PERSONAL PROFILE

CONSULTANCY

Maria Wilhelmer, Ing
Senior QA Consultant

Maria has over 2 decades of experience as a scientist and quality professional. She has been an independent consultant to more than 50 pharmaceutical companies over the last 20 years.

Her experience spans multiple disciplines, including quality systems and quality operations, aseptic processing, analytical and process development, and distribution.

Maria enjoys improving processes and quality systems and establishment of Quality Oversight. She has been certified in Lean + Six Sigma Green Belt.

Johanna Westerdijkstraat 48
2331 MZ Leiden
The Netherlands

+31 6 411 93 075
info@qaconsultancy.nl
www.qaconsultancy.nl

Kvk 28103201
Btw NL002406352B95

SIMPLIFIER
STRUCTIFIER
CLEARIFIER

EFFICIENT

SYSTEMS
COMMUNICATION
ORGANISATION

POI

Field of Expertise

Results

Talents

Skills

Process Improvement
Crisis Management
Quality Agreements
Creating Quality Oversight
GMP Coaching
~~Training and Validation~~ MAWI 08SEP2022

YOU CAN WAKE ME UP FOR THIS!

International Organizations
Biopharma
Generics and API
Wholesalers
Start-ups

Profitable Processes
Pragmatic Solutions
Quality Oversight

Operational Excellence Award 2022

Quick thinking
Abstract Intuition
Connecting
Goal oriented
Attention to detail
Problemsolver

Dutch / English / German
Lean-6-Sigma - Green Belt (2017)
Responsible Person (2016)
Aseptic Techniques
GMP / GDP

BIOSYNTH · Fagron personalizing medicine · DYNAVAX · NOVARTIS · Pharming · Sanquin · teva · Bilthoven Biologicals Cyrus Poonawalla Group · actavis · Universiteit Leiden

CONSULTANCY

since 2007

QA Consultancy
SINCE 2007

Hands on quality professional, target driven and goal oriented, without losing attention to detail.
All aspects of manufacturing (clinical & commercial), testing, R&D, Quality Assurance and Management.

Roles
- Improvement Specialist
- Director Quality Assurance (CMO)
- Senior QA Consultant
- Job Coach
- QA Manager
- Senior QA Officer
- QA Project Associate
- Production Manager
- QA Officer R&D (DQA)
- Project Leader

Tasks
- Product launch including development of related processes, as falsified medicines, recall, product defect & product complaint
- Generate quality oversight and compliance
- GAP analysis and reporting
- Process improvements, companywide
- Quality agreements backlog remediation and management
- Leading various sized teams (3-16 fte)
- Commissioning of a new production facility
- On the job coaching GMP / GDP
- Unrolled various new and improved processes: QA, QC, production, warehouse
- Quality systems and quality operations backlog remediation and management
- Revision and rebuilding of documentation systems
- Inspection preparation and support for various markets (GMP – EU / US and GDP)
- Audit and inspection observations remediation, integration and management
- General backlog remediation and management
- Batch record review clinical and commercial
- Batch record development clinical and commercial
- Warehouse and transport validation

228 Quality Agreements

142 Renewed improved Processes

54 Organisations

18 Inspection Preparations

Employee
1998 - 2006

- PQR, document and process improvement
- Setting up a monoclonal laboratory (R&D)
- Setting up a microbiological testing laboratory (GMP)
- Routine virus testing on influenza bulk, R&D Hybridoma and cell culturing