DELMIA

3DEXPERIENCE

DIGITAL TRANSFORMATION IN PRODUCTION PLANNING AND SCHEDULING FOR LIFE SCIENCES

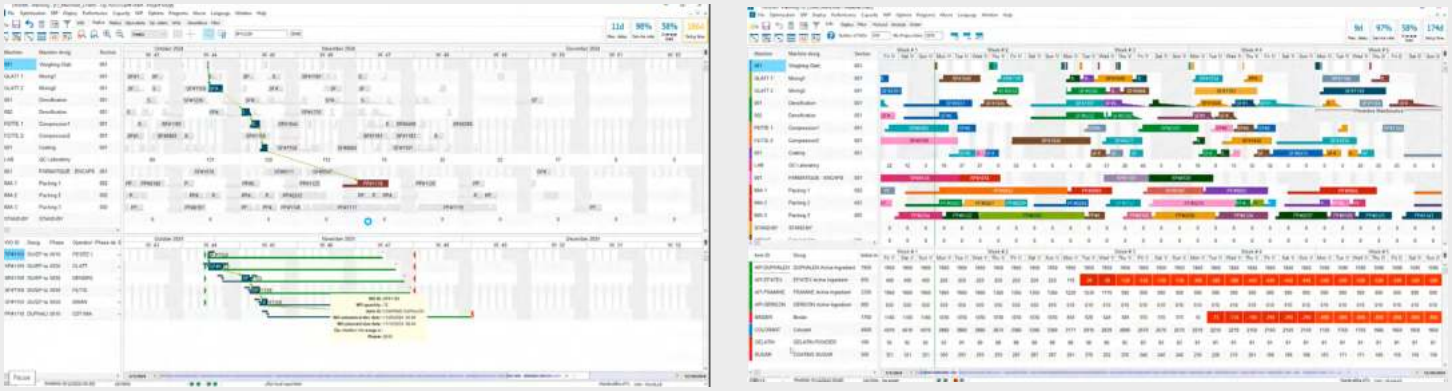
INTRODUCTION

Planning systems for Life Sciences' manufacturers have been around for half a century, and have evolved and grown with advancements in technology and management theory throughout that span of time. Many thousands of companies and facilities worldwide employ a diverse range of manufacturing planning systems to coordinate production, quality testing, laboratory analysis, procurement, minimize inventory, optimize customer service availability, utilize available resources effectively, and manage costs.

The real value of planning systems for manufacturers is that they serve as a communication and coordination vehicle for breaking down interdepartmental barriers (often called information silos). The plan includes all major activities required for producing a product, and is developed top-down from the best available prediction of demand (forecast). The plans and activities relate directly back to demand, the satisfaction of which is the definition of customer service. This centralized, coordinated plan, therefore, keeps everybody pulling in the same direction, working toward the same goal.

DASSAULT SYSTEMES

While many plants have and use planning systems on a daily basis, the sad truth is that most do not really take full advantage of what they have to offer. An alarming number of companies are using their systems primarily for accounting and for tracking customer orders, work orders and purchase orders. Many of these companies "run" the planning application, but do not really follow the recommendations. Sadly, the most commonly used "planning" system is the spreadsheet. This is especially true for overall planning including Demand Planning, Sales & Operations Planning, and Distribution/Supply Chain Planning. Spreadsheets are handy tools for organizing data and performing straightforward calculations but they are inherently personal user tools. It is difficult to share and collaborate on a spreadsheet. Spreadsheets do not plan; they merely organize information. Spreadsheets do not communicate or coordinate across the many elements of the enterprise that must work together to carry out the business of manufacturing.



Simple and intuitive user interface provides better foresight into production hazards and changes in demand.

We have entered a new era with planning systems, enabled by technological developments including manufacturing operations management systems and new hardware (sensors, smart devices) that provide a new level of visibility in the plant, new software including truly advanced planning and analytics, and more comprehensive and more capable "smart" systems that use simulation and optimization to develop and monitor realistic plans that boost productivity and help get the most out of all available resources.

These new planning systems usher in a new era in manufacturing and supply chain management that is fully in tune with the concept of smart manufacturing. We are finally at the point where all of the systems and technologies that have evolved in support of engineering, operations, and service have come together into a comprehensive digital environment that offers the opportunity to proactively manage manufacturing and the supply chain to new levels of efficiency and customer service.

Advanced Planning and Scheduling software (APS) changes paradigm by planning capacity simultaneously with material and laying out schedules using a finite capacity approach.

SMART MANUFACTURING AND LABORATORIES

The future of manufacturing, quality control and laboratories is digital. In fact, you could truthfully say that digital manufacturing is here today and quickly becoming the new normal across medical device, pharmaceutical and biopharma segments.

It starts with the creation of a digital twin, a detailed cyber representation of the part or product, that forms the basis for development, planning, manufacturing, and eventual deployment and use of the article being manufactured. As the item and its digital twin progress through the lifecycle, the digital side can pre-experience each step and activity, allowing the software and the custodians (people) to try different scenarios and "see" the results before any physical resources are expended. Smart manufacturing is the vehicle for responding to increasingly volatile customer demand, global competition in the age of the Internet, and the perpetual need to increase speed, reduce cost, and make the most of all available resources.

ENTERPRISE RESOURCE PLANNING (ERP) AND ADVANCED PLANNING AND SCHEDULING (APS)

Manufacturing Resource Planning (MRP, MRPII) and its successors including Enterprise Resource Planning (ERP) form the customary information management backbone for nearly all manufacturers throughout the world. ERP is not digital manufacturing. But ERP has a place in the digital manufacturing world as the keeper of customer order records as well as finance and accounting records.

The MRP/ERP approach is severely limited in that it relies on fixed assumptions rather than real-time information and it is not part of the digital thread—i.e., if it exchanges data with Manufacturing Execution System (MES), PLM and other parts of the digital thread, it is only as fixed, historical information like bills of materials and routings. ERP does not interact with these systems in any kind of dynamic manner. While out of scope of this white paper, customers that leverage the **3D**EXPERIENCE® platform are able to achieve true digital continuity from ideation extending out to manufacturing planning and execution with DELMIA; and going even further out to manage operations and logistics.

ERP systems traditionally build their planning function top down, which is top down MRP-style calculation based on a simple four-step material availability approach. MRP focuses on material quantities and dates and assumes capacity is or can be made available. Resource checking and capacity planning are addressed separately and only after the material plan is laid out. There is often a need to repeat the cycle: plan material, plan capacity, re-plan material, re-plan capacity, etc. until a manageable plan is attained.

Advanced Planning and Scheduling software (APS) changes paradigm by planning capacity simultaneously with material and laying out schedules using a finite capacity approach. In other words, material and capacity are given equal consideration in developing a realistic and feasible plan in a single iteration. The term APS has been applied to a wide range of software including finite schedulers, comprehensive manufacturing planning systems, and supply chain planning software.

FIRST TIME RIGHT WITH APS

For years, manufacturers have thought about ERP and its planning functions as "what if" simulations, but they are simulations in only the most basic sense. The plan and the projected results (inventory levels and availability dates) are a kind of simulation in that they predict what might occur if the plan is executed as laid out, all activities are completed in the standard lead-time, and so forth. There is little or no ability to try different scenarios and see the expected results in traditional ERP. And there is no realistic model of the plant that reflects experience or cause-and-effect; just standard processing times, lead times, bills of material (BOM), and a forecast that is likely to be less than completely accurate.

Introduced in the mid-1990s, APS software brings optimization to the logistics areas that they address. Finite schedulers overcome the limitations of using assumed lead times for laying out production schedules and resolve resource conflicts for a realizable plan. Using optimization, the scheduler will try different scenarios in an attempt to balance the workload at each workstation (capacity planning) against the required production needed to meet due dates. Applying optimization in the planning process empowers the system to consider trade-offs in developing the best (optimum) array of work orders and schedules, purchases, use of available resources, costs, and inventory levels. Similarly, master production scheduling (MPS), sales & operations planning (S&OP), demand management, and other manifestations of APS use optimization to develop a plan that balances the requirements and limitations of multiple aspects of manufacturing including resource capacity (manpower and skills, equipment rates and utilization), material availability, costs, customer service expectations, and more.

The development of advanced planning software was a major milestone in the evolution of ERP and supply chain management. Systems could now consider multiple factors while using real situational intelligence to make recommendations rather than relying on assumed (standard) capacity, lead times, and current workload. Some measure of "what if" analysis is possible with many APS optimization systems.

IIOT, MOM AND SIMULATION

While enterprise systems have been evolving with advances in computer and software technology, another area of technology has virtually exploded with the widespread growth of the Internet, social media and smart phones – the so-called Internet of Things (IoT). Now these two megatrends have come together. The inexpensive sensors and smart devices developed and produced in huge quantities for consumer markets are being adapted for industrial use and provide an unprecedented ability to provide Manufacturing Operations Management (MOM) and APS systems data to track and monitor shop activity, inventory movement (anywhere in the world), installed equipment status and performance, transportation and warehouse activity, and much more.

Data made available through the Industrial Internet of Things (IIoT) supercharges enterprise systems, allowing advanced planning optimization systems to identify and react to rapidly changing reality more quickly and more precisely than ever before.

A third leg of the technological evolution brings this together through the use of simulation to model the plant and the supply chain and provide true 'what if' capabilities. As new information is received (from IIoT as well as traditional data collection and reporting), simulation-based optimization systems immediately compare the new data to what was expected. When a deviation is detected, the responsible individual is immediately notified so immediate action can be taken to correct the situation. Alternatively, the user may choose to exercise the simulator models to explore the likely outcome if things are allowed to proceed, compared to the impact of alternative corrective measures, to find the most likely outcome.

As you progress further on this smart manufacturing journey looking for continuous improvement in addition to IIoT and simulation there is a need for tight integration of APS with your MOM system. Cohesive integration of your various manufacturing operations is critical to delivering on the promise of digital continuity and realizing transformative change across your value network.

An order is launched on time but is held up at the first workstation by a tooling issue; therefore, it will be late arriving at the second workstation. Since built-in wait time has been largely eliminated in this schedule (yielding much shorter manufacturing lead-time overall) it is likely that the second workstation will be ready before the order arrives. Would it be best to start any set-up needed before the order actually arrives or should another job be slotted in ahead of the one that was delayed? How would these two alternatives affect the ability to meet the due dates for these two orders? What would be the impact of this change on all other work currently in the shop, utilization on all work centers, job costs considering the changes in set-up that may be required if work sequence changes? Are there other alternatives that result in better on-time completion, lower cost, or higher productive utilization?

Simulation-based APS can try these two alternatives and many others, compare the results, and find the optimum solution – in seconds and immediately after the planner is notified of the delay. It also provides realistic, achievable completion estimates, so you are always on top of the status of every job, all the time. Bottom line, DELMIA Advanced Planning and Scheduling (APS) helps you meet target due dates, drastically reduce lead time, lower raw material and WIP inventory, increase throughput and utilization, and save time.

CROSSING BOUNDARIES

The most significant benefits of advanced planning come from the coordination of activities in pursuit of the common goal: delivering great customer service at minimal cost and optimum utilization of available resources. That's extremely difficult to do if your "plan" is on a spreadsheet, and a spreadsheet is not really a plan at all, it is not easily communicated through the organization and supply chain, and is not dynamically tied to ongoing activity.

The ultimate achievement is to develop an agile and responsive supply chain that is also efficient. There is a direct relationship between agility and cost. Said another way, there is a direct relationship between rigidity and efficiency. Lean Manufacturing has taught us that variation is the enemy of lean, efficient production. Lean focuses on strict procedures (standardized work) reliably carried out, with the elimination of variation that causes waste. Lean works very well when demand is predictable and relatively constant but those efficiencies go right out the window when demand changes, lot sizes shrink with product proliferation, or anything along the chain fails to maintain its synchronization. APS software solutions can be very complementary to assisting in achieving effective Lean practices.

Many efficient (lowest cost) supply chains rely on large lot sizes to reduce unit cost in purchasing, production, and distribution. Large lot sizes become a liability when customer demand is volatile or product lifecycles shrink. Product proliferation driven by global efficient transportation and easy on-line shopping also works against large lot sizes. Mass production is no longer the haven it was in the last century. Today's manufacturer must be extremely sensitive to trends and the uncertainty of demand and be able to respond to those changes quickly and efficiently. And because today's manufacturing is scattered across the globe, very few products are made in a single location. The entire supply chain must be agile, and highly coordinated.

It is quite easy to see this idea at work within the plant. Manufacturing is most efficient when required materials are available when needed for production. Is there anything more frustrating – or disruptive – than having to change the production schedule at the last minute because of a part shortage? And how much obsolete inventory is there in your plant, tucked out of sight in the corners of the stockroom or warehouse that is the direct result of insufficient agility coupled with failure to detect changing demand quickly enough.

Lead-time is arguably the biggest factor in agility. The ultimate in agility would be if the plant were able to produce any product on-demand, the day it is ordered. This implies no finished goods inventories and little or no set-up or changeover time in the plant (and all necessary components on-hand). This is actually possible where there is limited product variety and overall demand is relatively stable or at least predictable. After all, this is how every restaurant in the world operates. Few manufacturing plants can operate on the restaurant model – and truth be told, many restaurants fail to deliver acceptable customer service, run out of popular dishes at the most inconvenient times, and often change product arrays based on availability (daily specials and unavailable items from the standard menu).

IT'S REALLY ABOUT PRODUCTION

Focusing on efficient plant operations, advanced planning and scheduling are the keys to reducing cycle time, minimizing non-productive set-up time, and making flexibility an important competitive strength. Manual scheduling with spreadsheets and even computer-driven schedules using MRP logic are very limited, and completely unresponsive to current conditions. Without the direct link to real-time data and the ability to optimize and simulate, these methods rely on fixed assumptions and what amounts to rules-of-thumb that invariably misrepresent the reality of the plant floor.

Think about a schedule developed the traditional way, based on due date and standard lead times (move, set-up, run, wait). Through the insight of a skilled scheduler and a bit of luck, the schedule appears to be valid – all jobs are expected to complete more-or-less on time and equipment utilization is at a reasonable level. Good enough? Most schedulers would think so because experience has taught them that it's the best they can do.

But is it really? Based on the power of simulation and conducting what-if constraint and demand scenarios, DELMIA APS can find the most advantageous strategy. Companies using this advanced scheduling approach have been able to reduce cycle time by 50% and reduce set-up time by 25%, meaning increased throughput and higher productive utilization of people and equipment.

APS FOR MEDTECH, MEDSUPPLY, PHARMA AND BIOPHARMA

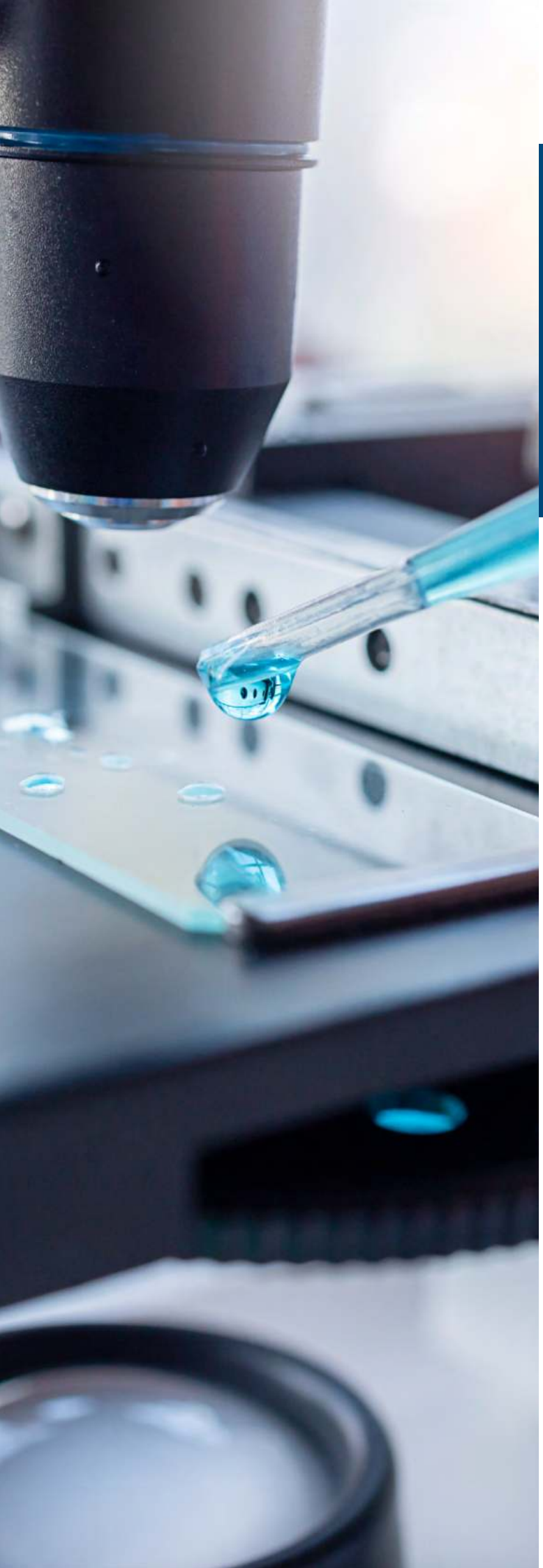
All manufacturers do the same critical tasks – procure components and raw materials; process those materials through the application of manpower and equipment; store and account for materials and finished goods; sell and deliver those goods to customers directly or through a distribution network; account for all of this activity and plan for the future. The advanced scheduling and dynamic management outlined above applies to all manufacturers in all industries, anywhere on the globe. And the more complex or volatile the supply chain is, the more these tools are needed and the less useful are spreadsheets and traditional ERP planners.

With DELMIA Solutions, we address both Manufacturing and Laboratory needs. Our capabilities span the strategic, tactical, and operational layers, including detailed scheduling. Similarly, for laboratories, we offer solutions for long-term, mid-term, and capacity management, allowing for better anticipation and adjustment of lab capacities.

Complex medical device manufacturing includes products with many parts – deep and/or broad BOM. These manufacturers manage many parts/components and therefore have many suppliers and considerable inventory to order, track, and coordinate. Medical device manufacturers may also have complex manufacturing processes with many steps and a lot of people and equipment to coordinate.

Medical device manufacturers face various management constraints, including:

- High product mix
- Expanding product references due to regulatory and certification requirements, varying by country
- Need for flexible production lines and multiple alternatives
- Synchronization challenges
- Shelf Life, temperature, and other environment considerations
- Setup time and campaign management (e.g., format changes)
- Labor and certification considerations
- Quality control
- Rapid rescheduling in response to unexpected events (e.g., breakdowns), disruptions, or health crises
- Priority adjustments driven by cost pressures and competition from generics
- Simulation of new product introductions and maintenance planning



In medical device manufacturing, excellence means meeting customer demands for quality, innovation, and reliability. Achieving this requires adaptability to navigate regulations, maintain flexibility, and ensure stringent quality standards, all while managing disruptions and evolving priorities.

High-volume medical supply manufacturers may have simpler bills and processes, but equipment scheduling is even more critical – keeping the production lines running is paramount. Raw material and component inventory is equally important as any shortage or quality issue may disrupt that all-important production schedule. Medical supply manufacturers are also likely to have a more complex distribution chain with customers who are very sensitive to availability and service levels. Distribution logic is as important to medical supply manufacturers as supplier management is to complex product makers.

Pharmaceutical and BioPharma manufacturers, like high-volume medical supply manufacturers, share similar concerns. They also operate under rigorous regulatory requirements for electronic records and sign-offs, quality mandates, and stringent traceability obligations. In parallel, control labs conduct numerous tests to ensure product quality throughout the process. In this fast-paced twenty-first-century manufacturing landscape, fully integrated systems with built-in quality management and electronic signatures are essential for compliance.

Key requirements for Pharmaceutical and BioPharma industries encompass:

- Finite capacity scheduling
- Traceability
- Campaign planning and setup time optimization
- Managing constraints, including allergens, cleaning, utilities, and material availability checks
- Simulation and what-if scenarios
- Certifications
- Maintenance schedules
- Labor and testing certifications

FUTURE PROOFING YOUR OPERATIONS

Your plant and supply chain are undoubtedly operating at some level of effectiveness today, but an honest and aware manager or executive can surely see room for improvement. And even if your supply chain is in fine shape today, how quickly are you able to identify a change in demand, availability of materials, location and progress of an incoming shipment or outgoing load of products. How quickly can you react to any of those changes so you can keep the plant operating efficiently and keep promises to customers?

Additionally, consider how much of the management of your plant and supply chain is in the hands, and more specifically the heads, of key individuals? If something were to happen to any one of them, what would happen to your plant and supply chain's performance? We are not suggesting that a planning system, even the best planning system available, can or will replace experienced, dedicated planners, managers and executives. However, you must recognize that the knowledge and experience residing with these key individuals is not easily replaced or propagated.

In addition, the operational knowledge buried in spreadsheets is every bit as vulnerable. The planning and scheduling that goes on in Excel is not systematized – the spreadsheet does not make the decisions or even recommend the choices. All that happens in the head of the scheduler and is not embedded in the spreadsheet. It is therefore not repeatable and not easily preserved or transferred.

On a more positive note, think about how the power of simulation has changed the world within and outside of manufacturing. Virtually all products made today start out as a digital design (model) that is thoroughly tested through simulation. The part or product is subjected to extreme environmental conditions, stresses and extended use, it is manufactured and assembled, and proven…all in digital space before the first prototype is made. And that prototype might be generated directly from manufacturing controls created from the digital model or 3D printed from those same digital instructions. Simulation is how we train aircraft pilots, nuclear plant operators, service technicians, doctors, and many others where it would be impractical or downright dangerous to have them learn their trade in real-world conditions. Simulation speeds up the design process, accelerates production ramp-ups, results in better products, and costs much less that traditional prototyping and testing. And, as you can understand from this paper, similarly transforms manufacturing operations.

This discussion has focused primarily on scheduling, but do not forget that real-time visibility is a key underlying element that enables the quick identification of changes and undesirable occurrences that allow schedulers to be proactive in managing plant, quality, lab and R&D activities. That visibility extends to the human schedulers and managers, as well, so their inherent knowledge and years of experience can be even more effective as they can keep an even better view of everything that is happening in the plant.

Modern supply chain management is heavily dependent on communications and coordination between and among supply chain partners as they work together to manage increasingly complex and dynamic supply networks. DELMIA APS is built around a collaboration platform that helps unite internal and external (human) resources to coordinate activities and keep each other fully informed of the status and plans of activities. Yet another way that DELMIA APS helps preserve and perpetuate the value that your planners and managers bring to your organizations.

NEXT STEPS

Manufacturers cannot afford to sit by and watch their competitors implement advanced planning and scheduling, increasing their effectiveness and reducing costs. The never-ending battle to reduce costs continues, of course, but the focus today has to be on efficiency and responsiveness. Demand changes more quickly than ever before. Product cycles are shorter, new products and product variations proliferate. Customers are ever more demanding as they can literally "shop the world" through the Internet such that even smaller, formerly localize producers must compete with manufacturers around the world every day, even for local customers.

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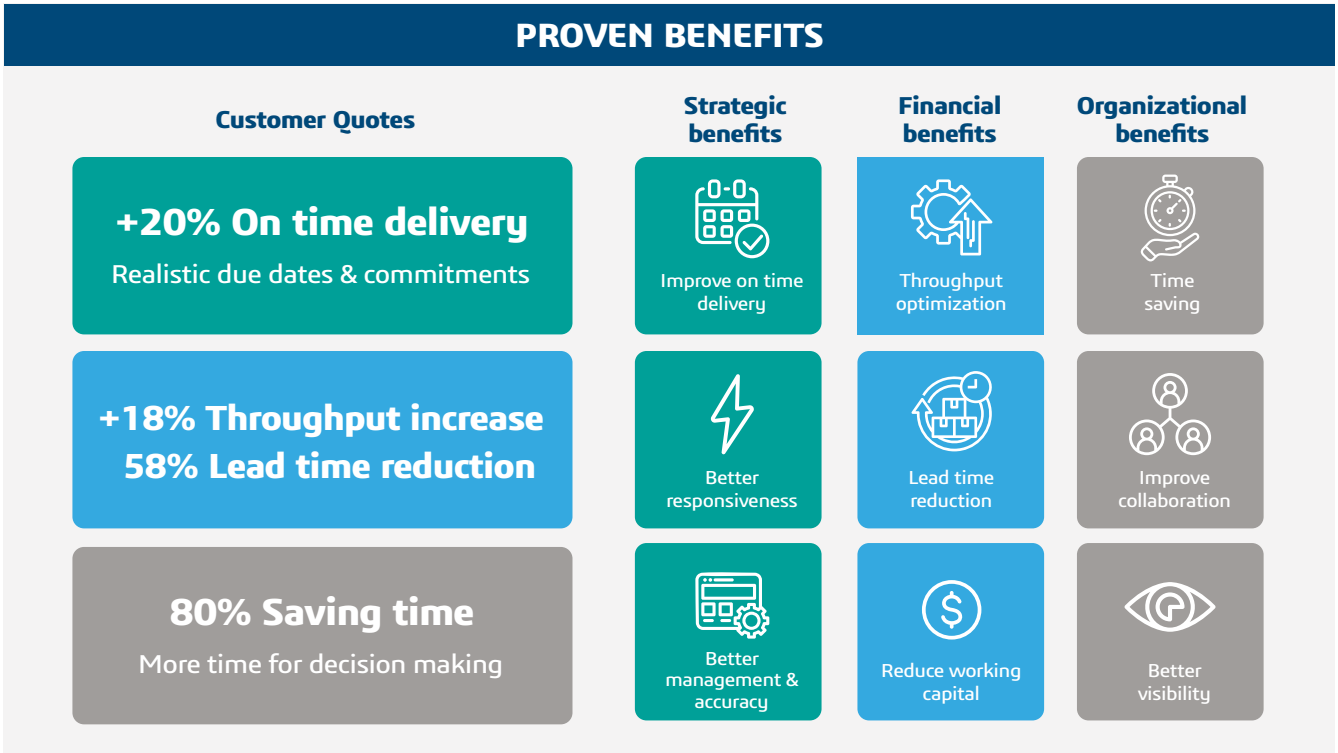
The front lines on this competitive battlefield are short lead-time and agility – the ability to respond quickly to new or changing demand and deliver well-made products quickly. It is clear that DELMIA APS software systems deliver those capabilities. Companies using DELMIA APS have been able to reduce lead times significantly as a result of better work flow, less waiting (and less WIP inventory) in work center queues, much less set-up and idle time on equipment, and the agility that comes from short cycle times and a firm grasp of real-time shop status and capabilities.

If your company is dependent on old-fashioned standards-based plans or, worst of all, manual scheduling spreadsheets, your business is vulnerable to competitors who are embracing modern advanced planning and scheduling systems. Do not wait for the markets and your customers to move in that direction, leaving your business behind. Take a close look at your current scheduling system. Assess the vulnerabilities to more efficient and more agile competition. Think hard about the tribal knowledge that goes into scheduling the plant and how devastating it would be if that knowledge were suddenly unavailable, for whatever reason. Plan for your business' future by embracing digital manufacturing and DELMIA APS, the advanced planning system built on digital manufacturing technologies that brings simulation-based optimization to plant floor planning and scheduling.

CUSTOMER AVERAGE ROI BENEFITS FROM DELMIA APS



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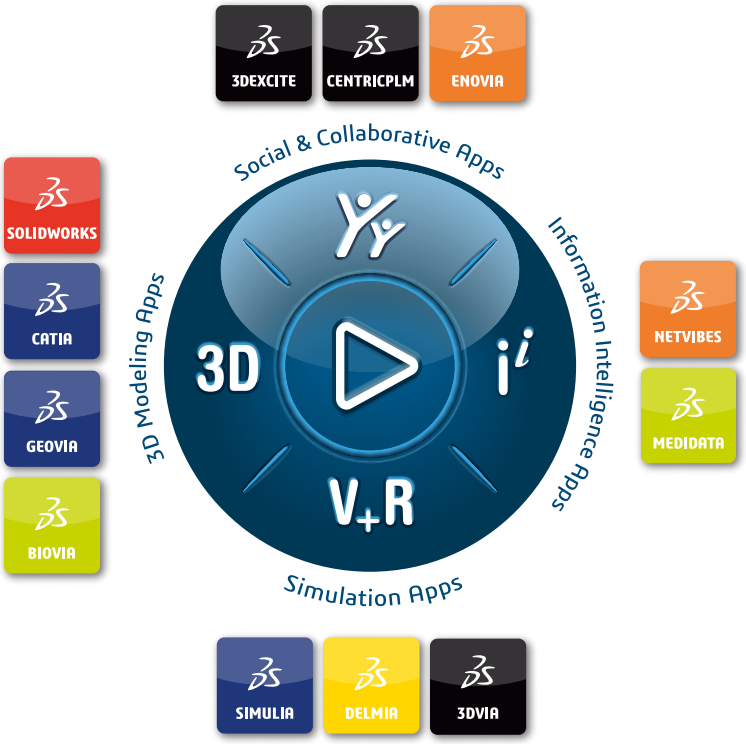

Our **3D**EXPERIENCE® platform powers our brand applications, serving 12 industries, and provides a rich portfolio of industry solution experiences.

Dassault Systèmes, the **3D**EXPERIENCE Company, is a catalyst for human progress. We provide business and people with collaborative virtual environments to imagine sustainable innovations. By creating virtual twin experiences of the real world with our **3D**EXPERIENCE platform and applications, our customers can redefine the creation, production and life-cycle-management processes of their offer and thus have a meaningful impact to make the world more sustainable. The beauty of the Experience Economy is that it is a human-centered economy for the benefit of all –consumers, patients and citizens.

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