Achim Orzechowski www.PKxpert.com



PRESENTATION

R&D Scientist & Manager with over 20 years of industry experience in drug discovery & development. Holder of senior management positions in AstraZeneca R&D leading the Drug Metabolism & Pharmacokinetics department in Södertälje for more than 6 years. Management of a portfolio of drug discovery & development programs in the CNS and Pain area in AstraZeneca, with a documented track record of delivery and significant experience collaborating both across national and cultural barriers. In depth experience in evaluating drug discovery & development programs for in-licensing including performing due-diligence.

Strong track record in strategic R&D management, portfolio evaluation and licensing of programs in stages from early discovery to Phase 2 clinical trials.

Specialist in Drug Metabolism and Pharmacokinetics. Degree in Chemistry and a PhD in Toxicology from the University of Tübingen in Germany, published more than 20 peer-reviewed articles.

PROFESSIONAL EXPERIENCE LIFE SCIENCE

CSO, Business Development and Senior Consultant, PKxpert AB (since 2014-present)

Core ADME expertise: Design, monitoring and evaluation of preclinical & clinical ADME studies such as Mass Balance, Distribution, WBA, Biotransformation (MIST), in vitro drug metabolism, CYP studies, Drug-Drug interaction studies. Develop screening strategies to optimize lead compounds with respect to their DMPK properties. Development of integrated Pre-Clinical Development Plans to provide all necessary documentation for IMPD /IND or NDA applications. Drug metabolism and pharmacokinetics (DMPK) regulatory documentation in preclinical & clinical phases.

CEO of Adduct Analys AB (part-time) (2015 - 2017)

Adduct Analys AB was founded in 2004 to commercialize technology developed at the Department of Environmental Chemistry at Stockholm University, Sweden. The company's main focus is to commercialize its unique and propriatary product series called TailorDose®. TailorDose® is a product line that meets the need for personalized cancer medicine relating to drugs that are difficult to dose.

CEO of Northern Light Pharmaceuticals AB (2012-2015)

Northern Light Pharmaceuticals AB (NLP) was a Swedish pharmaceutical research & development company founded in 2012.

Director External Collaborations, Astra Zeneca (2010-2012)

Program Director, responsible for leading the collaboration between AZ and Jubilant Biosys Ltd, India. This collaboration included four research programs in Pain, Neuroscience and Diabetes/obesity which were pursued jointly on a risk shared basis.

Overall accountability for all operational aspects of the collaboration including research plans, budget, timelines, quality of deliveries and compliance with AZ policies; Lead and manage AZ - Jubilant portfolio team including performance management of team members. Coaching of team members in their role and communication with their counterparts; Represent the collaboration towards AZ senior management for strategic decision making

Portfolio enhancement: Identification and scientific evaluation of in-licensing and academic collaboration opportunities within Neuroscience and Pain including deep fact finding and Due Diligence

Major achievements: Establishment of one of AZ largest drug discovery collaborations and successful delivery on project targets

Director Lead Generation, Astra Zeneca (2006-2010)

Responsible for the generation of new Drug Discovery projects in AZ Södertälje.

Responsible for the delivery of the Lead Generation portfolio to Lead Optimization

Accountable for resource allocation and prioritization of the Lead generation portfolio

Scientific review of Drug Discovery projects

Chairman of the Lead generation team

Member of the local Discovery management team

Director of Research DMPK department, Astra Zeneca (2000-2006)

Leading a department of 30+ staff

Provide scientific leadership in the field of Drug Metabolism, Pharmacokinetics and Bio analysis.

Develop and implement strategies to continuously improve the DMPK support to drug discovery projects.

Represent the department in both scientific and line management teams.

Chairman of the global AstraZeneca Drug Metabolism & Transporter Strategy group defining the overall strategy for new science & technology development in this area.

Responsibility for staff, budget, equipment, outsourcing, quality control.

Associate Director, Head of 'In vitro metabolism' group, 1997–1999 Astra Pain Control, Sweden

Senior Research Scientist, Drug metabolism, 1996–1997 Astra Pain Control, Sweden

Research Scientist, Drug metabolism, 1995-1996 Astra Pain Control, Sweden

Post doctoral fellow, 1994–1995 University Rene Descartes INSERM U 75, Paris,

Research fellow, 1990–1994 University of Tübingen

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ACADEMIC DEGREES

Post-doc studies: University Rene Descartes, Paris, 1994-1995 INSERM U75, Prof. P. Beaune

Ph.D. in Toxicology: University of Tübingen 1993, Supervisor Prof. K.W. Bock **Ph.D. student University of Tübingen,** Institute of Toxicology, 1990 – 1993

Diplom in Chemistry, University of Tübingen, 1990

SELECTED LIFE SCIENCES & LEADERSHIP COURSES

DMDG & Swedish Academy of Pharmaceutical Sciences Joint Meeting 16th-18th October 2018

DMDG - Peptide ADME Discussion Group - 1st Workshop 15th October 2018DMDG 4th Biologics Symposium: Development of Peptide and Oligonucleotide Drugs:

DMPK and Regulatory Perspectives. Mar 1-2, 2017, DK

Introduction to Phoenix WinNonlin, Amsterdam, June 2015

PK/PD advances course, M. Roland/T. Tozer, October 2002

Phamacokinetics & Biopharmaceutics, Swedish Academy of Pharmaceutical Sciences , April 1997

Descriptive statistics, Astra AB, Sept. 1997

Regulatory Toxicology, Gesundheitsbehörde, Hamburg, March 1997

Immunotoxicology, University of Berlin, June 1994

Clinical Toxicology , Medical School Hannover, October 1993

Pathology and Organtoxicology, University of Erfurt, July 1991

GLP

Workshop on the Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site

Studies, PKxpert AB, 4th August 2018

Principles on GLP & Compliance Monitoring Advisory Doc No. 17 and GLP to Computerised Systems, Mar 2017, PKxpert AB, Broeders

ROA EL0030: Advanced Good Laboratory Practice (GLP), Feb 2016, PKxpert AB, Broeders

GLP Refreshment Course, 15 Nov 2014, PKxpert AB, Broeders

GLP International Procedures OA, 11 Sept 2002, AstraZeneca

GLP International Procedures, 19 Dec 2000, AstraZeneca

Introduction and Update to GLP. 5-6 March 1996, AstraZeneca

Datoriserade system, 22 Nov 2002, AstraZeneca

Leadership education:

Player/Learner workshop, AstraZeneca, October 2011 Coaching: A Master Class, AstraZeneca, Sept. 2010 Quality Assurance update, AstraZeneca, January 2005 AstraZeneca Leadership course, AstraZeneca, October 2001

Future Leadership, Astra AB, June 1998

OTHER MERITS

Chairman, Section for Pharmacokinetics and Drug Metabolism, Swedish Pharmaceutical Society (2006-2011)

Lecturer in Pharmacokinetics & Drug Development at the University of Gothenburg, Sweden

Supervisor of graduate students performing research projects at AstraZeneca

Lecturer in Drug Metabolism in courses organized by the Swedish Pharmaceutical Society

PEER-REVIEWED PUBLICATIONS & AWARDS

Post doctoral fellowship by the European Science Foundation, Strasbourg, 1994-1995

Selected publications (20 publications in peer reviewed scientific journals):

Orzechowski, D. Schrenk and K.W. Bock, Metabolism of 1- and 2-Naphthylamine in isolated rat hepatocytes, Carcinogenesis 13, 2227-2232 (1992).

D. Schrenk, T.W. Gant, A. Michalke, A. Orzechowski, J.A. Silvermann, N. Battula and S.S. Thorgeirsson, Metabolic activation of 2-aminofluorene is required for induction of multidrug resistance gene expression in rat liver cells. Carcinogenesis 15, 2541-2546 (1994).

A. Orzechowski, L.R. Schwarz, U. Schwegler, K.W. Bock, R. Snyder and D. Schrenk, Benzene metabolism in rodent hepatocytes: role of sulphate conjugation. Xenobiotica 25, 1093-1102 (1995).

E. Krondahl, A. Orzechowski, G. Ekström and H. Lennernäs, Rat jejunal permeability and metabolism of selective tetrapeptides in gastrointestinal fluids from humans and rats, Pharm Res. 14, 1780-1785, (1997).

A.K. Sohlenuis- Sternbeck, E. Floby, M. Svertling and A. Orzechowski, High conservation of both phase I and phase II drug metabolising enzymes in cryopreserved rat liver slices. Xenobiotica 30, 891-903, 2000.

K.W. Bock, B. Bock-Henning, P. Münzel, J. Brandenburg, C. Köhle, M Soars, R Riley, B Burchell, O von Richter, M Eichelbaum, S. Swedmark and A. Orzechowski. Tissue specific regulation of canine intestinal and hepatic phenol and morphine UDP-glycuronosyltransferase by β-naphtoflavone in comparison with humans. Biochemical Pharmacology 63, 1683-1690, 2002

Sohlenius-Sternbeck and Orzechowski, Characterization of the rates of testosterone metabolism to various products and of glutathione transferase and sulfotransferase activities in rat intestine and comparison to the corresponding hepatic and renal drug-metabolizing enzymes, Chemico-Biological Interactions 148, 49-56, 2004

LANGUAGE SKILLS

German: mother language

English: fluently
Swedish: fluently
French: good

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