Curriculum Vitae

Dr. med. Klaus Rose (MD, MS)

Current Address

klausrose Consulting
Pediatric Drug Development & More
Aeussere Baselstrasse 308
4125 Riehen
Switzerland
Phone +41 61 312 05 10
Mobile +41 79 102 35 63 / +49 176 9966 9809
klaus.rose@klausrose.net

Personal Data

Born 2nd November 1953 in Heidelberg, Germany
Nationality: German
Married, two daughters

Current Position

Founder and Managing Director, klausrose Consulting, Pediatric Drug Development & more, Riehen, Switzerland

Education and Qualifications

2004	Master's Certificate in Project Management, The George Washington University School of Business, Washington D.C., USA
2000	Equivalence Certificate to Swiss Postgraduate Degree (FMH) in Pharmaceutical Medicine
1999	Diploma European Course Pharmaceutical Medicine (ECPM)
1992	German Postgraduate Degree in General Medicine
1986 – 1991	Postgraduate clinical training in General Medicine in Germany and England (pediatrics, psychosomatic medicine, internal medicine, surgery, geriatrics)
1979 – 1986	Study of Medicine in Berlin, Thesis in Medicine
1972 – 1978	Study of Latin Languages & Psychology in Heidelberg and Berlin, MS in Psychology

Employment History

March 2011 – today	Managing Director, klausrose Consulting, Riehen, Switzerland
2010 - March 2011	Principal Consultant at Granzer Regulatory Consulting, Munich, Germany

2005 – 2009	Global Head Pediatrics, F.Hoffmann-La Roche Pharmaceuticals, Basel, Switzerland
1997 – 2005	Novartis Pharmaceuticals, Switzerland 2001 – 2005 Global Head Pediatrics 2000 – 2001 Head, Special Projects, Clin Dev & Medical Affairs 1999 – 2000 Senior International Medical Advisor, Basel (HQ) 1997 – 1999 Medical Advisor in Bern (Swiss affiliate)
1996	Medical Director Lohman Medical, Neuwied, Germany
1991 – 1996	Clinical Research Associate, Byk Gulden Pharmaceuticals, Germany (today: Takeda); in parallel: Medical Director, Byk AG, Switzerland
1986 – 1991	Postgraduate clinical training in General Medicine in Germany and England (pediatrics, psychosomatic medicine, internal medicine, surgery, medicine for the elderly)

Other Professional Activities:

Regular speaker on international confererences on pediatric drug development; member of DIA and EAP, facultuy member of several institutions that train in drug development and clinical research (ECPM, FORUM, others)

International Leadership

05/2014 - 2017	Co-Chairman Organizing Committee, Basel International Conference on Drug Development in Pediatric & Rare Diseases
1/2005 to 12/2014	Chairman, EFGCP Children's Medicines Working Party
2006 – 2009	Chairman, DIA Pediatric SIAC
8/2008 – 10/2009	Chairman, IFPMA (www.ifpma.org) Pediatric Task Force

Professional Experience

After clinical training started in Byk Gulden, Konstanz, Germany (today: Takeda) as a clinical trial physician. Run two phase 1 trials and several large international pantoprazole phase 3 trials in Europe and Latin America. Worked in parallel at Byk Gulden Switzerland as Medical Director. Trained the sales representatives in gastroeneterology (pantoprazole), pneumology (theophyllin), cardiovascular diseases (omega-3-oil capsules), and other areas.

Worked ½ year in Lohman Medical Devices in Germany, buildung up the fundaments of a medical affairs team.

Worked in Novartis Switzerland as clinical trial physician in the areas of oncology, dermatology, pneumology, gastroenterology and central nervous system.

Was promoted to Novartis International Headquarter as Senior International Medical Advisor. Built up the international Medical Communication function and established the cross-functional Pediatric Advisory Group (PAG) in 2000 to improve the company's handling US pediatric legislation, specifically 6 months Pediatric Exclusivity (patent prolongation). Advised teams in building pediatric development plans across all development functions (preclinical toxicology & safety; galenic formulations; modelling & simulation (M&S) / Clinical Pharmacology; Clinical Development; Post-Marketing Commitments) and across all indication areas. Networked with

the top 20 pharmaceutical companies for cooperation in pediatric drug development, resulting in annual pediatric conferences between academia, regulatory authorities, and industry.

Moved to Roche in 2005, established there a cross-functional pediatric drug development structure. Worked with teams across all development functions and indication areas. Advised teams on EMA / PDCO (pediatric committee) pediatric investigation plans (PIPs) when the EU pediatric regulation came into force in 2007. Established and co-chaired the pediatric taskforce of the IFPMA (International Federation of Pharmaceutical Industries).

With the move to Granzer Regulatory Consulting in 2010 responsible for hands-on preparation, writing, submission & negotiation of PIPs with the EMA / PDCO. Sucessfully concluded 8 PIPs from early preparation to final acceptance by EMA.

With establishing an own company, advised US & EU based companies on strategies in handling FDA & EU regulatory pediatric requirements and continued to prepare, write, submit and negotiate PIPs (EMA) and pediatric plans (FDA). Established in 2015 the Basel annual international conference on drug development in pediatric and rare diseasese. The 3rd one will take place in February 2017

International networking in pediatric drug development: regular presentations on international conferences, publications in international scientific journals, and co-editing books on pediatric drug development.

Leadership Skills

Most responsabilities were performed in a matrix structure coordinating up to 25 people in general issues of pediatric drug development both in Novartis and Roche. Pediatrics was usually 10 – 20% of coordinated persons' KPI's which had to be evaluated annually. Maximum number of direct reports was five.

Publications

- Rose K. The Challenges of Pediatric Drug Development. Curr Ther Res Clin Exp. 2019, https://doi.org/10.1016/j.curtheres.2019.01.007
- Rose K, Neubauer D, Grant-Kels JM. Questionable Industry-Sponsored Studies in children and adolescents in Slovenia. Curr Ther Res Clin Exp. 2019, https://doi.org/10.1016/j.curtheres.2019.01.002
- Rose K, Walson PD. Are Regulatory Age Limits in Pediatric Melanoma Justified? Curr Ther Res Clin Exp. 2019, https://doi.org/10.1016/j.curtheres.2019.01.003
- Rose K, Grant-Kels JM. Pediatric Melanoma – The Whole (Conflicts Of Interest) Story. Int J Womens Dermatol 2018, https://doi.org/10.1016/j.ijwd.2018.10.020
- Rose K, Grant-Kels JM. The Meanings of "Pediatric Drug Development". A Review. Therapeutic Innovation and Regulatory Science 2018, https://journals.sagepub.com/doi/pdf/10.1177/2168479018812060
- Rose K, Grant-Kels JM. FDA/EMA-triggered paediatric studies: Do they really advance child health? Regulatory Rapporteur (TOPRA) Vol 15, No 9, September 2018

- Rose K. Kinder brauchen nur sinnvolle Studien (Children need only reasonable clinical studies). pädiatrische praxis 2018;90(4):705-716
- Rose K, Grant-Kels JM. Questionable International Pediatric Studies in the United States and Russia Triggered by Regulatory Authorities. Asian Journal of Research in Medical and Pharmaceutical Sciences 2018,3(3). http://www.journalrepository.org/media/journals/AJRIMPS_63/2018/Apr/Rose332018AJRIMPS40776.pdf
- Rose K, Grant-Kels JM. Questionable Industry-Sponsored Pediatric Studies in China Triggered by United States of America (US) and European Union (EU) Regulatory Authorities. SF Pharma J 2018,1:1. https://www.scifedpublishers.com/open-access/questionable-industry-sponsored-pediatric-studies-in-china-triggeredby-united-states-of-america-us-and-european-union-eu-regulatoryauthorities.pdf
- Rose K, Grant-Kels JM. Pediatric Melanoma and Drug Development. Children (Basel). 2018 Mar 20;5(3). http://www.mdpi.com/2227-9067/5/3/43
- Rose K, Grant-Kels JM. Questionable International Pediatric Studies With Swiss Participation. Swiss Med Wkly 2018, https://smw.ch/fileadmin/content/blog/PDF/Questionable_pediatric_studies_with_Swiss_participation.pdf
- Rose K, Grant-Kels JM. Most adolescents' melanomas are conventional malignant adult-type melanomas. Eur J Cancer. 2018 May;95:117-119.
- Rose K, Benisheva-Dimitrova T. EU paediatric investigation plans (PIPs) might harm children. Acta Med Bulg 2018, 45(1): 5-10. https://www.degruyter.com/downloadpdf/j/amb.2018.45.issue-1/amb-2018-0001/amb-2018-0001.pdf
- Tsilochristou O et al.: Current state and future of Paediatric Allergology in Europe: A road map. Pediatr Allergy Immunol. 2017 Nov 23
- Rose K, Walson PD. Do Pediatric Investigation Plans (PIPs) Advance Pediatric Healthcare? Pediatr Drugs 2017, 19(6), 515-522
- Rose K. Moderne Medikamente und ihre Entwicklung für Kinder - Leicht gesagt, schwierig umzusetzen: Die von der Europäischen Zulassungsbehörde geforderten Kinderentwicklungspläne für Allergenprodukte für die Spezifische Immuntherapie. Pädiatrische Allergologie 1/2017, 16-30
- Rose K, Happle R: The Impact of Regulation on Pediatric Psoriasis Drug Approvals: The Challenge of the European Union (EU) Pediatric Investigation Plans. Pediatr Dermatol. 2017 May;34(3):e154-e159.
- Rose K & Walson PD: Do the European Medicines Agency (EMA) Decisions Hurt Pediatric Melanoma Patients? Clinical Therapeutics 2017, 39(2), 253-265 https://www.clinicaltherapeutics.com/article/S0149-2918(17)30047-4/pdf
- Rose K: New Drugs For Rare Diseases in Children. Clinical Therapeutics 2017, 39(2), 246-252 https://www.clinicaltherapeutics.com/article/S0149-2918(17)30050-4/pdf
- Rose K: Gut gemeinte Regeln führen zu sinnlosen Studien - Abbruch zweier fragwürdiger pädiatrischer Melanomstudien. Ars Medici 22, 2016, 1014

www.rosenfluh.ch/media/arsmedici/2016/22/Gut-gemeinte-Regeln-fuehren-zu-sinnlosen-Studien.pdf

- Rose K: Fragwürdige Studien gefährden Patienten - Neue EU-Zulassungsvorschriften führen zu Diskussionen in der Schweiz. Pädiatrie 6/2016, 29-31 www.rosenfluh.ch/media/paediatrie/2016/06/Fragwuerdige-Studien-gefaehrden-Patienten.pdf
- Rose K: Medikamente und ihre Entwicklung für Kinder. Schweizerische Ärztezeitung 2016;97(46):1620–1622 www.saez.ch/docs/saez/2016/46/de/SAEZ-04880.pdf
- Rose K & Mueller T: Children with Multiple Sclerosis Should Not Become Therapeutic Hostages. *Ther Adv Neurol Disord* 2016, Vol. 9(5) 389–395 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4994785/pdf/10.1177_1756285616656592.pdf
- Rose K: Pediatric Strategies. In: Siegenthaler M & Sietsema W (Editors): Global Pharmaceutical and Biologics Regulatory Strategy. 2016, Regulatory Affairs Professionals Society, Rockville, MD, USA, pp. 83-95
- Rose K & Kopp MV: Pediatric investigation plans for specific immunotherapy: Questionable contributions to childhood health. Pediatr Allergy Immunol. 2015 Dec;26(8):695-701
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- Rose K & Spigarelli MG: Cystic Fibrosis Treatment: A Paradigm for New Pediatric Medicines, Globalization of Drug Development and the Role of the European Medicines Agency. *Children* 2015, *2*, 108-130; https://www.mdpi.com/2227-9067/2/1/108
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- Rose K: European Union Pediatric Legislation Jeopardizes Worldwide, Timely Future Advances in the Care of Children With Cancer. Clinical Therapeutics 2014, 36 (2), 163-177 http://www.clinicaltherapeutics.com/article/S0149-2918(14)00018-6/pdf
- Bar-Shalom D & Rose K: Pediatric Formulations – A Roadmap (Textbook). AAPS & Springer, 2014. ISBN: 978-1-4899-8010-6
- Bar-Shalom D & Rose K: Pediatric Formulations – A Roadmap (Textbook), introduction: free download @: http://www.springer.com/us/book/9781489980106#reviews
- Rose K: Clinical Testing in Children. In: Bar-Shalom D & Rose K: Pediatric Formulations – A Roadmap, AAPS & Springer, 2014: chapter 25, pp. 365 - 376

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- Rose K: Grosse Anstrengungen für die Kleinen. VSAO Journal 6 / 2009, 24-25 http://www2.vsao.ch/fileupload/2009112693351_pdf.pdf
- Rose K: Challenges in Pediatric Drug Development. A Pharmaceutical Industry Perspective. Pediatr Drugs 2009; 11 (1): 57-59
- Rose K: Ethical Principles of Pediatric Research and Drug Development. Chapter 11 in: Pediatric Drug Development – Concepts and Applications. Mulberg AE, Silber SA & van den Anker, JN (Editors), Wiley-Blackwell, 2009
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- Rose K: Ethical, Regulatory and Scientific Challenges in Paediatric Drug Development. Pharm Med 2008; 22 (4): 221-234
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- Rose K: European Draft Pediatric Regulation and Challenges in Pediatric Drug Development: Jap J Clin Pharmacol & Ther 2005;18 (1) 9-14

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- Rose K: Better medicines for children – where are we now, and where do we want to be? Br J Clin Pharmacol. 2005; 59(6): 657-659.

Languages

Fluent in German, English, Spanish, Italian, French. Basics of Portuguese, Hungarian, modern Greek.

Private interests

Family, Classical Guitar, Latin Culture, Hungarian Language, Cooking, Gardening, Wine

Riehen, February 2019