Curriculum Vitae

Personal data:

Family name:	Marsman
First name:	Cor (Cornelis)
Date of Birth:	23-12-'61
Nationality:	Netherlands
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Relevant education:

	Period:	
Study:	1990-'93	Human Biology, Neurosciences; MSc
Institute:		Free University; Amsterdam
Study:	1978-'82	HBO-a (BSc) Clinical chemistry/ Lab technician
Institute		Bakhuis Roozeboom instituut Beverwijk

Summary

Cor Marsman is a very experienced consultant and project manager. He has broad experience with interim QA management and is a proficient manager to a team of employees. Cor is "straight forward" and a nice person to work with.

Relevant Courses:

Year:	
1995	GMP (for middle management)
1995	Leadership (voor middle-management)
1998	European Guideline on a vigilance system for Medical Devices
2000	Auditing; KDI
2001	Validation of Pharmaceutical processes
2005	QP; role & responsibilities
2009	GCP auditing
2012-2013	Green Belt Lean/ Six Sigma

Personal interests/ hobbies:

Archery
Motor cycling
DIY
Fine cooking

Career:

2011-today **Progress-PME; Amsterdam**

Project Manager/ Consultant/ QP

- Several consultancy assignments at (bio-) pharmaceutical production companies;
- Interim QA management; QA operations; mid-size international company; reorganisation of QA department and assure continuation of commercial processes and QA activities related to those.
- Support QA development department; setting up the department and support in defining quality systems needed for development activities, clinical trial productions and preparation for marketing authorisation related to development of viral vaccines on cell culture. Implementing and maintaining a validation strategy and policy.
- QA support; defining improvement proposals for review processes
- QA support; defining proposals for improvement of quality systems related to an aseptic fill line
- Defining qualification and validation requirements for refurbishment and re-commissioning of a previously shut-down aseptic fill line
- QA support for qualification criteria and protocol preparation for new facilities; e.g.: hospital pharmacy and vaccine production site
- QA support at different companies; amongst others: assembling PQR documents and API production
- Execution of audits (lead auditor) and review of audit reports
- QC support; defining material specifications en improvement of incoming material control system
- Registered as additional QP for one of Progress-PME's customers

2008-2011 **Kiadis Pharma B.V; Amsterdam**

Director QA

- Batch review and release (sponsor's release) of Investigational Medicinal Product.
- Design, implementation and management of quality systems; including contract production and contract clinical investigation.
- Review of Quality System documentation, protocols and reports.
- Review of protocols and reports concerning product and process development, including tech-transfer of activities
- Implementing and maintaining a validation strategy and policy.

- Organisation and execution of quality audits, internal
- Organisation and execution of quality audits, external; supplier qualification program.
- Responsible for evaluation of project plans
- Ensure compliance to company licenses of own company and contract partners against GxP guidelines and regulations.

Specifics/ achievements:

- Complete re-vamp of quality system; from ISO-medical device based system to a GxP based system suitable for sponsorship and development laboratory. System also simplified to necessary processes only, all ballast removed.
- Specific process developed for Identification and traceability of products.
- Specific process developed for Use of non-conform product under special exemption regulation.
- Review and release planning initiated to ensure timely release of our products in line with the clinical trial plan.
- Organisation awareness created for requirements for manipulated cellular products.
- 1 Direct report.

2006-2008 **Solvay Biologicals BV; Weesp**

QA-manager Production bulk Influenza Vaccines/ Qualified Person

- Recognised as Qualified Person (**QP**) for the activities and bulk products related to the vaccine production of Solvay Biologicals BV.
- Review and release of bulk pharmaceutical product (influenza vaccine), starting materials, master- and working virus seeds, as well as master- and working cell banks.
- Review of validation protocols and reports and co-responsible for implementing and managing Solvay Biological's process validation policy and strategy.
- Responsible for providing advice to internal organisation and direct relations on GMP and organisational efficiency-issues.
- Organisation and execution of quality audits, internal.
- Organisation and execution of quality audits, external; supplier qualification program.

Specifics/ achievements:

- Member of the Quality Management Team and of the Management Team Manufacturing.
- Improvement project initiated for review and release planning.
- Enhanced organisation awareness on need for 'second' suppliers for critical raw materials
- Enhanced organisation awareness of requirements for process validation of the vaccine production based on cell culture. Co-responsible for defining validation strategies and writing Validation Master Plan

- Lead for organisation of audits by regulatory authorities (Dutch-IGZ, US-NIH, Brasil-Anvisa)
- 5 direct reports and additional –project based- 3 temporary employees

2001-2006 **DSM-Biologics; Groningen**

Function: QA Compliance manager/ Qualified Person

- Authorised to act as Qualified Person (**QP**) for the activities and bulk products related to the production activities and bulk pharmaceutical products of DSM Biologics; as of January 2005.
- Review and release of bulk pharmaceutical product (Biopharmaceutical/ biotechnology products), starting materials, master- and working master- and working cell banks.
- Review of validation protocols and reports.
- Review and evaluation of project plans and ensuring compliance to company licenses, guidelines and regulations.
- Responsible for ensuring GMP internally and advise direct relations concerning relevant GMP-matters.

Specifics/ achievements:

- Enhanced organisation awareness of requirements for process validation of different biotech production lines. Co-responsible for defining validation strategies and writing Validation Policy and plans
- QA guidance for the technical upgrade and validation of the prokaryotic production unit; after recognition of major design errors in the installation for fermentation and primary upstream processing
- QA guidance for the technical upgrade and validation of the HVAC system of the prokaryotic production unit; system aligned with requirements for GMP and BSL-2 activities
- QA guidance for the technical realisation and validation of an extension in the downstream processing facility; building and qualification of a new set of clean rooms
- Improvement project initiated for review and release planning. Release throughput time for prokaryotic products reduced from 4 months to 4 weeks
- Acted as direct QA contact for contract partners of DSM Biologics
- 2 Direct reports and additional –project based- 2 temporary employees

1998-2001 **NPBI International BV / Fresenius Hemocare; Emmer-Compascuum**
Function: Complaint manager/ assistant QA manager

Tasks/ responsibilities:

- Responsible for release of medical devices and bulk pharmaceutical products.
- Responsible for receipt, acceptance, evaluation, analysis and answering customer complaints.
- Responsible for initiation of improvement processes; management of corrective and preventive actions.
- Delegate QA manager for transfusion products.
- Responsible for design and execution of several external projects outside the company premises in Emmer Compascuum.

Specifics/ achievements:

- Complaint reporting and response system improved
- QA guidance provided in improvement projects
- Involved in design plus implementation of an ISO Quality system at the blood bank Leiden-Haaglanden.
- QA guidance provided for transfer of QA department of a Fresenius plant in St. Wendel (Germany) to Emmer-Compascuum (the Netherlands)
- 2 Direct reports and additional –project based- 2 temporary employees

1993-1998 **Blood bank Noord Nederland; Leeuwarden**
Function: Department manager for Production and logistics

Main tasks/ responsibilities:

- Daily management of a department of ±10 regular employees and 10 part time or temporary employees.
- Responsible for correct execution of defined procedures.
- Responsible to ensure quality of processed blood products, including small scale production of Factor-VIII from human plasma.
- Responsible for stock control and delivery services.
- Review and release of production and logistic SOP's.
- Responsible for implementation and management of a Bone Bank.

1982-1990 **Gemini, general hospital; Den Helder**
Function: Lab technician clinical laboratory

Main tasks/ responsibilities:

- All types of Analysis, related to chemical, haematological and immunological investigations.
- Responsible for training of new employees and students.