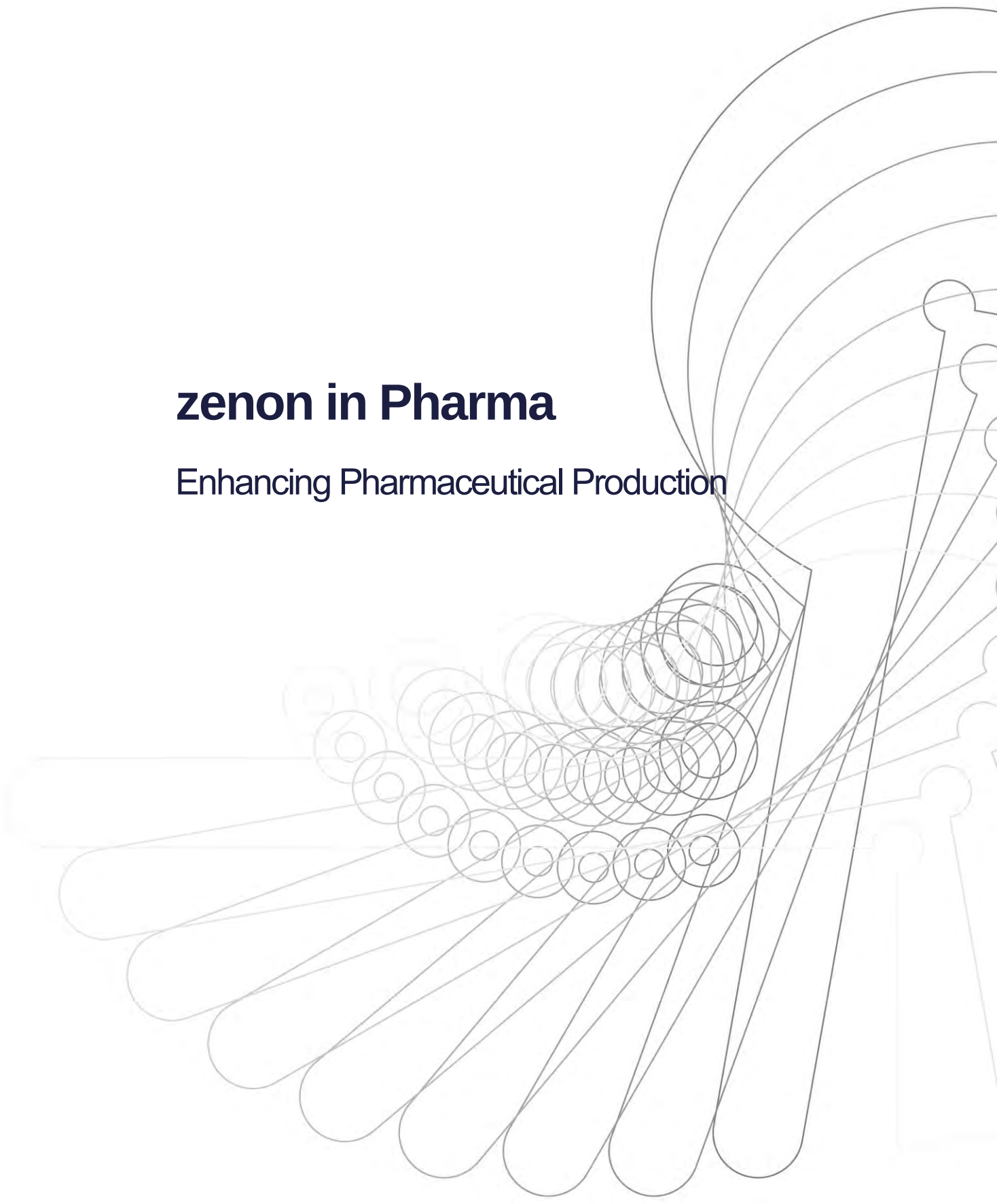
zenon in Pharma

Enhancing Pharmaceutical Production



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Introduction

The pharmaceutical industry is a demanding process industry and its performance has consequences which range beyond purchase and consumption. The challenges it faces are greater than just material production, since it must be concerned with compliance, patient safety and strict global regulation. COPA-DATA enhances pharmaceutical production with its sophisticated visualization software. And, through market penetration, zenon is gaining recognition for advanced pharmaceutical solutions. The rigors of regulation and validation, which impact on patient safety and business risk for the regulated producer, have been accommodated in zenon. Over the years, our customers' experiences have informed the further streamlining and advancement of the product.

Change and Challenges

One major change influencing the pharmaceutical industry is the so-called 'Patent Cliff', where high returns gained by patented branded products are being opened up to competitive generic competition. Simultaneously, recent history has changed the global business landscape with an uncertain economic climate, rising raw material costs, and tightening operational budgets: manufacturers are facing the toughest operational and strategic challenges in recent memory. These dynamics are forcing manufacturers to look to efficiency drives and effective plant innovation to enhance current strategies and performance. Since its infancy, COPA-DATA has embraced the ideal of easy engineering through its products. We strive to place more innovation and creativity in the hands of designers and engineers so they can achieve their vision of effective and efficient automation in production environments.

These changes are inspiring a quiet evolution in Pharmaceutical Manufacturing Practice. This, believe it or not, is a good thing: quality improvements coupled with efficient production have significant benefits to both the business and the environment - in terms of reducing operational costs and the 'green' advantages that come with reduction of waste and reduction of energy use.

Patent cliff

Market research predicts that generic drugs will account for around 85% of pharmaceuticals sold in the U.S. Market by 2015 (currently 75%, this has risen from 51% in 2003)[1]. Because the U.S.A. accounts for about 52% of all pharmaceuticals produced worldwide, this represents a significant change within the global market. This trend comes at a time of ongoing constraints originating from the financial crisis and healthcare reforms across the USA, EU, Russia, China & India, which are reshaping the models used to produce pharmaceuticals.
It is estimated that between now and 2016 branded drugs with about $255 billion in global annual sales are set to go off-patent[2]. The next year alone will begin the release of generic versions for seven of the world's twenty best-selling drugs, including the top two: 'Lipitor' & 'Plavix'. Although the patent-holding brands will continue to manufacture the branded product, the average market price of a generic drug in 2008 was $35.22 - whereas for the patent protected drug this figure was $137.90[3]. These contrasting values lay clear the significance an expired patent has on a big name brand: revenue can drop by three quarters overnight.
To add salt to the wound, the number of new drug approvals is falling, as is the market for new drugs where new products aren't delivering the growth as they have in the past; effective ways to treat the most common conditions have already been developed and orphan or speciality drugs developed to treat rare conditions don't hold the same financial incentives.
To retain price advantage, the most beneficial action the manufacturer of pharmaceuticals can take is to learn from similar process industries. The Lean manufacturing and 6 Sigma performance of the FMCG sector outshines most, if not all, in the Pharmaceutical sector. The fact these philosophies have not taken hold in the Pharmaceutical sector is widely recognized as having its origins in the influence of regulation, compliance and validation, which have inhibited innovation with a 'no-change = no-risk' philosophy.
The following table compares performance in the industries of Pharmaceutical, Fast Moving Consumer Goods (FMCG), Electronics, Aerospace and Automotive. Across all measures the Pharmaceutical industry has significant ground to cover in order to be up there with the leaders: the most striking figures are in the comparison of OEE where the Pharmaceutical sector ranges between 10-60% - against 70-90% in FMCG.
The reluctance to innovate to improve the manufacturing process in the Pharmaceutical industry stems from the financial benefits of the patent and the constraints of compliance. But the reality that the pharmaceutical industry is still 3-5 times more profitable than the automotive industry[4], reduces the necessity for the Pharmaceutical manufacturing process to change or advance.

[1] *source Institute of Mathematical Statistics*
[2] *source EvaluatePharma Ltd*
[3] *source National Association of Chain Drug Stores*
[4] source McKinsey & Co.

Historically, the modus operandi in this sector has been to produce all you can and the product 'costs what it costs' for healthcare consumers to buy, with no competition to balance the market price. Generic products will mean this sector will have to recognize the need for process innovation, effective operation and efficient production. The table below displays several indicators which demonstrate one fact: these efficiency changes are possible and are there for the taking. And a fast ROI is possible when deploying improvement orientated software products such as zenon.

Table 2. Benchmarks for Pharma vs. Other Industries

Measure	Pharma	Automotive	Aerospace	Computer	Consumer Packaged Goods
Overall equipment effectiveness	10% to 60%	70% to 85%	50% to 70%	80% to 90%	70% to 90%
Annual productivity improvement	1% to 3%	5% to 15%	5% to 10%	1% to 3%	5% to 15%
First-pass yield – zero defects	60%	90% to 99%	70% to 90%	90% to 99%	90% to 99%
Production lead times in days	120 to 180	1 to 7	7 to 120	5 to 10	3 to 7
Finished goods inventory in days	60 to 90	3 to 30	3 to 30	5 to 50	10 to 40
Labor value-add time	20%	60% to 70%	60% to 70%	60% to 70%	60% to 90%
Direct/indirect labor ratio	1:1	10:1	10:1	10:1	10:1

The pressure to lower drug prices will not ease off. In my opinion, to succeed and grow profitability will be attained through a combination of factors: the continued commitment to product and quality management, innovation, and engaging key technologies to empower production automation with better integration to achieve industrial intelligence across systems. Such a system requires a communication platform: ideally a collaboration of shop floor production systems (PLC, HMI, SCADA) connecting as one to the rest of the business through MES & ERP. Capacity within the production business is then holistically evaluated in terms of Operational Excellence, Continuous Improvement and Agility - thus creating business value and measurable ROI for the new technologies and measures introduced.

Lean manufacturing & Six Sigma

This so-called ‘Lean Six Sigma’ model aims at reducing slack in manufacturing systems and converting it into efficiency gains to reduce costs and increase profit. The simple points below aim to highlight the key concepts of this model:

Lean manufacturing

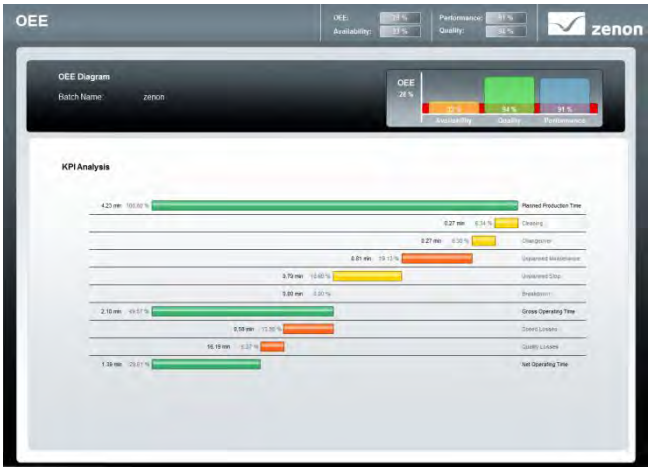
- Simplify & automate
- Optimize flow
- Error proof

6 σ

- Minimize variation
- Identify & remove causes of defects
- Improve process understanding
- DMAIC: Define-Measure-Analyze-Improve-Control
- Stable & predictable process results

Although the two philosophies have different aims - Lean is concerned with efficiency and Six Sigma with quality improvement - the two overlap and both are dependent on a firm foundation of real-time communication and data from production systems. It is not hard to see how implementing a good platform of visualization and communication to utilize production and equipment data across a facility, can have a significant positive influence to both objectives.
Automating production environments to not only execute manufacturing commands, but to facilitate a ‘closed loop’ philosophy which implements quality management, will optimize flow and remove the causes of defects. Embracing the DMAIC (Define-Measure-Analyze-Improve-Control) of Six Sigma requires process understanding through visual tools with a focus on predictable production so waste can be minimized.

Six-sigma pioneered KPI usage:
the calculation of OEE is one example where visualization based on a reliable communication platform moves the quality management initiative forward.



realtime OEE Diagram on a zenon process screen

History, experience and a vision for the future drive innovation and operational excellence.

Applying innovation within strict guidelines

Traditionally, the Pharmaceutical industry has been very conservative because regulation, and the business risk change represents has inhibited innovation. This is now changing as the shift from patent-protected drugs to generic drugs forces a shakeup in terms of effective production and efficiency.
Regulations are evolving: not only to tighten quality controls to ensure greater patient protection, but also to allow and encourage the industry to innovate and take a hold of technological advances. The ISPE GAMP 5 guidelines bring the equipment and software supplier into the regulation circle, so that 'supplier leverage' documentation created by the OEM or software company can be used as validation evidence. This reduces a significant amount of duplication in validation evidence. But it also invokes another key aspect of business risk: the manufacturer's relationship with, and confidence in, the supplier. Our preferred method of working is in a partnership that is organic in nature, so that knowledge can be transferred in both directions, thereby promoting growth and understanding.
It is a philosophy that we at COPA-DATA firmly embrace as a company: to build relationships with our clients, delivering good support also offers beneficial learning opportunities for our consultants and development teams - making progression a sure fact.

COPA-DATA Pharmaceutical

We live in exciting times, where the ‘one that is most adaptable to change’ will be the clear leader in navigating the next generation of pharmaceutical production.
COPA-DATA focuses on the pharmaceutical industry with dedicated resources and has developed a strong infrastructure committed to delivering solutions and success through our multiple global offices offering local, regional, and international experience tailored directly to your needs.
Please visit our web site www.copadata.com, or contact me at RobertH@copadata.com

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