# CURRICULUM VITAE

## KIM TANG HVISTENDAL

**Name:**
**Kim Tang Hvistendal**
**Senior Consultant, Pharmac**

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### *Summary*

More than 20 years' experience within the pharmaceutical industry, e.g. GDP and Supply Chain Management, Solid Dosage commercial manufacturing and packaging operations in a cGMP environment, QA and compliance support.
Overall responsible in various companies for the management and coordination of all clinical supplies from small phase 1 clinical studies up to big budget, global phase 3 clinical studies.
Department responsible during inspections by the Danish Health Authority and the FDA. Further, executed +15 CMO/vendor GMP and GDP audits at external partners, ranging from initial qualification audits to regular bi-annual and for-cause audits.

### *Current position*

**2019 – present: Senior Consultant – Pharmac**
Consultancy expertise within CMC and Quality Assurance support, GDP and distribution, commercial manufacturing and packaging operations, Outsourcing and Supply Chain support, Clinical Trial Supplies, IRT systems, GCP and Clinical Operations support.

### *Previous Positions*

**2017 – 2019: Senior Clinical Trial Supply Manager – Zealand Pharma A/S**
Responsible for implementing a new Clinical Trial Supply Department.
Define optimal clinical packaging and blinding needs for each project and clinical phase. Secure implementation of appropriate clinical supply management systems.
Drive the selection process and qualification according to GDP and GMP of clinical contract packagers, distribution depots and IRT providers.
Drive the setting up and maintenance of a quality system (SOPs) for clinical trial supply procedures: e.g. Label text procedures, Clinical Trial Supply Plan (CTSP), shipment procedures, IRT Systems SOP, Inventory and Returns procedures.

**2016 – 2017: Senior Consultant – Pharmac /PharmaSultant AB**
Consultancy expertise within Clinical Trial Supplies, IRT/CTMS systems, Outsourcing and Supply Chain support, commercial manufacturing and packaging operations, CMC and Quality Assurance support, GCP and Clinical Operations support.

**2014 – 2016: Director, Technical Operations - Veloxis Pharmaceuticals A/S**
Managing the logistical operations planning of the Envarsus® commercial material manufacturing at our CMO (EU and US markets).
Extensive experience with Technical Operations processes:
Development and updating of product and packaging Master Batch Records and

Product Specifications.
Hands-on manufacturing support e.g. Batch Record review, Change Request, Deviation handling. Ensure execution of ongoing product GxP investigations.
Support the maintenance of the Veloxis Quality System e.g. procedures, SOPs.
Development of supplier contracts, Technical and Quality agreements.
Materials, API and new excipients sourcing incl. specification development and approval.

**2009 – 2014: Director, Clinical Supply - Veloxis Pharmaceuticals A/S**
Department head, managing a team of direct reports. Overall responsible for the management of the clinical supplies need in all Veloxis sponsored clinical studies.

**2008 - 2009: Manager, Clinical Supply Europe - LifeCycle Pharma A/S**
Responsible for implementing a new Clinical Supply Department incl. CMO/vendor management procedures. Responsible for all CSM department and clinical supply project related budgets.

**2006 - 2007: Clinical Supplies Coordinator -Novo Nordisk A/S**
Part of the Locals-group within Clinical Supplies Coordination. In Nov 2006 transferred to phase III studies within the Biopharm-group.

**1999 - 2006: Principal Technician - Novo Nordisk A/S**
Technician within Solid Dosage Forms Pilot Plant. Responsibilities included: Development and up scaling of new solid dosage forms to be used for clinical testing. GMP-production, technical expert on compression technologies and other solid dosage forms processes. Responsible for the SDF Pilot Plant's GMP-facility.

**1994 - 1999: Technician - Ferring A/S**
Commercial scale manufacturing in GMP facility. Extensive experience with following processes; fluid-bed and extrusion granulation, blending processes, tableting, tablet film-coating.

## *Education*

**2016 – 2020(est.):**

Master of Industrial Drug Development
University of Copenhagen, Denmark
2018: Chemical Process Development and Production of Active Pharmaceutical Ingredients (API)
2018: Discovery and Development of Medicines
2017: QA, QC, GXP for Pharmaceutical Production
2016: Drug Regulatory Affairs in Drug Development
2016: Drug Formulation and Delivery

April- May 2017:
Lead Auditor – QMS ISO 9001:2015,
FORCE Technology – Kolding, Denmark

1986 - 1988:
Laboratory Assistant,
Esbjerg Tekniske Skole, Denmark

## *Courses*

2019:
Good Distribution Practice
Whitehall Training – On-line, UK

2017:
Phase Appropriate GMP's for IMPs,
Karen Ginsbury - Copenhagen, Denmark

2016:
Procesvalidering,
Pharmakon – Horsholm, Denmark

2015:
GMP Updates, Karen Ginsbury
IFF – Copenhagen, Denmark

2013:
Outsourcing Pharmaceutical Operations
CfPA – Amsterdam, Holland

2009:
Basic cGMP Training
LifeCycle Pharma – Copenhagen, Denmark

2008:
Conducting Clinical Trials under ICH GCP
Barnett International – New York, USA

2007:
Preparation, Packaging and Labelling of Clinical Trial Materials
CfPA – Amsterdam, Holland

2006:
Fundamentals of Clinical Research & GCP
Brookwood International Academy – Copenhagen, Denmark

2005:
cGMP Interpretation and Application
Novo Nordisk A/S – Bagsværd, Denmark

2005:
Granulation, Tabletting and Capsule Technology
CfPA – Boca Raton, Florida USA

## *Other relevant experiences*

### *Conference presenter*

**2014:**

Clinical Supply Europe conference – topic: "*Key Considerations When Outsourcing"*
Pharma IQ – Frankfurt, Germany

### *Seminars*

**2018:**

Clinical Trial Supply Europe
Arena-International - Milano, Italy

**2012:**

Clinical Supply Seminar
IQPC – Basel, Switzerland

**2010:**

Clinical Trial Supply Conference
Arena International – London, England

## *Languages and Computer skills*

Danish - speaks and write on business negotiation level.
English - speaks and write on business negotiation level.
Swedish - speaks fluently.

Microsoft suite - Word, Excel, Power Point, Project, Outlook, Visio.
Oracle Interactive Response Technology (IRT) – super user.
Perceptive Informatics IV/WRS – user
iMedidata Balance (IRT) – user