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. (IGQC B.V)**
Current activities covered the following

- GCP Head QA for midsize biotech company (2021-current)
- Develop GxP SOPs for start-up biotech company and QA support (2020-current)
- Improve QMS Medical Device Company incl. ISO14155:2020 training (2021)
- Improve QMS for Dutch Children research hospital (2021)
- QA Consultant for CRO Data Management and Pharmacovigilance Projects (2018-current)
- QA Consultant for CRO for statistics, programming and medical writing (2019-current)
- Audits for several companies (current)
- 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 clinical research in Oncology (2018 – 2019)
- Set up Quality Management System for a research institute involved in research 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 Quality Assurance Management at a top 10 Pharmaceutical Company (2011 – 2013)
- Process audits at a top 10 Pharmaceutical Company (2011 – current)
- 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)
- Pharmacovigilance CROs (qualification- and compliance audits)
- CROs for Data Management (qualification- and compliance audits)
- CROs for Biostatistics and statistical programming (qualification- and compliance audits)
- Audits at laboratories
- Computerized system audits
- Clinical Site audits (compliance audits)
- Sponsor audits (internal audits)
- Mock audits (CRO, hospital)

Inge van Gasteren (Apr 2, 2022 17:33 GMT+2) Apr 2, 2022

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

Inge van Gasteren Apr 2, 2022 17:33 GMT+2

RELEVANT COURSES

Quality Assurance and Regulatory Training:

2021 : Webinar ICH GCP (R3) – Ich.org
2021 : ISO 14155:2020 (Trainer)
2020 : ICH-GCP E6 (R2), ICH E3, ICH E9 refresher training (Trainer)
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

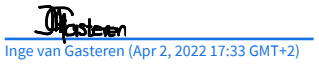
Inge van Gasteren (Apr 2, 2022 17:33 GMT+2) Apr 2, 2022

MEMBERSHIP
DARQA (Dutch Association for Quality Assurance)

SKILLS

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

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


Inge van Gasteren (Apr 2, 2022 17:33 GMT+2)

Apr 2, 2022

20220402_CV Inge van Gasteren

Final Audit Report 2022-04-02

Created:	2022-04-02
By:	I.M van Gasteren (info@van-gasteren.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAASUZK6OzhrDG2o-z49l-UFhF4X0SLAXQc

"20220402_CV Inge van Gasteren" History

Document created by I.M van Gasteren (info@van-gasteren.com)
2022-04-02 - 3:30:31 PM GMT- IP address: 84.85.223.76

Document emailed to Inge van Gasteren (inge@van-gasteren.com) for signature
2022-04-02 - 3:32:31 PM GMT

Email viewed by Inge van Gasteren (inge@van-gasteren.com)
2022-04-02 - 3:32:46 PM GMT- IP address: 66.249.81.145

Document e-signed by Inge van Gasteren (inge@van-gasteren.com)
Signature Date: 2022-04-02 - 3:33:41 PM GMT - Time Source: server- IP address: 84.85.223.76

Agreement completed.
2022-04-02 - 3:33:41 PM GMT