JOHN KWOK SHING CHEUNG

Professional summary

Dedicated and organised Head of Operations (Development) and effective leader with over 18 years of experience using bespoke planning and support initiatives to cut costs, streamline operations and increase productivity. Decisive and resourceful team builder versed in management and process improvement. Possess broad knowledge of multi-disciplinary operational management within the pharmaceutical industry, including Clinical Trials, Nonclinical Development, Regulatory Affairs, Drug Supply Management, Records Management and Archiving, and Drug Safety Oversight. Effective and loyal cross-functional communicator and problem solver seeking to leverage GxP background into operations or management role within growing or established organisations.

Work history

Head of Operations (Development), 02/2018 - 10/2022
TauRx Therapeutics Ltd., Aberdeen

- Collaborated with the Head of Technical to establish and manage the programme for supply chain(s) management for clinical trials and CMC submission packages suitable for registration of the lead drug candidate in territories, as advised by Executive Management
- Partnered with the Head of Operations (Clinical) to oversee TauRx Drug Safety Oversight activities
- Deputised for the Head of Operations (Clinical) as a point of escalation for operational (Clinical) issues
- Managed internal team consisting of, but not limited to, the following Drug Supply Management, CMC Logistics, Regulatory Affairs Operations, Records Management and Archiving roles within TauRx Operations (Development) and joint management of Drug Safety Oversight with TauRx Operations (Clinical):
    - Drug Supply Management Lead
    - CMC and Regulatory Lead
    - Records Management and Archiving Lead
    - Medical Oversight Lead (joint responsibility with the Head of Operations (Clinical))
    - Senior Business Analyst (joint responsibility with the Finance Director).

Skills

- Workflow optimisation
- Change management
- Operational planning
- Strategic decision making
- Talent management
- Lean management principles
- Conflict management
- High-pressure environments
- Contract management
- Logistics expertise
- Relationship building
- Multidisciplinary collaboration
- Communication improvements
- Resource planning and allocation.

Work history

- Managed relationships and operational/strategic interactions with external consultants consisting of, but not limited to, the following areas of subject matter expertise:

    • Good Manufacturing Practice
    •Pharmaceutical Development and Formulations
    •Analytical Chemistry (to support clinical trials and CMC submission packages)
    •Commercial Supply Chain Management
    •Regulatory Affairs
    •Records Management and Archiving

- Ensured appropriate management of CMOs for drug product manufacture and testing for Clinical Trial Supply and drug product

- Led the Commercial Manufacturing Team in preparation of launch stock for market supply in the USA (and at a later stage EU and ROW territories)

- Oversaw staff operations, training and performance to accomplish objectives

- Managed strategic planning activities as the lead within the Regulatory Working Group, based on operational progress, current available clinical trial data, and company business direction

- Member of the Development Management Committee; accountable for all matters pertaining to Operations (Development)

- Collaborated with cross-functional teams, including the Head of QA, to develop and implement new SOPs and Core Policies

- Planned implementation of new organisational policies

- Mentored and shared performance coaching techniques with the Drug Supply Management Lead, CMC and Regulatory Lead and Records Management and Archiving Lead.

Work history

Head of CMC Operations, 01/2017 - 01/2018
TauRx Therapeutics Ltd., Aberdeen

- Deputised for and collaborated with the Head of Technical to establish and manage the programme for supply chain management for clinical trials and CMC submission packages
- Managed internal team consisting of drug supply management, operational and logistics roles within the TauRx Technical Function
- Managed external consultants consisting of, but not limited to, the various areas of expertise, including GMP, pharmaceutical development and formulations, analytical chemistry (to support clinical trials and CMC submission packages) and commercial supply chain management
- Ensured proactive management of CMOs for drug product manufacture and testing for clinical trial supply and drug product required for CMC submission
- Managed a preliminary Commercial Manufacturing Team, consisting of the Head of Technical, a GMP Consultant and a Commercial Supply Chain consultant.
- Managed external consultants consisting of, but not limited to, the various areas of expertise, including GMP, pharmaceutical development and formulations, analytical chemistry (to support clinical trials and CMC submission packages) and commercial supply chain management

CMC Logistics Project Manager, 05/2015 - 01/2017
TauRx Therapeutics Ltd., Aberdeen

- Managed a complex project team (including contractors) for CMC development and IMP supply
- Planned drug supply strategy with the Regulatory Affairs Function and the CMC team
- Managed cross-functional activities
- Monitored project progress and adjusted plans
- Facilitated project communications and documentation
- Collaborated with the team to resolve issues and organised team to execute any corrective actions
- Ensured project work complied with established practices, policies, and processes
- Provided project management support as deemed necessary by TauRx Development Management Committee (DMC)

Work history

Chief Development Officer/Drug Supply Manager, 12/2012 - 05/2015
TauRx Therapeutics Ltd., Aberdeen

- Oversight of Drug Supply Management activities for all clinical trials
- Responsible for Global oversight of Nonclinical Development
- General management of external Contract Research Organisations (CROs), including but not limited to Piramal Healthcare, Charles River Preclinical Services, IntraLinks, Mewburn Ellis LLP, Covance Laboratories, BioClinica
- Finance Control
- Coordination of CMC-related activities in conjunction with the Head of Technical
- General IT and technical support for the TauRx Team
- Management of the company's trade mark portfolio
- General support of the Intellectual Property Officer

Acting Director of Clinical Operations, 01/2012 - 12/2012
TauRx Therapeutics Ltd., Aberdeen

- Oversight of clinical development at the operational level
- Management of clinical trial CROs and consultants as directed by the CEO and Executive Chairman
- Ensured that all clinical operations activities were conducted in accordance with TauRx policies and appropriate functional SOPs; where applicable, functional SOPs provided by external organisations may apply, provided that they were consistent with TauRx's core policy for Clinical Operations and other relevant TauRx policies
- Liaised with TauRx's Strategic Management Committee (SMC) to obtain strategic information, advice and input to ensure appropriate study design
- Cooperated with the Head of Quality Assurance to ensure that operational activities include QC checks and are supported by the quality assurance programme
- Regularly communicated with the Head of Regulatory and the Head of Medical Monitoring and Safety to ensure that the Risk-benefit profile of a TauRx development product was kept up-to-date as required
- Worked with the Head of Technical to ensure that procedures and responsibilities have been defined for drug product manufacture and management

Work history

Global Head of Non-Clinical Development, 01/2007 - 01/2012
TauRx Therapeutics Ltd., Aberdeen

- Global oversight of nonclinical development, including establishment of candidate product toxicological and safety profile
- Management of external nonclinical experts / consultants
- Selection and approval of CRO(s) for nonclinical study conduct
- Contract and finance management for nonclinical-related activities
- Test article management in conjunction with the Head of Technical
- Provision of finalised nonclinical study reports to the Regulatory function
- Review of nonclinical sections of regulatory documents, including IND submissions and Investigator's Brochure
- Management and oversight of more than 25 nonclinical studies (toxicology, ADME/PK and safety pharmacology across multiple test species) pertaining to the development of 3 different salt forms of the lead drug molecule.

Development Officer, 07/2004 - 01/2007
TauRx Therapeutics Ltd., Aberdeen

- Provided direct assistance to the Executive Chairman in matters of private business development
- Managed external CROs as directed by line manager
- Provided direct assistance to the Head Chemist in CMC issues
- Controlled and monitored outgoing clinical trial-related finances, including regular liaisons with more than 20 clinical trial centres located within the UK
- Provided direct assistance to the Finance Director
- Supported the clinical trial team on a technical / administrative level
- Supported the company's Regulatory Affairs Consultant
- Supported the Safety Pharmacologist in matters of nonclinical studies
- Provided general IT and technical support for the TauRx Team
- Provided general support of the Intellectual Property Officer

EDUCATION

Ph.D., Medicine and Therapeutics, 2004
University of Aberdeen - Aberdeen

B.Sc. (Hons), Pharmacology, 1999
University of Aberdeen - Aberdeen

2 x A-Levels, 1993
The Glasgow Academy - Glasgow

6 x Scottish Highers, 1992
The Glasgow Academy - Glasgow

8 x GCSEs, 1991
The Glasgow Academy - Glasgow

REFERENCES

Professor John M. D. Storey
Head of Technical / Chief Chemist
TauRx Therapeutics Ltd., Aberdeen

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Dr. Charlie Harrington
Chief Scientific Officer
TauRx Therapeutics Ltd., Aberdeen

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