Personal details

Ir. José Houtman

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General

José is an experienced self-employed quality consultant in the pharmaceutical industry. Since 1995, she has worked in sterile (vaccine) and drug manufacturing facilities, as well as API plants and CMOs, including Bilthoven Biologicals, Patheon, MSD, Solvay Pharmaceuticals (currently Abbott), and Fort Dodge Animal Health. She has also worked with several other prominent organizations, including SVM, the Dutch Vaccine Institute, Octoplus, Crucell, Centocor, AMT, Nobilon, XCTM (a joint venture between Xendo and UMCG), Sanquin, Viropharma, Astellas, and LAB Ofichem. Since 2021, she has served as a Qualified Person at Centrafarm, where she oversees batch release and certification.
José's technical education in bioprocess technology enables effective communication with technical departments, R&D, and production teams, as well as providing valuable technical insight into (biological) manufacturing processes. Over the course of her career, she has acquired a broad range of pharmaceutical knowledge and skills and has become deeply familiar with the implementation of quality in pharmaceutical manufacturing.

As a self-employed consultant since 2008, she offers her clients a wealth of experience and expertise in quality assurance and pharmaceutical manufacturing. She has a particular strength in her role as a Qualified / Responsible Person, ensuring regulatory compliance, efficient quality management, CMO management and continuous improvement across all operations.

Experiences

- **Batch Release and Certification:** Reviewing, releasing, and certifying drug product batches (all dosage forms including sterile) manufactured worldwide and marketed in the Netherlands, ensuring compliance with Annex 16, importing products in accordance with Annex 21.
- C**ontinuous Improvement of manufacturing processes:** Thorough root cause investigation and implementation of a functional, effective CAPA system decreasing the number of deviations and improving robustness of processes.
- **Quality Management Systems:** Implementation and continuous improvement of systems for Deviations, CAPAs, Change Control, Complaints, PQR's, Auditing, Environmental Monitoring, and Media fill.
- **Regulatory Compliance:** MA compliance, extensive, thorough and up-to-date knowledge of GMP, GDP, and related guidelines. Direct contact with RA and operational sites for transfers, and changes to assure product compliance.
- **Efficiency Improvement:** Enhanced QA department and interdepartmental workflow efficiency by improving communication and implementing key performance indicators (metrics) using a Lean approach.
- **CMO Management:** Managing quality in product development, commercial production, transfers and investigation at CMO's worldwide, supplier qualification.
- **Audit and Inspection Management:** Leading (self-)inspections as lead auditor and representing the company during audits and inspections, including plant preparations for FDA inspections and conducting FDA GMP gap analysis and follow-up.
- **Regulatory Collaboration:** Worked closely with the regulatory department to ensure compliance of all activities to MA, regulatory requirements and guidelines.
- **Project Management:** Managing QA & release departments and overseeing QA & Production projects (Manufacturing & Packaging).

Business experiences:

- **QP | Centrafarm (2021- 2025)**
  Batch certification for Dutch market and all related activities, interaction with CMO's

ALLIONE
2008-current

worldwide, qualifications, audits, GMP Compliance, regulatory compliance.
Training and supporting Responsible Persons in their tasks and GDP regulations.

- **QA Specialist | InnoCore**
  Designing QMS for CDMO based on ISO-9001:2015
- **QA Specialist | Centrafarm**
  Managing PQS, including PQR management, self-inspections and external audits & inspections.
- **QA Compliance Specialist and Operational Manager of QMS | Bilthoven Biologicals**
  Ensuring compliance for all manufacturing plants.
- **QA Compliance Manager / Quality Product Lead | Patheon (Thermo Fisher Scientific)**
  Quality Investigation & Improvement cross-functional teams.
- **Pharmaceutical Specialist (Manufacturing Pharmacist) | MSD**
  Support QMS in a Sterile manufacturing.
- **QA Manager API Plant | LAB Ofichem**
  Responsible for API release, QMS management, and managing compliance and validation.
- **QA Projects Manager Pharmaceuticals | Astellas**
  Improved control systems and validation at packaging lines, led compliance projects, and enhanced QMS tools.
- **Validation Manager Pharmaceuticals | Astellas**
  Drug manufacturing process and system validation.
- **QA Consultant | Sanquin & Viropharma**
  Conducted gap analysis of QMS.
- **Interim Manager Sterile Manufacturing at a CMO | XCTM**
  Start-up of a clinical trial material manufacturing.
- **Tech transfer consultant | XCTM**
  Managed tech transfer of sterile biological processes from development to GMP manufacturing at a CMO.
- **Interim QA Manager at Human and Veterinary Vaccine Manufacturer | Nobilon**
  Managing QA department of sterile manufacturer.

Xendo Pharma Services – Leiden
Sr project associate
2001-2007

- Managing of validation studies (process, equipment, utilities).
- Training and implementation of QA systems (GMP/GLP).
- Interim-management QA-systems.
- Interim production management.
- Internal & external auditing.
- Review of CMC-files.
- Managing and implementation of courses.

Further business experiences:

- **1999 – 2000** | **Sichting tot bevordering van de Volksgezondheid en Milieuhygiëne (SVM) – Bilthoven** - Business Unit Manager Production associate
- **1996 – 1999 | Solvay Duphar Weesp/Fort Dodge -** Analyst Bacteriology, tech transfer fermentation process
- **1995 – 1996 | Solvay Duphar Weesp** – development analyst humane influenza vaccine support and aftercare.

Key Skills and Attributes

- **Continuous Improvement:** Focused on the continuous improvement of people, departments, and processes (Lean & Six Sigma).
- **Hands-On Mentality:** actively engaging with operational processes, identifying practical solutions on the work floor, and translating insights into effective, GMP-compliant improvements.
- **Motivational & Natural Leadership:** Naturally inspiring and guiding teams, recognizing individual strengths, encouraging open collaboration, creating an environment where people feel empowered to perform at their best.

- **Strong interpersonal and relationship building skills**: easily accessible even in an online environment, active listener, effective collaborator and ability to switch quicky.

Education and Technical Skills

- **Technical Education:** Background in bioprocess technology, facilitating effective communication with technical departments, R&D, and production.
- **Technical Insight:** Strong understanding of (biological) pharmaceutical manufacturing processes.
- **Pharmaceutical Knowledge:** Comprehensive knowledge and skills acquired over years in the pharmaceutical industry, integrating quality into every aspect of pharmaceutical manufacturing.

Education incl. traineeship

1992 – 1995	**Wageningen University of Agriculture -** Bioprocess technology, including 6 months internship @Hofmann La Roche Basel, Swiss.
1988 – 1992	**Hogeschool Rotterdam en Omstreken (HR&O) -** Biotechnology
1982 – 1988	**Het Nederlands Lyceum - The Hague -** V.W.O.

Courses

- CMO management (12-2025 – ECA)
- QP Forum 2024 - IMP pre-conference & workshops (11-2024 - ECA)
- ATMP seminar (09-2024, DARQA)
- GMP & GDP 3 daagse (03-2024, Pharmatech)
- Good Distribution Practices (04-2021, Pharmatech)
- Quality Management in Pharma and Biotech (2020, PAO Pharmacy).
  - The role of the Qualified Person in the Pharmaceutical Industry.
  - Drug development from quality by design to clinical studies.
  - Sterile manufacturing: sterile assurance challenges.
  - Quality and safety for the manufacturing of biopharmaceuticals.
- Black Belt (Lean, Six Sigma & DoE) (2017, Maruna).
- GMP Compliant Product Transfer (10-2014, ECA).
- Effective Pharmaceutical Audits and Self-Inspections (11-2011, DBA).
- Risk based decision making for Quality Professionals and QP's (11-2010, DBA).
- Pharma Quality Excellence (11-2010, ECA).
- Pharmaceutical areas and HVAC /Pharmaceutical waters and steam.
- Pharmaceutical Filtrations /Tangential Flow Filtration.
- Cleaning Validation.
- Computer Validation / GAMP4 & 21 CFR part 11.
- Microbiology for non-microbiologists.
- Validation & Qualification.
- Guidances, registration and inspections.
- Scaling-up and technical transfer of a chromatographic purification process.

Languages

Dutch	native
English	fluent
German	fluent