



Robert E. Davis, Ph.D.

SUMMARY

Pharmacist with Ph.D. in Pharmaceutical Sciences and 36 years experience centered on quality and teamwork in project management and strategic planning; experience ranging from formulation, process ruggedness and optimization, scale-up, and commercialization in R&D and manufacturing for oral solid, oral liquid and sterile dosage forms. Technical expertise in oral solids and liquids manufacturing and operations, scale-up, technology transfers, resolving process problems and validation. Successfully transferred 29 new oral solid and sterile products representing 84 potencies from R&D and alliance partners plus site to site transfer of 19 new and older drug entities. Practical experience in CMC submissions, Process Robustness, Quality Assurance, Quality Control, Regulatory Sciences, Process Analytical Technology, equipment standardization, and cGMP compliance.

PROFESSIONAL EXPERIENCE

Director, Oral Solids and Sterile New Products Optimization & Transfer, Bristol-Myers Squibb: 1999-2004; retired 2004.

- Responsible for optimization, transfer, and scale-up of oral solid and sterile new products into manufacturing facilities for products developed in R&D and in-licensed from business partners.
- Directed efforts of 20 scientists/engineers

Associate Director, Sterile-Liquid-Semisolid Products & Generic Development, Bristol-Myers Squibb: 1997-1999

- Responsible for optimization and transfer of new sterile, liquid and semisolid products plus formulation development and transfer of generic products developed for BMS Apothecon Generic Division.
- Led efforts of a team of scientists/engineers/analytical chemists and successfully filed 4 ANDAs in two years.
- Additionally, supported worldwide sterile manufacturing sites.

Associate Director, Oral Solids New Products Optimization & Transfer, Bristol-Myers Squibb: 1991-1997

- Led group in the transfer of oral solid new products from R&D, alliance partners and generic division into manufacturing sites as well as transfer of products from site to site after merger.
- Directed a group of scientists/engineers responsible for new equipment/material vendor qualification, process justification and process validation of tablets, capsules and powders for oral suspension.
- In five years, successful transferred and validated 7 new drug entities representing 34 product potencies and 12 older drug products to six different manufacturing sites worldwide.

Manager & Scientist, Product Development, Bristol-Myers Squibb: 1968-1991

- Over 23 years of R&D dosage form development experience in oral liquids, immediate and controlled release tablets, softgels, chewable tablets, capsules, radiopharmaceuticals, etc.
- Developed patented steroid suspension used for AIDS cachexia
- Developed unique and stable system for pediatric vitamin/fluoride drops
- Developed 3-D, film-coated "Smurfs" chewable vitamin tablets
- Complete reformulation of the entire Bristol-Myers cough-cold product line
- Developed long acting, wax-matrix cold tablet.



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EDUCATION

Ph.D., University of Mississippi, Oxford, MS: 1968
Major: Pharmaceutics

B.S., University of Mississippi, Oxford, MS: 1965
Major: Pharmacy

Post-College Training: Probability, Advanced Statistics, Technical Writing, Improved Drug Activity through Physicochemical Modification, EEO Awareness, Conflict Resolution, Achieving Your Potential, Time Management, Interpersonal Communications, Contemporary Tablet Coating, Kepner-Tregoe Analytical Problem Solving, Stress Management, Project Managing Skills, Delegation, Managing Interpersonal Relations, Introductory Statistical Analysis Systems, OSHA Hazard Communications, Innovation, Statistical Analysis Systems Processing, Successful Leader Behavior, Louis Allen Managers Seminar, Managing Human Performance, Strategy of Experimentation, Microsoft Office Systems, Managing the Stress of Change.

PUBLICATIONS

Davis, R.E., Hartman, C.W. and Fincher, J.H., "Dialysis of Ephedrine and Pentobarbital from Whole Human and Simulated Saliva", *J. Pharm. Sci.*, 60, 429 (1971).

Brooke, D, Bequette, R.J., and Davis, R.E., "Chemical Stability of Cyclophosphamide in Parenteral Solutions", *Amer.J. Hosp. Pharmacy*, 30,134 (1973).

Brooke, D., Davis, R.E., and Bequette, R.J., "Chemical Stability of Cyclophosphamide in Aromatic Elixir USP", *Amer. J. Hosp. Pharmacy*, 30, 618 (1973).

Davis, R.E., "The Future of the Pharmacist in Industry", *Ole Miss Pharmacist*, **1**, No.2, 9(1975) and *The Purdue Pharmacist*, 52, No.3, 6 (1975).

PATENTS

Megestrol Acetate Suspension (Megace), US Patent No. 5,338,732, issued 8-16-94.

MEMBERSHIPS

American Association of Pharmaceutical Scientists Society of Manufacturing Engineers