Curriculum vitae

Dr. Manuel Zahn

December 2022

Current Position

Since January 2008: Managing Director at 3R Pharma Consulting GmbH (www.3rpc.com)

Education and Qualifications

2009	APIC Certified Auditor for GMP audits of API manufacturers
1981	Qualified Person (QP) according to Directive 2001/83/EC, Art. 49 and 51
June 1978	Doctoral degree (Dr. rer. nat.)
Oct 1969 – July 1975	Chemistry (Dipl.-Chem.) University of Karlsruhe, Germany

Employment History

Jan 2005 to Dec 2007	Director Regulatory CMC Global Regulatory Affairs	AstraZeneca R&D, Plankstadt, Germany
Jan 2002 – Dec 2004	VP, Head Global Regulatory CMC	AstraZeneca R&D, Södertälje, Sweden
May – Dec 2001	Acting Site Manager Regulatory Affairs, Head of Country Support	Knoll GmbH (Abbott Lab., now AbbVie)
April 2000 – April 2001	Head of Country Support	Knoll AG
Sept. 1996 – March 2000	Head of Regulatory Support	Knoll AG
April 1988 – Aug 1996	Head of Regulatory Affairs	Knoll AG Ludwigshafen, Germany
Jan 1985 - March 1988	Head of International Regulatory Affairs	ASTA Pharma AG Frankfurt am Main, Germany
Aug 1981 - Dec 1984	Head of Regulatory Affairs	Biologische Heilmittel Heel GmbH, Baden-Baden
Aug 1978 – July 1981	Head of Quality Control	Abnoba GmbH, Pforzheim

Other Professional Activities

Professional Committees - Regulatory Affairs

March 1991- October 1993	Chairman BPI Supporting Group 'Regulatory Affairs' (BPI = Bundesverband der Pharmazeutischen Industrie)
1994 - 1997	Member of the VFA Subgroup 'Regulatory Affairs' (VFA = Verband Forschender Arzneimittelhersteller)
February 1991 - March 1998	Member of EFPIA´s Expert Group 'Regulatory Affairs' (EFPIA = European Federation of Pharmaceutical Industries and Associations)

Professional Committees - CMC/Quality

1991 – 2003	Member of EFPIA's Expert Group Quality
1991 – 1997 2001 – 2003	EFPIA Topic Leader Stability in ICH Expert Working Group Q1
1991 – 2003	Member of EFPIA's Expert Group Stability Chairman of this group 1992-1998
1997 – 2001	Member of EFPIA's Expert Group 'Common Technical Document – Quality' (CTD-Q)

Contribution to International Conferences, Workshops and Seminars

Dr. Zahn presented scientific/technical topics at conferences, workshops, educational seminars, and tutorials in Europe, the US, Canada, Central America, Japan, South Korea, the Middle East and South East Asia. He also organised and chaired international conferences, sessions and courses, e.g.:

- Program Chair of the 4th Annual DIA EuroMeeting, Basel, Oct. 1992
- Head Lecturer (Lehrbeauftragter) at the Postgraduate Course in Pharmaceutical Medicine, University Witten/Herdecke, Germany, 1998 - 2001.
- Chairman and/or speaker at informa (former ibc) International Conferences on Stability Testing (1994, 1996, 1997, 1998, 1999, 2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017)
- Program Co-Chair of the 14th Annual DIA EuroMeeting, Basel, March 2002

Publications

- More than 30 original articles in journals or books, most of them addressing trends in CMC regulations and quality related issues.
- Correspondent of 'The Regulatory Affairs Journal' 1991 – 1998.
- Member of the Editorial Board of 'SCRIP Regulatory Affairs' 1998 - 2014.

Professional Associations

1987 – 1995	Member of the British Institute of Regulatory Affairs (BIRA)
Oct 1991 – 2001	Member of the European Society of Regulatory Affairs (ESRA)
1989 – 2009	Member of the Drug Information Association (DIA)

Dr. Zahn is currently a member of the following organisations:

- Deutsche Gesellschaft für Regulatory Affairs (DGRA)

Awards

1995	Outstanding Service Award Drug Information Association (DIA)

Languages

German	mother tongue
English	fluent

Advisor

For almost 12 years, Dr. Zahn has been involved in International Conference for Harmonisation (ICH) Quality topics, starting as European pharmaceutical industry (EFPIA) topic leader 'Stability' in 1991. He has been a member of the ICH Expert Working Group developing the ICH Stability Guidelines until 2003. As EFPIA co-topic leader from 1997 to 2001, he contributed to the development of the ICH Common Technical Document (CTD) Guideline M4-Q.

From 2001 to 2005, Dr. Zahn represented the international pharmaceutical manufacturers (IFPMA) when the Association of the Southeast Asian Nations (ASEAN) Stability Guideline has been generated.

As a World Health Organization (WHO) Temporary Advisor, he has been involved in developing a regional stability guideline for the WHO Eastern Mediterranean Region (EMRO) starting in Amman, Jordan, in 1993, followed by a workshop in Damascus, Syria, in 1994. A revised version of the guideline has been developed in Jeddah, Saudi Arabia, in 2006. This document was then used as a draft for the new global WHO Stability Guideline released in 2009.

Dr. Zahn supported the innovative Process Analytical Technology / Real Time Release (PAT / RTR) concept in discussions with the EMEA Quality regulators and inspectors. He took over the regulatory lead for a PAT/RTR project in 2006 and managed the submission of the first pilot product for PAT/RTR using the pilot EU Work sharing Procedure and achieved a positive decision in 2007.

Experience in Biologics

- Three successful EC Multi-State procedures:
  - a pancreatic enzyme (submitted in 1989),
  - an ointment containing collagenase for wound healing (submitted in 1990),
  - a low molecular mass heparin (submitted in 1990).
- Support of biotech products, e.g., TNF in ascites, anti-TNF in sepsis, r-Hirudin, including successful negotiations with FDA, Canadian HPB and European authorities.
- Support of a biological product in-licensed from Japan.
- Initiation of an EU Centralised Procedure for a biotech Part B-product.
- GMP audit of the manufacturing of a recombinant Adeno-Associated Virus (AAV) vector in the US (in 2009).
- Support of a Clinical Trial Application for a liposome dispersion of a proteasome inhibitor belonging to the chemical class of peptide-semicarbazones (2010/11).
- Support of a Clinical Trial Application for a biopolymer extracted from seaweed (2009/10).

Experience in GMP Auditing

In 2009, Dr Zahn started to conduct audits of API manufacturers according to ICH Q7 and EU GMP guidelines, contract labs, distributors (GDP), and manufacturers of finished dosage forms, in particular aseptic processing, including Investigational Medicinal Products (IMPs).

The audits took place in Europe (EU, Switzerland), USA, Canada, and Far East (Vietnam, Taiwan, India, South Korea).

All kind of products were covered, from small molecules and biopharmaceuticals to autologous human cells and recombinant virus vectors.

Dobel, 01 December 2022