PROFESS®
Profess Medical Consultancy B.V.

CURRICULUM VITAE

PROFESS® Medical Consultancy B.V.

Name	:	Pauline Cornelia Meewisse
Date of birth	:	26 August 1960
Nationality	:	Dutch

FUNCTIONS TO DATE

Since 10/1998	**QA Consultant at Profess® Medical Consultancy B.V.**
07/1997 – 10/1998	Head Quality Assurance at Tramarko B.V.
01/1997 – 07/1997	Head Clinical Research ad interim, Tramarko B.V.
1995 – 01/1997	Head Quality Assurance at Tramarko B.V.
1992 – 1995	GCP auditor at Tramarko B.V., Almere Additional responsibilities regarding study medication packaging
1991 - 1992	Pharmacist in public pharmacy Diemer Apotheek, Diemen Apotheek Wassenaar, Huizen
1985 - 1991	Pharmacist in public pharmacy Apotheek Vredeveld, Assen

EDUCATION

1966 - 1972	Primary school in Voorburg
1972 - 1978	Secondary school (Atheneum in Utrecht)
1978 - 1985	Study Pharmacy at the University of Utrecht
1990	Radio-activity C-level, University of Groningen

WORKING EXPERIENCE

Independent auditing for major pharmaceutical, food and medical device companies and CROs, including phase I units. More than 120 on-site audits and numerous system/organisation audits in all EU Member States and India.
Design of Quality Systems for various companies (pharmaceutical, medical device, food, adjudication, CRO), including a system for investigator-initiated studies.
Design, preparation and monitoring of a medical device study set-up by Profess.
Interim regulatory affairs management jobs for various companies and familiar with regulatory database and document management system.

Languages
Dutch
English (fluently)
German (moderate)
French (moderate)

31-Jan-2023

Member of the following associations:
DARQA

31 January 2023

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TRAINING RECORD Pauline Meewisse, Profess® Medical Consultancy

1993	Course: Practical GCP compliance auditing, DIA
1994	Course: Good Distribution Practices
1995	Course: Total Quality Management
1996	Course: Gene therapy
1996	Course: ISO Quality Management
1997	Working group Validation on Computer Systems
2000	Course on New Registration Procedures
2001	Course: Auditing of Validation of Computer systems for (Pre-) Clinical Research
2002	CCMO meeting: Medical Research Involving Human Subjects Act (WMO)
2003	ACRP meeting: European Directive for Clinical Research and national legislation
2004	NVFG meeting: Implementation of Clinical Trial Directive in the Netherlands
2005	CBG/NIA: Workshop 'Review 2001': Implementation per 1 November 2005, consequences for industry and national agencies CCMO/NVFG meeting: EU CTD between the lines; the practical implication
2006-2008	DARQA meetings, including a meeting of the ICT working group about GAMP 5 and meeting about inspection readiness
2009	CCMO symposium "The surveilance of safety of subjects in clinical research"
2009	EPD day 2009 (Electronic Patient File)
2010	Masterclass GCP AMC PPN meeting Nov 2010: Inspection readiness and SOPs
2011	DARQA meeting Risk Management CBG/RegNed/NVFG Workshop Risk Minimisation Activities Company training Inspection Readiness PPN meeting
2012	Refresher course ICH GCP, Profess Medical Consultancy CBG meeting Nov 2012: Practical Aspects of new Pharmacovigilance legislation
2013	Refresher course regulations in clinical research in the Netherlands and Europe, Profess Academy, 19 April 2013
2013	Risk-based monitoring: opportunities and challenges in clinical development Pharmaceutical Statistics and Data Management Event, 2 September 2013

2014	Refresher course regulations clinical research in the Netherlands, Profess Academy 11 April 2014
2014	DARQA GMP/GCP conference: GCP meets GMP: Management and QA of study medication in clinical trials
2015	Refresher course ICH GCP on 11 September 2015, Profess Academy
2015	DARQA meeting on 2 October 2015: GLP meets ICT: eData integrity and archiving
2016	ISO 9001:2015 Lead Auditor course DNV 25-27 May 2016
2016	Refresher course ICH GCP on 16 September 2016, Profess Academy
2016	DARQA meeting on 23 September 2016: Quality Metrics
2017	e-day Medicine Evaluation Board (Regulatory)
2017	DNV study day HKZ (Harmonisatie Kwaliteitsbeoordeling in de Zorgsector)
2017	Biostatistics in Clinical Research; in-company training Astellas
2017	Refresher course ICH GCP, Profess Medical Consultancy B.V.
2017	Clinical Compliance Experience, Profess Medical Consultancy B.V.
2019	DARQA meeting on 24 May 2019: European Clinical Trial Regulation, what will change
2020	Webinar Remote auditing - Effective Implementation RQA Webinar 25 June 2020
2020	DARQA Webinar - Remote auditing - 10 July 2020
2020	DARQA Webinar - Remote site auditing - 9 October 2020
2021	DARQA Conference - Quality beyond Compliance - 17 September 2021
2022	DARQA Webinar - Electronic signatures - 18 February 2022
2022	DARQA Webinar - Auditing of IT system: how to start - 16 September 2022
2022	DARQA Conference Cybersecurity and data integrity: what should you pay attention to - 14 October 2022
2023	DCRF Webinar CTR - Implementation of CTIS - 17 January 2023