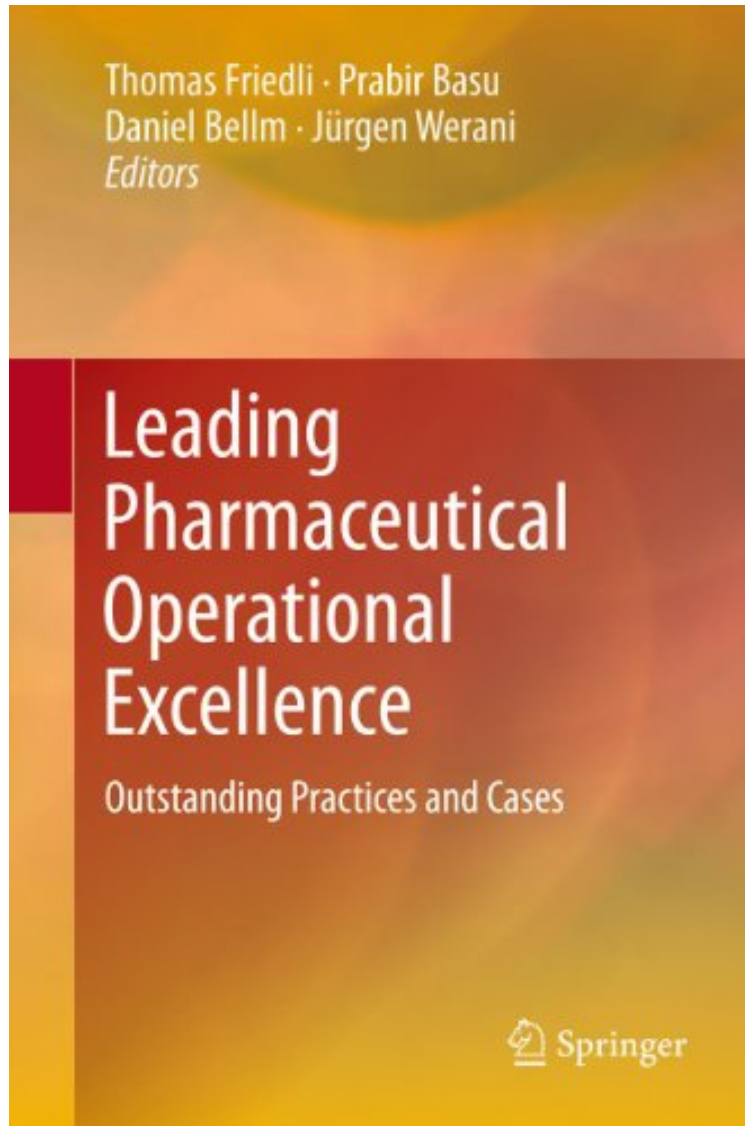


(Mobile ebook) Leading Pharmaceutical Operational Excellence: Outstanding Practices and Cases

Leading Pharmaceutical Operational Excellence: Outstanding Practices and Cases

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Achieving operational excellence is a challenge for the pharmaceutical industry, with many companies

setting successful examples time and again. This book presents such leading practices for managing operational excellence throughout the pharmaceutical industry. Based on the St.Gallen OPEX Model the authors describe the current status of OPEX and the future challenges that have to be dealt with. The ample theoretical background is complemented hand-in-hand by case studies contributed by authors from leading pharmaceutical companies.

From the Back Cover Achieving operational excellence is a challenge for the pharmaceutical industry, with many companies setting successful examples time and again. This book presents such leading practices for managing operational excellence throughout the pharmaceutical industry. Based on the St.Gallen OPEX Model the authors describe the current status of OPEX and the future challenges that have to be dealt with. The ample theoretical background is complemented hand-in-hand by case studies contributed by authors from leading pharmaceutical companies.

About the Author

Thomas Friedlin Thomas Friedli is Managing Director at the Chair of Production Management, and Vice Director, Institute of Technology Management, University of St.Gallen (Switzerland). Thomas Friedli's main research focus is the management of manufacturing enterprises. His area of expertise is in operational excellence in the pharmaceutical industry, collaboration management, management of industrial services and management of global production. In 2004, Thomas habilitated and became Adjunct Professor in St.Gallen. His team of 12 postgraduate students develops new management solutions for manufacturing companies. The Chair is largely financed through external funds, while most of the research projects are industrial projects. In 2007 he became an associate member to the International Academy for Quality (IAQ) and joined the SAQ (Swiss Association for Quality and Management Systems) as an advisory council in 2009. Since 2010, he is member of the board of the Swiss Institute of Service Sciences (SISS). Thomas is teaching in several executive programs in St.Gallen, Fribourg, Dornbirn, Salzburg and Aachen; moreover, he is visiting lecturer at the Business School of Bordeaux. In fall 2008, he spent several weeks as Adjunct Associate Professor at the Purdue University in West Lafayette, Indiana, USA. Since 2011, Thomas is Senior Lecturer of the Executive MBA program in St.Gallen and since 2012 also Senior Lecturer of the St.Gallen full time MBA program.

Prabir Basu Prabir Basu is an independent consultant advising on pharmaceutical manufacturing and cGMP issues. From 2005 till June, 2013, Prabir was the Executive Director of the National Institute for Pharmaceutical Technology and Education (NIPTE) which is currently a non-profit organization supported by 13 leading universities in the U.S. NIPTE's goal is to address long-term fundamental research and education on the science of pharmaceutical development and manufacturing. As the Executive Director of NIPTE, Prabir built a strong relationship with the U.S. FDA and secured funding from the FDA for research and education programs to modernize drug manufacturing. Working with the U.S. FDA, Prabir was also able to secure a U01 Grant for NIPTE in 2011 worth up to \$35 million over 5 years to improve drug manufacturing standards. From 2004 to 2010, along with his role as Executive Director, NIPTE, Prabir was also the Managing Director of the Pharmaceutical Technology Education Center at Purdue University's Discovery Park. In this role, Prabir, along with colleagues at Purdue and scientists from the industry, organized and offered various training courses on cGMP, Pharmaceutical Development and Manufacturing. Prabir, along with his colleagues at Purdue University also founded NIPTE at Purdue in 2005. Prior to joining Purdue University, Prabir worked in the pharmaceutical industry (Pfizer, Pharmacia and Searle) for over 20 years in various capacities in research, development and manufacturing. During that period, Prabir had broad-ranging global senior management responsibilities for product development, manufacturing and outsourcing.

Daniel Bellm Daniel Bellm is Research Associate at the chair of production management of the University of St.Gallen and as group coordinator responsible for the topic "Operational Excellence - Pharmaceutical". His research focus is the management of operational excellence programs and complexity management. He is currently working on his PhD-thesis. Daniel graduated in Business Engineering (Dipl.-Wi.-Ing.) at the Karlsruhe Institute of Technology (former University of Karlsruhe (TH), Germany). During his studies, Daniel worked at the Porsche AG (Germany), MTU Friedrichshafen (Germany), Porsche Asia Pacific Pte. Ltd. (Singapore), and Volkswagen Consulting (Germany).

Jürgen Werani Jürgen Werani was born in Vienna, Austria, in 1951. He is a citizen of Switzerland. From 1971 until 1976, he studied pharmacy at the University of Graz, Austria. He received his doctorate in natural sciences in 1978. In 1998, he obtained a degree in Business Administration at the University of St.Gallen. In 2008, he received his Lean Expert qualification from the Lean Management Institute Germany. Between 1979 and 1995, Dr. Werani held a number of leading positions in pharmaceutical manufacturing at Sandoz Pharma AG in Basel, Switzerland. There he finally took on the role of Head of Solids Production. In 1995, he transferred to Warner Lambert Company where he became Managing Director of the Gouml;decke AG Freiburg plant. In 1998, he joined Gouml;decke AG's Board of Management. From 2000 onwards, he was member of the Board of Management of Pfizer Germany GmbH. From 2003 to 2008, Dr. Werani was responsible for the implementation of the Operational Excellence Program in Europe which included its deployment to a total of 15 sites. Since 2008, he has been member of the Managing Board of Schuh Co. Complexity Management AG in St.Gallen, Switzerland. Dr. Jürgen Werani has gained broad experience in the field of Operational Excellence and Lean Thinking in the pharmaceutical industry as well as in state-of-the-art methods of corporate management and leadership. He is the author and co-author of reference books on these subjects, wrote numerous publications and is a sought-after speaker

at congresses and seminars on corporate change management. During his time at Pfizer Freiburg, Dr. Werani introduced the principles of Lean Manufacturing on a broad scale, thus helping to turn the site into a leading Lean Manufacturing production site in the pharmaceutical industry. Since 2008 he has been leading several projects in different companies addressing Operational Excellence, Cultural Change and Leadership Development programs. He also acts as a mentor and coach for Executives and operational leaders.