Rajan Bawa
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EXPERIENCE & ACCOMPLISHMENTS:

CARE Research Fort Collins, Colorado (2010 - present)
Care Research, LLC http://www.careresearchllc.com is a pre-clinical laboratory that provides surgical and toxicological services to pharmaceutical, biotech, device companies and governmental agencies

Chief Scientific Officer (2010-present)

- ***Increased the customer base of clients of the company 500% over 14 years by attracting new clients and convincing them to choose CARE services by explaining our unique USP***
- ***Coordinated and managed relationships between sponsors, pathologists, scientists and diverse functional groups, accelerating project completion by 35% over competitors***
- Conducted all Official Responses Ensuring Compliance to FDA audit findings
- Encouraged staff to attend workshops and training seminars to sharpen their skills
- Provided technical leadership for identifying and implementing innovative methods and processes.
- Consulted in the areas of pharmaceutical and biomedical device product development, including regulatory strategies in the area of parenterals, ophthalmics, orthopedics, GI, pulmonary, cardiac, biomolecules, growth factors, dental and anti-neoplastic agents.

Chief Executive Officer (2010-2020) (In 2020 Sold the company)

- ***Increased the gross revenues of the company 600% over 10 years.***
- Hired and maintained an independent QAU unit
- Developed and managed budgets
- Set and executed successful business strategy for state-of-the-art toxicological and surgical testing laboratory.
- Hired and created a diversified professional team, including women and minorities

Colorado Histo-Prep., Fort Collins, Colorado (1999- 2019)
Colorado Hist-Prep (CHP) www.histoprep.com was a pre-clinical laboratory that provided histo-pathology and clinical pathology services to CROs, pharmaceutical, biotech, device companies and governmental agencies

President.

- ***Increased the gross revenues of company 400% over 5 years***
- ***Coordinated and managed relationships between sponsors, pathologists, scientists and diverse functional groups, resulting in accelerated project completion 35% quicker than competition***
- Conducted all Official Responses Ensuring Compliance to FDA audit findings
- Maintained an independent QAU unit
- Test Site Management

- Developed and managed budgets by monitoring spending and expenses
- Set business strategy for state-of-the-art histopathology and clinical pathology laboratory.
- Hired and created a diversified professional team, including women and minorities
- Encouraged staff to attend workshops and training seminars
- Provided technical leadership for identifying and implementing innovative methods and processes.

Atrix Laboratories, Fort Collins, Colorado (1997 - 1999)

Atrix Labs (now part of Indivior)http://indivior.com/ a global pharmaceutical company focused on addiction treatments and Tolmar http://tolmar.com/ a fully integrated pharmaceutical company specializing in developing controlled drug delivery treatments for oral, oncology as well as dermatological conditions.

Director, Pharmaceutical Development

- Managed the research & development activities of a diverse multifunctional development department comprising of analytical chemistry, process research, packaging and formulation development.
- Developed innovative processes for powder filling of drugs as well as lyophilization of injectable polypeptides in plastic syringes. This enabled the development of commercial scale production of leuprolide acetate currently marketed as **ELIGARD®**
- Conceived and implemented development and regulatory strategies resulting in the rapid approval and marketing of unique injectable, in-situ gelling formulations for the treatment of prostate cancer. Resulted in a multi-million dollar contract with European partner Indivior, PLC for extended release buprenorphine (for treatment of opioid induced addiction) marketed as **SUBLOCADE®**
- Developed formulations containing an antibacterial agent for the treatment of periodontal disease. **ATRIGEL®**
- Provided technical analyses, evaluation and advice to the licensing department for research collaboration with other companies.

Alcon Laboratories, Fort Worth, Texas (1993 - 1997)

Alcon Labs (Division of Nestle) www.alcon.com is a worldwide leader in ophthalmic products

Associate Director, Drug Delivery/Formulations Research

- Developed a unique environmentally responsive gel platform for antiglaucoma drugs and antiinfectives. Intensive efforts resulted in the rapid progression of strategic formulations through ANDA & NDA targets and subsequent successful marketing under Alcon's branded generic Falcon line. Alcon was acquired by Novartis www.novartis.com and subsequently brought into its Sandoz Division www.sandoz.com. Coordinated submission of regulatory documents meeting aggressive timelines.
- Developed unique formulations improving the solubilization of poorly soluble drugs (such as prostaglandins, (such as latanoprost) using innovative ingredients to enable expeditious global regulatory approval (especially Japan & Europe) and subsequent worldwide marketing
- Developed novel topical formulations (NSAID, antiglaucoma) directly targeting leading competitors and bypassing their patents (diclofenac sodium, Timolol maleate)
- Developed physico-chemical methods for materials/formulations characterization to support (505)2b claims for extended release timolol maleate

- Provided technical analyses, evaluation and advice to the licensing department for acquisition of new compounds and technologies.
- Negotiated and coordinated research with other companies
- Refocused department activities to align with R& D strategy. Resulted in acceleration of key programs by 6-8 months.
- Developed and managed operating plan for department.
- Developed strategic plan for department geared toward superior/differentiated product stream including inserts/implants.

Bausch & Lomb, Rochester New York (1984 - 1993)

Bausch & Lomb (www.bausch.com) is an eye health company, dedicated to perfecting vision and enhancing life for consumers around the world. Core businesses include soft and rigid gas permeable contact lenses and lens care products, and ophthalmic surgical and pharmaceutical products

Manager, Technology Integration (1991 - 1993)

- Developed a strategy to address process manufacturing problems. Successfully executed and implemented to prevent product recall.
- Established programs to aggressively pursue external technologies to supplement internal product development efforts.
- Attacked a critical manufacturing problem. Identified cause, developed and implemented solution leading to cycle reduction from seven months to 3 days. Success led to development and marketing of second lens following same developmental model.
- Proposed a new strategy for implementing short and long term action plans for R&D projects. This proposal resulted in timely commercialization of new soft contact lenses.
- Led multifunctional teams responsible for process improvement and cost reduction projects.

Manager, New Concepts Development (1988 - 1990)

- Developed unique characterization methods for hydrogels and silicone polymers for contact lens applications.
- Conceptualized a revolutionary family of sterile and versatile ocular drug delivery systems (both bioerodible as well as nonerodible) for antinfectives and lubricants.
- Led a diverse project team addressing formulation, characterization, analytical, clinical and regulatory aspects through successful development of the minidisc containing an antiinfective biomolecule
- Directed activities of multidisciplinary group of chemists and engineers to conceive of new product and process concepts and develop through feasibility.
- Invented and developed innovative lens production processes based on ***supercritical fluid technology*** that allowed development and successful marketing of cutting edge new products for the global marketplace.

Senior Scientist (1984 - 1987)

- Invented & implemented unique product ideas for contact lenses & drug delivery systems
- Developed innovative processes and methods of characterization and analyses for new materials.

Hoffman La Roche, Inc., Nutley, New Jersey *(www.roche.com)* (1981 - 1983)

Research Engineer

- Prepared parenteral clinical supplies of thymosin and interferon for use in oncology

- Investigated skin permeation kinetics of prostaglandins and interferon for transdermal systems using mice and cadaver skin.
- Conceived and developed targeted systems for antiinfectives and anticancer agents using pH-sensitive polymers.
- Evaluated the release characteristics of benzodiazepines from a unique safe sustained delivery system lengthening the gastric emptying time. This enabled "evergreening" the status of diazepam and converting it's use to once daily vs. three times daily.

Teaching Experience:

BITS-Pilani (Goa Campus)Tier 1 School
Visiting Professor Dept of Chemical Engineering (Jan 2022-Dec 2022)

- Developed & Taught a 4 unit course
  "Introduction to Biomedical Engineering" BITS F418
  As COVID-19 was widespread for the couple of beginning months of 2022, taught the course on-line, initially and subsequently from March to December taught the course in person for 2 semesters
- Developed and co-Taught a 3 unit core "Separations Processes II" course (80 students)
- Counselled undergraduate students on course choice and curriculum
- Counselled undergraduate and graduate students on career choice and internships
- Guided two undergraduate students for a Process Design course
- Advised undergraduate chemical engineering student for his research thesis:
  "Microfludic Ocular Model for an opthalmological Drug Delivery System"
  Counselled the student on choosing the research topic, discussed the relevance and met frequently with him to guide him in his investigations. Conducted evaluations and awarded grade
- Advised undergraduate mechanical engineering student for his project research:
  "Physico-chemical investigations of Drug/Polymer Films of a Novel Polymeric System"
  Counselled the student on choosing the research topic, discussed the relevance and met frequently with him to guide him in his investigations. Conducted evaluations and awarded grade
- Helped guide several PhD students on their thesis research including biosurfactants and gas hydrates

Education: University of Rochester, Rochester, New York
(Dissertation in polymeric controlled release elucidated the parameters affecting the release of hydrophilic drugs from hydrophobic matrices. Studied the fundamental mechanisms operative in a development product - the minidisc, a sterile ocular insert, containing an antiinfective)
Ph.D. - Chemical Engineering

Massachusetts Institute of Technology, Cambridge Massachusetts (Advisor: Robert Langer; Thesis involved microstructural and kinetic characterization of ethylene vinyl acetate-protein matrices: prototype implants)
M.S. - Chemical Engineering
M.S. - Biochemistry & Metabolism

Birla Institute of Technology & Science, India
B.E. ChE - Honors, Chemical Engineering

Patents and Publications:

Patents:

"Method for Lyophilizing an Active Agent", USP#7,467,482 (2015), C.L. Yarborough, D.G. Madril and R. Bawa

"Method for Lyophilizing an Active Agent", USP#7,467,482 (2008), C.L. Yarborough, D.G. Madril and R. Bawa

"Method for Lyophilizing an Active Agent", USP#6,907,679, (2005), C.L. Yarborough, D.G. Madril and R. Bawa

"Process and Delivery Container for Lyophilizing Active Agent" USP#6,722,054 (2004), C.L. Yarborough,D.G. Madril and R. Bawa

"Stoppering Method to Maintain Sterility", USP#6,626,870, (2003) C.L. Yarborough, M.R. Duncan, R.L. Norton, R. Bawa, D.G. Madril and C.J. Barrett

"System for Use in Lyophilization Comprising Delivery Containers and a Cover Plate", USP#6,610,252, (2003) D.G. Madril, C.L. Yarborough and R. Bawa

"Treatment of Contact Lenses with Supercritical Fluid" USP#6,610,221 (2003), R.Bawa, F.Tasber and D.Hahn

"Cover Plate For Use In Lyophilization" USP #6,566,144 (2003), D.G. Madril, C.L. Yarborough, R. Bawa and C.J. Barrett

"Gelling Ophthalmic Compositions Containing Xanthan Gum"
USP #6,261,547 (2001), R. Bawa, R. Hall, B. Kabra, J. Teague, G. Cagle, K. Markwardt and M. Shah

"Treatment Of Contact lenses With Supercritical Fluid"
USP #6,180,031 (2001), R. Bawa, F. Tasber and D. Hahn

"Gelling Ophthalmic Compositions Containing Xanthan Gum"
USP #6,174,524 B1 (2001), R. Bawa, R. Hall, B. Kabra and J. Teague.

"Storage-Stable Prostaglandin Compositions"
USP #6,011,062 (2000), W. Schneider, R. Bawa and A. Weiner

"Treatment Of Contact lenses With Supercritical Fluid"
USP #6,071,439 (2000), R. Bawa, F. Tasber and D. Hahn

"Topical Ophthalmic Acidic Drug Formulations"
USP #5,558,876 (1996), S. Desai and R. Bawa

"Process For Making Silicone Containing Hydrogel Lenses"
USP #5,260,000 (1993), M. Nandu, R. Bawa and Y.C. Lai

"Spincasting Process For Producing A Series Of Contact Lenses Having Desired Shapes"
USP #5,260,001 (1993), M. Nandu and R. Bawa

"Ophthalmic Article" (Minidisc Patent)
USP #5,137,728 (1992), R. Bawa

"Sustained Release Formulation Containing an Ion - Exchange Resin"
USP #4,931,279 (1990), R. Bawa and D.V. Ruscio

"Manufacture of Polymeric Contact Lenses"
USP #4,732,715, (1988), R. Bawa and W.G. Deichert

"Method of Forming Iris Variegation Patterns on Contact Lenses"
USP #4,719,657, (1988), R. Bawa
"Contact Lenses Having Fluorescent Colorants and Apparatus for Making Such Lenses"
USP #4,702,574, (1987), R. Bawa

"Sustained-Release Formulation containing an Amino Acid Polymer with a Lower Alkyl (C1-C4) Polar Solvent"
USP #4,713,244, (1987), R. Bawa and W.G. Deichert

"Sustained-Release Formulation Containing an Amino Acid Polymer"
USP #4,668,506 (1987), R. Bawa

Publications:

"Use of a bioactive and robust 3D printed soft implant for repairing critical sized cartilage lesions in a goat knee model" AAOS 2019 Annual Meeting, March 12-16 in Las Vegas, Nevada, B. Holmes, N.Castro, S. Lee, C. Rossi, C.Cannova, R. Bawa and M. Oetgen

"The 3DBiopsy System: Preclinical Investigation of a Needle, Actuator, and Specimen Collection Device Allowing Sampling of Individualized Prostrate Lengths Between 20 and 60 mm," Urology 107 (2017), pp 257-261, N. N. Stone, V. Mouraviev, D. Schechter, M. S. Lucia, E.E. Smith, P. Arangua, J. Hoenemeyer, J. Rosa, R. Bawa, E.D. Crawford Fitzsimons Innovation Campus, Bioscience Park Center, Aurora, CO

"Ocular Inserts", Ophthalmic Drug Delivery, Marcel Dekker 1993, pp.223-260, R. Bawa

"The Mechanism of Controlled Release of Hydrophilic Drugs from Hydrophobic Polymers", (1992), R. S. Bawa (Ph.D. Thesis), University of Rochester, Rochester, NY

"Physico-chemical Considerations in the Development of an Ocular Polymeric Drug Delivery System," Biomaterials, 11 (9), (1990), pp 724-728, R. Bawa and M. Nandu

"An Explanation for the Sustained Release of Macromolecules from Biocompatible Polymers," J. Controlled Release, 1, (1985), pp 259-267, R. Bawa, R.A. Siegel, B. Marasca, M. Karel and R. Langer

"Polymers for Sustained Macromolecular Release: Kinetics, Applications and External Control," AICHE Symposium Series, Controlled Release Systems, 206, (1981) , pp. 10-20, R. Langer, D.S.T. Hsieh, A. Peil, R. Bawa and W. Rhine

"Controlled Release of Macromolecules from Ethylene-Vinyl Actetate Copolymer Matrices: Microstructure and Kinetic Analyses", (1981), R. S. Bawa (Masters' Thesis), Massachusetts Institute of Technology, Cambridge, MA

"Polymers for the Sustained Release of Macromolecules: Applications and Control of Release Kinetics," Controlled Release of Bioactive Materials, Academic Press, 1980, pp 83-98, R.S. Langer, W.D. Rhine, D.S.T. Hsieh and R.S. Bawa

Abstracts:

"Polymers for the Sustained Release of Macromolecules: Microstructural Studies and Their Application to Kinetic Models" 87th National AICHE Conference, 1979

"Polymers for Sustained Drug Release: Applications and Methods of Control," 89th National AICHE Conference, 1980

"Recent Advances in Controlled Release Systems for Macromolecules," Proceedings of the 8th International Symposium on the Controlled Release of Bioactive Materials, 1981

"New Extended Release Ocular Drug Delivery System - Design, Characterization and Performance Testing of Minidisc Inserts," Proceedings of the 15th International Symposium on the Controlled Release of Bioactive Materials, 1988, R.Bawa, M. Dias, M. Nandu and J.R. Robinson

"The Role of Microscopy in the Study of Diffusion in Polymeric Drug Delivery Systems," Diffusion '89, (1989), R. Bawa and R.S. Langer

"Physico-Chemical Considerations in the Development of a Nonbioerodible Ocular Device (Minidisc) for the Controlled Release of Hydrophilic Drugs", Polymer Preprints:1, 30:1 (1989), R. Bawa, S. Coffey and M. Nandu

"Recent Studies on the Continuing Characterization of Minidisc inserts for Ocular Therapy", Proceedings of the 16th International Symposium of the Controlled Release of Bioactive Materials, 1989, R. Bawa, M. Nandu, W. Downie and J.R. Robinson

"Characterization and Stability Testing of an Ophthalmic Polymeric Drug Delivery System," Polymer Preprints, 31:1, (1990), R. Bawa and S. Coffey

"Manipulating Release Kinetics of Gentamicin sulfate by altering crosslink length and polarity of novel hydrophobic matrices", Proceedings of the 18th International

Symposium on the Controlled Release of Bioactive Materials, 1991, R.Bawa and H.J. Palmer

"Manipulating Release Kinetics of Gentamicin Sulphate from Novel Hydrophobic Polymer Matrices", 100th National AICHE Conference, 1991, R. Bawa and H.J. Palmer

"Sustained Release of Leuprolide Acetate: Development of a Novel In-Situ forming Biodegradable polymeric implant as the Delivery Vehicle", B. Chandrashekar, D. Anna, D. Madrill, K. Tow, C. Balliu and R.S. Bawa, 1998 AAPS Annual Meeting Abstracts, Nov 1998, Vol#1, pg 414

"Development and Characterization of Novel Bioerodible Drug Delivery Systems Containing Doxycycline", L.A. Moore, J. Barrall, C. Yarborough, R. Grousnick and R. Bawa, Society for Biomaterials Annual Meeting, 1999.

"An In-Situ Forming Guided Tissue Regeneration Barrier with Doxycycline", J.S. Garrett, K.M Holland, B.A. Coonts, L.A. Moore, K.E. Cady, C. Yarborough, R. Bawa and R.L. Dunn, Society for Biomaterials Annual Meeting, 1999.

"Sustained Release of Leuprolide Acetate from an In-Situ Forming Biodegradable Polymeric Implant as the Delivery Vehicle", Proceedings of the 26th International Symposium on Controlled Release of Bioactive Materials,1999, B.L. Chandrashekar, D. Madril, K. Tow and R. Bawa

"Effect of Decalcification and Processing Parameters in Trout Histology", Proceedings of the 9th Annual Whirling Disease Symposium, 2003, R. Bawa, P. Walker and C. Smith

"Identification of Myxolobus cerebralis Triactinomyxon Proteins using a Novel Histochemical Procedure", Proceedings of the 10th Annual Whirling Disease Symposium, 2004, R. Bawa, A. Miller and E.J. Wagner

Patents
Filed: Five additional patent applications filed

Other Training:

Dale Carnegie
Numerous ISO 9000 courses
Numerous management,team building and leadership courses.
SQA Basic GLP Training (4/2013)
Rocky Mountain Regional Chapter SQA (11/2012)
(Taking the EEEEE Out of Compliant Electronic Records)

On Job Training

Operation of the Fidex Micro CT for Imaging (7/2017)
Basic GLP Course (SQA) (5/2013)

GLP Training Course	(5/2011)
FDA Parallel Comparisons	(12/15/00)
Techniques of Hematology & Urine Analysis	(11/11/04)
Comminuted Meat Samples screening	(02/22/05)
Certified Histotech	(2001)

Scientific Advisory Board Positions

Scispot www.scispot.com is a leading Lifescience Tech Stack provider transforming companies into digital biology entities, (2024)

Hemp Bioscience, LLC www.titr8.com a company focused on providing solutions for pain management using naturally derived ingredients as an alternate to addictive opioids (2020)

Nanochon *www.nanochon.com* a company focused on 3D printing of materials used for bone replacement (2017- present)

3D Biopsy www.3dbiopsy.com a company focused on innovations for directed biopsies for the diagnosis of prostate cancer (2016 - present)

Ram Chameli Chadha Vishvas Girls College www.rccvgc.com
An educational institution focused on providing college level education exclusively for women. If the students are unable to afford the tuition or living expenses, both these expenses are waived (2013-present)

Canadian biotechnology company (2006-2008) No longer in business

Board Member

IANC (Indian Association of Northern Colorado)- Board Member (2017- 2019)
Rocky Mountain Regional Chapter of SQA (Society of Quality Assurance)- Board Member (2018-2019)
Rocky Mountain Regional Chapter of SQA (Society of Quality Assurance)- President (2017-2018)
Rocky Mountain Regional Chapter of SQA (Society of Quality Assurance)- Vice President (2016-2017)
Rocky Mountain Regional Chapter of SQA (Society of Quality Assurance)- Board Member (2013-2015)
IANC (Indian Association of Northern Colorado) – General Secretary (2010)

Memberships

Society of Quality Assurance
Society of Toxicology
American Institute of Chemical Engineers
Wound Healing Society
Rocky Mountain Chapter Society of Quality Assurance (Member of Board of Colorado Chapter)
Sigma Xi
American Society of Mechanical Engineers
American Society of Clinical Pathology (H.T.)

Personal

Member of Rotary International (Fort Collins) *(2010 - 2016)*
Participated in Polio Revaccination Program (Bihar, India) *(2013 Rotary Exchange)*