**CURRICULUM VITAE**

**Hedley Rees, Managing Consultant, PharmaFlow Ltd**

**Profile**

Hedley Rees is the Managing Consultant at PharmaFlow Limited, a UK based consultancy specializing in supply chain management within the pharmaceutical and life sciences sector. Clients range from large pharmaceutical companies to emerging biotech, and also include investors, lawyers, other consultancies, facility design & build specialists and third party logistics providers (3PLs). Assignments span early stage clinical trial supply chains up to complex multi-product supply networks covering global territories.

Prior to this, Hedley held senior positions at Bayer UK, British Biotech, Vernalis, Ortho-Clinical Diagnostics and OSI Pharmaceuticals. His skill set covers the range of competencies from strategic procurement, production and inventory control, distribution logistics, information systems and improvement. His early career was spent as an industrial engineer in the automotive, consumer durables and FMCG sectors.

As an expert in Lean Thinking and Production Systems, Hedley is a zealous advocate of the regulatory modernization frameworks of FDAs 21st Century Modernization and ICH Q8 – Q11. He graduated from the University of Wales as a production engineer and holds an Executive MBA from Cranfield University School of Management. Affiliations and qualifications include:

* Corporate member of the Chartered Institute of Purchasing and Supply (MCIPS)
* Former member (2007 – 2011) of the UK BioIndustry Association’s (BIA) Manufacturing Advisory Committee
* Advisory Board Member of the International Institute for Advanced Purchasing & Supply (IIAPS)
* Advisory Board Member of Marken, the only supply chain service provider dedicated 100% to the pharmaceutical and life science industries.
* Editorial Board Member GMP Review (GMP = Good Manufacturing Practice)
* Selected as a Founding Member of Expert Industry Panel for CPhI Worldwide (UBM plc)
* Steering Committee Member Pharma Integrates 2013 Conference in London.
* Supply chain consultant to UK Government’s Cell Therapy Catapult
* Supply Chain Advisor to UK’s HealthTech & Medicines Knowledge Transfer Network

Hedley regularly delivers podcasts, webinars and speaks at international conferences and is co-chair of the highly regarded FDA/Xavier University sponsored PharmaLink Conference (formerly FDA/Xavier Global Outsourcing Conference) held in Cincinnati annually.

**Publications include:**

Book

“Supply Chain Management in the Drug Industry: Delivering Patient Value for Pharmaceuticals and Biologics”, J Wiley & Sons, Hoboken, NJ 2011

Reviews include the following from James O'Reilly, Professor in FDA Law at the University of Cincinnati and Chair of the FDA Committee of the American Bar Association

"37 years in the industry but I never saw the production side in this light; I have learned a lot. Using charts, graphic imagery and guest writers' insightful comments, this text delivers an excellent message for the corporate executive, the investor in pharma stocks, the regulatory professional and (last and least) the lawyers who advise the company.... Every reviewer has a list of wished-for items, but I’m pleased to say that Rees's book met all of my needs and then some.... "

Journals

“EU QP: Custodian of quality or piggy in the middle?”GMP Review April 2013

“Regaining supply-chain control: Is Pharma missing the target?” GMP Review January 2013

“What can Pharma manufacturing learn from Lean Thinking?”GMP Review October 2012

“Optimal planning for clinical supply”, Clinical Trials Insight, June 2012 (electronic)

“Cutting Through the QbD foliage: Aiming for the Roots, Pharma QbD, June 2012

“Two Stage Drug Development Model Required to Cut Attrition Rates”, InPharmaTechnologist, (PodCast) and Pharma QbD, May 2011

“A New Model for Product Development”, Chemistry Today (peer reviewed), Jan/Feb 2011

“Delivering 21st Century Modernization Through Effective Supply Chain Management” European Biopharmaceutical Review, Autumn 2010

“ICH Q9 and Beyond”. European Biopharmaceutical Review, Autumn 2009

“Virtual Pharma, But Not Virtual Responsibility”, Pharmaceutical Formulation & Quality, Feb/Mar 2009.

**Current and previous assignments include:**

*Client: Manufacturer of Gene Therapy products*

Lead consultant on a successful UK funding bid (7.2M) in Advanced Manufacturing Supply Chain, building a consortium of collaborators across industry, academia and National Health Service.

*Client: Manufacturer of biologic*

Lean manufacturing consultant working on multi-disciplinary team designing a new build biologics facility scaling up for commercial launch. Through a process of current and future state value stream mapping, increased capacity four-fold+ by reducing value stream cycle time from 16 days to 45 hours.

*Client: Private equity/Strategic Consultancy*

Carried out technical due diligence as part of consulting team advising global private equity player on acquisition of a Bulgarian Animal Health Company. Compiled full analysis of technical and supply chain processes, quality systems etc and reported back on three sites – 2 in Bulgaria and 1 in St Louis, US.

*Client: UK arm of leading global generics company.*

Provided purchasing management services while incumbent supply chain manager was seconded to an SAP implementation project. Procured goods globally, both inter-company and from third parties.

*Client: Generics Company operating in Speciality Pharma*

Set-up a commercial supply-chain for a range of generic urology products sourced in EU/EEA and imported for UK distribution. This included tendering (RFP) and awarding contract for third party storage and logistics services for product distribution throughout UK.

*Client: EU arm of Japanese PharmaCo*

Advised Japanese PharmaCo launching a statin in Europe, covering requirements to register a robust, compliant supply-chain in Europe and also supply 3 different licensing partners.

*Client: Large Swiss based top 10 PharmaCo*

Advised on Sales & Operations Planning and capacity planning processes in preparation for implementation of mySAP APO into UK site. This included studying ERP processes and capacity planning methods across the site and connectivity with Swiss headquarters.

*Client: EU Healthcare arm of large US based Logistics Integrator*

Devised a supply chain services strategy for the Italian hospital market, in conjunction with Central Purchasing Organisation of large Swiss based PharmaCo. Identified relevant hospitals, interviewed staff and determined critical 3PL service needs.

*Client: UK based Biotech Company*

Designed, constructed and operated a clinical trials supply-chain for a large phase III trial in autism, end-to-end, from starting materials through to delivery of drug to US/EU investigator sites, including tendering for strategic partners to deliver CRO/CMO services.

**Previous Employment**

###### OSI Pharmaceuticals, Oxford

###### October 2003 – Mar 2005 Director, Supply Chain Management

* Negotiated multi-million pound contractual agreements relating to commercial supply of pharmaceutical intermediates, active ingredients and finished products.
* Lead member of manufacturing launch team (Genentech/OSI) delivering product to market within 2 days of FDA approval (approved under Pilot 1).
* Implemented supply management processes for fully outsourced supply-chain.
* Member of cross-functional business team undertaking definition, planning and implementation phases of ERP system (Oracle OPM 11.5.9) to support clinical and commercial supply-chains in a highly regulated environment.

###### Ortho-Clinical Diagnostics (a Johnson & Johnson Company), Cardiff

###### March 2001 – September 2003 Director of Supply Chain

* Re-engineered supply chain processes and organisation structure in a lean production environment to deliver value stream alignment.
* Defined and implemented an innovative sourcing strategy, building in sound commercial, risk mitigation and critical to quality parameters.
* Segmented the purchasing portfolio, introducing procurement methodologies appropriate to the segmentation, delivering significant cost and value benefit.
* Introduced supplier technical agreements and more comprehensive supply agreements to vastly enhance control of contractors for key materials and services.

###### Vernalis Limited (previously Vanguard Medica), Winnersh, UK

###### September 1999 – February 2001 Director of Procurement and Facilities

* Created a new procurement function following a business merger, defining resources, purchasing policies, procedures and processes for the expanded company.
* Member of multi-disciplinary project team, responsible for negotiating supply arrangements with contractors for development and launch of a Central Nervous System (CNS) product into regulated US and EC markets.
* Worked closely with senior management and licensing partners, both EU and US, to define joint working practices to support global sales.
* Agreed and documented supply-chain SOP’s with marketing partners, contractors and internal stakeholders.

###### British Biotech Pharmaceuticals, Oxford

###### July 1996 – August 1999 Head of Logistics & Procurement

* Achieved major cost and value improvement through purchasing ‘best practice’, covering non-clinical CRO/CMO’s and clinical CRO’s.
* Project team member, covering inventory management and procurement, for implementation of SAP R/3
* Tendered and placed contracts with third party logistics organisations delivering time-sensitive clinical trial and production supplies to international sites, including detailing of Service Level Agreements.
* Introduced structured master production scheduling procedures, converting market forecasts into time phased manufacturing and procurement schedules, gaining agreement to associated cash commitment from relevant parties.

###### Bayer Diagnostics Manufacturing Limited, Bridgend

###### 1990 - 1996 Site Supply Chain Head

* Re-structured supply-chain organisation and contributed to plant wide change process, introducing leading edge methodologies and significantly upgrading professional competencies within the group.
* Successfully rationalised the base of key suppliers, introducing performance partnership agreements, resulting in purchase cost savings of between 15 and 20%.
* Project team representative on Bayer UK implementation of SAP R/3.
* Spearheaded transfer of work from sister plant in France, on-time, within budget. This additional work resulted in a 40% increase in production volume.
* Initiated total review of warehousing to meet 5 year projected throughput, specifying resource and facility requirements.

###### 1988 - 1990 Purchasing Manager

###### 1985 - 1988 Planning & Inventory Control Manager

###### 1979 – 1985 Senior Industrial Engineer