct due diligence audits for potential acquisitions, partnerships or research funding
- Develop roadmap of activities from development through product commercialization

- Develop documentations systems that include batch records, process specifications, product and material specifications
- Access current in-house capabilities and future needs based on project market forecast
- Provide a gap analysis to identify areas requiring additional support, documentation and equipment
- Provide technical assessment of current processes in terms of needed technical transfer/scale-up of development scale to the commercial scale process

Biopharma Consulting LLC

September 2005 - Present

105 Old Turnpike Ave.

Port Murray, N.J. 07865

Principal Consultant – Consult on Sterile and non-sterile Pharmaceutical Products, Processes and Compliance

- Provide technical support to QA and Operations in developing procedures, processes and systems for the start-up of commercial operations in Asia for a drug/device combination product
- Support drug regulatory personnel on combination drug /device products regulations
- Provide direction and support on technology transfer of products between facilities and at third party contractors
- Provide technical assessment of processes, scale-up, engineering and facility designs
- Conduct Process, Due Diligence and cGMP audits of 3rd party pharmaceutical facilities

Schering Plough Corp.

2004 – August 2005

Cranford, NJ

Global Manager Technology Transfer – Parenterals and Inhalation Products

Assisted R&D in the dosage form and process development of scale-up activities and supportive studies for a sterile suspension product in phase II. Key projects and accomplishments:

- Responsible for new product transfers within Schering Plough facilities – Parenterals
- Provided engineering process design and review for the full scale commercial process
- Developed studies to support process changes, terminal sterilization and stability studies

JOHNSON & JOHNSON FAMILY OF COMPANIES

OrthoBiotech/PSGA, Raritan, NJ

1999 - 2004

Principal Scientist – Parenterals

Performed technical support and process improvements for a Parenteral Facility in San German, PR that manufactured parenteral and ophthalmic products for Drugs and Biologics. Key projects and accomplishments:

- Developed compatibility and stability studies for existing and new products
- Qualified new drug substances, excipients and packaging components
- Responsible for third party contractor sites for parenteral products in terms of process and systems audits, compliance and technology transfer
- Consulted in the design of a new \$250 MM Parenteral Facility for the production of therapeutic and cytotoxic compounds employing the use of automatic filling, lyo loading/unloading systems and isolation technology

- Led the most significant Black Belt project team for the J&J Pharm Sector across multidisciplinary companies involving a \$7 MM COG's project which resulted in an annualized COG's savings of \$ 0.6 MM
- Led a task force for qualifying a new primary flexible container by replacing the current supply, upgrading and revalidation of sealing equipment thereby eliminating a significant number of sealing rejects
- Led a task force for the scale-up and transfer of Levaquin® IV which included the qualification of the film extrusion for the flexible primary container, flexible container fabrication, terminal sterilization validation, stability and Process Validation
- Performed audits at third party contractors in support of PAS's

Novartis Pharmaceutical
East Hanover, NJ

1997 – 1999

Senior Scientist II - Liquids

Responsible for process/dosage form development and technical support of liquid products for clinical studies and commercial products. Key projects and accomplishments:

- Assisted in the development of an oral suspension product for phase III supplies and stability
- Responsible for PAI activities and technology transfer of liquid products within domestic and international Novartis facilities
- Process scale-up and validation of liquid and suspension products

JOHNSON & JOHNSON FAMILY OF COMPANIES

RWJ Pharmaceutical Research Institute, Raritan, NJ

1995 - 1997

Senior Scientist – Process Development - Parenterals

Performed technical support and process/dosage form development activities for phase III and commercial parenteral Drug and Biologic Products. Key projects and accomplishments:

- Performed process scale-up and validation of Drug and Biologic parenteral products
- Responsible for clinical batch production and audits of clinical records
- Led a successful PAI and on-time product launch for LEVAQUIN®IV at two third party contractor sites
- Liaison for preapproval FDA inspections and technical support

BP Associated Consultants, Inc.

1994 - 1995

Port Murray, NJ

President

Audited and assessed QA Systems for compliance to cGMP requirements.

Developed QA Systems and Procedures for adherence to cGMP's and ISO 9000 standards.

JOHNSON & JOHNSON FAMILY OF COMPANIES

Ethicon, Inc., Somerville, NJ

1990 - 1994

Sr. Pharmaceutical Mfg. Coord./Pharmaceutical Mfg. Coord

Responsible for auditing Pharmaceutical Manufacturing of several parenteral products in phase III clinical trials that were being developed for commercial scale and also to develop the commercial process for Drugs and Biologic Products. Key projects and accomplishments:

- Developed delivery systems for a sterile Biologic/Device combination Product

- Developed low temperature terminal sterilization and tyndallization procedures for Drugs and Biologics
- Audited third party contractor facilities during clinical product manufacturing for adherence to cGMP
- Developed tracking system for monitoring of clinical supplies inventories and studies
- Conducted GLP and GCP audits
- Developed SOP's, batch records and product specs

Product Coordinator

1988 - 1990

Responsible for developing the QA program for new products and managing the Chemical QA. Department. Key projects and accomplishments:

- Audited Manufacturers and Managed Chemical Quality Assurance
- Implemented QA Systems and Procedures for new products
- Audited suppliers for cGMP compliance and recommended corrective measures
- Planned and implemented manpower, expense and capital budgets
- Developed and implemented QA Systems for quality standards, documentation implementation, instrument deviation and product complaints

Quality Assurance In-Process Sutures Manager

1987 - 1988

Managed the In-process Suture Department for the inspection and release of all in-process suture products for Somerville. Key projects and accomplishments:

- Responsible for department budgets, manpower planning and GMP training

New Products Coordinator/Asst. to Plant QA Manager

1985 - 1987

Coordinated the Quality Assurance programs to transfer new products from research and pilot plant operations to manufacturing. Key projects and accomplishments:

- Assured that all of the documentation such as test procedures, test methods and specifications were developed, approved and implemented to support new products

Chem Lab Supv/Supv In-Process QA/Supv Spec. Mfg. QA

1974 - 1985

Supported Manufacturing, Process Development and Research Projects for phasing in of Pilot Projects prior to production start-up for absorbable technology processing of polymeric compounds (polyglycolide and lactide). Key projects and accomplishments:

- Conducted periodic GMP and GLP audits of laboratory areas, chemical processes, manufacturing areas and affiliated plants
- Reviewed and wrote test procedures, specifications, CM&C section for N.D.A.'s
- Solved product or process problems for domestic and foreign affiliates
- Reviewed, dispositioned and released raw materials and finished products
- Supervised process control activities and had statistical reports issued and corrective measures employed monthly to reduce possible rejections

MBH Chemical Corp

1973 - 1974

Orange, NJ

Manager Oral Products Dept.

Responsible for the manufacturing of pharmaceutical solid dosage forms. Operations included blending, wet granulation, drying, compression and tablet coating.

EDUCATION

Military Training – Fort McClellan, AL – Chemical Defense Training Facility – 1971
Two years equivalent college level laboratory training courses in Chemistry, Microbiology and Radiological studies

Fairleigh Dickinson University
B.S. Degree in Chemistry, 1973

Fairleigh Dickinson University
12 credits towards Masters Degree in Systems Engineering, 1975

Stat-A-Matrix, Piscataway, NJ
ISO 9000 Lead Auditor Certification Program, 1994

Johnson and Johnson Certified Black Belt - October 2002

County College of Morris
Mechanical Engineering Technology, 2003

MILITARY

Teledyne Isotopes, Inc., 1968 – 1970, Radioactive Sample Testing for US government contracts, Top Secret classification

US Army Reserves, 1970 – 1976, 400 th Chemical Caven Point NJ, Mobile Chemical, Biological and Radiological Laboratory Operation, Top Secret classification

AWARDS

Johnson & Johnson:

- Innovation: Procedure improvement that reduced finished product rejects 30%
- Pride: Process Improvement for parenteral products
- Team: Process & Product Improvement for a major suture defect
- Team: Leustatin MS Project
- Black Belt: Major reduction in Pharmaceutical Returns - \$0.6 MM annualized savings

RECOGNITION

Novartis

- Oral Suspension Interaction Resolution

PUBLICATIONS

- Coauthor for a Chapter in a text for Technology Transfer on Liquids

PRESENTATIONS

- Novartis – Oral Suspension Interaction Resolution
- Novartis – Preapproval Inspections Update
- Arden House Technology Transfer Conference – Process Troubleshooting Case Study

- Ethicon Research Conference – Hyaluronic Acid Formulation Process
- Ethicon – In-vitro Test Method Improvement