GAYLE HEFFERNAN, R.Ph.

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(908) 563-4034

EXPERIENCE

INDEPENDENT CONSULTANT (8/89-Present)
Solicited prospective buyers for a client with a patented new indication for a previously approved drug. Prepared oral and visual presentations for patent advantages. Prepared a Drug Master File (Type 1 with provisions for Type 2) for FDA submission for a pharmaceutical equipment manufacturer. Project included reviewing and recommending site improvements needed to conform to DMF for manufacturing, writing and instituting SOP's for all aspects of material management, manufacturing, quality control and testing. Prepared cost estimates for project. Acted as company FDA liaison. Aided retail pharmacy in production and marketing of progesterone suppositories to NJ physicians. Prepared Marketing program for pharmaceutical firms to aid in physician detailing of their products.

BRISTOL-MYERS SQUIBB (12/87-7/89) RESEARCH INVESTIGATOR - Liaison between Engineering, Manufacturing and R&D for product support. Projects included qualification and cycle development on a fully automated, sterile suite which included a vial washer, hot air tunnel, automatic filler/weight check, robotically transferred product into two ft lyophilizers. Responsibility for support of International subsidiaries concerning facility, formulation, and production issues. Squibb representative for batching of third party production performed with Ben Venue, Liposomes, or MarSam by writing batch sheets and supervising for new products. Evaluated alternate suppliers for active and inactive ingredients. Evaluated products for terminal sterilization, lyophilization, stability, component compatibility, filtration mechanisms, etc.

SANDOZ PHARMACEUTICALS (5/86-12/87) RESEARCH PHARMACIST - Responsible for sterile product formulation and development. Set-up, supervised, and scaled-up product batching for Monoclonal Antibody research. Performed development on 6 compounds in support of Phase I through IV clinical supplies, including Tritium and C14 tagged studies. Coordinated and handled Calcitonin and Sandostatin third party subcontracting at Schering-Plough. Coordinated research batching for clinical supplies at the University of Tennessee. Performed justification, FDA presentation and design of $5 MM (5500 sq ft) Sterile Facility for R&D support. Included project coordination, contract negotiation, specialized equipment design, and facility support.

SQUIBB PHARMACEUTICAL PRODUCTS (9/84-5/86) ASSISTANT RESEARCH INVESTIGATOR -Participated in a cross-training program which included vitamin tablet manufacturing process support (Theragran and Theragran Jr.), formulation changes (sugar to film coating), equipment implementation and raw material evaluation. The cross-training also included sterile manufacturing process support, batch reworks, trouble shooting process/equipment problems, product component formulation compatibility, raw material evaluation, container closure integrity, and filter evaluation. Provided technical guidance to various departments within Squibb domestically and internationally.

RESEARCH ASSOCIATE (9/80-9/84) - Responsible for qualification and validation of manufacturing processes to prove accuracy and reproducibility of production operations with compliance to FDA regulations (cGMP's). Active in the design, execution, documentation, and reporting of the validation program of Squibb's automated parenteral manufacturing facility completed in 1984. Included verifying hardware process flow diagrams, software control, application modifications, and software validation. Evaluated and contracted outside vendors regarding purchase of equipment, supplies, and services. Designed and conducted experiments to

develop new manufacturing methods providing required processes, equipment, and products. Responsible for writing Standard Operating Procedures used in production and validation.

EDUCATION

Rutgers College of Pharmacy, New Jersey (1975-1980) Degree Received: B.S. in Pharmacy
Registration: N.J. Registered Pharmacist (1980-present)

EXTERNSHIPS

John F. Kennedy Medical Center, Edison, N.J. (Clinical)
Somerset Medical Center, Somerville, N.J.
Hoechst-Celanese, Somerville, N.J.

HONORS

Dean's List 3 Semesters
National Pharmaceutical Council Industry Internship Recipient

Additional Computer Science Course Work in BASIC, Pascal, Data Structures, DOS, Lotus, Symphony, Word Processing (Word Perfect, PC Writer).

PUBLICATIONS and PRESENTATIONS

Heffernan, G.; "Container Closure Integrity", Parenteral Drug Association, Poster Presentation
Heffernan, G.; "Validation of Automated Terminal Sterilization", Parenteral Drug Association Podium Presentation.
Heffernan, G. & Burns, L., "Dry Heat Sterilization and Depyrogenation Validation and Monitoring", 36 page Chapter in Validation of Aseptic Pharmaceutical Processes, Marcel Dekker, NY. 1986.
Heffernan, G; "Practical Steps in Validation of Terminal Sterilization", Parenteral Drug Association Podium Presentation.
Heffernan, G; "Washing of Rubber Components", Parenteral Drug Association, Poster Presentation.

AFFILIATIONS-SOCIETIES

Parenteral Drug Association, American Pharmaceutical Association, American Academy of Pharmaceutical Sciences, Middlesex County Pharmaceutical Association, New Jersey Validation Discussion Group, Interactive Computer Users Group

CONTINUING EDUCATION

Principles of Aseptic Filtration, Closure Technology, Filtration Fundamentals, Steam Sterilization, Dry Heat Sterilization, Validation of Pharmaceutical Processes