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CURRICULUM VITAE

EMPLOYEE INFORMATION

Full Name: Martial Verschoot, MSc Biomedical Sciences

Job Title: Managing Director and Founder of VERBO CQA B.V. (Clinical Quality Assurance)

Country of Residence: Belgium

Regular / Temp Status: Regular

Summary

MSc, Biomedical Sciences, Vrije Universiteit Brussel, Belgium

Postgraduate, Pharmed Course (Pharmaceutical Medicine and Pharmacology), Université Libre de Bruxelles, Belgium

Male Nursing Diploma, IC Dien Nursing School, Roeselare, Belgium

FORMAL EDUCATIONAL HISTORY

Last Date Attended	Institution name, Country	Education Level/Degree	Area of Study	Completion Status
07/1975	Ic Dien, Belgium	Diploma Nursing	Nursing	Completed
07/1992	Vrije Universiteit Brussels, Belgium	MSc	Biomedical Sciences	Completed
07/1993	Université Libre de Belgique, Belgium	Certificate	PHARMED Course (Pharmaceutical Medicine & Pharmacology	Fully Attended - Not completed
07/1994	CCKL, Tilburg, Netherlands	Certificate	Health Care laboratories & preparation, packaging and labelling of clinical supplies	Completed
04/1995	IQA International Register of Certified Auditors, (ISO), United Kingdom	Certificate Lead Assessor, #A006133	ISO 9000 Lead Assessor	Completed
08/2020	Drug Information Association (DIA)	Certificate	Pharmacovigilance Quality Management System	Completed

Docusign Envelope ID: D6EFCAAE-2E0E-4165-B542-3BEE0A70A140

01-02FEB2023	RQA (BARQA)	Certificate	Implementing Good Clinical Laboratory Practice	Completed
22FEB2023	Brookwood Global	Certificate	GCP Refresher: Are you ready for … a Sponsor GCP inspection?	Completed
28FEB2023	Brookwood Global	Certificate	GCP Refresher for Sponsors – Inspection Challenge	Completed
08FEB2024	GCPPL	Certificate	ICH-GCP Basic Refresher training-Sponsor initiative	Completed
27MAR2024	RQA (BARQA)	Certificate	Audit Programs and Risk Assessment	Completed
01JUL2024	EFGCP	Certificate	EFGCP Quality/Ethics Working Party: Workshop 2024, "I think, Therefor I do Clinical Trials", 01JUL2024, (8 hours F2F Meeting)	Completed
29JAN2025	WIRB-Copernicus Group (WBC)	Certificate	ICH E6(R3) What you need to know	Completed
03FEB2025	Brookwood Global	Certificate	GCP is Changing-What's new in E6(R3)	Completed
18MAR2025	RQA	Certificate	Good Laboratory Practice Refresher and Hot Topics	Completed
27MAR2025	RQA	Certificate	Audit Programs and Risk Assessment	Completed
Year 2023 and 2024-2025	Criteria for auditing in Italy	Spreadsheet with details available	Fulfills criteria to be allowed auditing in Italy.	Completed

EMPLOYMENT HISTORY

IQVIA and its Affiliated Companies Employment History

Date of employment: 03/1995 – 05/1997

Job Title: QA Manager

Key Responsibilities: Conducting audits, follow up on customer relations, audit metrics.

Date of Employment: 06/1997 – 08/1999

Job Title: Executive Director QA

Key Responsibilities: Create Quality Services & Consultancy Department, management of 15 QA staff members.

Docusign Envelope ID: D6EFCAAE-2E0E-4165-B542-3BEE0A70A140

Date of Employment: 09/1999 – 03/2000

Job Title: Business Development – EU Representative at HQ Research Triangle Park, NC, USA.

Key Responsibilities: Business Development, Liaison between US and Europe, and conducting audits in the US.

Date of Employment: 04/2000 – 04/2001

Job Title: Director Legal & Quality Services

Key Responsibilities: Auditing, hosting regulatory Inspections, develop customer relationships, working closely with inspectorates EMA/FDA/National Authorities.

Date of Employment: 05/2001 – 09/2001

Job Title: Acting Product Development Director & Head Clinical Operations Belgium in the Clinical Pharmaceutical Company. Site Head of the Quintiles LLN Belgian Office.

Key Responsibilities: Site Head Quintiles LLN Office, Head ClinOps for approximately 25 ClinOps staff, Product Development Director in the CPO Structure.

Date of Employment: 10/2001 – 04/2004

Job Title: Director Quality Services

Key Responsibilities: Conducting audits, hosting regulatory Inspections, develop customer relationships within the European Legal & Quality Services Department.

Date of Employment: 05/2004 – 04/2008

Job Title: Senior Director QA

Key Responsibilities: Conducting audits, hosting regulatory Inspections, develop customer relationships within the European Legal & Quality Services Department.

Date of Employment: 05/2008– 10/2010

Job Title: Executive Director CRO QA Europe

Key Responsibilities: Regional QA Head for CRO QA Europe QA Department, management of all EU QA functions including management of 34 QA staff members + Acting QA Head Phase I Units (UK London, Sweden Uppsala and Hermelinen).

Date of Employment: 11/2010 – 12/2018

Job Title: Executive Director CQA

Key Responsibilities: Global Head for the External Customer QA Lead Department, management of all QA related tasks for the assigned Customers including management of 30+ QA Lead staff members.

Development of a QA Centralized Services Department in Mumbai, India; standardisation of QA work, improving Quality with increased efficiency; recruitment and management of 20+ QA staff members.

Non - IQVIA Employment History

Date of employment: 08/1975 – 01/1989

Name of Employer: Kliniek Zwarte Zusters

Job Title: Head Male Nurse Dialysis Centre

Docusign Envelope ID: D6EFCAAE-2E0E-4165-B542-3BEE0A70A140

Key Responsibilities: Designed with Nephrologist the regional dialysis centre, responsible for operational, para-medical and administrative tasks, team of 5 staff members.

Date of employment: 01/1989 – 02/1991

Name of Employer: Sheraton Corporation, Rogiersplein, Brussels

Job Title: Front Office, reception, night service (Improvement English language during university studies)

Key Responsibilities: Front Office, reception, telephone

Date of employment: 02/1991 – 02/1995

Name of Employer: Bristol – Myers Squibb

Job Title: QA Auditor

Key Responsibilities: Conducting audits, management Qualities Issues, provision QA support to project teams.

Date of employment: 01/2020 - Ongoing

Name of Employer: VERBO Clinical Quality Assurance B.V.

Job Title: Managing Director, Founder, GCP Auditor

Key Responsibilities: GCP Consulting and conducting GCP audits and regulatory inspections, (including follow up on inspection findings); Vendor re-qualification; Implementation Quality Management System (ISO9001); Quality Issue(s) Management; GCP Training and provision of QA support to Customer QA and Project teams.

DEPARTMENT SPECIFIC EXPERIENCE

Category	Experience
GCP Audits and/or GCP Regulatory Inspections support (460+ audits and 40+ Regulatory Inspections) both in-house and on-site	Yes
Feasibilities	Yes
Contract negotiations and business proposals (contracted and internal audit and inspection programs)	Yes
Investigator Meeting Attendance and presentations	Yes
Monitoring Visits & Source Data Verification	Yes
Customer Representative for multiple large pharma Customers	Yes
GCP training (basic & advanced) and QA support to different project teams and Customers	Yes
QA staff management 30+ staff members	Yes
Member of the overall Company Senior QA Management team	Yes
Due Diligence [Good Clinical Practice (GCP), as part of a Due Diligence Team]	Yes
GCP Vendor Qualification and Vendor Re-Qualification (Part of Vendor Management)	Yes
GCP Remote/Sponsor Location Trial Master File Audits (Project, Country, Site)	Yes
GCP Implementation Quality Management System, including creation SOP and Quality Documents (Small Biotech-Clinical Development with extrapolation to other departments)	Yes

Docusign Envelope ID: D6EFCAAE-2E0E-4165-B542-3BEE0A70A140

LANGUAGE(S)

Language	Speaking	Reading	Writing
Dutch-Flemish	Fluent	Fluent	Fluent
English	Fluent	Fluent	Fluent
French	Fluent	Fluent	Business level

CURRENT MEMBERSHIPS PROFESSIONAL ORGANIZATIONS

- Drug Information Association (DIA)
- European Forum of GCP (EFGCP)
- Research Quality Association (RQA)

Publications, Thesis

- How to set up an emergency dialysis unit in catastrophic circumstances: The Armenian earthquake, 1987 (Organization with Red Cross, Artsen zonder grenzen (AZG) and ORPADT humanitarian intervention (JP Vanwaeleghem, G Verpooten, M Verschoot)
- Evaluation of costs and materials in dialysis, an overview, Local Study Clinic Ypres 1990 (M Verschoot)
- Waar naartoe met Terminale Patiënten die hospitalisatie nodig hebben na een omschakeling van V-naar RVT-diensten, VUB MSc thesis, 1991-1992

Comparative Publications

- Comparison between several types of artificial kidneys concerning the relation between surface area and membrane structure; Comparison between the clearance to different artificial kidney membranes; Comparison between coagulation of different types of Heparin, (Ypres Clinic local study), 1985
- Participation in multicenter study on Eprex (Erythropoietin) prior to registration (University Leuven)
- Participation in multicenter study:Life expectancy and survival of fistula's. Uni- or bipunction system (University of Antwerp)
- Participation in multicenter study concerning aluminium accumulation in patients with End Stage Renal Disease (ESRD),(University of Antwerp)

Publications/presentations related to Regulatory Compliance and QA

- Training new assessors how to conduct internal assessments, Rome, Italy (05-06July 1993)
- Training new assessors how to conduct internal assessments, München, Germany, (07-08July 1993)
- Member of faculty, training course for GCP inspectors and country Counsellors on Clinical Trials, Warsaw, Poland (09-13 May 1994), Auditing techniques, Auditing experience, Practical aspects of auditing
- The European Investigator Qualifications & Responsibilities, (G Nys, M Verschoot), Bristol-Myers Squibb (BMS), Worldwide Regulatory Compliance, Clin. Research Focus, Vol 5, N°7 (October 1994)
- ISO 9001, The relation to Quality Assurance Good Clinical Practice, (M Verschoot), (BMS) November 1994, Pharma QA Meeting (five pharma QA teams), Strasbourg, France
- Took part in 157 Systems and Study audit reports in the field of GCP, (ongoing research studies) against current EU GCP and FDA regulations, ISO1011-1,2,3, National and local legislations and requirements (February 1991- February 1997)
- Presentation on general inspection and auditing techniques to Egypt inspectorate, August 2018
- Delivery of multiple GCP training presentations (EMA/FDA Inspections preparation, support and follow up until closure), between July 1995 and December 2019

Docusign Envelope ID: D6EFCAAE-2E0E-4165-B542-3BEE0A70A140

Other Relevant Information

Licenses and Certifications

- Barnett GCP course Basic and Advanced, 2014
- Barnett GCP course Expert, 2016, 2017
- ISO 9000 Lead Assessor, 1995 to 2001 (due to senior management role, license not renewed subsequent to 2001)

Relevant Non – Clinical Training

Described in Learning Curve (Quintiles/IQVIA training document system), numerous courses

and meetings over multiple years (various topics) e.g. Ethical Conduct, Sarbanes

Oxley Act, Understanding Phishing, Conducting Appraisals, Offences under the

Clinical Trial Directive, European Clinical Trials Directive, Cliënt Focussed Learning,

SPIN selling skills, etc.

Other

- Training Database Administrator and Data Management Audits, (13-14 and 15-17 January 2003), Quintiles
- MHRA Risk based inspections seminar, 22 May 2009, certificate of attendance
- Provision of QA training and support to Danish Pharma Company including

  relocation (6 months) to Denmark
- During previous years QA/QC/ICH GCP teaching assignments as member of the faculty at:
  - Rotterdam Hogeschool, The Netherlands; ESAME Foundation, Spain; University Limoge, France; BARQA (RQA), Master class, Cranfield University, UK; University of Antwerp, Belgium
  - During career, delivered QA presentations to BfArM, Italian, Romanian, Egyptian Regulators
  - Lead Auditor (Quintiles) in the EMA/FDA audit(s) initiative on the Inspection Harmonization Initiative (presented review at DIA meeting, Genève, Switzerland in presence of participating Regulatory Authority Inspectors

GCP Audits conducted (subsequent to COVID-19 pandemic re-opening of business MAY2021-DEC2022)

1. Seven (7) GCP Audits conducted in Europe (various types on-site and remotely) during 2021
2. Fifteen (15) GCP Audits conducted in Europe (different therapeutic areas, on-site and remotely) during 2022
3. One (1) GCP CRO Re-qualification Audit (remotely) during 2022
4. One (1) GCP eTMF Audit (remotely) during 2022

GCP Audits conducted during 2023

1. GCP Inspection Readiness program, Investigator Site Quality Assessments (ISQA), eTMF Audit, Phase III Clinical Trial (4 different regions EU/USA/LAM/SAF), APR-DEC2023:
   a. Six (6) GCP ISQAs, Phase II and III Trial, MAY-OCT2023
   b. GCP eTMF Audit, Phase III Trial, Sponsor Inspection Readiness Audit, SEP-OCT2023
   c. GCP Mock Inspection, Sponsor Inspection Readiness Audit, 10-13OCT2023
   d. GCP QA Consultancy 01OCT-31DEC2023 & prolongation 01JAN-31MAR2024
2. GCP CRO Audits, 3-4Q2023 (repeated business-conducted):
   a. Two (2) GCP ISA, Phase III Trial

Docusign Envelope ID: D6EFCAAE-2E0E-4165-B542-3BEE0A70A140

Activities undertaken, including GCP Audits 2024

1. GCP QA Biopharma Company: Consulting, Implementation Quality Management System, 15DEC2023-31JUL2024 (Completed)
2. GCP ISQAs, Pharma Company: 01JAN2024-30MAR2024 (repeated business; extension to existing contract (Completed)
3. GCP ISA, CRO Phase III Trial, Latin-America, 29JAN-31JAN2024 (repeated business, Completed)
4. GCP Periodic Review Assessment of VERBO CQA B.V. by Sponsor Vendor Management Department (15FEB2024, Requalified)
5. GCP ISA, CRO Phase III Trial, Latin-America, MAR2024 (repeated business, Completed)
6. GCP ISA, CRO Phase III Trial, USA, MAY2024 (repeated business, Completed)
7. GCP remote eTMF Audit, 02JUL-22AUG2024: (repeated business, Completed-10JAN2025)
8. Review VERBO CQA B.V. SOPs, 25AUG2024-30OCT2024 (Completed)

Activities undertaken, including GCP Audits 2025

1. GCP ISA, CRO Phase III Trial, Turkey, MAY2025, (Completed)
2. GCP ISA, CRO Phase III Trial, Belgium, JUN2025, (Completed)

Activities contracted/Planned, including GCP Audits 2026

1. Two ISA, CRO Phase III Trial, Azia and Europe (1Q2026)
2. TMF Audit (2Q2026)

Courses and Webinars followed 2024-2025

Year 2024

1. RQA Quality Conversation: CSV/CSA Experiences from Both a Validation Expert and Vendor Perspective, 09JAN2024 (one hour Webinar-discussion)
2. RQA Quality Risk Management: Book Purchased-Self reading, 17JAN2024
3. DIA Direct: De-Mystifying AI in Healthcare: Common Challenges AI Can Help Solve, Webinar 18JAN2024 (one hour Webinar-discussion)
4. ICH-GCP Basic Refresher Training, as part of Customer employee training, Webinar 08FEB2024 (three hours Webinar training course)
5. RQA Digital preservation and sustainable access to software and data, Webinar 13FEB2024, (One hour Webinar-discussion)
6. A Joint US-FDA | MHRA-UK | Health Canada Good Clinical Practice & Pharmacovigilance Compliance Workshop on 13 &14FEB2024 (On line seminar-training 16 hours)
7. Completed training Fountayn eCRF database, Modules 01, 02, 03 and 12, (mandatory training) 05MAR2024 (Certificates) (2 hours)
8. RQA Course R4211 Audit Programmes and Risk Assessment, Webinar on 27MAR2024, (7.30 hours Webinar training), Completed, Certificate
9. EFGCP Quality/Ethics Working Party: Workshop 2024, "I think, Therefor I do Clinical Trials", 01JUL2024, (8 hours F2F Meeting), ICH-GCP E6(R3), QbD & Risk Assessment Relationship; Audits of Complex Clinical Trials; SB Trial Oversight; Ethical Considerations; Risk-Based TMFs and Oversight Activities, (Completed)
10. RQA Community, Effective Audit Communication Part 2a, Audit Conduct, Webinar 12AUG2024, (1 hour)
11. RQA Community, Question Time, Webinar, 14AUG2024, (1 hour)
12. IQVIA Technologies, Operational Oversight in Clinical Research: Integrations and Insights, On demand Webinar 19AUG2024 (1 hour)
13. IQVIA Technologies, What eTMF is Right for You?, Live Webcast, 11SEP2024, (1 hour)
14. ARGOS, Workshop Basic AI (Artificial Intelligence), Classroom course, 13SEP2024, (2 hours)
15. Ernst & Yong, EU Pay Transparency Directive Explained webinar, 26SEP2024, (1 hour)
16. RQA Community, Question Time, Webinar 27SEP2024, Artificial Intelligence in Quality (1 hour)
17. RQA Community, Question Time, Webinar 02OCT2024, WHO 2024 Guidance for best practices in clinical trials (1 hour)
18. RQA, Implementing the new UK Clinical Trials regulations, Webinar 15OCT2024, (1 hour)

Docusign Envelope ID: D6EFCAAE-2E0E-4165-B542-3BEE0A70A140

19. RQA, GLP Committee Quality Conversation: Vendor Assessment, Webinar 15OCT2024, (1 hour)
20. 75th WMA General Assembly, Declaration of Helsinki, Finland, October 2024, 25OCT2024, Self-reading, (1 hour)
21. Navigating Generative Artificial Intelligence: Use Cases That Drive ROI, Webinar 29OCT2024, (1 hour)
22. Introduction into Artificial Intelligence VUB/ULB AI Laboratory -EN Session, Class Room Training, 06NOV2024, (8 hours)
23. RQA, GCP ICH E6(R3) Question Time, Webinar 12NOV2024, (1 hour)
24. RQA, GCP Question Time: ICH E6(R3) - Annex 2 Draft, (discussion forum), Webinar 20NOV2024, (1 hour)
25. Brookwood Global, Overview of the draft E6(R3) Annex 2, released for consultation on 15NOV2024, covering additional GCP considerations and in particular decentralized trials, pragmatic and real world data trials, Webinar 21NOV2024, (1.25 hours).
26. Flax House, Ypres Auris Auditorium, Ter Waarde, Artificial Intelligence (AI) Digibank, Class Room Training, 21NOV2024, (1.30 hours)

Year 2025

1. RQA, R5161 Good Laboratory Practice Refresher and Hot Topics, Webinar 18MAR2025, (8 hours)
2. RQA, Hosting an MHRA GCP inspection at an NHS site, Webinar, 13NOV2025, (2hours)
3. RQA, Question Time (monthly), Webinar 17NOV2025, (1hour)
4. DIA, How Leading Global Pharma Embraces AI to Automate Regulatory and Medical Documents with QC, Webinar 17NOV2025, (1hour)
5. DIA, EMA Information Day on submission predictability of initial marketing authorization, Webinar 03DEC2025, (4hours)
6. RQA, GCP - GVP Overlapping Inspections/Audits, Webinar 27NOV2025, (1hour)
7. RQA, The future of Auditing, Webinar 28NOV2025, (1hour)
8. RQA, Question Time (monthly), Webinar 04DEC2025, (1hour)
9. TRENDS Z TV Channel Special: VERBO CQA B.V. pre-selected company for interview: Ode to West-Flanders for local companies (declined participation since Customers are international, (airs on 20-23DEC2025)

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Martial Verschoot 11/25/2025 X
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