

## Information

### Scientific Chairs

**Dr. med. Ludger Tüshaus** AG Pediatric medical devices and surgical instruments, Klinik für Kinderchirurgie der Universität zu Lübeck **Prof. Dr. med. Lutz Wünsch** Klinik für Kinderchirurgie der Universität zu Lübeck

**Dr.-Ing. Robert Wendlandt** Labor für Biomechanik, Klinik für Orthopädie und Unfallchirurgie Universität zu Lübeck

### Advisory Board

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### Venue and Travel

Radisson Blu Senator Hotel | Willy-Brandt-Allee 6  
23554 Lübeck, Germany | [www.senatorhotel.de](http://www.senatorhotel.de)

Rooms at special rates available: Booking code *PedMedDev*.

Discounted train tickets | [www.infinite-science.de/bahn](http://www.infinite-science.de/bahn)

### Schedule

Nov 15	2 pm - 6 pm from 7 pm	Workshops Scientific Get-together
Nov 16	from 8 am 8.30 am 5 pm	Registration Welcome Farewell

### Registration

Please register online: [www.pedmeddev.org/registration](http://www.pedmeddev.org/registration)  
Different rates are available.

### Host and Organization



Infinite Science | Conferencing

Infinite Science GmbH | Campus Lübeck

[info@pedmeddev.org](mailto:info@pedmeddev.org)

[www.pedmeddev.org](http://www.pedmeddev.org)

## Support

### The Symposium is kindly supported by

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Regulatory Affairs & Research and Development

2nd Symposium

## Pediatric Medical Devices

Safety and Protection by Innovation  
and Development (6 CME points)

**November 16, 2018 | Lübeck, Germany**

Preconference-Workshops  
November 15, 2018

[www.pedmeddev.org](http://www.pedmeddev.org)

# Welcome

Dear Ladies and Gentlemen and Colleagues,

With great pleasure we invite you to the 2nd symposium on „Pediatric medical devices: safety & protection by innovation & development“. It follows up on the successful kick-off event two years ago, this time addressing an international audience.

The use of medical devices in pediatric practice varies widely, and much can be learned by the leaders of the field. So the scope of the symposium is exquisitely practical: workshops with international opinion leaders and summarizing sessions will provide both oversight and focus on the most exciting areas of development.

Regulatory Affairs will receive special attention this year and the R&D sessions cover the whole range of pediatric and pediatric surgical subspecialties. Active participation is highly encouraged to foster the exchange of ideas and to challenge the participating experts from clinics and development on individual medical technologies, projects and solutions for children.

Safe innovation for children may appear desperately complicated and economically high-risk. But much can be gained if efforts are combined and a larger perspective is embraced. So, take your experience, ideas and questions to the symposium and gain valuable feedback from multiple perspectives and international experts. We look forward to your participation and hope for a constructive multilateral dialogue for the benefit of children.

Kindest regards

Dr. med. Ludger Tüshaus

Dr.-Ing. Robert Wendlandt

Prof. Dr. med. Lutz Wunsch

# Program

November 15, 2018 from 2 pm

## Preconference Workshops (2 pm - 6 pm)

GCP Refresher Course

Virtual & Augmented Reality in pediatrics / pediatric surgery

Moonshot Ideation Workshop - Get into your Rocket

## Scientific Get-together (from 7 pm)

November 16, 2018 from 8:30 am

### Greeting

Prof. Gabriele Gilleßen-Kaesbach, President of University of Lübeck, Germany

### Virtual & Augmented Reality in pediatric surgery

### Ideas and needs from the bedside: the clinicians' view:

#### Pediatric Cardiology

Prof. Dr. Peter Ewert, München, Germany

#### Pediatric Orthopedics

Prof. Dr. Annelie Weinberg, Graz, Austria

### Coffee break

## Breakout Sessions: Regulatory Affairs | R&D

### Defining and finding clinical needs

Prof. Gwennyth Fischer, Minneapolis, USA

### Greeting

Dr. Heiner Garg, Minister of Social Affairs, Health, Youth, Family and Seniors, Land Schleswig Holstein, Kiel, Germany

### Lunch

## Breakout Sessions: Regulatory Affairs | R&D

### Coffee break

### 3D printing, rapid prototyping & custom made devices for children

### Panel Discussion and Summary, followed by Farewell

## Breakout Sessions (Nov 16, 2018)

### REGULATORY AFFAIRS (Manufactures, Authorities, CRO)

Chair: Prof. Heike Wachenhausen, Lübeck, Germany

**Medical product safety and application aspects in children** | Dr.-Ing. Wolfgang Lauer, BfArM, Bonn, Germany

**From the idea to the safe pediatric medical device**  
Dr. Gerhard Pohlmann, Fraunhofer ITEM, Hannover, Germany

**Pediatric clinical data - challenges for hospital and manufacturer**

Dr. Susanne Stahlkopf, Olympus Europe, Hamburg, Germany

**Pediatric medical devices: the view of a notified body**  
Nicole Eun Joo Heimerer, TÜV-Süd, München, Germany

**The European Paediatric Regulation for the development of medicine for children: results and experiences**  
Prof. Mark Turner, Liverpool, UK

**Getting EU and US market approval for pediatric/orphan medical devices**

Hendrik Heinze, Berlin Heart, Berlin, Germany

**Incentivizing Orphan Product Development: United States Food and Drug Administration Orphan Incentive Programs**

### RESEARCH & DEVELOPMENT (Clinicians, Scientists, Engineers)

#### Neonatology

Prof. Christoph Härtel, Lübeck and Prof. Thomas Schaible, Mannheim, Germany

#### Global health

Prof. Jenny Dankelman, Delft, NL and Dr. Judith Lindert, DTHM (Liv), Lübeck, Germany

#### Robotics

Dr. Anne-Françoise Spinait, Gent, BE, Dr. Fritz Kahl, Göttingen and Prof. Floris Ernst, Lübeck, Germany

#### Pediatric Cardiology

Prof. Dr. Peter Ewert, München, Germany

#### eHealth: telemedicine and beyond

Dr. Simone von Sengbusch, Lübeck, Germany et al.

#### Implants & Osteosynthesis

Prof. Annelie Weinberg, Graz, Austria and Prof. Arndt-Peter Schulz, Lübeck, Germany