

Igor Gonda, PhD
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- One of the longest working pharmaceutical inhalation scientists still active – started in 1975 when there was practically nobody else in universities interested and very few Rx products existed; many former students and colleagues now in leading positions in academia, industry and CROs
- In-depth experience with pharmaceutical inhalation product development at all stages including regulatory interactions with FDA and EMA
- Current and past history of consulting for government, industry and pharmaceutical compendia in US, Australia and the UK, particularly in pulmonary and nasal inhalation products
- Experienced senior executive (CEO, CSO) and Board member of private, public and not-for-profit life science organizations in USA and Australia
- Stewardship of pharmaceutical industrial teams developing products from preclinical through commercial stages in USA, EU and Australia
- Advocate of patient-focused development of therapies for severe diseases with unmet needs, facilitating global cooperation between patient advocacy groups, industry and regulators
- Formation and leadership of university and industrial research and development organizations in the United Kingdom, Australia and USA
- Author, Inventor, expert witness in patent litigations
- Teacher, mentor and coach
- Recipient of international awards for contributions to the development of knowledge on therapeutic and diagnostic aerosols and products for the benefit to patients

EMPLOYMENT HISTORY/BOARDS

2020-

Inspiring Pty Ltd (Australia)

Non-executive Board member

2020-

Scendea (UK)

Principal Consultant

2018-

Respidex LLC – Founder and CEO

Consulting for pharmaceutical and medical device companies

March 2013 – October 2019

Board Director, The Alpha-1 Project (fully owned subsidiary of the Alpha-1 Foundation)

Pro-bono advice for the venture philanthropy branch of this patient advocacy group

August 2006 – February 2018:

Chief Executive Officer and President of Aradigm Corporation, Board Member (2001-2018), Hayward, CA

Fundamentally transformed the mission and the business model that required to restructure and refinance the company, develop new products and new partnerships and provide vision and motivation for the employees. Established a culture of collaboration within and outside the company focused on the patients with severe rare respiratory diseases with unmet needs that included working closely with patient advocacy groups, key opinion leaders, regulatory authorities and contract research and manufacturing organizations. Provided leadership to obtain the means for the development and commercialization of a highly innovative treatment for severe respiratory infections through funding with new strategic investors, industrial partnership, government support (including funding of a substantial international biodefense program), sale of non-strategic assets and R&D tax rebates.

December 2001 – 2006:

Chief Executive Officer and Managing Director, Board Member, Acrux Limited, Melbourne, VIC, Australia

Lead the development and rapid growth of the company from its university base in 2001 to become listed on ASX as one of the leaders in the emerging Australian life science sector. Responsible for building shareholders' value through development and commercialization of multiple transdermal and dermal drug delivery human and veterinary healthcare products. Overall responsibility for directing the development, operations and quality assurance of the company and its wholly owned subsidiaries. Leadership in the key business development activities including partnering with other organizations. Securing company's financing prior to commercial product sales through private and public equity raisings (IPO in 2004), funding by partners and government grants. Public and investor relationship management. Development of the company's workforce by implementation of infrastructure that promoted alignment of personal growth with corporate goals and generation of socioeconomic value.

July 2000 – December 2001:

Chief Scientific Officer, Aradigm Corporation, Hayward, CA

Leadership of the New Product Research Department focused on preclinical and clinical exploration of new therapeutic and technological opportunities. Responsible for strategic science and technology development, R&D alliances, public relations with the scientific and clinical communities, intellectual property management in a leading public pulmonary drug delivery company. Key contact for comparative technology assessment of Aradigm's R&D for the investment community. Appointed to the Board of Directors, April 2001. Chairman of International Scientific Advisory Board of Aradigm Corporation until August 2006.

October 1995 – June 2000:

Vice President, Research and Development, Aradigm Corporation, Hayward, CA

Leading the R&D organization containing initially 12 people. In 5 years, R&D and engineering parts of the organization grew to ~100 people engaged in multidisciplinary research and development of products for major pharmaceutical markets such as diabetes and pain management. Provided challenging career development programs for the R&D employees. Key technical person for forming strategic business alliances with major pharmaceutical and biotechnology companies. Essential member of the executive team in successful mezzanine financing, the initial public offering and subsequent public

and private financing rounds. Principal Investigator on a National Institute of Health/National Cancer Institute Small Business Industrial Research Grant for gene therapy.

January – September 1995:

Senior Scientist and Group Leader, Pharmaceuticals, Pharmaceutical R&D, Genentech, Inc., South San Francisco, CA

Responsible for the development of non-parenteral delivery of protein, peptides and gene products. Supervised 15 scientists and technicians.

February 1992 – December 1994:

Senior Scientist and Group Leader, Aerosol Drug Delivery Group, Pharmaceutical R&D, Genentech, Inc., South San Francisco, CA

Prepared and executed the development plan for pulmonary delivery of the first human recombinant protein administered by inhalation (rhDNase, brand name Pulmozyme). The product went in record time (4.5 years) from cloning to FDA approval and is now used globally as a major part of therapy of cystic fibrosis. Founded and led a multidisciplinary group (protein and peptide formulation and analysis, aerosol physics and engineering, pulmonary disease and absorption models, lung delivery of viral gene vectors) that provided key techniques and findings for one of the most rapidly growing branches of the biotech industry. Involved in partnering between Genentech and other companies. Facilitated development of people who now play leading roles in industrial and academic R&D.

September 1983 – January 1992:

Senior Lecturer/Lecturer, Department of Pharmacy, University of Sydney

January – July 1990:

Visiting Associate Professor, School of Public Health, Johns Hopkins University, Baltimore, MD

July – December 1989:

Visiting Scientist, Advanced Drug Delivery Research, Ciba-Geigy, Horsham, England

1982 – 1983:

Research Scholar, School of Mathematics, Physics and Chemistry, Macquarie University, Sydney, Australia

Summer 1978:

Senior Visiting Research Fellow, Department of Chemistry, Clarkson College of Technology, Potsdam, NY

October 1975 – August 1982:

Lecturer, Department Pharmacy, University of Aston in Birmingham, UK

October 1974 – September 1975:

Project Chemist, Nicholas Research Laboratories, Slough, UK

Degrees

BSc (Chemistry) and PhD (Physical Chemistry), University of Leeds, England

KEY PROFESSIONAL EXPERIENCE AND ACHIEVEMENTS

Invited speaker and session chairperson at many national and international scientific, business development and investor conferences, member of editorial boards of several journals in the areas of pharmaceutical sciences and drug delivery.

1978	External Examiner in Pharmaceutics, University of Dar-es-Salaam, Tanzania
1979 -1981	Course Tutor (Chemistry), Open University, UK
1982 -1988	Member of the 'Ad Hoc' Committee on Standards for Aerosol Inhalations, British Pharmacopoeia Commission
1986 & 1987	Visiting Research Professor, Department of Pharmaceutics, Hoshi University, Tokyo, Japan
1986 - 1992	External Evaluator for the Drug Marketing Approval Submissions to NBSL, Canberra
1986 & 1987	Examiner for PhD students, University of Queensland, St. Lucia
1989 - 91	Member of the Working Party on Metered Dose Aerosols, Australian Drug Evaluation Committee
1990/91	Co-organizer of the Satellite Symposium, "Aerosols for 1990's -Putting Respiratory Therapy in the Right Place", organized by the Thoracic Society of Australia and New Zealand and the Australian Society of Respiratory Technology, April 1990, Lorne, Victoria
1990 - 91	Member of the Working Party on the Therapeutic Goods Order for Metered Dose Pressurized Inhalations, Therapeutics Goods Administration, Canberra, Australia
1990- 92	Convenor of an international symposium on "Advances in Delivery of Therapeutic and Diagnostic Agents" sponsored by the Australian Pharmaceutical Sciences Association, Controlled Release Society, the Australasian Society for Clinical and Experimental Pharmacology and the Royal Australian Chemical, Institute - Polymer Division
1991-92	President, the Australasian Pharmaceutical Science Association
1991-95	Member of the International Board, International Society for Aerosols in Medicine

1991-92	Representative on the International Membership Committee, The Controlled Release Society
1997	Co-organizer with M. Newhouse and A.R. Clark of ISAM Focus Symposium "Towards meaningful laboratory tests for evaluation of pharmaceutical aerosols", San Juan, Puerto Rico
2001-2	Founding Member of the Board of Directors, International Pharmaceutical Aerosols Consortium – Regulatory Science
2001	Astra-Zeneca Industrial Achievement Award
2004	The Thomas T. Mercer Joint Prize of the International Society for Aerosols in Medicine and the American Association for Aerosol Research, for Excellence in Pharmaceutical Aerosols and Inhalable Materials
2004 - 2006	Member of the Australian Stock Exchange/Ausbiotech working group for the development of the Code of Best Practice of Reporting by Life Science Companies
2013	Member of the External Advisory Panel, California Institute of Regenerative Medicine, San Francisco, CA, USA
2018 –	California Life Sciences Institute Advisor

PATENTS and PUBLICATIONS

More than 120 issued patents and patent applications in USA, plus a large number of issued and pending patents in other countries.

Author of well over 100 research articles, invited reviews and book chapters in the areas of treatment of respiratory diseases, pulmonary drug delivery and other aspects of clinical and pharmaceutical sciences.

Selection of publications:

I.Gonda "A Semi-Empirical Model of Aerosol Deposition in the Human Respiratory Tract for Mouth Inhalation", J.Pharm. Pharmacol., 1981 33 692-696.

I. Gonda, J.B. Kayes, C.V. Groom and F.J.T. Fildes "Characterisation of Hygroscopic Inhalation Aerosols", Particle Size Analysis 1981 (conference organised by the Royal Society of Chemistry), September 1981, N. Stanley-Wood and T. Allen, Eds., Heyden, London, 1982, pp. 31-43.

I. Gonda and A.F.K. El Khalik "On the Calculation of Aerodynamic Diameters of Fibres", Aerosol Sci. Tech., 1985 4 233-238.

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