

LEONARD SLOAN

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PROFESSIONAL SUMMARY

Highly motivated results-oriented professional with over 23 years of experience in Pharmaceutical Manufacturing Process Development, Process Optimization, Process Validation, Troubleshooting, Facility Start-up, and Process Scale-up. Highly skilled and trained, ready to perform.

SPECIFIC AREAS OF EXPERTISE

Process Validation
Troubleshooting
Facility Start-up

Technology Transfer
Sterile Manufacturing
Lyophilization

Technical Writing
Training
Filtration/Fermentation

SUMMARY OF QUALIFICATIONS

- Over 9 years providing contract Pharmaceutical Validation, Process Development, Manufacturing consultation.
- 2 years, Director of Operations in charge of Ophthalmics facility re-design and start-up.
- 14 ½ years Management and Technical Services, sterile parenterals, lyophilized products, otics, ophthalmics, suspension products, oil-based products.
- Highly Skilled in Product Validation, Process Validation, Facility re-design, Project Management, Design of Experiment, Statistical Analysis.
- Experienced in all aspects of parenteral component preparation, compounding, filling, Sterile Filtration, Lyophilization, fermentation, support services, equipment preparation and cleaning.
- Capable trainer able to meet the diverse ability levels and interests of employees.

PROFESSIONAL HISTORY

ECVS, Inc / AVST, Inc.

2001 – Present

Tucson, Arizona & Sarasota, Florida

Independent Contractor/Consultant

Provide services to client in Product Development, process evaluation and validation, process troubleshooting, SIP/CIP process design and validation, equipment IQ/OQ, Line Set-up and optimization, SOP preparation, process and document Audits, Project Management, technical transfer assistance, technical expert/resource to team. Work at clients include: Eli Lilly (insulin) and Pfizer (antibiotics & inhaled insulin).

Ocumed, Inc.

1999 – 2001

Sarasota, Florida

Director of Operations

Facility Re-design, water system re-design, sterile suite and packaging layout re-design. Developed a document system for protocols, SOPs, training modules, and forms.

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Schein Pharmaceutical Inc., Steris Laboratories Division

1985 – 1999

Phoenix, Arizona

Process Development Scientist IV

1989 - 1999

Senior Production Supervisor

1985 - 1989

Product Investigations, Anomaly and OOS investigations, 483 responses, Lyophilizer Validation, Cleaning Validation, Product Filter Validation, Alternate screw cap closure, Product launches, Aseptic filling process design, Batch Folder design, Forms Control and Design,

G. Heileman Brewing Company

1980 – 1985

Phoenix, Arizona & Auburndale, Florida

First Assistant Brewmaster

Responsible for operation of Brewhouse and cellars, overseeing all Union work.
Superintendent of Brewing and Quality Control for Auburndale, FL facility, 1982-1983

Spring Mountain Vineyards

1979 – 1980

St. Helena, California

Assistant to Winemaker

Performed all winery and laboratory functions involved in vinification and packaging of wine.

Stag's Leap Wine Cellars

1977 – 1979

Napa, California

Senior Supervisor

Performed all winery and laboratory functions involved in vinification and packaging of wine.

EDUCATION

B.S. in Fermentation Science, University of California at Davis, 1978
(with emphasis in biochemistry, bacteriology, and life sciences)

Continuing Education Coursework

Freeze Drying and Lyophilization workshop, Ed Trappler instructor

Project Management Mentors 5-day workshop, Patti Raya instructor

Systems Validations and cGMP workshop, J. Agallaco trainer

Stat-Ease 3-day workshop, Response Surface Methods for Process Optimization (DOE)

American Management Assoc. 3-day workshop, Project Management, Sharon Schrick instructor

University of Wisconsin, 3-day workshop, Pilot Plant Studies and Process Scale Up for Batch and

Semi-Batch Processing, Gary Tatterson instructor

Member, ISPE

ADDITIONAL COMPETENCIES

Proficient in Microsoft Office (Word, Excel, Project, PowerPoint), WordPerfect, Quattro-Pro, CSS Statistica, Design-Expert (DOE), gown qualified for work in Aseptic, antibiotic facilities.