

Edward J. Smith
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PROFESSIONAL PROFILE

Innovative technical manager with 22 years of experience in pharmaceutical packaging, regulatory affairs, R&D, technical support and training. Strong technical background with excellent interpersonal and communication skills. Proficient in interfacing with customer, regulatory and compendial groups

EXPERIENCE

HELVOET PHARMA INC., Burlington, NJ 1995-1999

North American location of the Pharmaceutical Packaging Division of Dätwyler Holding Inc., which manufactures packaging components for the pharmaceutical and medical device industries, with world-wide sales of \$650MM annually.

Vice President, Technical Affairs (1995-1999)

- Recommended and implemented equipment upgrade in raw material and in-process control laboratory; reduced analysis time 20% to 80% and enhanced customer delivery time.
- Interfaced directly with customers and regulatory agencies (FDA, HPB) regarding product approvals.
- Directed validation of process for production of "Pre-Processed" closures including WFI and cleanroom systems.
- Developed a Technical Support laboratory function; hired and trained personnel and added in-house particulate, bioburden, endotoxin and moisture testing capabilities which saved \$150K annually.
- Developed and presented a fifteen-hour in-house course on Process Improvement to all salaried personnel (4 groups/44 people) which led to formation of process improvement teams; saved \$30K in training costs; served as facilitator for teams.
- Designed and delivered sales/marketing presentations for all product introductions.
- Managed key customer projects on closure sterilization and medical device development with annual sales potential of \$2-5MM.
- Selected as technical liaison with company's European facilities to bring North American perspective to planning and operations.

THE WEST COMPANY, INC., Lionville, PA 1976-1995

Now known as West Pharmaceutical Services, Inc., the largest global manufacturer of packaging components for the pharmaceutical and medical device industries. Also provides laboratory testing, contract packaging, clinical services and drug delivery development. Annual sales of \$500MM.

Vice President, Scientific Affairs and Technical Training (1993-1995)

- Authored a technical marketing presentation called "Tech-Pac" which introduced products and services to pharmaceutical packaging engineers; this value-added program has been continued annually.

- Designated as a Qualified Trainer in 20 4-day worldwide Total Quality/MRPII Workshops; trained 480 people.
- Appointed as a Qualified Instructor in the “Train-the-Trainers” TQ Program; trained TQ trainers for local plant sites.
- Designed 15 technical/product training modules for sales/marketing and technical managers.

Vice President, Technical Service and Regulatory Affairs (1989-1993)

- Facilitated customer approval and sale of rubber components by interfacing with customers and FDA on drug-package compatibility issues.
- Managed company’s “Rubber Formulation Characteristics” database consisting of product specifications, USP, ISO, EP and JP technical data; interfaced with US and international compendial groups.
- Managed and controlled Drug Master Files and access letters for US customers.
- Directed Technical Service group which provided chemical, physical and biological test data to customers on compatibility, compendial and quality issues.
- Established technical support groups in South America and Asia/Pacific Rim.

Vice President, Research (1985-1989)

- Spearheaded development and commercialization of a unique rubber-closure coating that reduced drug-closure interactions and replaced silicone oil as a lubricant.
- Integrated a group of chemists/engineers from Plastics Div. plant into central R & D laboratories to form a Thermoplastic Elastomers Group. Commercialized TPR infant feeding nipple, which resulted in annual savings of \$1.8MM to company and customer. Led technical development of medical tubing product line.

Director of Laboratory Operations (1983-1985)

- Directed the establishment of a nitrosamine testing laboratory to meet new FDA mandates on infant feeding nipples protecting a multimillion business.

Assistant Director of Laboratories (1978-1983)

- Managed 54 scientists/technicians in the Technical Support and QC laboratories.
- Developed and implemented an on-line computer system to track the status of laboratory samples received daily from 5 US plants, reducing turnaround time from 4.3 to 2.4 days.

Group Manager, Material Evaluation and Control (QC) (1978)

- Managed 47 scientists/technicians in the analytical control laboratory of a \$200MM division.

Technical Consultant (1976-1978)

- Implemented and equipped a Liquid Chromatography laboratory.
- Developed LC methods for analysis of elastomers and additives.
- Designed and taught a “Pharmaceutical Packaging” course to sales and marketing groups.

ST. JOSEPH’S COLLEGE, Philadelphia, PA. 1968-1978

Now St. Joseph’s University, a mid-size liberal arts-based university with strong science departments.

Assistant Professor of Chemistry (1969-1978)

- Directed M.S. thesis research of 17 students in subjects such as analytical photochemistry, NMR shift reagents, and computer simulation of chemical reactions.
- Developed and taught graduate courses in Spectroscopy and Separations.
- Developed and taught undergraduate course in Electronics for Scientists.
- Taught Instrumental Analysis, Quantitative Analysis and General Chemistry.

Instructor in Chemistry

(1968-1969)

- Developed new curriculum for Quantitative Analysis lecture and laboratory.
- Added analytical instrumentation to laboratory courses.

PROFESSIONAL DEVELOPMENT and EDUCATION

- AMA 4-Week Management Course...TQ/MRPII...cGMP...Drug/Device Regulations...Deming Quality Management
- Ph.D., Chemistry
Seton Hall University, So. Orange, NJ, 1968
- M.S., Chemistry
Seton Hall University, So. Orange, NJ, 1966
- B.S., Chemistry
Villanova University, Villanova, PA, 1964

PROFESSIONAL AFFILIATIONS

Parenteral Drug Association (PDA)

- Served on Board...Member of Technical Council...Leader of Packaging Science Interest Group...Teach at PDA Training & Research Institute...Served on Education Committee

Organization for International Standards (ISO)

- Active member of ISO TC 76 on pharmaceutical packaging standards

American Association of Pharmaceutical Scientists (AAPS)

Regulatory Affairs Professional Society (RAPS)

National Committee for Clinical Laboratory Standards (NCCLS)

American Chemical Society (ACS)

Institute of Packaging Professionals (IOPP)

American Society for Testing Materials (ASTM)

Philadelphia Rubber Group