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 40 pharmaceutical companies over the last 15 years.

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

Maria enjoys building quality systems, preparing inspections and improving processes. She has been certified in Lean + Six Sigma Green Belt.

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SIMPLIFIER
STRUCTIFIER
CLEARIFIER

EFFICIENT

SYSTEMS
COMMUNICATION
ORGANISATION

POI

Field of Expertise

Results

Talents

Skills

Process Improvement
Crisis Management
Quality Agreements
Creating Quality Oversight
Inspection Preparation
~~Training and Validation~~

YOU CAN WAKE ME UP FOR THIS!

International Organizations
Biopharma
Generics
Wholesalers
Start-ups

Profitable Processes
Pragmatic Solutions
Order and 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

DYNAVAX · NOVARTIS · Pharming · Sanquin · teva · Bilthoven Biologicals Cyrus Poonawalla Group · actavis · MSD · Jeroen Bosch Ziekenhuis · 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)
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

214
Quality Agreements

124
Renewed improved Processes

50
Organisations

17
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