Maarten Nas GmbH
Clinical QA Consultancy & Auditing Services

Curriculum Vitae

PERSONAL

Name:	(Maarten) Cornelis Martinus NAS
Nationality:	Dutch

EDUCATION

1987 – 1993	ST. RADBOUD UNIVERSITY, Nijmegen, The Netherlands. MSc Degree in Medical Biology
1992 – 1994	ACADEMIC HOSPITAL ST. RADBOUD, Nijmegen, The Netherlands. Alternative Military Service; Department of Gastro-Enterology, Internal Medicine

LANGUAGES

Dutch:	native
English:	fluent
German:	intermediate
Spanish, French:	basic

Memberships	RQA (former BARQA), European Forum GCP work-party Clinical QA

BUSINESS EXPERIENCE

Summary

More than 18 years of experience in both global pharmaceutical company and CRO industry. Management of worldwide acting clinical QA function in different settings. Initiate and lead continuous process improvements. Detailed knowledge of GCP, GLP, GPvP and Clinical Regulations in US and EU and general Quality Management. Demonstrated ability to effectively interact with Competent Authorities. Excellent leadership and communication skills. Strong drive for results and problem solving skills with solid scientific background. Commitment to teamwork and flexibility.

Auditing: independent review of systems/data according to internationally accepted standards for Investigational Product and Medical Device (e.g. study audits, system audits, protocol/report audits, CSV validation audits GAMP5)

QA Support: Assistance, consultation and guidance on subjects involving quality, ethical and regulatory issues

Compliance: Co-monitoring visits, TMF checks, inspection preparations

Training: Coaching, teaching and instructing on GCP and GPvP, Quality Management, Clinical Operations, Inspection and Auditing

Inspection experience

Directly involved in hosting inspections (more than 50) from FDA, EMA, MHRA, IGZ, DKMA, AFSSAPS, ANVISA, BfArM etc. on PV and GCP (sponsor, vendor and site inspections)

Key areas of competence

- Clinical: Clinical studies Phase I-IV, Bioequivalence, Pharmacovigilance, Data Management, Project Management, Monitoring, Archive/Document Management, Central Laboratories, Central Reading Services, e-Trails/IVRS.
- Pre-Clinical: Toxicology, Pharmacology, Pathology, Central Laboratories
- IT Validation: validation of computerised systems for clinical/pre-clinical, vendor audits
- Risk-Based Approach in Audit and Compliance, including trend analysis and strategy setting
- Setting up structures and processes for study/vendor oversight, escalation and Serious Breach internal review
- Expert GCP and GPvP knowledge
- Inspection Preparation, Handling and CAPA resolution
- Planning, conduct and reporting of Audits
- Line Management

MAARTEN NAS GmbH Independent Consultant for Clinical QA and Auditing
Jul 2014 –

- Planning, conduct and reporting of audits in GCP, GcLP, GPvP and IT validation
- Clinical QA services
- Compliance activities, e.g. co-monitoring, TMF reviews
- Inspection preparations and handling
- Risk assessment
- Training in GCP, GLP and GPvP

SANDOZ INTERNATIONAL GmbH, Holzkirchen, Germany
Sept 2011 – Jun 2014 **Head Global Clinical Quality Assurance**

- Build up and maintain a functional global, regional and local CQA structure and organisation
- Liaise with stakeholders globally
- Strategic goal setting
- Develop strategy for pre-, during and post-inspection activities
- Identify gaps and deficiencies, perform root cause analysis, propose corrective/preventative actions and support timely resolution
- Set-up and maintain global operating procedures aligned with Novartis Quality Modules
- Set-up and maintain links to global training group and global audit/compliance group
- Expert GCP support and consultancy advice function
- Set-up and maintain budgets and timelines
- Line-Manager for 3 direct and 20 indirect Clinical QA Managers

GENZYME EUROPE BV, Naarden, The Netherlands
2010 – Sept 2011 **Senior Director Corporate Audit Management – Pharmacovigilance Systems**

- Set-up new global group for QA Strategy specific for safety systems (QMS, Training and Auditing)
- Liaise with stakeholders globally & strategic goal setting
- Set-up and maintain budgets and timelines
- Set-up and maintain risk-based approach to PV Systems audits
- Official represent the company during inspections
- Peer review audit reports

- Trend analysis and focus setting for safety compliance
- Line-Manager for 6 global FTEs

2009 – 2010 **Director Quality Systems Europe**

- Head of Department Quality Systems Europe (25 FTEs), consisting of Training & Education, Compliance/Process Improvement-group and QA-Helpdesk
- Liaise with Senior Management within EU and USA
- Strategy of QA within company
- Set-up and maintain budgets and timelines
- Officially represent the company during inspections
- Review and approve system improvement projects
- Peer review audit reports
- Trend analysis and focus setting for compliance

2008– 2009 **Director BMRA Quality Systems & Compliance**

- Line-Manager for 6 QA Auditors, 2 System Consultants, 2 Senior Managers and 1 Group Assistant
- Strategic goal setting
- Set-up and maintain budgets and timelines
- Liaison with international QA departments

2005 – 2007 **Associate Director Compliance**

- Line-Manager for 4 QA Auditors, including appraisal, review of audit reports, competency mapping, training and education

2004 – 2005 **Senior QA Auditor**

- Planning, conducting and reporting of Investigator's Site Audits, Internal Audits, Country Audits and Vendor Audits

ASTRAZENECA BV, Zoetermeer, The Netherlands

2002 – 2003 **Clinical Process Manager**

- Internal QC/QR & Writing local SOPs and templates
- Certified Trainer

2000 – 2002 **Clinical Project Leader**
2 oncology trials (phase II and III)

NOVARTIS PHARMA BV, Arnhem, The Netherlands, Lead CRA

1998 – 2000 5 pulmonary trials (phase I, II and III)

1996 – 1997 **INNOVEX/QUINTILES, Hoofddorp, The Netherlands**
CRA/Clinical, Trial Manager

1994 – 1996 **CITY OF NIJMEGEN, The Netherlands, Social Public Service**

- Intaker and Financial Service Provider