



Supply Chain Management in the Drug Industry: Delivering Patient Value for Pharmaceuticals and Biologics

By Hedley Rees



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This book bridges the gap between practitioners of supply-chain management and pharmaceutical industry experts. It aims to help both these groups understand the different worlds they live in and how to jointly contribute to meaningful improvements in supply-chains within the globally important pharmaceutical sector. Scientific and technical staff must work closely with supply-chain practitioners and other relevant parties to help secure responsive, cost effective and risk mitigated supply chains to compete on a world stage. This should not wait until a drug has been registered, but should start as early as possible in the development process and before registration or clinical trials. The author suggests that CMC (chemistry manufacturing controls) drug development must reset the line of sight – from supply of drug to the clinic and gaining a registration, to the building of a patient value stream. Capable processes and suppliers, streamlined logistics, flexible plant and equipment, shorter cycle times, effective flow of information and reduced waste. All these factors can and should be addressed at the CMC development stage.



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Editorial Review

Amazon.com Review

From the Author: Avoiding Common Pitfalls in Pharmaceutical Supply Chain Management (SCM)

- Remember, early decisions in development set the supply chain foundation for life. Seek to understand the chemistry, manufacturing & controls (CMC) information submitted to the regulatory filing. Your supply chain is limited to what goes in there – make it your business to know and influence Module 3 (CMC) of the common technical document (CTD/eCTD).
- There is no such thing as a ‘quick fix’ in supply chains because of the complex interrelationships. To get to true root-cause, it is necessary to follow the ‘systemic’ path for answers – and the path can lead to very unexpected quarters – such as the door of the supplier to your supplier’s supplier!
- Integration is king – the various disciplines of Production & Inventory Control, Procurement, Transportation/ Storage & Distribution, Information Systems and Improvement must link closely together, and with external stakeholders, to deliver the optimum results for the customer.
- Tools and techniques have their place – but firstly focus on common sense principles based on management of The Wholesome Trinity – inventory, capacity and lead-time.
- Use big picture maps and A3 Management to get your arms around issues and opportunities in the internal and extended supply chain.
- Beware of placing too much dependence on Enterprise Resource Planning (ERP) systems – only use the essential functionality identified by your strategic review of Information System needs.
- Improvement is important to maintain competitive advantage, but it must be carefully targeted at the areas that can make a difference. A kaizen event to increase overall operational effectiveness (OEE) on a non-bottleneck machine or operation, it likely to merely increase waiting time.

Review

"A recommended read for all wishing to shift performance to greater levels." (Supply Management, 1 February 2012)

"This book is ideal reading for those entering or currently working in the field of supply chain management, such as clinical supply managers, or those in operations or production and planning ... This book would be an excellent resource for small pharmaceutical companies that may have limited experience of supply chain implementation or outsourcing, giving a thorough overview of the process and plenty of food for thought." (The Pharmaceutical Journal, 16 November 2011)

"This is a solid text that is equally suitable for the newcomer or experienced professional in the pharmaceutical/biologics industries . . . Overall, I recommend the book for its educational perspective on the industry and the significance of effective SCM for its future success." (*Quality World*, 1 July 2011)

Review

"In a series of well researched and documented chapters about the pitfalls of inappropriate practice in the end-to-end supply chains for pharmaceuticals and drugs this volume demonstrates the key problems faced by the industry in managing supply chains holistically and for customer value. It also provides useful insights

into the major positioning methodologies that the industry should use to make appropriate make/buy and strategic sourcing decisions with suppliers."

—**Professor Andrew Cox**, Chairman, Advisory Board, International Institute for Advanced Purchasing & Supply (IIAPS)

"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 not least) the lawyers who advise the company.... Every reviewer has a list of wished-for items, but I pleased to say that Rees's book met all of my needs and then some.... Rees has a keen eye for what could go wrong in the drug maker's supply chain."

—**Professor James O'Reilly**, University of Cincinnati

"I found it to be a knowledgeable and insightful overview of the role of Supply Chain Management in the Pharmaceutical Industry. I found that it touches knowledgeably on both the small and large molecule products, which most texts fail to do. Hedley has done the industry a significant favor by laying out, in a single volume, a road map for how Supply Chain should function in today's Pharmaceutical Industry."

—**James Donlevie**, Former VP - Worldwide Logistics, Global Biologics Supply Chain, Johnson and Johnson; Currently GPPS, Inc.

"Through his passion to make a difference in the Pharma industry, Hedley has masterfully addressed the complexities of total supply chain management from product development through commercialization. Building on his years of experience within Pharma and with other regulated industries, Hedley offers solutions that are insightful, proven, holistic and impactful. This easy-to-read book offers a refreshing style that keeps the reader engaged."

—**Marla A. Phillips**, Ph.D., Director, Med-XU, Xavier University

"Hedley's interesting exploration of SCM issues includes business, control, regulatory and technical aspects. The book is salted with many personal experiences which keep the reader entertained as well as informed. This book is a must read for those entering into the SCM fields as well as all those who intersect with SCM."

—**Bob Coleman** former FDA National Expert Drug Investigator and currently Senior Compliance Expert - Pharmaceuticals, IHL Consulting Group, Inc., Atlanta, GA

"This book provides guidance to help modernize the way drugs are developed, made and sold, and presents the argument that counterfeiting and poor SC [supply chain] visibility have their roots in the early stage of drug development.... The author does a great job of demonstrating the need for development of Supply Chain practices in the Pharmaceutical world. With input from various expert sources, the text reads as a 3-part case introducing those in Supply Chain to the world of Pharmaceuticals, those in Science to the world of Supply Chain, and finally a roadmap for a solution.... It may take a while longer to convince those in the Pharma world that involving SC with their R&D teams can [be a] benefit, but the change will come. Those who follow the advice of this author may well lead the way."

—**Rick Cleveland**, P.Log., President, Altered Perspectives

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Thomas Smith:

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