

Richard J. Johnson, Ph.D.

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SUMMARY

Protein biochemist with extensive experience in biopharmaceutical and medical device development. Broad expertise in protein chemistry, immunology, cell and molecular biology. Recognized for technical acumen and innovation in product development. Areas of strength include:

- Protein Isolation, Characterization and Modification
- Receptor-Ligand Interactions
- Inflammation and Innate Immune Response
- Flow Cytometry
- Protein Structure-Function Analysis
- Complement Biochemistry
- Cell Isolation and Culture
- Phage Display (Peptide Libraries)

PROFESSIONAL EXPERIENCE

BIOPHIA, Lake Forest, IL 2014 to Present
Biotechnology, pharmaceutical and medical device consulting company providing expertise from discovery to commercialization of novel therapies.

Principal Consultant

Provides advice in the areas of protein biochemistry, material biocompatibility, inflammatory and immune response and cell therapy to companies developing and producing medical products.

BAXTER HEALTHCARE, Round Lake, IL 1986 to 2013
Manufacturer and marketer of biopharmaceuticals, drug and nutritional formulations and medical devices.

Principal Scientist, Science and Technology Group (2011 to 2013)

Conducted research activities with strategic impact to Baxter, guided doctorate and professional level scientists, and provided advice and advanced technical expertise to meet business needs. Collaborated with a network of external investigators and provided global technical vision for new product development to senior management.

- Demonstrated the efficacy of a novel biopharmaceutical product by completing feasibility studies in models of Age-Related Macular Degeneration, Rheumatoid Arthritis, and Antibody-Mediated Transplant Rejection. This protein is now in late preclinical development in preparation for IND review.
- Completed clinical trials for Vivia, a new Home Hemodialysis Device, by utilizing biocompatibility expertise to model the system in vitro, that permitted replication of clotting issues seen in the clinic and identified approaches to eliminate them. The team was recognized with a Medical Products Achievement Award in 2013 for this accomplishment.
- Introduced new technologies into Baxter utilizing an Open Innovation Strategy by partnering with Northwestern University. Reviewed 100 research proposals annually, selected relevant proposals to be funded by Baxter, and monitored progress of the grants. Several technologies are now in development at Baxter.
- Impacted issues relevant to the regulation of medical devices and biopharmaceuticals by:
 - Reviewing and re-writing sections relevant to complement activation testing in the current update of ISO 10994 Part 4 (Selection of tests for the interaction with blood).
 - Publishing a review paper on models to assess the impact of protein aggregation on immunogenicity.
 - Addressing FDA concerns of possible complement component C3a generation by, or contamination in Baxter products.
 - Writing proposals for forced degradation studies requested by the FDA.

Senior Director, Exploratory Science Group (2007 to 2011)

Directed and managed the activities of 15 scientists (doctoral and professional level researchers). Established business and technical goals and provided advice on innovative problem solving efforts.

- Created an ideation process that led to several exploratory programs (several won corporate awards).
- Managed an internal IP process that contributed to over 10 patents per year.
- Developed several exploratory project ideas through the feasibility stage, including:
 - Factor H for AMD.
 - Novel nutritional formulations.
 - Anti-microbial coating technologies.

Senior Director, Life Science Group (2005 to 2007)

Managed a group of over 50 scientists in the Technology Resource Division responsible for pre-clinical studies, meeting budget expectations, numerous project milestone goals and managing limited hiring opportunities.

Senior Director, Exploratory Sciences Group (1997 to 2005)

- Discovered several groups of novel peptides with the use of phage display technology. One set of peptides were optimized into extremely active complement inhibitors, working at nanomolar concentrations.
- Provided technical due diligence on several new product concepts:
 - Novel EPO analog with unique glycosylation characteristics.
 - Extended potential uses of IVIG, leading to clinical trials for neuropathology applications.
 - Contributed to the re-deployment of the Isolex Cell Selection device for cardiovascular applications (currently in phase III for treatment chronic myocardial ischemia).

Director, Material & Membrane Technology Center (1993 to 1997)

- Developed a number of applications for a reversible avidin-biotin chemistry (invented by Dr. Meir Wilcheck, Weizmann Institute); licensed this technology to Molecular Probes.
- Developed new flow cytometry techniques including a method for rare-event analysis (measuring WBC contaminants in leukodepleted platelet products for Fenwal) and WBC-Platelet co-aggregates for Renal Therapy (utilized to monitor these entities in End Stage Renal Disease patients).

Senior Research Scientist, Material & Membrane Technology Center (1990 to 1993)

- Contributed to the development of the Isolex Cell Separator device for blood cancer applications.
- Contributed to the FDA approval of heparin-coated wound drains (Jackson Pratt Gold®), by providing efficacy data on device patency using a novel in vitro model.
- Developed a new PEO-coating approach to limit protein-device interaction and applied this coating technique to various medical devices.

Research Scientist I & II, Material & Membrane Technology Center (1986 to 1990)

- Developed cost effective manufacturing approach for the maleic anhydride-modified cellulose membranes for Renal Therapy, providing efficacy and stability analysis on hollow fiber membranes.
- Developed a unique Hirudin analog and attachment chemistry to produce a non-thrombogenic surface.
- Developed a biocompatibility capability for Baxter, focused largely on complement and WBC activation:
 - Invented a maleic anhydride modified cellulose membrane for hemodialysis applications that did not activate complement.
 - Isolated sheep C5a and lactoferrin and developed unique RIAs to monitor complement activation and WBC activation in in vivo models.

Post Doctoral Fellowship, USCD/VA Medical Center (1982 to 1986)

Identified structure-function correlations of the complement fragment and inflammatory mediator, C5a, leading to C5a-receptor antagonists. Using chemical modification, including the chemical synthesis of a unique photoreactive, hetero-bifunctional crosslinking reagent, subsequent studies resulted in the first biochemical identification of the human C5a receptor.

EDUCATION

Ph.D., Biochemistry, Duquesne University, Pittsburgh, PA

Thesis: The Primary Structure of Bovine Brain Glutamine Synthetase

MS, Biochemistry, Duquesne University

BA, General Arts & Science, Pennsylvania State University

PROFESSIONAL DEVELOPMENT

- FDA Regulatory Training (Baxter)
- Flow Cytometry (Becton Dickinson)
- Combinational Chemistry Seminars
- Bioinformatics Course (University of Michigan)
- Project Team Management (Baxter)
- Advanced Course in Immunology (AAI)
- Molecular Biology Summer Course (New England Biolabs)

PROFESSIONAL AFFILIATIONS

American Association of Immunologists (AAI)

Chicago Innovation Mentors (CIM)

California Separation Science Society (CASSS)

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Patents:

1. Methods of manufacturing nucleophilic material modified for improved biocompatibility, Richard J. Johnson, Dennis E. Chenoweth, Daniel R. Boggs, and Michael J. Lysaght. Patent No. 4,882,106. Issued 11-21-89.
2. Methods of manufacturing nucleophilic material modified for improved biocompatibility (CIP-DIV). Richard J. Johnson, Dennis E. Chenoweth, Daniel R. Boggs, and Michael J. Lysaght. Patent No. 5,073,265. Issued 12-17-91.
3. Whole blood leukodepletion and platelet filter, S. Neng Ung-Chhun and Richard J. Johnson. Patent No. 5,647,985. Issued 7-15-97.
4. Analogs of hirudin. Jullian Breillatt, Richard J. Johnson and Cecilia Ku. Patent No. 5,837,808. Issued 11-17-98.
5. Method of separating leukocytes from blood cells using a Leukodepletion Filter, S. Neng Ung- Chhun and Richard J. Johnson. Patent No. 5,795,483. Issued 8-18-98.
6. Blood cell separation devices having a membrane with particular coating, S. Neng Ung-Chhun and Richard J. Johnson. Patent No. 5,972,217. Issued 10-26-99.
7. Analogs of hirudin. Cecilia Ku, Richard Johnson and Jullian Breillatt. Patent No. 6,028,170. Issued 2-22-2000.
8. Method for producing improved medical devices and devices so produced. Neng S. Ung- Chung and Richard J. Johnson. Patent No. 6,306,454. Issued 10-23-01.
9. Method for producing improved medical devices and devices so produced. Neng S. Ung- Chung and Richard J. Johnson. Patent No. 6,648,922. Issued 11-18-03.
10. Peptides that inhibit complement activation. Shelley Maves and Richard J. Johnson. Patent No. 7,348,401. Issued 03-25-2008.
10. Removal of substances in dialysis solutions and dialysis components by ion exchange adsorption. Richard Johnson, Beverly Johnson and Valerie Leesch. 12/052,508. Filed 03-20-08.
11. Destruction of microbial products by enzymatic digestion. Richard Johnson and Valerie Leesch. 61/038,297. Filed 03-20-08.
12. Manufacture of Factor H (FH) and FH-Derivatives from plasma. Shawn Bairstow, Richard Johnson, Sindhu Ramachandran, Ruth Madlener, Wolfgang Teschner, and Hans Peter Shwarz. 8,304,524. Issued 11-6-12.
13. Isolation of Factor H from Fraction I Paste. Shawn Bairstow, Sindhu Ramachandran and Richard Johnson. Filed 03-2013.
14. Factor H for Treatment of Rheumatoid Arthritis. Richard Johnson. Filed 03-2013.
15. Factor H for Transplantation. Richard Johnson and Jenny Zhang. Filed 03-2013.

Awards:

1. Applied Sciences Outstanding Scientific Award, "SWAN -A Non-Complement Activating Membrane" 1989.
2. Applied Sciences Outstanding Scientific Award, "Release Technology for Purification of Stem Cells Using Magnetic Beads" 1991.
3. Baxter Achievement Award, "Development of an Affinity Membrane Immunoabsorption Device" 1998.
4. Baxter Achievement Award, "Reclassification of High Permeability Hemodialysis Systems" 1999.
5. Technology Resources Achievement Award, "Excalibur" 2001/2002. Technical Due Diligence Analysis of Epo Omega.
6. Technology Resources Achievement Award, "Ingenuity" 2002/2003. Development of Complement Inhibiting Peptides.
7. Medical Products Stellar Award for 2012, Vivia Home Hemodialysis (HHD) Clotting Mitigation and Clinical Trial Support.

Original Papers:

1. Johnson, R.J. and Piszkiwicz, D. (1985) Primary structure and peptides from bovine brain glutamine synthetase: Comparison with sequences of glutamine synthetase from other organisms. *Biochem. Biophys. Acta* 827, 439 - 446.
2. Johnson, R.J. and Chenoweth, D.E. (1985) Structure and function of C5a anaphylatoxin: Selective modification of tyrosine-23 alters biological activity but not antigenicity. *J. Biol. Chem.* 260, 10339.
3. Johnson, R.J. and Chenoweth, D.E. (1985) Labeling the granulocyte C5a receptor with a unique photoreactive probe. *J. Biol. Chem.* 260, 7161.
4. Johnson, R.J., Tamerius, J.D. and Chenoweth, D.E. (1987) Identification of an antigenic epitope and receptor binding domain of human C5a. *J. Immunol.* 138, 3856.
5. Johnson, R.J. and Chenoweth, D.E. (1987) Synthesis of a new photoreactive C5a analog that permits identification of the ligand binding component of the granulocyte C5a receptor. *Biochem. Biophys. Res. Commun.* 148, 1330.
6. Johnson, R.J. (1989) The design of cellulosic membranes that do not activate complement. *Medical Progress through Technology*, 15, 77.
7. Johnson, R.J., Boggs, D.R., Lelah, M. and Sutliff, T.M. (1990) A modification of cellulose that facilitates the control of complement by factor H. *Blood Purification*, 8, 318.
8. Johnson, R.J., Simpson, S., Van Epps, D.E. and Chenoweth, D.E. (1992) Wheat germ agglutinin inhibits the C5a-receptor interaction: implications for receptor microheterogeneity and ligand binding site. *J. Leukocyte Biol.*, 52, 3.
9. Burhop, K., Johnson, R.J., Simpson, J., Chenoweth, D.E. and Borgia, J. (1993) Biocompatibility of hemodialysis membranes: evaluation in a sheep model. *J. Lab. Clin. Med.*, 121, 276.
10. Van Epps, D.E., Simpson, S.J. and Johnson, R.J. (1993) Relationship of C5a Receptor Modulation to the Functional Responsiveness of Human Polymorphonuclear Leucocytes. *J. Immunol.* 150, 246.
11. Johnson, R.J., K. Burhop, and D.E. Van Epps. (1996) C5a Infusion in Sheep Mimics Pathophysiological Responses of Dialysis. *J. Lab. Clin. Med.* 127, 456.
12. Bairstow, S., J. McKee, M. Nordhaus and R. Johnson. (2009) Identification of a simple and sensitive microtiter plate method for the detection of oversulfated chondroitin sulfate in heparin products. *Anal. Biochem.* 388, 317-321.
13. J. McKee, S. Bairstow, C. Szabo, J. Ray, T. Wielgos, P. Hu, E. Chess, M. Nordhaus, T. Hai, J. Campbell, S. Donovan, N. Viseux, N. Riedel, J. Cammack and R. Johnson. (2010) Structure elucidation and biological activity of oversulfated chondroitin sulfate contaminant in Baxter heparin. *J. Clin. Pharmacol.* 50, 1159.

Invited Papers:

1. Johnson, R.J. and Chenoweth, D.E. (1988) Complement activation resulting from blood- materials interaction; in *Biomedical Materials and Devices*, Mat. Res. Soc. Sump. Proc. Vol. 110, J.S. Hanker and B.L. Giammar (eds.) pg 747.
2. Johnson, R.J. (1990) Complement Activation by Biomaterials, in *Apheresis*, Alan R. Liss, New York, pg. 507.
3. Johnson, R.J. (1994) Complement activation during extracorporeal therapy: biochemistry, cell biology and clinical relevance. *Neph. Dial. Transplant.* 9 (Suppl.2), 36.
4. Johnson, R.J. (1997) Involvement of Complement Components in Renal Disease. *Current Opinion in Nephrol. Hypertension.* 6, 120.
5. R. Johnson and W. Jiskoot. (2012) Models for the evaluation of relative immunogenic potential of protein particles in biopharmaceutical protein formulations. *J. Pharm. Sci.* 101:3586.
6. Chess, E., Bairstow, S., Donovan, S., Havel, K., Hu, P., Johnson, R., Lee, S., McKee, J., Miller, R., Moore, E., Nordhaus, M., Ray, J., Szabo, C. and Wielgos, T. (2012) Case Study: Contamination of Unfractionated Heparin with Over-Sulfated Chondroitin Sulfate. In *Heparin- A Century of Progress*, R. Lever, B. Mulloy and C. Page, eds. *Handbook of Experimental Pharmacology*, Vol. 207, Chapter 5a.
7. Johnson, R.J. (2013) The Complement System, Pages 533-545 in "*Biomaterials Science: An Introduction to Materials in Medicine*", B. Ratner, A. Hoffman, F. Schoen and J. Lemons (eds.) Third Edition, Academic Press, New York.

Abstracts:

1. Johnson, R.J. and Piszkiwicz, D. (1981) Structure and regulatory properties of bovine brain glutamine synthetase. *Fed. Proc.* 40, 1797.
2. Johnson, R.J. and Chenoweth, D.E. (1984) Nitrotyrosyl-C5a des Arg displays diminished binding to the human neutrophil C5a receptor. *Fed. Proc.* 43, 1449.
3. Johnson, R.J. and Chenoweth, D.E. (1985) Photoaffinity labeling the granulocyte C5a receptor. *Fed. Proc.* 44, 1259.
4. Johnson, R.J. and Chenoweth, D.E. (1986) Characterization of the isolated granulocyte C5a- receptor. *Fed. Proc.* 45, 1135.
5. Johnson, R.J., Nazimek, C. and Chenoweth, D.E. (1987) Complement activation by biomaterials immunodetection of surface-bound C3b and fluid phase anaphylatoxins. *Fed. Proc.* 46, 983.
6. Lelah, M., Johnson, R.J., Chenoweth, D.E. and Cooper, S. (1988) Complement activation on ionic polyurethanes. *The Third World Biomaterials Congress.*
7. Burhop, K. Jesmok, G., Chenoweth, D.E., Johnson, R.J. and Borgia, J. (1988) The role of complement activation during endotoxemia in sheep. *Fed. Proc.* 47, 1176.
8. Burhop, K., Johnson, R.J. and Van Epps, D.E. (1989) Cardiopulmonary response of C5a in awake sheep. *Fed. Proc.* 48, 910.
9. Johnson, R.J., Burhop, K., Lively, M. and Van Epps, D.E. (1989) Isolation and characterization of sheep C5a. *Fed. Proc.* 48, 912.
10. Burhop, K., Lorenz, J., Gokoo, C., Parada, L., Johnson, R.J., Dinarello, C. and Joob, A.(1990) Acute effects of cardiopulmonary bypass (CPB) in sheep. *Fed. Proc.* 49, 348.
11. Breillatt, J., Johnson, R.J., Ku, C., Ung-Chhun, S.N., Pokropinski, S., Turner, P., Lindon, J.N., Wielgos, T. (1992) Recombinant hirudin analog designed for attachment to polymers. *FASEB J.* vol.6, 2222.
12. Srinivasan, G., Chang, H. and Johnson, R.J. (1994) Activation of platelets by complement- dependent mechanisms. *FASEB J.* vol. 8, 2906.
13. Srinivasan, G., C. Nazimek, B.A. Johnson, K.A. Earles, S. Pokropinski, C. Subach, and R.J. Johnson. 1995. Formation of Platelet-WBC Complexes During In Vitro Hemodialyzer Evaluation is Mediated by Complement Activation. *Soc. Biomat. Trans.* vol. 18, 12.
14. Srinivasan, G., B.A. Johnson, S.K. Mujais, H. Chimeh, and R.J. Johnson. 1996. Platelet-WBC Complex Formation Is Augmented In Uremia. *Joint Conference on Atherosclerosis, Thrombosis, and Vascular Biology.*
15. H. Chimeh, R. Johnson, G. Srinivasan, and S. Mujais. 1996. Enhanced Platelet-Leukocyte coaggregates in ESRD. *J Amer. Soc, Nephrol.* vol. 7(9), 1476.
16. Johnson, R., H. Chimeh, G. Srinivasan, D. Falls and S. Mujais. 1996. Elevated levels of Lp(a) and s-P-Selectin in uremic blood may influence the formation of platelet-granulocyte coaggregates. *J Amer. Soc, Nephrol.* vol. 7(9), 1485.
17. Srinivasan, G., R. Johnson, H. Chimeh, and S. Mujais. 1996. IL8/ADP induce augmented platelet-PMN complexes in uremic blood pre dialysis. *J Amer. Soc, Nephrol.* vol. 7(9), 1499.
18. Johnson, R.J., G.S. Vijay, L. Kastrup, M. Serres, S. Peters, and R. Brown. 1997. Apheresis platelet concentrates with low levels of WBC do not accumulate cytokines. *Transfusion*, 37 Supp., 10S
19. Johnson, R.J., L. Kastrup, K. Unversagt, L. Farrell, M. Serres, and M. Harvey. 1998. Analysis of WBC subsets in leukoreduced blood products. *Blood* vo. 92 (10), 3172.
20. Johnson, R.J., G.S. Vijay, H. Chimeh, and S. Mujais. 1998. Formation of platelet-granulocyte complexes is augmented in hypertension. *Blood* vo. 92 (10), 3550.
21. Johnson, R.J., S.A. Maves and L. Kastrup. 2004. Development of novel inhibitors of complement. *FASEB J.* 2004.
22. Johnson, R.J. and S.A. Maves. 2004. Development of peptides that augment complement activation. *FASEB J.* 2004.
23. Muller, M., S. Pokropinski, S. Bairstow, J. Svatek, S. Young, R. Johnson and A. Bernardo. (2012) American Society of Nephrology Abstract # 850, Nov. 2012.