Curriculum Vitae

Dr. med **Jens-Ulrich Stegmann**, RN, MD

- *Global leadership for clinical development, clinical safety, pharmacovigilance and risk management.*
- *Global responsibilities for pharmaceuticals and vaccines at all stages of clinical development and post-marketing.*
- *EU-QPPV for pharmaceutical as well biologic company*
- *Experience in a wide range of therapeutic areas including Infectious diseases, pain, central nervous system, oncology, contraceptives, biologics, and vaccines.*
- *Interaction with all relevant regulatory authorities worldwide including presenting at Ad-Coms (e.g., FDA, EMA, MHRA, PMDA)*

Education:

School career	Primary School in Neuss/ North-rhine Westphalia	09.1974 - 06.1978
	Grammar school (Marie-Curie Gymnasium Neuss)	08.1978 - 11.1982
	Grammar school (Städtisches Gymnasium Goch)	11.1982 - 05.1987
Civilian Service and apprenticeship	Civilian Service (Heilpädogisches Heim Bedburg-Hau)	09.1987 - 07.1989
	Apprenticeship as male nurse	05.1989 - 03.1992
	Exam as registered nurse	03.1992
University studies	Preclinical medicine (Justus- Liebig Universität Gießen)	04.1992 - 04.1994
	First and second phase clinical medicine (Christian-Albrechts-Universität Kiel)	04.1994 - 01.1998
	Third phase clinical medicine (GH Universität Essen) Focus: Anaesthesiology Overall grade: 1.8 (rank: 1-5)	01.1998 - 05.1999
Studies abroad	Anaesthesiology and General Surgery Universityhospital Praque	09.1994 - 10.1994
	Gynaecology and Obstetrics (Baragwanath Hospital / Johannisburg (South-Africa)	02.1996 - 03.1996
	General Surgery (Ngwelezana Hospital Empangeni/KwaZulu Natal [South-Africa])	04.1998 - 08.1998

Doctor Thesis (Dr. med.)	Doctoral dissertation at the “Physiologisches Institut (Lab: Prof. Dr. W. Jänig)” “ Investigation of functional recovery of nociceptive afferents in the rat”	08.1994 - 12.1998
	Promotion (magna cum laude)	01.2001

Publications

- ca. 20 fullpapers as author or co-author in peer-reviewed journals
- ca. 50 abstracts for national and international conferences

Professional career

Resident as Anaesthesiologist at the University hospital in Düsseldorf 07.1999 – 02.2003

Certificate of Specialist Training “Emergency Medicine” 12.2000

Grünenthal GmbH

Clinical Project Scientist within Clinical Development; Grünenthal GmbH 03.2003 – 05.2005

this functions includes.:

- Design, preparation and conduct of clinical studies (mainly for Tapentadol)
- Medical and scientific support of investigators
- Continuous monitoring of clinical studies including signal detection of adverse events
- Participation at „Risk-Benefit-Committee“ for continuous evaluation of investigational medicinal products

International Clinical Project Leader Therapeutic Area Analgesics; Grünenthal GmbH 05.2005 – 09.2006

this functions includes.:

- Design, preparation and conduct of clinical development programs (for Tapentadol, Axomadol and others)
- Participation at „Risk-Benefit-Committee“ for continuous evaluation of investigational medicinal products
- Co-author of periodic reports about safety profile of investigational products
- Responsible author for Investigator Brochure

Scientific Advisor / Deputy Head Therapeutic Area Analgesics; Grünenthal GmbH 10.2006 – 08.2007

Head of Pain Projects 2 / Deputy Head Therapeutic Area Analgesics; Grünenthal GmbH 09.2007 – 10.2008

this functions includes.:

- Line manager of four International Clinical Project Leader within “Therapeutic Area Analgesic”
- Member of „Risk-Benefit Committee“
- Co-author of periodic reports about safety profile of investigational products and marketed products (e.g. PSURs)

Head Global Drug Safety; Grünenthal GmbH 10.2008– 12. 2011

this functions includes.:

- Line manager of 5 Group Heads (Application Management, Data Management, Drug Safety Governance, Safety Operations, Medical Evaluation) with in total 40 associates at HQ in Aachen and as „Global Line Function“ for „Local Responsible Persons Pharmacovigilance“ in 30 affiliates within Grünenthal Group
- Deputy QPPV
- Deputy commissioner of the graduated plan “Stufenplanbeauftragter” according German law
- Member of „Risk-Benefit Committee“
- Chair of „Case Conference“ as continuous surveillance of the safety profile of marketed products
- Member of the quality assurance conference as regular information of the Corporate Executive Boards

GSK

Head Safety Evaluation and Risk Management; GSK Biologics 1.2012-3.2014

this functions includes.:

- Member of „Vaccine Safety Monitoring Board“
- Member of “Vaccines Product Quality Board”
- Member of “Product Incident Review Board”

In addition to the above 6.2013
Deputy QPPV GSK Corporate

Head Clinical Safety and Pharmacovigilance; GSK Biologics 4.2014

Responsible for all aspects of pharmacovigilance and risk management for GSK biologics.

- Co-chair of „Vaccine Safety Monitoring Board“
- Chair of “Safety Governance and Labelling board” GSK corporate
- Member of “Global Safety Board” GSK corporate
- Member of “Vaccines Product Quality Board”
- Member of “Product Incident Review Board”

In addition to the above

EU- QPPV for GSK and ViiV Healthcare 3.2019

Global Head Clinical Safety and Pharmacovigilance; GSK 2.2020

Responsible for all aspects of pharmacovigilance and risk management for GSK

- Chair of „Global Safety Board“
- Member of “Development Review Board” GSK
- Member of “Development Leadership Team”

Status: August 2023