

# Scott R. Rudge

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## Experience

- 2004-present **RMC Pharmaceutical Solutions** – Partner and Cofounder. RMC Pharmaceutical Solutions was founded to provide consulting and contracting services to the pharmaceutical industries. Specific expertise offered:
- Product development and formulation
  - Process development and risk analysis
  - CMC generation and evaluation
  - Facility design, construction project management, commissioning and validation
  - Process, product and analytical method validation
  - Clinical trial material monitoring and reconciliation
  - Data analysis, including statistical process control, process analysis and troubleshooting, stability trending reports
  - Due diligence reports
  - Intellectual property assistance, patents, trademarks and trade secrets
- 2000-Present **University of Colorado, Boulder** Professor Adjunct, Department of Chemical Engineering. Serve on graduate thesis committees, participate in collaborative research with faculty. Teaching duties: Case Studies in Biotechnology (CHEN5831), Downstream Processing in Biotechnology (CHEN5823), Introduction to Biotechnology (CHEN5830).
- 1997-2004 **FeRx Incorporated** Vice President of Operations and Colorado Site Director. Generally responsible for manufacturing and operations in start-up drug delivery research and development company. Specifically, responsible for operations in the research and development facility, including GMP manufacturing, process development and engineering, calibration and validation. Initiated quality systems, recruited quality group and developed most product release and characterization tests. Oversaw stability program, authored regulatory filings for CMC sections in the US, Europe and Asia. Responded to due diligence inquiries and audits. Reported progress on responsibilities to the board of directors on a quarterly basis. Responsible for facility operations, expansions and budget, and implemented a \$1.2M capital project, including clean utilities. Manage company's IP portfolio, including patents and trademarks, and was listed as inventor on four patents. Supervise ten technical people and manage outside contract manufacturing and testing labs.

1994-1997 **Amylin Pharmaceuticals, Inc.**, Associate Director, Process Development and Engineering. Responsible for all process development and engineering, from synthesis of bulk drug substance to the aseptic fill of the finished drug product. Established in house engineering functions, such as calibration, facilities, equipment, and process validation, and pilot plant fermentation and purification . Managed a group of 12 scientists and engineers. Served on the corporate product team, the development subteam, and the validation subteam (lead). Lead a recombinant development task force in collaboration with research that reports to the VP, New Business Development and the CEO.

1991-1994 **Synergen**, Senior Engineer, Process Engineering. Responsible for start up, production, and manufacturing process support in 1600 liter and 10,000 liter scale E. coli fermentations of therapeutic protein. In addition to being the primary process/product support for biochemistry, microbiology and purification equipment issues, I was also responsible for establishing company policies on matters such as statistical process control, campaign summaries, process validation, and other technical process matters. Specialize in large scale purification processes and equipment.

1989-1991 **National Institute of Standards and Technology**, Chemical Engineer. Program leader for chemical engineering problems in chromatography. Responsibilities included developing original ideas, proposal writing, methods development, interactions with chemical engineering sciences and biotechnology groups.

1984-1989 **Purdue University**, School of Chemical Engineering, Research Assistant and Teaching Assistant

1983 **DuPont**, Beaumont, TX, Summer Research Associate

#### **Education:**

1989 PhD in Chemical Engineering, Purdue University  
Thesis: Applied Electric Fields in the Size Exclusion Chromatography of Proteins  
Advisor: Prof. M. R. Ladisch

1986 M.S. Chemical Engineering, Purdue University

1984 B.S. Chemical Engineering, Worcester Polytechnic Institute. Senior Thesis: Algal glycerol fermentations

#### **Honors and Memberships**

Colorado BioScience Association Technology Transfer Working Group  
Board of Directors, Colorado Institute for Research in Biotechnology  
Colorado Alliance for Bioengineering Steering Committee  
Working Group Colorado Biotechnology Council

Controlled Release Society  
Drug Information Association  
American Institute of Chemical Engineers  
American Chemical Society  
American Association for the Advancement of Science  
Parenteral Drug Association  
ASTM Biotechnology Standards Committee

**National Conferences:**

- 1993 CoChair "Nonchromatographic Separation Techniques" National ACS Meeting, Denver CO.
- 1993 CoChair "Optimization and Evaluation of Downstream Processing in Biotechnology" National ACS Meeting, Denver CO.
- 1989 CoChair "Electrochromatographic Separations" National ACS Meeting, Boston, MA.

**Publications:**

- Rudge, S.R., "Electroseparations(Electrophoresis)" *Kirk-Othmer Encyclopedia of Chemical Technology*, Howe-Grant, M., ed., John Wiley & Sons, New York, (in press).
- Harrison, R.G., P. Todd, S.R. Rudge and D.P. Petrides, Bioseparations Science and Engineering, Oxford University Press, New York, (2003).
- Rudge, S.R., C. Peterson, C. Vessely, J. Koda, S. Stevens and L. Catterall, "Adsorption and desorption of chemotherapeutic drugs from a magnetically targeted carrier (MTC)", *J. Controlled Release*, 74(1-3), 335-340 (2001).
- Rudge, S.R., T.L. Kurtz, C.R. Vessely, L. Catterall, S. Stevens and D. Williamson, "Preparation, characterization, and performance of magnetic iron/carbon composite microparticles for chemotherapy", *Biomaterials*, 21(14), 1411-1420 (2000).
- Rudge, S.R., and C. Monnig, "Electrophoresis" *Sep. Purif. Methods*, 29(1), 129-148 (2000).
- Rudge, S.R., and K.M. Markey, "Electroseparations(Electrophoresis)" *Kirk-Othmer Encyclopedia of Chemical Technology*, Howe-Grant, M., ed., John Wiley & Sons, New York, (1993).
- Rudge, S.R., S.K. Basak, and M.R. Ladisch, "Solute Retention in Electrochromatography by Electrically Induced Sorption", *AIChE J.*, 39(5), 797, (1993).
- Peskin, A.P., and S.R. Rudge, "Optimization of Large-Scale Chromatography for Biotechnological Applications", *Appl. Biochem. Biotech.*, 34/35, 49, (1992).

Hawker, D.T.L., P. Todd, R.H. Davis, R.C. Lawson, and S.R. Rudge, "Electrokinetic Isolation of Vesicles and Ribosomes Derived from Serratia marcescens", *Biotechnol. Prog.*, 8, 429, (1992).

Rudge, S.R., H.J.M. Hanley, G.C. Straty, "Swelling of Sephadex Chromatography Gels", *The Manuel Lujan, Jr. Neutron Scattering Center LANSCE Experiment Reports 1990 Run Cycle, LA-12194-PR*, Los Alamos, NM, 203, (1991).

Rudge, S.R., and P. Todd, "Applied Electric Fields for Downstream Processing", *Protein Purification, ACS Symposium Series 427*, Ladisch, M.R., R.C. Willson, C.C. Painton, and S.E. Builder, eds., 244, (1990).

Ladisch, M.R., S.R. Rudge, K.W. Ruettimann, and J.K. Lin, "Bioseparations of Milk Proteins", *Bioproducts and Bioprocesses*, Feichter, Okada, and Tanner, eds., Springer-Verlag, Berlin, 209, (1989).

Rudge, S.R., and M.R. Ladisch, "Electrochromatography", *Biotech. Prog.*, 4(3), 123, (1988).

Neuman, R.P., S.R. Rudge, and M.R. Ladisch, "Sulfuric Acid - Sugar Separations by Ion Exclusion", *Reactive Polymers*, 5, 55, (1987).

Rudge, S.R., and M.R. Ladisch, "Process Considerations for Scale-Up of Liquid Chromatography and Electrophoresis", *Separation, Recovery, and Purification in Biotechnology, ACS Symposium Series, 314*, Asenjo, J.A., and J. Hong, eds., 122, (1985).

#### **Presentations and Invited Lectures:**

Rudge, S., A. Katti, "Process Chromatography Scale Up and Economics", Colorado Institute for Research in Biotechnology, Fort Collins, CO, 14Sep00.

S. Rudge, C. Peterson, C. Vessely, J. Koda, S. Stevens, L. Catterall, "Adsorption and Desorption of Chemotherapeutic Drugs from a Magnetically Targeted Carrier (MTC)", International Symposium on Tumor Targeted Delivery Systems, National Cancer Institute and Controlled Release Society, Bethesda, MD, 26Sep00.

Hafeli, U., G. Tapolsky, S. Rudge, A. Killam Bonneville, T. Kent, "Magnetically Targeted Carriers for the Delivery of Rhenium 188", Controlled Release Society, Paris, 13Jul00.

Rudge, S., C. Vessely, C. Peterson, J. Koda, A. Killam Bonneville, S. Goodwin, J. Johnson, "Magnetically Targeted Carriers for the Treatment of Solid Tumors", Controlled Release Society, 10Jul00.

"Validation of Process Chromatography in the Purification of Proteins and Peptides", Prep2000 conference of Preparative and Process Chromatography, Washington DC, 14May00.

“Pramlintide Purification Process Development”, IBC “Tides 2000” conference on Oligonucleotide and Peptide Technology, Las Vegas, 11May00.

“The Impending Bloom of Biotechnology” American Institute of Chemical Engineers, Rocky Mountain Section, 15Feb00.

“Thermodynamics, Rate Processes and Electrodynamics in Chromatography” Colorado School of Mines, 06May91.

**Patents:**

T.B. Kent, M.J. Johnson, S.R. Rudge, “Magnetically Guided Particles for Radiative Therapies” filed October 15, 2003

G.H. Tapolsky, Y. Li, S. Failing, S.R. Rudge “Metallic Iron Delivery Compositions” filed January 5, 2003

R. Mitchiner, T.B. Kent, C. Peterson and S.R. Rudge “Permanent Magnet Keeper-Shield Assembly” issued US 6,488,615, 6,663,555, filed 31Mar00.

S.R. Rudge, T.L. Kurtz, G.H. Tapolsky, Y. Li, “Magnetic targeted carrier composed of iron and porous materials for the targeted delivery of biologically active agents” filed 13Oct00, issued in New Zealand and Singapore.

**Specialized Training:**

“Basic Radiation Protection for Uranium Mills, Biennial Retraining for Radiation Safety Officers” by Dr. Janet Johnson, CHP, of Shepherd Miller, Fort Collins, CO, 01May00.

“Radiation Safety Training”, Los Alamos National Laboratory, Los Alamos, NM, 1990.