PHARMAC

CURRICULUM VITAE

KIM TANG HVISTENDAL

Name: Kim Tang Hvistendal
Date of Birth: 14-July-1968
Contact info:
E-mail: kth@pharmac.dk
Mobile: +45 5121 0377

Summary

20 years' experience within the pharmaceutical industry, e.g. commercial product manufacturing and packaging operations in a cGMP environment, clinical supplies management, commercial supply forecasting and planning.
Extensive experience with outsourcing of all parts of the supply chain e.g. GMP production, packaging operations and distribution activities, IRT services, label text translation services etc.
Long proven managerial track-record; CMOs, CROs, suppliers, vendors, consultants, projects and a team of direct reports.
For the past 9 years, overall company responsible 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.
Participated +15 CMO/vendor audits at external partners as a co-auditor, ranging from initial qualification audits to regular bi-annual and for-cause audits.

Current position

2016 – present: Consultant - Pharmac/PharmaSultant

Consultancy expertise: 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.

Previous Positions

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).
Essential Technical Operations processes I have extensive experience with:

- Development and updating of product and packaging Master Batch Records, Product Specifications.
- Hands-on manufacturing support e.g. Batch Record review, Change Request, Deviation handling.
- Ensuring timely production execution and on-going manufacturing support.
- Production forecast plans and product supply planning.
- 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.

- Defining and maintaining a communication strategy with external partner.
- Materials, API and new excipients sourcing incl. specification development and approval.
- PO development, shipping execution, invoice handling, incoming product approval, supporting release documentation.

2009 – 2014: Director, Clinical Supply - Veloxis Pharmaceuticals A/S

Managing the clinical supplies need in all clinical studies according to cGMP, GCP, GDP and ICH guidelines. Department head, managing a team of direct reports. Essential clinical supply processes I have extensive experience with:

- Interpret global needs for clinical trial materials in all clinical studies initiated by Veloxis Pharmaceuticals.
- Develop clinical supply CMO handling and outsourcing strategies.
- Defining the optimal clinical packaging configuration incl. product blinding requirements, shelf life and optimal production considerations, considering patient compliance and product distribution requirements.
- IV/WRS development, set-up and validation according to FDA 21CFR part11 requirements incl. statistical specifications and requirements for patient and product randomization scheme.
- Requirements for comparator sourcing and interpreting the comparator product requirements as listed in the SPC (Summary of Product Characteristics) into the context of the clinical study supplies.
- Develop manufacturing plans, project timelines and ensure deliverables execution.
- Develop relevant drug sections in the clinical trial documents e.g. clinical study synopsis and protocol.
- Develop country specific and global clinical label texts and perform clinical label approvals, considering and interpreting requirements specified by EMA, FDA, Health Canada and other regulatory bodies.
- Develop, maintain and approve product specific production and packaging Master Batch Records.
- Handle and approve clinical product specifications and process changes according to the company quality system e.g. Change Request, SOPs and Deviations.
- Hands-on support during execution of the packaging operation incl. in-process sampling and testing, Batch Record approval and deviation handling.
- Clinical Site initiation and drug reconciliation visits.
- Management of warehouses, local depots and drug shipments according to GMP, GCP and GDP requirements.

Therapeutic areas: Organ Transplant/Immune-suppression, Cardiovascular/Lipid Lowering agents.

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. My responsibilities included:

- Support to the quality system e.g. SOPs, Procedures, Change Requests, Deviation handling.
- Develop clinical supply CMO and outsourcing strategy.
- Selection of contract packagers and distribution centres.
- Setting up supply contracts and Vendor management plans.
- Defining the optimal clinical packaging configuration.
- IV/WRS set-up and testing.
- Forecast drug demand to internal department and comparator sourcing.
- Develop manufacturing plans, project timelines and ensure deliverables execution.
- Comment on study relevant documents e.g. study synopsis and protocol.
- Label text set-up and label approvals.
- Develop, approve and execution on packaging MBR and BR.
- Participation in packaging operation e.g. bottle filling and labelling operations.
- Clinical supplies packaging and distribution within the EU.
- Department budget and clinical supply project related budgets.
- Support finalization and implementation of quality agreements with CMOs.

Therapeutic areas: Organ Transplant/Immune-suppression, Cardiovascular/Lipid Lowering agents.

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**.** Responsibilities included:

- Interpret needs for clinical trial materials in Novo Nordisk initiated clinical studies.
- Defining the optimal clinical packaging configuration incl. product blinding requirements, shelf life and optimal production considerations, considering patient compliance and product distribution requirements.
- Develop delivery plans, project timelines and ensure deliverables execution.
- Develop and give input to relevant drug sections in the clinical trial documents e.g. clinical study synopsis and protocol

Therapeutic areas: Diabetes Care, Growth Hormone Therapy, Hormone Replacement Therapy

1999 - 2006: Principal Technician - Novo Nordisk A/S
Technician within Solid Dosage Forms Pilot Plant. My 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. Processes I gained extensive experience with; fluid-bed and extrusion granulation, blending processes, tableting, tablet film-coating.

1988 - 1993: Laboratory Assistant - Skjern Papirfabrik A/S
In-process and finish goods testing of recycled paper and cartons.

Education and courses

2016 - 2018:
Master of Industrial Drug Development
University of Copenhagen, Denmark

2015:
EU GMP update: Production, equipment, customer complaints and validation,
Lone Cleveland Andersen
Veloxis – Copenhagen, Denmark

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

2015:
Guidelines on good Distribution Practices for Active Substances for Medicinal Products for Human use, Lone Cleveland Andersen
Veloxis – 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

2004:

Cleaning Validation Seminar
Institute of Validation Technology - San Francisco US

2001:

Variations during tablet manufacturing,
Pharmakon – Hillerød, Denmark

1998:

Tablet manufacturing,
Pharmakon – Hillerød, Denmark

1995:

GMP and Communications,
Pharmakon – Hillerød, Denmark

1986 - 1988:

Laboratory Assistant,
Esbjerg Tekniske Skole, Denmark

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 – super user
Oracle InForm – user

Other relevant experiences

Conference presenter

2014:

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

Seminars

2012:

Clinical Supply Seminar
IQPC – Basel, Switzerland

2010:

Clinical Trial Supply Conference
Arena International – London, England

2007:

15th International Seminar on Global Trial Logistics and Cold Chain Management. World Courier – Copenhagen, Denmark

2003:

Controlled Release Seminar
FMC Biopolymer – Brussels, Belgium