

MAXIMIZING PRODUCTION THROUGHPUT

PACIRA USES BIOVIA DISCOVERANT FOR
MANUFACTURING PROCESS OPTIMIZATION

CUSTOMER STORY



Challenge:

Manual, tedious and time-consuming data gathering resulting in a lack of process understanding and non-optimal processes

Solution:

BIOVIA Discoverant for Tech Transfer and early commercialization

Results:

- End-to-end process understanding
- 3 full headcounts no longer hunting data—now producing, discovering and designing
- Reduction in material scrap and rejected lots
- \$20K-500K savings in scrap avoidance depending on the stage of the process
- Improved quality and yield
- Faster time-to-market through shorter cycle times
- Increased profitability

CUSTOMER: A SPECIALTY PHARMACEUTICAL COMPANY

Pacira is an emerging specialty pharmaceutical company headquartered in the US that focuses on the clinical and commercial development of new products that meet the needs of acute care practitioners and their patients. The company's emphasis is the development of non-opioid products for post-surgical pain control. Pacira has developed a proprietary product delivery technology (DepoFoam®) that encapsulates drugs without altering their molecular structure and then releases them over a desired period of time. This improves products' efficacy and safety, making a critical difference to patients in terms of dosing frequency and administration. The product EXPAREL® based on this technology is marketed to replace opioids for post-surgical treatments eliminating addiction and overdose deaths. It is manufactured in San Diego, US and Swindon, UK. The production of the emulsion is very difficult to control, involving two emulsion steps: solvent stripping and buffer addition for storage and potency adjustment.

CHALLENGE: MANUAL PROCESSES LEADING TO HIGH COSTS AND A LACK OF PREDICTIVE CAPABILITIES

The company's goal in the manufacturing space is to achieve maximum product throughput with zero defects. To support this strategy Pacira started a Continuous Improvement journey in 2016 leveraging Lean and Six Sigma methodologies. Lean helps to ensure the required stability of manufacturing processes, eliminating waste and allowing steps to flow smoothly with no interruptions, delays or bottlenecks for improved time to market. It also allows customers to "pull" the product as needed. Six Sigma helps to reduce variability using appropriate statistical tools for in-process control. Additionally, Design for Six Sigma can improve process robustness. All these approaches rely on leveraging data generated across the organization.

Data gathering was previously very cumbersome for Pacira, as data resided in paper-based documents, spreadsheets and complex equipment systems. For data to be useful, it is necessary to know what data is available, when it was created, its format, and whether it is qualitative or quantitative data. Gathering and formatting data was taking too long and they were unable to garner insights from the data for impactful decision making. Manually aggregated data sets represented only 15% of the total parameters their teams measured and the model could only explain 59% of the results. These gaps were what drove Pacira to look for a solution that could accelerate data aggregation, modeling and prediction.

SOLUTION: IMPLEMENTING BIOVIA DISCOVERANT TO ACHIEVE BUSINESS-DRIVEN RESULTS

Pacira identified BIOVIA Discoverant as the solution for Tech Transfer and early commercialization, which best supports their goal to improve yield and time-to-market while optimizing product quality.

BIOVIA Discoverant automatically aggregates and preformats content from disparate systems, acting as a central point of data access without duplicating the content. Users do not need to waste time gathering and formatting data to make it available for analysis and decision making. With more data now easily accessible, models can provide more meaningful predictions on a wider range of topics. Data is turned into useable information.

BIOVIA Discoverant performs statistical analysis and Multiple Linear Regression modeling using derived parameter functionality. With its advanced statistical analysis capabilities, it enables faster root cause identification and process optimization with fewer resources. This allows the organization to maximize yield at optimal concentration while significantly reducing subsequent Out-of-Specification (OOS) test results scrapping lots that didn't meet the specification. BIOVIA Discoverant's capabilities for manufacturing monitoring during the production process allow course corrections in real time and avoid in-process scrap. With its customizable report generation, BIOVIA Discoverant has also become Pacira's primary reporting tool, providing multiple organizational levels with dashboards, and both standard and custom reports supporting standardization and improved efficiency.

**"With BIOVIA Discoverant
I can see things I didn't
even dream of before."**

— Ron Ortiz,
Director Manufacturing Science & Technology

RESULTS: REDUCED CYCLE TIMES, INCREASED YIELD AND ACCELERATED PROFITABILITY

BIOVIA Discoverant helps Pacira identify critical process parameters and their impact on the process, advancing their strategic goal to gain a deeper understanding of their complex production process. BIOVIA Discoverant makes data easily accessible and automates workflows, which leads to significant time savings by eliminating data gathering. Three FTEs can now be reallocated to more productive and meaningful tasks in the production, discovery and design of new drugs.

With BIOVIA Discoverant delivering the data and analytics for process optimization and root cause analysis, Pacira can improve product quality and reduce batches that don't comply with quality specifications. This has led to a reduction of scrap material and rejected lots, which translates into savings of \$20K to \$500K per failure depending on the process stage where it occurred.

Using the diagnostic and predictive capabilities of BIOVIA Discoverant, Pacira can reduce process and product variability and increase the quality yield of the product.

The automation capabilities of BIOVIA Discoverant have removed non-value added activities and waste from their manufacturing processes. The resulting elimination of bottlenecks supports Pacira's Lean initiative, reduces cycle times and improves time to market.

By improving product quality and yield while reducing time-to-market, BIOVIA Discoverant ultimately helps Pacira to increase profitability and improve the bottom line.

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