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PEDIATRIC DRUG DEVELOPMENT MASTERCLASS

EU EVENT

ONLINE MASTERCLASS | 17-19 FEBRUARY, 2026

AT GLANCE

EVENT INTRODUCTION

Pediatric Drug Development (PDD) is a controversial matter. Its basic ideas emerged when in the 1950s babies were treated with antibiotics and toxicities were observed. Now the new discipline of developmental pharmacology wanted more pediatric drug studies, emphasizing that children are not small adults. Since 1997 US law rewards pediatric drug studies with patent extension; since 2007 the EU demands pediatric investigation plans (PIPs). Without an approved PIP, EU approval is blocked. However, the children-are-therapeutic-orphans and children-are-not-small-adults mantras are partially correct in babies, but not until the 18th birthday. Companies benefit from US patent extensions. The EU demands studies early in drug development, the reward might come a decade later. Minors are not another species. They need assessment of doses and safety, not repeated proof of efficacy. It is an open secret in industry that many regulatory pediatric studies are questionable. Dr. Rose's papers and textbooks offer a systematic analysis across all clinical areas. In negotiating with the FDA and the European Medicines Agency (EMA), companies can and should argue against exaggerated demands and the claim that these studies benefit child health. The authorities know that scientifically their demands are on shaky grounds. Companies should not be confrontational from the start. But: speak softly and carry a big stick. FDA & EMA will try to avoid controversial public discussions. Negotiating FDA initial study plans (iPSPs) and EMA PIPs has become a routine where regulatory "pediatric" assumptions are accepted. But companies should become more bold in pushing back. Participants will learn which trials in minors make sense, which ones are pointless, and which ones are even harmful. Good negotiations can save millions of US $ and can avoid potential US damage lawsuits.

WHO SHOULD ATTEND?

From life science industry:

- Regulatory affairs
- Clinical development
- Project management
- Communication
- Preclinical development
- Formulation development
- CMC
- Clinical pharmacology
- Safety
- Medical affairs

From academia:

- Students and postgraduates of medicine, pharmacology, life sciences and public health

METHODOLOGY

- Introduction into the historical background of pediatric drug development
- Overview FDA and EMA pediatric decisions
- Overview how the FDA is gradually relenting in its pediatric demands
- Literature research on the internet
- Internet research for FDA and EMA pediatric decisions
- Interactive discussion with participants

REGISTER NOW!

YOU WILL LEARN ABOUT

- Minors need dose assessement, not repeated proof of efficacy
- Pediatric legislation blurs different meanings of the term "child"
- Companies waste time and money with questionable "pediatric" studies and might even face damage lawsuits
- Pediatric drug treatment emerged "off-label" long before the term "off-label" existed.
- Behind the children-are-therapeutic-orphans concept there are hidden conflicts of interest
- Most pediatric drug studies advance pediatric careers, not child health
- Minors need only reasonable studies
- Better negotiating PIPs can save millions
- The FDA is gradually relenting

MEET THE TRAINER

Dr. Klaus Rose

CEO

KLAUSROSE CONSULTING

25+ YEARS OF EXPERIENCE

Dr. Rose studied medicine, psychology, and Latin languages. In 1997, he joined pharmaceutical industry. He was intrigued by the idea of drug development for children, also because his older daughter had the (very rare) Sturge-Weber syndrome. He was Global Head Pediatrics Novartis 2001-2005, same position in Genentech/Roche 2005-2009 (both's HQ in Switzerland), independent since 2011. He speaks at international conferences, publishes in peer-reviewed journals, and has authored medical textbooks, including: "Considering the Patient in Pediatric Drug Development," Elsevier, London, 2020; "Blind Trust," Hammersmith, London, 2022; "Abuse of Minors in Clinical Studies," Ethics International Press, Bradford, UK, 2023; and "The COVID-19 Pandemic: A Global High-Tech Challenge at the Interface of Science, Politics, and Illusions," Elsevier, London, UK, 2022. Married. Private interests: mediterranean cooking, gardening, Latin languages, Hungarian, classical guitar.

WHAT PEOPLE SAY ABOUT OUR TRAININGS

"High attention to detail in course content and very well delivered"

"Great course, impressed with the knowledge of the trainers and ability to answer wide variety of questions!"

"Very good training led by two knowledgeable and open experts. Excellent insight given on many complex topics. Interactive and highly useful"

DAY 1

BACKGROUND AND OVERVIEW

13:55	JOINING THE COURSE
14:00	INTRODUCTIONS OF LECTURER AND PARTICIPANTS
14:30	BACKGROUND: DRUG DEVELOPMENT AND THE ORIGINS OF US & EU PEDIATRIC LAWS
	• Modern drug development triggered by World War II: penicillin • Early reports about toxicities in babies in the 1950s • The thalidomide desaster 1957-1961 with birth defects observed wordwide • The 1962 amendment to the US Federal Food, Drug, and Cosmetic Act. • Origins of developmental pharmacology and separate pediatric studies • Origins of the demand for separate pediatric studies • US pediatric legislation since 1997 • EU pediatric legislation since 2007
15:45	CLINICAL STUDIES AND DRUG DEVELOPMENT
16:15	THE THREE BASIC PARTS OF PEDIATRIC DRUG DEVELOPMENT
	• Pediatric formulations (tablets vs. fluids vs. orodispersible modern formulations) • Juvenile animal studies • Clinical studies
16:30	COFFEE BREAK
17:00	US & EU REGULATORY PEDIATRIC REQUIREMENTS
	• EMA pediatric investigation plan (PIP) • FDA initial pediatric study plan (iPSP) • Negotiation procedures of iPSPs and PIPs
18:00	Q&AS
18:30	END OF DAY 1

DAY 2

GOING DEEPER

13:55	JOINING THE COURSE
14:00	MEDICAL ASSESSMENT OF REGULATORY PEDIATRIC REQUIREMENTS
	• Physiological development from conception through birth into adulthood • The legal and the physiological meanings of the term “child” are different • The body matures long before the 18th birthday • Conflicts of interest in pediatric drug development • The value of pediatric studies for COVID-19 vaccines
15:30	TECHNIQUES IN CLINICAL STUDIES
	• Modelling & simulation (M&S) • Physiologically based pharmacokinetic modelling and simulation (PBPK) • Randomized double-blind placebo-controlled studies vs. clinical registries • Pediatric data collection in an “opportunistic” study
16:00	COFFEE BREAK
16:30	SHIFTING FDA & EMA PEDIATRIC REQUIREMENTS
	• FDA easing in adolescents, dermatology, and other areas • Special case: FDA demands in minors <12y with cancer • Expanded EMA demands into diseases that occasionally occur in minors; • FDA and EMA easing in epilepsy; pediatric use of remdesivir for treatment of COVID-19 • the EMA demands for “pediatric” studies for drugs and vaccines for COVID-19 • The EMA has also closed PIPs after demanding pediatric studies for many years.
18:00	Q&AS
18:30	END OF DAY 2

ALL DATES AND TIMES ARE EXPRESSED IN UTC/GMT+1 ON THE AGENDA (CET TIME ZONE).
STARTING TIME – GMT 13:00 P.M.

WE RESERVE THE RIGHT TO MAKE SLIGHT ADJUSTMENT IN THE TRAINING PROGRAM

DAY 3

TECHNICAL AND POLITICAL CHALLENGES

13:55	JOINING THE COURSE
14:00	PROTOCOL WRITING FOR PEDIATRIC STUDIES
	• Same basic rules as in adults • Additional requirements for informed consent and assent • Blood samples children
15:00	PATIENT RECRUITMENT IN PEDIATRIC CLINICAL STUDIES
	• Role of patient advocacy groups • Role of clinical specialists
15:30	COFFEE BREAK
16:00	RECOMMENDATIONS FOR COMPANIES' PEDIATRIC STRATEGIES
	• When to address young patients in the company strategy [Answer: very early!] • Distinguish company's internal vs. official opinion • Inclusion of young patients into pivotal studies • Identify and select clinical opinion leaders • How to deal with unfeasible regulatory demands • PIP strategies beyond the first PIP negotiation round • The lost litigation of Nykomed at the • Is there a chance to sue the EMA at the European Court of Justice (EuCJ)? • Beware of being sued for harmful pediatric studies

17:30	INTERNET SEARCH EXERCISE
	• FDA Written Requests and other pediatric documents • PIP decisions • Documents on the EMA and FDA website • Completed and ongoing pediatric studies in clinicaltrials.gov • Literature research on PubMed
18:00	Q&AS
18:30	FEEDBACK/EVALUATION SESSION
18:40	END OF DAY3

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BUSINESS COMMUNICATION MASTERCLASS

04-05 November, 2025 | 2 pm to 6 pm

INFO

GLCEUROPE.COM | MARKETING@GLCEUROPE.COM | +36 1 848 05 96

EVENT INTRODUCTION

The training will focus on key components of communication. We will explore key topics including Emotional Intelligence, Asking, Listening, Feedback, Verbal and Non-verbal Communication, Teamwork, and will touch on Conflict Resolution. By definition, these are all substantial topics in and of themselves, so , of necessity we'll focus on the practical understanding and application in real-life scenarios. Content will include a combination of slides, images and video clips. The event will be interactive, with plenty of opportunity for questions.

COMPETENCY GOALS

• Enhanced communication skills • Facial recognition skills • Body language awareness • Advanced listening skills • Increased ability to cultivate trust • Understanding of the dynamics of feedback • Utilising the power of silence • Advanced observational skills • The art of asking questions • Application of Emotional Intelligence

JOSEPH MCGUIRE

FACIAL PROFILER

CLEARSIGHT COMMUNICATIONS

UPCOMING EVENTS

EU PHARMA AND BIOTECH MASTERCLASSES		US PHARMA AND BIOTECH MASTERCLASSES	
PSUR and RMP - Benefit Risk MasterClass with workshop	22-24 September	PSUR and RMP - Benefit Risk MasterClass with workshop	22-24 September
Entry Level CMC MasterClass	24-25 September	Setting Drug Product Specification MasterClass	06-08 October
Setting Drug Product Specification MasterClass	06-08 October	Risk based Quality management in Clinical Trials MasterClass	14-15 October
Risk based Quality management in Clinical Trials MasterClass	14-15 October	AI for pharma, bio, and life-sciences lawyers MasterClass	27-28 October
AI for pharma, bio, and life-sciences lawyers MasterClass	27-28 October	ICHQ7 Compliance challenges in modern API manufacturing MasterClass	04-06 November
ICHQ7 Compliance challenges in modern API manufacturing MasterClass	04-06 November	Fundamentals of Pharmacokinetics MasterClass	05-06 November
Fundamentals of Pharmacokinetics MasterClass	05-06 November	Process Validation for Biotechnological Products MasterClass	10-13 November
Key Aspects of Analytical Development MasterClass	10-11 November	Interest Rate Risk in the Banking Book (IRRBB) MasterClass	10-13 November
Process Validation for Biotechnological Products MasterClass	10-13 November	Advanced Pharma Technology Transfer MasterClass	12-14 November
Interest Rate Risk in the Banking Book (IRRBB) MasterClass	10-13 November	Pharma Contract Drafting MasterClass	17-20 November
Advanced Pharma Technology Transfer MasterClass	12-14 November	Patient engagement in gene therapy MasterClass	18-19 November
Pharma Contract Drafting MasterClass	17-20 November	PKPD in drug discovery and development MasterClass	19-20 November
Patient engagement in gene therapy MasterClass	18-19 November	Nitrosamine impurities MasterClass	20-21 November
PKPD in drug discovery and development MasterClass	19-20 November	Advanced Pharmacovigilance MasterClass	24-26 November
Advanced Pharmacovigilance MasterClass	24-26 November		

ABOUT GLC

THE COMPANY

Global Leading Conferences (GLC) is an industry leader the field of business intelligence. We provide interactive & impactful business platforms and networking opportunities for senior level executives by bringing them together for B2B Conferences, Global Summits, Training & Workshops. Being customer focused and having our client's priorities at the forefront, are amongst our core values and is of high importance to the way we operate our business.

Our passion for customer satisfaction and results, drive us to work with industry experts closely - who fully understand their peers interests and day-to-day challenges - in order to deliver the most impactful events. We are specialized in industries such as; Pharmaceutical, Banking & Finance, Energy, Oil & Gas, IT & Communication, Sales & Marketing, Law and Human Resources. Our commitment is to deliver the latest information to our clients, while maintaining highest quality and standards. By attending GLC events your company will be able to apply advanced strategies to your operations, gain the latest knowhow's and benchmark yourself higher against the competition while enjoying a 5 star environment.

CONTACT US FOR MORE INFORMATION AND TAILORED DETAILS:

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14+	600+	4000+	25,000 +
Years of experience	Events organized	Speakers	Attendees

GLC'S CUSTOM IN-HOUSE TRAININGS

WHAT IS IT?

No travel or logistic expenses for the team (we deliver it at your facilities) Maximize ROI with a depth tailored content accordingly to your corporate needs 360 degrees GLC Learning experience – Individual pre-questionnaire for each participant, several case studies and post training diagnose with participants

MEDIA PARTNERS

GLC

Pediatric drug development Masterclass | 17-19 February, 2026

REGISTRATION FORM

PLEASE COMPLETE THIS FORM AND SEND BACK TO marketing@glceurope.com
You are able to type the required details by clicking on the text fields.

YOUR GLC CONTACT PERSON: DS74
danodya@glceurope.com

DATE:

REGISTRATION DETAILS DELEGATE 1

Firstname:

Lastname:

Job Title:

E-mail:

Phone:

REGISTRATION DETAILS DELEGATE 2

Firstname:

Lastname:

Job Title:

E-mail:

Phone:

BILLING DETAILS

Company Name:*

VAT/TAX number:

Postal code: * City: *

Address: *

Country: *

Finance/Accounts or Payable Contact Person: *

GROUP REGISTRATION

Group Name / Organization:

Number of Members Registering:

Contact Person Full Name:

Contact Email Address:

Contact Phone Number:

MASTERCLASS FEE DS74

○ Attendance Fee	€ 1998 / 1 or 2 DELEGATES*
Business Communication Attendance Fee	€ 99 / delegate*

38 EUR administration charge will be applied

Participation fee includes:
- Full access to the live virtual training
- Course material
- Digital certificate
- Recording

* The offer is valid for limited number of seats only
** The recording will be shared on Vimeo and will be available for a limited time

PAYMENT METHOD

○ Via VISA or MasterCard card with a secured link

After you send your filled registration form, you will receive a secured payment link. Follow the instructions and pay directly with your credit/debit card.

○ Via Bank transfer

After you send us the filled registration form, our finance department will issue an invoice, so you can pay by bank transfer.

REGISTRATION CONFIRMATION & LEGAL ACKNOWLEDGMENT

☑ By filling out and returning the registration form via email to a GLC Representative, I acknowledge and agree that this constitutes a legally binding commitment, even without a physical signature. I confirm that I have read, understood, and agree to GLC Europe's General Terms & Conditions and Privacy Policy.