CURRICULUM VITAE

Name : Inge van Gasteren
Location : The Netherlands
Website : www.van-gasteren.com
E-mail : Info@van-gasteren.com

Professional career in Clinical Quality Assurance Activities

March 2011 – current **Director of Inge van Gasteren Quality Consulting B.V.**
Current activities covered the following

- QA Manager at CRO for medical devices (2024-current)
- QA support for a biotech company (2023-current)
- QA Manager at a small CRO for statistics, programming and medical writing (2021-current)
- QA support for a Medical Device Company incl. ISO14155:2020 training (2021 - current)
- QA Manager at a Data Management and Pharmacovigilance CRO (July 2020 – current)
- Develop GxP SOPs for start-up biotech company and QA support (2020-2024)
- Various audits for several companies and hospitals (2011 - current)
- Head QA for midsize biotech company in Switzerland (2021-2024)
- Improve QMS for Dutch Children research hospital (2021)
- QA Consultant for CRO for statistics, programming and medical writing (2019-2022)
- Interim Head QA for Swedish company rare long disease (2020-Feb 2021)
- Head QA for Swish start-up biotech company (2018-Feb 2021)
- Set up QMS for CRO Medical Device Studies (2019-2020)
- GCP auditor for a global biotech company involved in Gene Therapy (2017 - 2018)
- Coaching QA officer (2018 – 2019)
- Set up Quality Management System for a CRO involved in Oncology (2018 – 2019)
- Set up Quality Management System for a research institute involved in Africa (2017- 2018)
- Set up Quality Management System for a Dutch research institute (2017)
- Sr. QA Specialist GCP expert for a company involved in Gene Therapy (2016 – 2018)
- Coaching a Project Manager involved in a medical device study (2016 – 2018)
- Provide customized GCP training at several CROs (2015 – current)
- Quality Process Improvement and training on GCP in a Dutch research hospital (2013 – 2016)
- Process audits at Phase I CRO (2011 – 2016)
- Supplier audits for a CRO (2011 – 2016)
- Training on GCP and company SOPs (2011 – 2013)
- Interim Lead QA Manager at a top 10 Pharmaceutical Company (2011 – 2013)
- Process audits at a top 10 Pharmaceutical Company (2011 – 2019)
- SOP revisions for a US Medical Device company (2011)

Lead auditor at various GxP- and ISO14155 audits since 2011 - current:

- Global Full Services CROs qualification-, compliance audits
- Phase I units qualification- and compliance audits
- Post-marketing Pharmacovigilance qualification- and compliance audits
- CROs for Data Management qualification- and compliance audits
- CROs for Pharmacovigilance qualification- and compliance audits
- CROs for Biostatistics and statistical programming qualification- and compliance audits
- Audits at laboratories
- GxP IT Computerized system audits
- Clinical Site compliance audits
- Mock audits (CRO, hospital)

Inge van Gasteren (Feb 16, 2025 09:31 GMT+1)

October 2005 – Dec 2010 :**Astellas Pharma Europe BV, various positions**

- **Associate Director Operational Services**
  - Global Process Improvement
  - Development of Clinical SOPs
  - Training of Clinical and Medical staff
- **Associate Director Clinical Development**
  - Supervision of study managers
  - Process Improvement
  - Training of Clinical and Medical staff
- **Clinical Research Manager**
  - Study Management for multi-national studies in various indications
  - Communication with affiliates, USA and Japan
  - Coaching of Japanese study manager

March 2004 – Oct 2005 **Factory Medical Device CRO, Bilthoven**

- **Project Manager** Clinical Operations
  - Management of international Medical Device studies in different fields
  - Budget management
  - Bi-annually appraisals with Dutch CRAs
  - Development of SOPs
  - Staff training on ISO14155 / GCP and monitoring skills

Feb 2003 – March 2004 **PharmaScope, CRO, Zaandam**

- **International Clinical Research Manager**
  - Start up and management of several phase II, III studies in the Netherlands and Serbia.
  - Management of the Serbia office and staff
  - Co auditing of studies and processes

Sept 1999 – Jan 2003 **Novo Nordisk Pharma, Alphen aan den Rijn**

- **Clinical Research Associate /Trial Manager**
  - Start up and monitoring of various phase II, III and IV studies in diabetic and growth deficiencies
  - Budget management for clinical studies
  - Contact person between Sales department and Medical department

Sept 1997 – Aug 1999 **Lundbeck Netherlands B.V., Amsterdam**

- **Clinical Research Associate**
  - Start up and monitoring an International, multicentre Schizofrenia Post Marketing study working for and directly reporting to headquaters in Denmark

Sept 1992 – Aug 1997 **VERUM MIRAI, CRO, Amsterdam**

- **Several positions** (see below)
  - On-site monitor, outsourced to Solvay Duphar, Weesp, Phase II and IIIa studies in depression trials
  - On-site monitor, VERUM MIRAI
  - Phase III studies for several Pharmaceutical companies
  - DataFax monitor / in-house monitor, VERUM MIRAI
  - Data-entry / project assistant, MIRAI

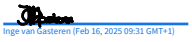
RELEVANT COURSES

Quality Assurance and Regulatory Training:

2025 : ICH GCP E6 (R3) webinar training by Brookwood, UK
2024 : ISO 14155:2020 (trainer)
2024 : General Data Protection Regulation – refresher training (trainer)
2024 : European Clinical Trial Regulation – refresher training (trainer)
2023 : ICH GCP E(6) R2 refresher training (several times as trainer)
2023 : Guideline on computerized systems and electronic data in clinical trials (EMA/INS/GCP/112288/2023), Brookwood
2023 : GAMP-5 training – certified by CIMS, Denmark
2022 : Medical Device Regulation – certified by MyGCP, NL
2022 : Site Suitability Procedure_VGO – certified by DCRF Acadamie, NL
2022 : European Clinical Trial Regulation – certified by DCRF Acadamie, NL
2022 : General Data Protection Regulation (Trainer)
2021 : Webinar ICH GCP (R3) – Ich.org
2021 : ISO 14155:2020 (Trainer)
2019 : ICH E9 (R1) – Author!, NL
2020 : ICH-GCP E6 (R2), ICH E3, ICH E9 refresher training (Trainer)
2020 : Good Pharmacovigilance Practice – EMA GVP modules
2020 : Webinar Inspection Findings (Brookwood, UK)
2020 : Current Data Integrity Challenges in Clinical Trials, COVID19 (Brookwood, UK)
2020 : ISO 14155:2020 by NEN, NL
2019 : ICH-GCP E6 (R2) refresher training (Trainer)
2019 : The Impact of the ISO14155 update on Clinical Research, TRIUM, Be
2019 : The Impact of the new MDR on Clinical Research, TRIUM, Be
2018 : Principles of the General Data Protection Regulation (GDPR), Brookwood, UK
2017 : ICH-GCP refresher training including implementation of ICH GCP R2 (Trainer)
2017 : The impact of dealing with Genetically Modified Organisms (GMO), uniQure, NL
2016 : European QA Conference, Nice, FR
2015 : ICH-GCP refresher training by TAPAS Group, NL
2012 : ICH-GCP training including test, Novartis, NL
2010 : Fraud and Misconduct in Research, Medicolegal-investigations, UK
2010 : ICH-GCP advanced including EU directives, Institute of Clinical Research, NL
2004 : ISO 14155 course, Factory, NL
2004 : Update ICH-GCP course including the directives, Factory, NL
2003 : Practical GCP Compliance Auditing of trials & systems (3 day course), DIA, UK
2002 : Advanced ICH/GCP course, Brookwood, UK
2001 : ICH/GCP course, Brookwood, UK
1996 : ICH-GCP training, VERUM MIRAI, The Netherlands

Clinical Research Training:

2006 : Clinical Development in India, Foreign Exchange translations, USA
2006 : IMPACT training, Astellas, NL
2006 : General EDC training, Medidata, UK
2001 : Impact training, Novo Nordisk Farma B.V., The Netherlands
2001 : Focus training, Novo Nordisk Farma B.V., The Netherlands
1996 : Pharmacology training, VERUM MIRAI, The Netherlands
1995 : Communication training related to on-site monitoring, VERUM MIRAI, The Netherlands
1995 : On the job training by UK Senior Monitor, VERUM MIRAI, The Netherlands
1992 : Basic inhouse course GCP for data-entry, MIRAI, The Netherlands



Management Training:

2006	: Microsoft Projects, Broekhuis, NL
2005	: Working with Japanese, Waterbridge International Limited, NL
2001	: Communication training, Targa, The Netherlands
2000	: Time management training, Novo Nordisk Farma B.V., The Netherlands
2000	: PSSIII sales training, Novo Nordisk Farma B.V., The Netherlands
1998	: Communication training, H.Lundbeck A/S, Denmark

EDUCATION

2006 – 2007	: Middle Management	- NEMAS, The Netherlands, qualified
1996 – 1998	: Sport Massage	- NGS, The Netherlands, qualified
1994 – 1995	: Primary Medical Knowledge	- LOI, The Netherlands, qualified
1990 – 1992	: Chemical Engineering	- Polytechnic University, The Netherlands
1989 – 1990	: Atascadero High School	- California, USA , qualified
1985 – 1989	: HAVO	- The Netherlands, qualified

MEMBERSHIP

DARQA (Dutch Association for Quality Assurance) including active member of GCP group

SKILLS

Languages:	Dutch	: Native speaker	Computer:	SharePoint, TEAMS
	English	: Fluent		Word, Excel
	German	: Workable knowledge		PowerPoint
				Electronic Data Capture, various systems

Personal:
Loyal team worker
Flexible
Good organisation skills
Practical
Good communication skills

Inge van Gasteren (Feb 16, 2025 09:31 GMT+1)

16-Feb-2025

CURRICULUM VITEA

Final Audit Report 2025-02-16

Created:	2025-02-16
By:	I.M van Gasteren (info@van-gasteren.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAEVZIHESwYVlpDECRxPAe54r_o6yciXnd

"CURRICULUM VITEA" History

Document created by I.M van Gasteren (info@van-gasteren.com)
2025-02-16 - 8:30:09 AM GMT- IP address: 188.89.195.38

Document emailed to Inge van Gasteren (inge@van-gasteren.com) for signature
2025-02-16 - 8:30:13 AM GMT

Email viewed by Inge van Gasteren (inge@van-gasteren.com)
2025-02-16 - 8:31:00 AM GMT- IP address: 66.249.81.133

Document e-signed by Inge van Gasteren (inge@van-gasteren.com)
Signature Date: 2025-02-16 - 8:31:46 AM GMT - Time Source: server- IP address: 188.89.195.38

Agreement completed.
2025-02-16 - 8:31:46 AM GMT