CURRICULUM VITAE Klaus Rose, MD, MS

Current Address

klausrose Consulting
Pediatric Drug Development & More
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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; faculty 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 Special Interest Area Committee (SIAC)
8/2008 – 10/2009	Chairman, IFPMA (www.ifpma.org) Pediatric Task Force

Professional Experience in klausrose Consulting

I advise US and EU-based companies in FDA & EMA regulatory pediatric requirements. Prepared, submitted and negotiated pediatric investigation plans (PIPs) and initial pediatric study plans (iPSPs) in collaboration with clinical and regulatory teams and external clinicians. Co-organized many international conferences. Many papers in peer-reviewed journals. Co-edited three textbooks on pediatric drug development. Authored a first critical medical textbook on pediatric drug development, just released by Elsevier. Finalized a book that informs parents about clinical studies (Hammersmith, London, UK).

Professional experience

After clinical training started as clinical trial physician in Byk Gulden, Konstanz, Germany (today Takeda). In parallel Medical Director, Byk Gulden Switzerland. Trained the sales representatives in gastroenterology, pneumology, cardiovascular diseases, and other areas.

Half year medical director, Lohman Medical, Germany

Worked from 1997 on as clinical trials physician in Novartis Switzerland (Bern) in oncology, dermatology, pneumology, gastroenterology and central nervous system. Moved in 1999 to Basel (international headquarter). Established international medical communication and a cross-functional pediatric advisory group. Advised teams in pediatric development across all functions (preclinical toxicology & safety; galenic formulations; modelling & simulation / clinical pharmacology; clinical development; post-marketing commitments) and across all indication areas. Networked with the top 20 pharmaceutical companies in pediatric drug development.

Moved to Roche in 2005, established a cross-functional pediatric drug development structure. Advised teams on EU pediatric investigation plans (PIPs) since 2007. Established and co-chaired the pediatric taskforce of the IFPMA (International Federation of Pharmaceutical Industries).

Moved to Granzer Regulatory Consulting in 2010. Wrote & negotiated many PIPs with the EMA.

Leadership Skills

Most responsabilities were in matrix structures, coordinating up to 25 people in pediatric drug development both in Novartis and Roche. Pediatrics was usually 10 – 20% of coordinated persons' key performance indicators (KPIs), evaluated annually. Up to five direct reports.

Publications

- Rose K. Blind Trust - How parents with a sick child can escape the labyrinth of lies, hypocrisy and false promises. Hammersmith Books, London, UK, 2021. https://www.chapters.indigo.ca/en-ca/books/blind-trust/9781781612026-item.html and https://www.amazon.com/-/de/dp/1781612021/ref=sr_1_2?dchild=1&qid=1620137631&refinements=p_27%3AKlaus+Rose&s=books&sr=1-2
- Rose K, Grant-Kels JM, Ettienne E, Tanjinatus E, Striano P, Neubauer D. COVID-19 and Treatment and Immunization of Children – The Time to Redefine Pediatric Age Groups is Here. Rambam Maimonides Med J. 2021. Online first, https://www.rmmj.org.il/issues/online-issue/articles-online/1209
- Rose K, Grant-Kels JM, Ettienne E, Tanjinatus E, Striano P, Neubauer D. Comment on: A review of the experience with pediatric written requests issued for oncology drug products. Young patients with malignancies need reasonable studies with therapeutic intention. Pediatric Blood & Cancer 2021. Online ahead of print. https://doi.org/10.22541/au.161280832.22407928/v1

- Rose K, Tanjinatus O, Ettienne E. The term "Juvenile Idiopathic Arthritis (JIA)" is misleading. It will not be sufficient to just replace this term. Editorial. Pharmaceut Med. 2021 Jan 16 https://rdcu.be/cdH1x
- Rose K, Tanjinatus O, Grant-Kels JM, et al. Minors and a dawning paradigm shift in "pediatric" drug development. J Clin Pharmacol 2020, Dec 23. Online ahead of print
- Rose K. Pediatric Oncology At The Crossroads: A Call for Change. Editorial. Pharmaceut Med 2020 Oct 7. https://rdcu.be/b8drm
- Rose K. Considering the Patient in Pediatric Drug Development. How good intentions turned into harm. Elsevier, London, 2020. https://www.elsevier.com/books/considering-the-patient-in-pediatric-drug-development/rose/978-0-12-823888-2 and https://www.sciencedirect.com/book/9780128238882/considering-the-patient-in-pediatric-drug-development
- Rose K, Neubauer D, Fumi L, Grant-Kels JM. Comment on: Mumme M et al. Tissue engineering for paediatric patients. Swiss Medical Weekly 2020. https://smw.ch/article/doi/smw.2020.20239
- Rose K, Neubauer D, Grant-Kels JM. Ethical Issues in Pediatric Regulatory Studies Involving Placebo Treatment. J Pediatr Epilepsy 2020; 9(03): 073-079 https://www.researchgate.net/publication/342200539
- Rose K. Pediatric Strategies. In: Global Pharmaceutical and Biologics Regulatory Strategy. Sietsema WK, Meachem MM (Editors). Second Edition. Regulatory Affairs Professional Society, Rockville, MD, USA, 2020, chapter 11, p. 117-132
- Rose K. Warum erhalten junge Menschen später Zugang zu wirksamen Medikamenten? Monitor Versorgungsforschung 2020. https://www.monitor-versorgungsforschung.de/archiv/ausgaben-2020/mvf-02-20/view
- Rose K, Neubauer D, Grant-Kels JM. Too Many Avoidable Suicides Occur Worldwide In Young Patients. A Review. Rambam Maimonides Med J. 2019, Sep 18. https://www.rmmj.org.il/userimages/965/1/PublishFiles/977OnlineFirst.pdf
- Rose K, Fumi L, Grant-Kels JM. Reader Response: Clinical trials of disease-modifying agents in pediatric MS: Opportunities, challenges, and recommendations from the IPMSSG. Neurology 31MAY2019, https://n.neurology.org/content/reader-response-clinical-trials-disease-modifying-agents-pediatric-ms-opportunities
- Rose K, Neubauer D, Grant-Kels JM. Rational Use of Medicine in Children – The Conflict of Interests Story. A Review. Rambam Maimonides Med J. 2019 Jul 18; 10(3): e0018. Review. doi:10.5041/RMMJ.10371. https://www.rmmj.org.il/userimages/928/2/PublishFiles/953Article.pdf
- 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,Nov 19;5(2):110-115. doi: 10.1016/j.ijwd.2018.10.020 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6451736/pdf/main.pdf
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- Rose K. Kinder brauchen nur sinnvolle Studien (Children need only reasonable clinical studies). pädiatrische praxis 2018;90(4):705-716
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- 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.
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- Rose K, Walson PD. Do Pediatric Investigation Plans (PIPs) Advance Pediatric Healthcare? Pediatr Drugs 2017, 19(6), 515-522
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- 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
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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, Switzerland, May 2021