

James G. Yarger, Ph.D.
Endece, LLC.
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PROFESSIONAL
EXPERIENCE

Endece, LLC, Mequon, WI (2006 – Present)
Chief Executive Officer and Co-Founder

Responsible for all phases of establishing the start-up biotechnology company (Endece, LLC.) including business plan, scientific plan, legal documentation and filings, securities and obtaining investors. Primary responsibility for scientific programs including identification of candidates for drug development programs at Endece, designing and managing pre-clinical trials on our own lead new drug candidates and managing the Phase I and Phase II human clinical trials for our most promising drug candidates based on pre-clinical study results and potential importance to human health. Filed two patents in first six months on newly discovered anti-cancer drugs.

Cedarburg Pharmaceuticals, Grafton, WI (1997 - 2006)
President and Co-Founder

Responsible for all phases of founding the start-up company (Cedarburg Pharmaceuticals, Inc) focused on small scale commercial cGMP custom manufacturing, research and process development of active pharmaceutical ingredients (APIs) for the pharmaceutical and biotechnology industry: business plan development; financing/investing; building design and construction; equipment sizing, purchase, and installation; customer contracts; employee hiring; business growth and strategic development.

Key Accomplishments:

Founded a grass-roots, custom manufacturing company in one year from conceptualization with purpose of developing and manufacturing active pharmaceutical ingredients. Accomplished the business startup, which included business concept, full funding, building construction, equipment purchase, installation and employee hiring, within a 12 month period. Grew company to 45 employees and over \$6 million of revenues and profitability in eight years. Company is poised to reach over \$20 million in revenues by 2009 based on upcoming FDA approvals of both Cedarburg's generic products and customer's proprietary new products manufactured at Cedarburg. Was successfully audited by the FDA three times for Pre-Approval Inspections prior to FDA approval of generic and patented drugs manufactured at Cedarburg.

Company filed two process patents and two provisional process and use patents.

Cambridge Chemical, Inc., Germantown, WI (1996)
Director, Regulatory Affairs, Quality Assurance, Quality Control

Responsible for Regulatory Affairs and Quality Assurance of bulk pharmaceutical custom manufacturing company. Responsibilities include interactions with FDA (site audits) and required in-house documentation to ensure compliance with FDA regulations, advising and assisting clients on FDA documentation and NDA submissions, and management of Quality Assurance and Quality Control personnel.

Responsible for the design, budget, installation and validation of new pilot plant facility for manufacturing of active pharmaceutical ingredients. Responsible for customer contacts for business growth and development.

Amoco BioProducts Corporation, Naperville, IL (1987 - 1996)
Manager, Regulatory Affairs, Quality Systems,
Quality Control (1993 - 1996)

Responsible as part of Management Team for all start-up efforts of Amoco BioProducts Corporation as a new entrepreneurial company including writing a business plan, developing sources of funding, budgeting, marketing and customer development.

Also responsible for Regulatory Affairs worldwide covering risk assessments, U.S. and International regulatory submissions, approval processes, and registrations; design, implementation, validation and management of both Quality Systems and Quality Control programs to ensure regulatory and product compliance worldwide; the design, implementation and interpretation of product research trials and customer product evaluation trials for the successful commercialization of new products; and successful maintenance / retention of technical and intellectual properties during period of corporate downsizing.

Amoco BioProducts Corporation, Naperville, IL (1987 - 1992)
Staff Scientist, Coordinator Regulatory Affairs

Research and Development Management: Successful scale-up of fermentation process to 50,000 gallons for commercial production of vitamin D analog. Managed research group responsible for metabolic engineering, successful cloning and expression of multiple homologous and heterologous genes in yeast and E. coli for the synthesis of vitamin D analogs and carotenoids. Filed five patent applications.

Miles Laboratories, Inc. (Bayer, AG), Elkhart, IN (1983 - 1987)
Senior Research Scientist

Met regularly with parent company (Bayer) in Germany to develop strategy for and manage progress of successful production of Aprotinin from genetically

engineered microorganisms. Managed research group responsible for cloning, expression and secretion of foreign genes in yeast and aspergillus. Developed yeast expression vectors for proprietary synthetic gene expression. Discovered novel yeast transcription terminators and novel mechanisms of promoter regulation in yeast.

EDUCATION

Harvard University, Department of Biochemistry and Molecular Biology, Cambridge, Massachusetts (1981 - 1983)

Post-Doctoral Fellow

Determined molecular mechanisms of positive gene transcription in eukaryotes including positive gene regulation by GAL4 gene product in *Saccharomyces cerevisiae* (gene cloning, yeast in vitro transcription, promoter analysis).

Brandeis University, Department of Biology, Rosenstiel Basic Sciences Research Institute, Waltham, Massachusetts (1975-1981)

Ph.D. Biology, 1981

University of Iowa, Department of Zoology (Biology), Iowa City, Iowa (1970-1974)

B.A. Zoology, 1974

PATENTS **AWARDED**

1. Phytoene Biosynthesis in Genetically Engineered Hosts, 1996, Patent No. 5,545,816
2. Lycopene Biosynthesis in Genetically Engineered Hosts, 1996, Patent No. 5,530,189
3. Beta-Carotene Biosynthesis in Genetically Engineered Hosts, 1996, Patent No. 5,530,188
4. Beta-Carotene Biosynthesis in Genetically Engineered Hosts, 1997, Patent No. 5,656,472
5. Biosynthesis of zeaxanthin and glycosylated zeaxanthin in Genetically Engineered Hosts, 1997, Patent No. 5,684,238
6. Use of 25-hydroxycholecalciferol in a Dietary Supplement, Process for Ameliorating the Effects of Tibial Dyschondroplasia in Poultry While Maintaining Weight Gain, 1997, Patent No. 5,695,794

PUBLICATIONS

1. Yarger, J, Stults, K, and Soll, DR (1974): Observations on the growth of Dictyostelium discoideum in an axenic medium; evidence for an extracellular growth inhibitor synthesized by stationary phase cells. J. Cell Science 14:681-690.
2. Yarger, J, and Soll, DR (1975): Transcription and division inhibitors in medium of stationary phase cultures of the slime mold Dictyostelium discoideum. Biochem. Biophys. Acta 390:46-55.
3. Soll, DR, Yarger, J, and Mirick, M (1976): Stationary phase and the cell cycle of Dictyostelium discoideum in liquid nutrient medium. J. Cell Science 20:513-523.
4. Fahrner, K, Yarger, J, and Hereford, L (1980): Yeast histone mRNA is polyadenylated. Nucl. Acids Res. 8: 5725-5737.
5. Yarger, JG, Bostian, KA, and Halvorson, HO (1982): Developmental regulation of enzyme synthesis in Saccharomyces cerevisiae. In Cell Growth, Plenum Publishing, New York, N.Y., pp. 271-304.
6. Yarger, JG, Halvorson, HO, and Hopper, JE (1984): Regulation of galactokinase (GAL1) enzyme accumulation in Saccharomyces cerevisiae. Molec. and Cell. Biochem. 61:173-182.
7. Halvorson, HO, Bostian, KA, Yarger, JG, and Hopper, JE (1984): Enzyme expression during growth and cell division in S. cerevisiae: A study of galactose and phosphorous metabolism. In Recombinant DNA Approaches to Studying Control of Cell Proliferation, Academic Press, New York, N.Y., pp. 49-86.
8. Yarger, JG, Gorman, MC, and Polazzi, J (1985): Regulation of GAL7 gene expression in the yeast Saccharomyces cerevisiae. Developments in Industrial Microbiology. 26:189-192.
9. Yarger, JG, Armilei, G, and Gorman, MC (1986): A transcription terminator-like element within a yeast promoter region. Molec. and Cell. Biol. 6:1095-1101.
10. Anderson, MS, Yarger, JG, Burck, C L, and Poulter, CD (1989): Farnesyl diphosphate synthetase: Molecular cloning, sequence, and expression of an essential gene from Saccharomyces cerevisiae. J. Biol. Chem. 264:19176-19184.
11. Yarger, JG, Saunders, CA, McNaughton, JL, Quarles, CL, Hollis, BW, and Gray, RW (1995): Comparison of dietary 25-Hydroxycholecalciferol and cholecalciferol in broiler chickens. Poultry Science. 74:1159-1167.

12. Yarger, JG, Quarles, CL, Hollis, BW, and Gray, RW (1995): Safety of 25-OH-vitamin D3 as a source of vitamin D3 in poultry rations. Poultry Science. 74: 1437-1446.

PUBLISHED ABSTRACTS

1. Yarger, JG, and Hopper, JE (1979): Positive control of inducible galactose pathway enzymes in yeast. Eleventh Miami Winter Symposium, Miami, Florida.
2. Hopper, JE, Yarger, JG, and Perlman, D (1979): Regulatory gene activity in the galactose pathway of yeast. ICN-UCLA Symposia-Eukaryotic Gene Regulation Conference.
3. Yarger, JG, Bostian, K, Lemire, J, Halvorson, HO, and Hopper, J(1981): Regulation of the acid phosphatase (PHO5) and galactokinase (GAL1) genes during the cell cycle in *Saccharomyces cerevisiae*. The Molecular Biology of Yeasts, Coldspring Harbor, NY.
4. Halvorson, H, Bostian, K, Yarger, JG, and Hopper, J (1982): Regulation of acid phosphatase and galactokinase during the cell cycle of *S. cerevisiae*. Cell Cycle Symposium, San Antonio, TX.
5. Yarger, JG, Bostian, K, and Halvorson, HO (1982): Molecular basis of temporal enzyme synthesis during the cell cycle in *Saccharomyces cerevisiae*. Eighteenth Harden Conference, Cell Cycles, Wye, England.
6. Yarger, JG, Gorman, MC, and Armilei, G (1984): Regulation of GAL7 Gene Transcription in the Yeast *Saccharomyces cerevisiae*. 12th International Conference on Yeast Genetics and Molecular Biology, Edinburgh, Scotland.
7. Yarger, JG, Armilei, G, and Gorman, MC (1985): A yeast transcription terminator works efficiently in both orientations. The Molecular Biology of Yeast Conference, Cold Spring Harbor, NY.
8. Yarger, JG, Armilei, G, and Gorman, MC (1986): Transcription terminator-like elements within promoter regions of yeast. First Annual ASM Conference on Biotechnology, Washington, DC.
9. Yarger, JG, Armilei, G, and Gorman, MC (1986): A portion of the yeast URA3 promoter region can function as a bi-directional transcription terminator. Yeast Genetics and Molecular Biology Meeting, Urbana-Champaign.
10. Yarger, JG, Armilei, G, and Gorman, MC (1986): Yeast promoters contain sequences capable of highly efficient transcription termination activity in vivo. RNA polymerase and the regulation of transcription. The 16th Steenbock Symposium, Madison, WI.

11. Yarger, JG, Armilei, G, Gorman, MC, and Campbell, D (1987): Are terminons integral parts of *Saccharomyces cerevisiae* promoters? The Yeast Genetics and Molecular Biology Meeting, San Francisco, CA.
12. Yarger, JG, Burck, CL, Anderson, MS, and Poulter, CD (1989): Molecular cloning, characterization, and expression of the farnesyl diphosphate synthetase (FPP) gene from *Saccharomyces cerevisiae*. The Yeast Genetics and Molecular Biology 1989 Meeting, Atlanta, GA
13. Ausich, R, Brinkhaus, F, Mukharji, I, Proffitt, J, Yarger, JG, Yen, HCB, Fink, M, Hardin, L, Hatch, E, Hunsaker, W, Wilber, K, and Wohlfahrt, L (1990): Isolation of the genes for geranylgeranyl pyrophosphate synthase and phytoene synthase and the use of these genes for phytoene production in bacteria and yeast. International Carotenoid Meeting, Kyoto, Japan.
14. Joung, J, Jurgens, K, Bigelis, R, Bittner, M., Wolf, F, Lanenga, M, Saunders, C, Simmons, R, and Yarger, JG (1993): Production of sterols by genetically engineered *Saccharomyces Cerevisiae*. ASM 93rd General Meeting, Atlanta, Georgia.
15. Yarger, JG, Saunders, CA, Wolf, F, Joung, J, and Bittner, M (1994): Metabolic engineering in *Saccharomyces cerevisiae* resulting in accumulation of cholesta-5,7,24-triene-3 α -ol. 9th Workshop on Vitamin D, Orlando, Florida.
16. Yarger, JG, Quarles, CL, Hollis, BW, and Gray, RW (1994): Performance and toxicity related to the use of 25-OH-vitamin D3 in poultry. 9th Workshop on Vitamin D, Orlando, Florida.
17. Yarger, JG, Mc Naughton, JL, Ziegel, E, and Gray, RW (1994): Feeding 25-OH-vitamin D3 in comparison to vitamin D3 improves weight gain, feed efficiency, and breast meat yield in broiler chickens. 9th Workshop on Vitamin D, Orlando, Florida.