Operational Solutions for The Pharmaceutical and Biological Pharmaceutical Industries

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Purpose of This White Paper

Information systems, automation and ERP help pharmaceutical and biological pharmaceutical companies comply with governmental regulation and ensure the safety/quality of their products. They also cut costs and allow a processor to integrate information in keeping with the increasingly vertical way that the processor does business.

The purpose of this white paper is to outline new technology solutions for pharmaceutical and biological pharmaceutical companies. At the plant level, there are critical issues—unique to the processing industry—which affect pharmaceutical and biological pharmaceutical companies in particular.

The Pharmaceutical Industry: An Overview

Today's pharmaceutical industry is going through a period of major change that is characterized by increased competition, industry globalization and a wave of mergers and partnerships. In addition, the pharmaceutical industry is faced with multiple internal and external challenges such as high research and development costs, government guidelines, and extremely stringent manufacturing and distribution requirements. All this makes it a complex industry for which “close enough” just won't do.

Just as your product and processes must be extremely accurate, your information systems must be able to support the details. Losing track of these details is not acceptable. Many Enterprise Resource Planning (ERP) systems can only get close to what you need.

Pharmaceutical Industry: General Issues and Trends

At all times, a pharmaceutical company faces challenges from all sides –

- Pressure to reduce cost to the customer
- Heavy global market place pressure and competition
- The need to acquire new technology instead of developing new products
- Pressure to maintain long pipelines for development of new drugs and delivery systems
- Significant regulatory issues, in a global business (including compliance to FDA and various Ministry of Health requirements)
- The need to maximize (or integrate) IT applications to deal with variability.

As a result, pharmaceutical companies are especially concerned with quality, safety, good manufacturing practices, cost containment, new product introductions, inventory, change management and computer system validation.

Quality

Pharmaceutical processing involves tremendous exposure. If something goes wrong with one lot or if one package is tainted, the risk to public health andsafety and the risk of negative publicity is quite significant. Failure to manage quality and control is a catastrophic mistake. A drug contamination scare may ruin a company’s image for years, causing sales and/or market share to plummet. Recording and tracking quality is therefore critical. In the final analysis, pharmaceutical companies strive for the highest quality standards they can achieve.

Safety

Pharmaceutical safety is a concern of governments across the world. Periodically, safety issues such as drug tampering ((e.g. Tylenol), blood borne pathogen scares for plasma derived drugs, AIDS and hepatitis are big news in the global press. Industry regulators are intensifying regulations for quality control of raw materials, process validation and pharmaceutical safety requirements amid growing concerns for public safety . Pharmaceutical companies invest heavily in the identity, safety, purity, potency, quality and efficacy of their products. They need to track and control microbiological and bacterial (Pyrogenic) issues and require sterility assurance at all times. To this end, they invest in compliance, inspection and insurance. They also demand quality assurance and lot traceability at every step of the production process.

Current Good Manufacturing Practices (cGMP)

Today's code of cGMP as regulated by health departments and governments place specific requirements on pharmaceutical manufacturers to implement manufacturing systems.

Electronic Quarantine

The industry requires that materials used in the product and certain printed packaging materials must be strictly controlled from the time of receipt to the shipment of finished product to the customer On arrival, these materials need to be quarantined, sampled and tested. Only authorized staff can release the material from quarantine. "Quarantine" here means that it is not possible to issue this material to production or the customer. Traditionally, a quarantined product was isolated in a physically separate, secure warehouse area.
Electronic quarantine means that the computer logic allows the user to give materials a quarantine "status" in the computer. The system subsequently prevents the user from issuing quarantined materials to production. Only authorized staff can change the material status.

Quarantine Release by User and Material Type

GMP requires that staff who release material from quarantine be appropriately trained and authorized for the work that they do. An important issue here is that the computer system should take into account the fact that there are different categories of material that are electronically quarantined. For example, a packaging inspector who is trained and authorized to inspect and electronically release labels, cartons, etc., probably won't be trained to release active drug materials. A computer system should meet this need.

Printed Material Control/Obsolete Components

GMP emphasizes the importance of controls of labels and other printed packaging because of the risk mis-labeling presents to the end user. Therefore, the

manufacturer must have systems in place to ensure that obsolete or old versions of packaging materials are used before new ones are issued (or run the risk of expensive write-offs). If a computer system is used, automated label tracking can provide better insurance and reliability over manual tracking techniques.

Lot Control/Material Segregation

Incoming raw materials, components, and manufactured items must be lot controlled segregating each supplier's lot or manufacturing lot with a unique identifying number that can be correlated with the manufacturer's lot number. Materials must be segregated at the lot level within a pharmaceutical warehouse, so that, not more than one manufacturer's lot can be stored in one location either physically or electronically..

Lot Tracking

In the event of a product recall, a pharmaceutical company must be able to forward track the lot in question to the customer that the product was sold to, and also, if required, back track to any of the ingredients/components that produced the lot. The computer system MUST be able to provide this information in a timely manner.

Drug and Hazardous Reconciliation

At any moment in time, a manufacturer needs to be able to identify the amount of hazardous material it has received, where it is located, when and where it has been used and who it has been shipped to. In a world where control and traceability is critical, the business cannot afford to make a mistake.

Supply Chain Pressures

As distribution processes become streamlined, a shorter supply chain eventually pushes back into the manufacturing plant, with the assumption that the supply chain will be more responsive. Plant executives need systems to respond to that demand for shorter response times. Variable customer requirements, reduced inventory levels, ever-changing schedules, and shorter production runs also impact plant operations requiring the use of automation techniques to ensure peak efficiency.

The industry is trending toward vertical integration with many of the large players now running lines starting from raw or intermediate material production to final processing. These companies face significant challenges in streamlining/combining operations and aligning information with integrated systems.

Cost Containment

Under pressure by governments to reduce health costs, hospitals and health care organizations are constantly under fire to minimize expenses. As a result, drugs are targeted as areas for cost containment controls, increasing the pressure on manufacturers to reduce manufacturing costs.

A major component of cost control and cost reduction is the ability to follow detail through every step in the manufacturing process. Plant managers maintain a close watch on yields and labor and track material usage varying their shift operations to maximize capacity.

Inventory Issues

Pharmaceutical plant manufacturers often handle active ingredients. It is common for these materials to be very expensive in small quantities, and are often reused and/or recycled several times. The system must be capable of modelling the processing and reprocessing of these materials.

Total Quality Management, Material Requirements Planning II and Class A manufacturing all strive to improve processes by "managing by facts and data," and the pharmaceutical industry is focused on evaluating manufacturing data to improve the business.

As volume, scope, and competitive levels of import/export increase, tracking of finished product inventory becomes increasingly critical.

Change Management

There is no one single reason why pharmaceutical products change. These changes may be regulatory in nature, process improvements or the demands of new marketplaces, especially in the growing global marketplace for healthcare.

Mergers and acquisitions do take place in the pharmaceutical industry. New affiliations impact the industry and contribute to rapid levels of change. Brand variations occur as a result of acquisitions requiring new formulas, new production methods, and new characteristics, not to mention the validation required before bringing these products to market. Labeling requirements may need to meet multi-language requirements, even within a single country. A manufacturer must meet the challenges presented by changes in an environment where it can be slow to earn business, but quick to lose it.

Computer System Validation

The validation of computer systems used in the pharmaceutical manufacturing environment is a fundamental requirement during the selection and implementation process of an ERP package. Many pharmaceutical companies have partnered with

computer vendors to address this validation issue, however, validating computer systems with source code modified at the user site further complicates the validation process.

Key Success Factors for ERP Systems

This white paper focuses on key issues that affect pharmaceutical companies, regardless of size and term these issues "Critical Success Factors." If these issues are not addressed, you cannot run your business efficiently. You may be able to work around them, but you cannot work efficiently.

- Modeling the Production Process
  - Multiple Co-Products and By-Products
  - Recycles and Waste
  - Multi-Stage Processes
  - Product Variations
  - Yield Losses or Gains
  - Costing the Process
  - Planning the Process
- Potency
- Inventory Control
- Lot/Sublot Control
- Process Control
- Process Validation
- Automation integration
- Quality Assurance
- Close–loop Scheduling

Modeling the Production Process

Pharmaceutical companies encounter by-products, co-products, recycles, waste, multiple stage processes, product variations, yield losses/gains and many more business issues throughout the production process. The production process of any pharmaceutical category could be modeled to illustrate the multiple stages involved;. Figure 1 displays a diagram of a typical process for plasma fractionation.

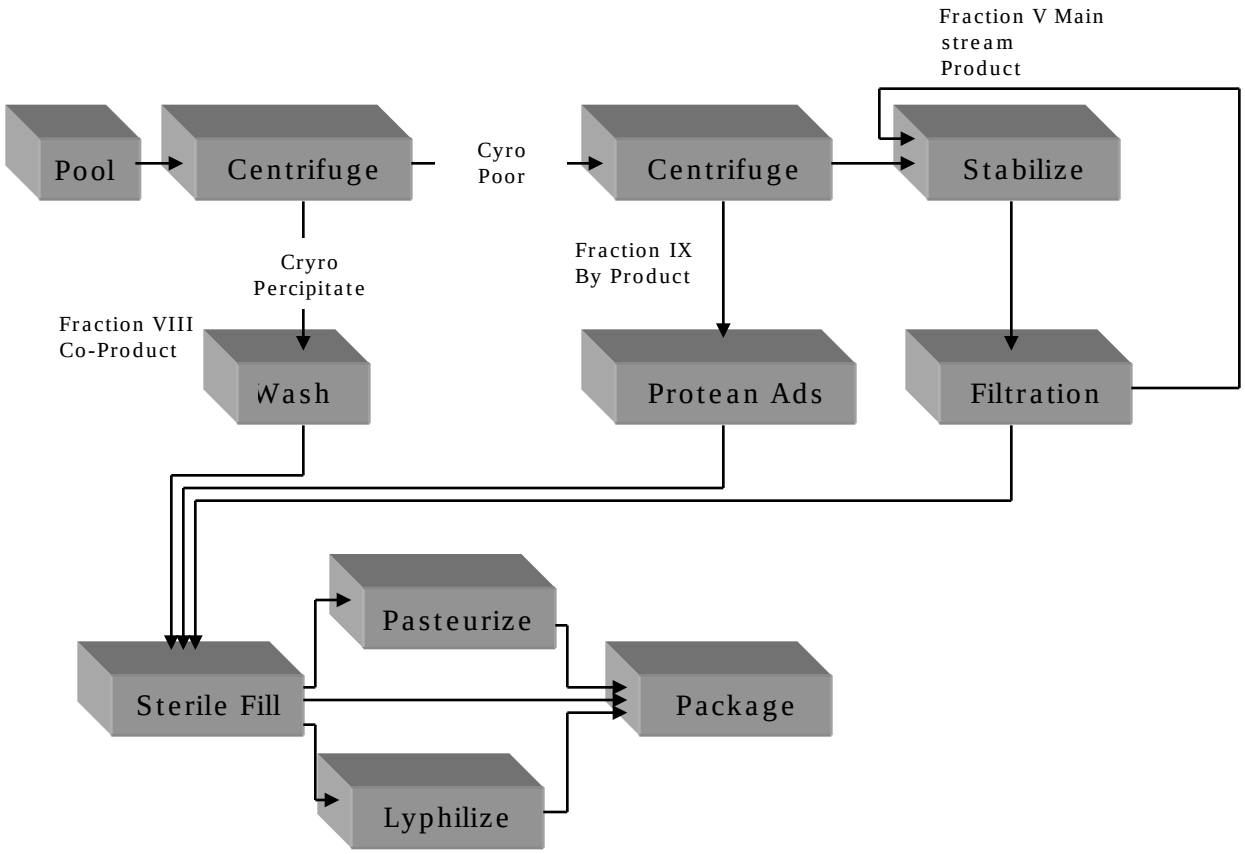


Fig. 1 - Production Model for Plasma Fractionation

Multiple Co-Products and By-Products

The co-products and by-products produced in pharmaceutical and biological pharmaceutical processing vary widely. For example, in the plasma fractionation industry, plasma is fractionated into multiple finished products, Fraction VIII, Fraction II, Fraction IV, and albumin. These products are produced in various units of measure in both dried (lyophilized), and liquified states and can and will change it's potency based on the selected processing methods. Regardless of the particular by-products your plant produces, as a pharmaceutical processor, you require a manufacturing system that supports a highly varied and flexible processing model.

Waste and Recycles

At many steps in pharmaceutical processing, there may be materials produced that are used in other processes in addition to recycled waste.

Waste products must be separated from the finished product, sometimes inspected and often treated before further use or disposal. Certain waste products may yield a net realizable value – such as alcohol recovery systems. Recyclable materials must be assigned a cost correctly when they are produced and used again within the

process and validated for further processing. In addition, allowances must be made for planning material requirements and scheduling

Multi-Stage Processes

Every pharmaceutical process seeks to balance planning and control while minimizing inventory and costs. Many factors affect the cost of making the product (machinery, labor, utilities, etc.) and capacity constraints and bottlenecks must be considered.

The Production Model

A production model is the center of all production activity and is used to define production standards, plan capacity and material requirements, define production rates, model costs, and measure performance.

A production model combines formula requirements and operational information into a single entity. This entity contains a complete list of all resources required for production, and accommodates unique process requirements including:

- formulas and routings that may vary slightly based on a process schedule
- fluctuations in yield
- recycles
- energy
- waste
- labor and equipment planning
- co-product and by-product production.

As displayed in Figure 2, Protean's Production Model capabilities consist of one or more user-defined "process stages". Stages represent the sequence of events necessary to manufacture the produced resources and are the lowest level at which you can report and analyze yield, production and consumption. At each stage, it is possible to define what is consumed and what is produced from the process. These can include anything that you need to record, analyze, cost or plan by (e.g. raw materials, packing materials, labor, machines, energy, produced resources, by-products, co-products, waste, scrap, and recycles.).

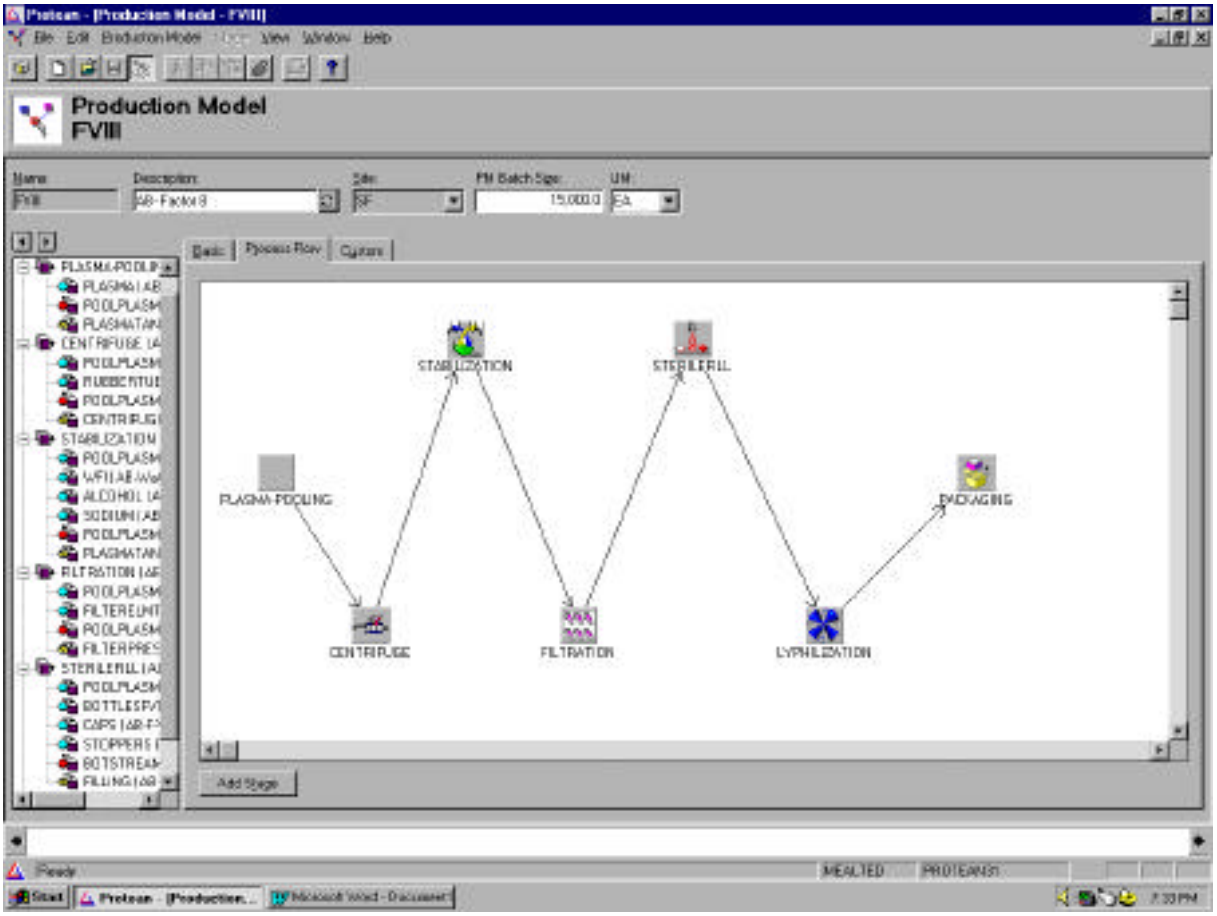


Fig. 2 A Production Model Interface for the Pharmaceutical Industry Inquiry

Product Variations

Most pharmaceutical processes are affected with several reasons for product variations, most notably the variability of raw materials. The quality of materials going into the process affects the formula you manufacture as well as the quality of what you produce. In most cases, you cannot produce until you determine the quality of the raw materials coming into the plant. This is further compounded by customer demands influencing product variations. The number of SKU's can explode based on packaging variations demanded by regulatory requirements and the global marketplace. In most software packages, this can result in an unmanageable number of Bills of Materials (BOMs).

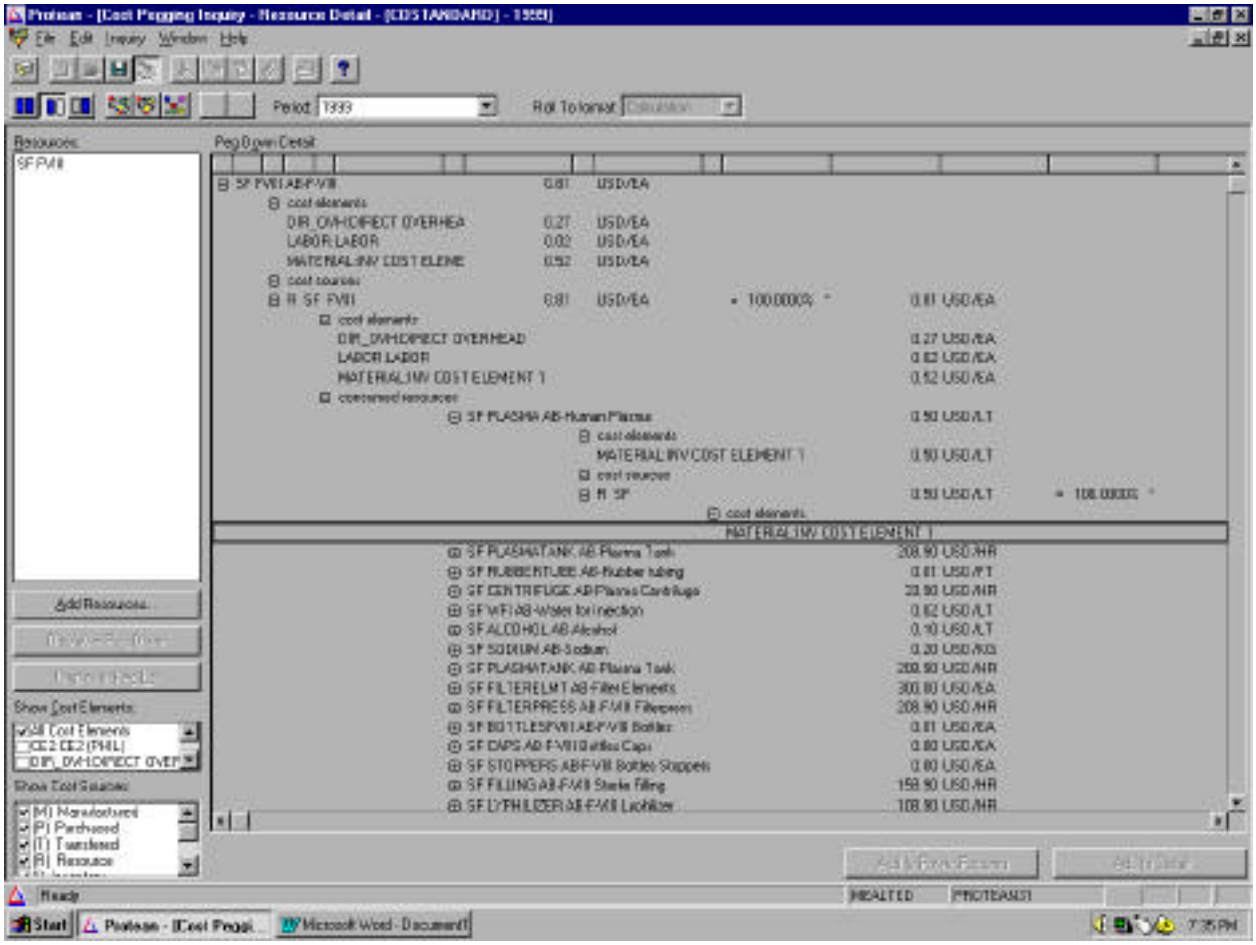
Planning for product variations requires manufacturing software that allows you to define additional levels of information or characteristics about the resources used in your production process. These characteristics can then be used to record specific results based on the variations that might result
from a production process, e.g., packing variations, quality specifications. The resulting benefits of this approach include:

- Minimizing the effort required to create and maintain formulas and production sheets.
- Controlling the production of products with significant variability in consumed and produced materials.
- Control of specification and quality parameters (for example, grade) for an ingredient or machine acceptable for use.
- Ability to record actual results against the variable attributes on a produced resource (e.g., grade, potency, packaging, etc.).

Your software solution should allow you to model you production process, and provide the flexibility to schedule production at a generic level to accommodate multiple choices of which resources to use or produce. For example, you may know that your product will require the use of a packing machine in a packing line, but do not know which machine will be used until the time of production.

It should also allow you to account for variability in raw materials that affect output to accommodate for fluctuations in material quantities and adjust production schedules accordingly.

The flexibility to schedule a generic resource and then specify the actual resource at a later point in the process (up to and including reporting of production) is a significant attribute desired for pharmaceutical industry requirements for packaging variation. This becomes evident for a product with packaging variations for one brand such as multiple language labeling requirements. But it's equally important to update automatically update the system based on specific characteristics assigned by the process.



Costing the Process

The integrity of costing your products is improved using a system that models your production environment. Using applications that can cost your raw materials, ingredients, packaging, labor and machines, as well as quality, energy, maintenance and waste, improves your ability to manage the bottom line and ultimately profitability. Systems that support these requirements define cost elements that apply a greater level of precision to a resource's cost allowing you to directly understand your direct labor, freight, and overhead costs. Protean's production modelling provides the capability to define cost distributions for multiple finished products, by-products, co-products and recycles with the level of accuracy required by pharmaceutical customers.

Systems also need to support the ability to calculate the cost of multiple finished products and "What if" simulation to determine the least expensive an most efficient way of manufacturing a product (i.e. Least Cost Formulation).

Planning the Process

Systems have to determine material availability, capacity constraints, scheduling and sequencing rules (finite forward loading) and provide all the necessary standards/rates to make calculations so you can plan for multiple end products. Protean's Plant Planning and Quick Scheduler applications use the Production Model to satisfy these requirements.

Further advances in technology and software integration are requiring close loop planning and scheduling which will be available in a future release of Protean.

The Workaround: How Other Products Function

The vast majority of ERP products are based upon the Bill of Material (BOM)and is the only way these systems can model production processes. This different foundation (originally created for other, unrelated industries) forces it's process oriented users to develop workarounds to accomplish some or all of the requirements.

The reason for this incompatibility is that the BOM was designed to handle **one finished product**. Thus, if you have a process with more than one finished product (co-product, by-product, waste, etc.), you have to adjust your implementation, typically, by creating a BOM with one produced item and several consumed items carrying negative quantities. Although this serves the immediate need it cannot be used effectively by the costing, planning and production applications (e.g How do you plan for a negative quantity?)

Since BOM-based systems include only material requirements of known specifications required for a route or step it becomes difficult to track variability in raw material characteristics or cost and plan the utilities, labor and machinery. The conclusion is that these systems are incomplete because they have a fundamentally limited design, **and do not work in the world of pharmaceutical processing.**

Most of these systems force you to create individual product master records and BOMs for every variation of a product resulting in thousands of product codes and BOMs. Production variations common in the pharmaceutical industry, would result in hundreds if not thousands of end product codes and BOMs.

Inventory Control

Pharmaceutical processing requires the ability to classify, control and record specific values for inventory so it's is extremely important that the tracking systems you use can perform these functions. For example, a plant manager needs to be able to monitor all stock, aging (tempering, maturing), hold, quarantine, and available inventory levels. The following short list of questions are asked by plant managers every day:

- Do I have enough **good** inventory to satisfy this order?
- When will lot 1234 be released from **quarantine**?
- How much longer does lot 1234 need to be **aged, matured** or **tempered** before releasing for consumption?
- How many batches with **deviations** do I have?
- How much **discrepant material** do I have?
- How much **rework** do I have?
- What raw materials have been **rejected** but not yet returned to the supplier?
- What is the **expiration date** of a specific lot?
- What lots are currently in **inspection**?
- If I assume that all inventory being **tested** at present will be available as planned, can I satisfy the customer demands projected for the future?

The software you select should provide the capability to define various types of inventory states and rules to track the movement, availability and usage of inventory. You should also be provided with sophisticated and customizable inquiries that allow you to ask difficult questions to obtain the answers that enable you to run your business.

Inventory Inquiry

Protean's inventory inquiry capabilities demonstrate the level of functionality a pharmaceutical processing plant **should** have to run their business. This includes multiple views of their data to obtain an exact picture of what is available, where it is, and the specific properties of each resource. Figure 3 displays Protean's inventory inquiry application and demonstrates how easy it is to answer:

- How many lots of material with an expiration date after the 1st of the month do I have?
- Where are they located?
- How is it packed?
- How many pallets are they on?

Answering these questions and others becomes easier using Protean's "Hide and show capabilities" which allow you to customize the inquiry to display only the information you're interested in reviewing.

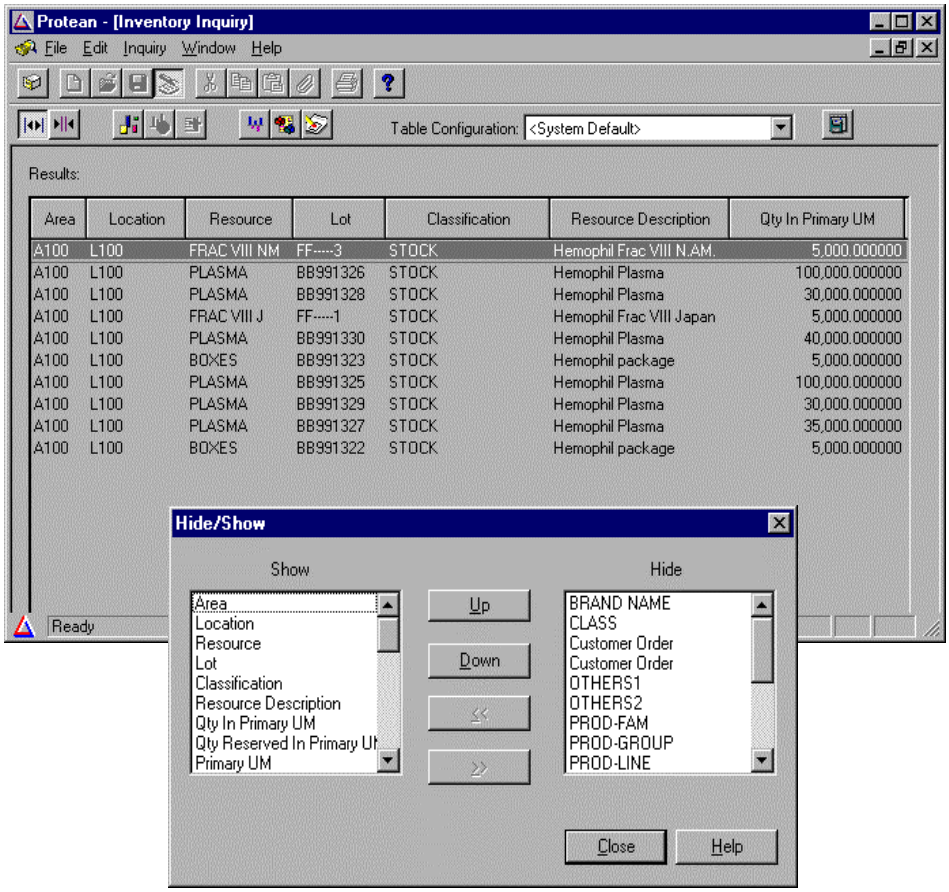


Fig. 3 - Inventory Inquiry

Available to Promise

Customer service requires accurate information to maintain customer satisfaction. The software you select should provide "Available to Promise" (ATP) functionality that shows the projected inventory level of any resource throughout the enterprise at any point in time. Inventory fluctuations due to purchase order, production order, transfer order and customer order transactions, need to be reflected in ATP inquiries to support an efficient supply chain.

Figure 4 displays Protean's ATP inquiry. "Available to Promise" results reflect the realities of inventory transactions resulting from inspections, resource expirations, and other activities impacting the availability of product. The results are based on the addition and subtraction of purchase orders, production orders, transfer orders and customer orders to the available inventory and reflect the inventory transactions mentioned previously.

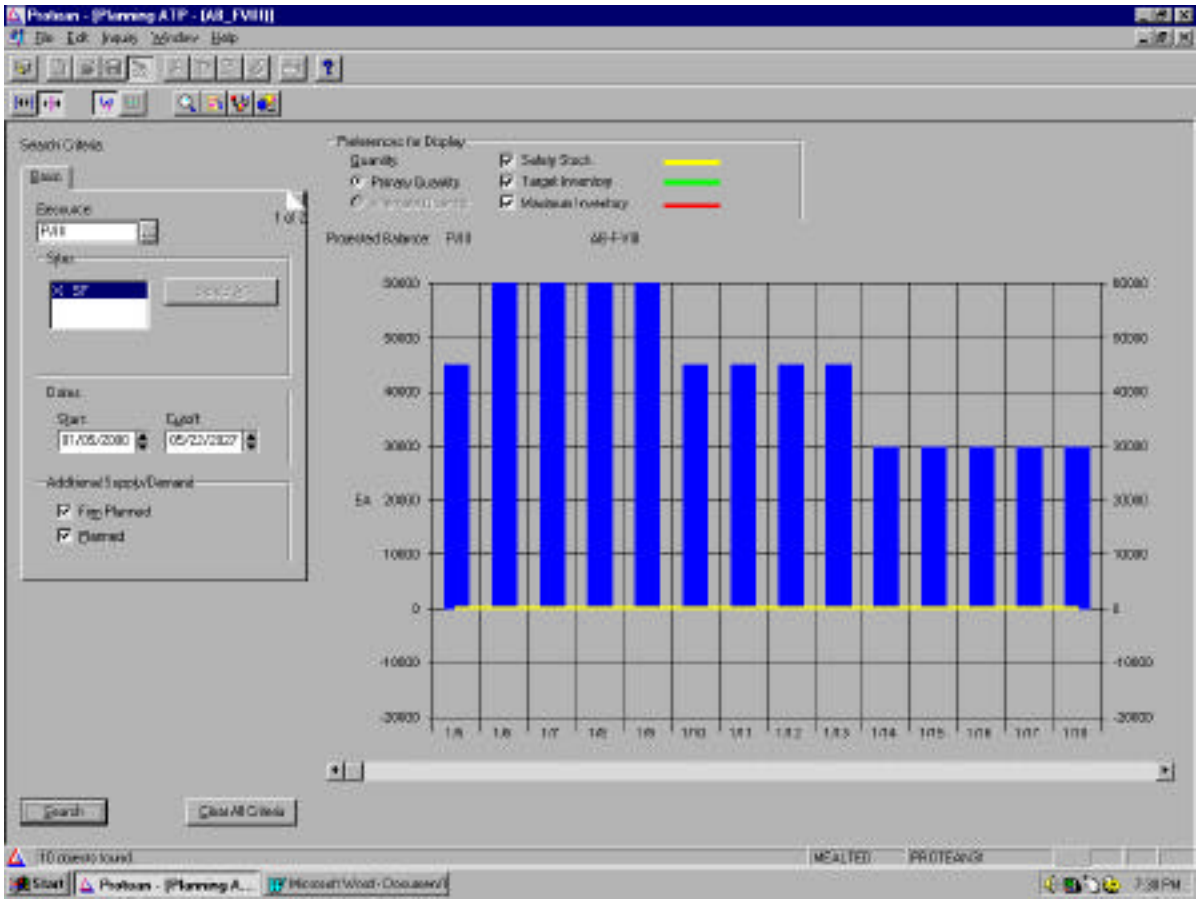


Fig. 4 - Available To Promise Inquiry

Label Generation and Control

The pharmaceutical environment requires the ability to control label production and usage throughout the supply chain, from raw material receipt through work in process inventory and production, to shipping and distribution. The software you select should provide:

- approval control
- reconciliation of label usage
- version control with effectivity dates
- historical tracking of label design and usage
- audit reporting and querying capability
- the functionality to produce the correct number of labels
- scrap or returned label accountability for each label produced
- a message and suffix on reprinted labels
- restrictions on superseded label formats
- the ability to record the name and revision level on each label

Characteristics: "The Devil is in the Detail"

Characteristics are user-defined fields in Protean, which describe your product's and material's properties. The following is a short list of different types of pharmaceutical and biological pharmaceutical processes:

- What is the **% grade** in a specific **lot/sub lot**?
- What is the **hazardous nature** of the product in tank 27?
- How many cases with a special **labeling requirement** are inventoried**?**
- Do I have enough **product with a specific potency** to satisfy a customer order**?**
- What is the **quality status** of lot 1234**?**
- What is the pH factor and strength of a specific lot/sub lot?
- How can I record Critical Control Point values?
- Which lots are labeled?

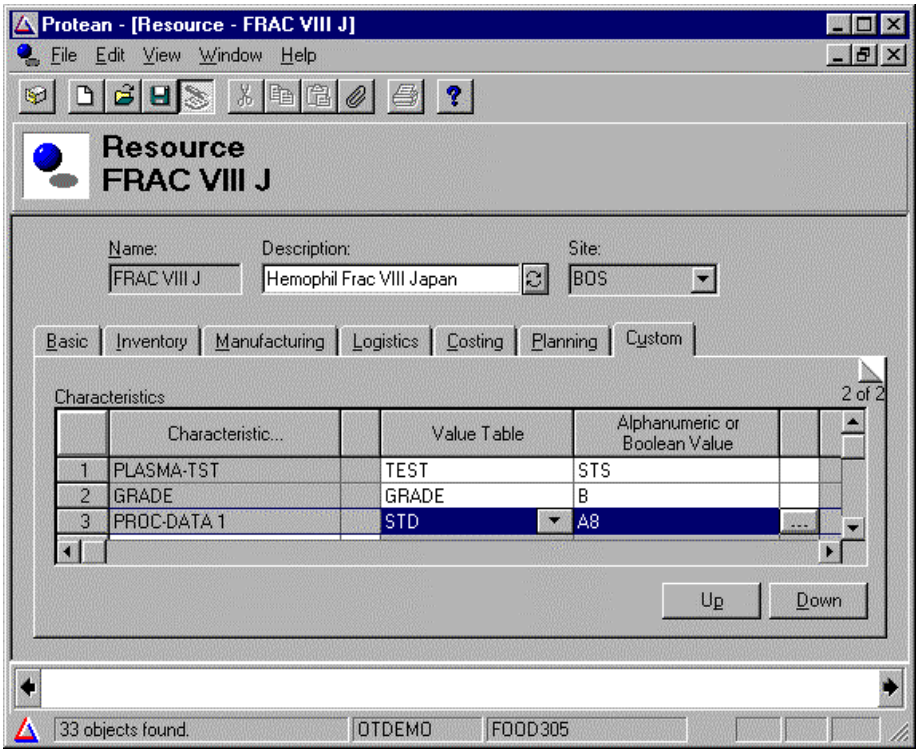


Fig. 5 Characteristics

Functionality of Characteristics

Characteristics extend the inventory function by providing user-defined properties to further describe inventory. Figure 5 displays Protean's *characteristics* feature, which allows additional information to be tracked for any variable (i.e., the quality or potency) extending to the lot or sub-lot level. Protean also records expected values and restrictions of these values, so you can control the values recorded during certain types of transactions.

Characteristics in Planning

Demand generated from a customer order is submitted to the planning division with or without characteristics. Protean's planning process totals supply (inventory, schedules) at the characteristics level, and recommends production for a finished product with required characteristics.

Lot/Sub-lot Control

Recent history has shown that accurately tracking inventory and performing timely and cost effective product recalls is critical to the pharmaceutical industry. Specialized inventory items need to be tracked, monitored, and controlled in different ways and at very detailed levels. Each individual plant or warehouse may have different resources, which require different levels of control and analysis.

The Recycle Trap

Recycled materials cause most ERP packages to lose track of the lot trail. Re-labeling or changing the identity of material is another difficult problem for most lot control systems.

The pharmaceutical industry requires the ability to specify, by item, which resources need to be tracked at the Lot Level and Sub-lot Level. The software you select should allow you to identify specific inventory and automatically record transaction history.

Lot Control

Most systems provide the ability to track inventory, although many use the "discrete industry" term "serial number." Yet the needs of pharmaceutical companies demand much more detail than most software programs can provide. The software you select should allow you to identify specific inventory lots/sub-lots and automatically record transaction history – including the history of all of the specific raw materials (and their associated lot numbers) used to make the final product. And should facilitate an efficient recall transaction identifying all the materials that have been involved in rework or recycle situations.

Lot Track and Trace

Few products on the market today offer the lot tracking and tracing functionality that a pharmaceutical company requires, but most software packages resolve this by generating excessive paper records.

Software used at the plant level should provide a quick, easy and informative inquiry tool to track lots through all the manufacturing and logistics operations. The pharmaceutical industry requires software that facilitates product recalls, lot traces (both forward and backward) and production analysis in a timely and cost effective manner to maintain a profitability. Figure 6 displays Protean's lot tracking inquiry, which supports the pharmaceutical industry's requirements.

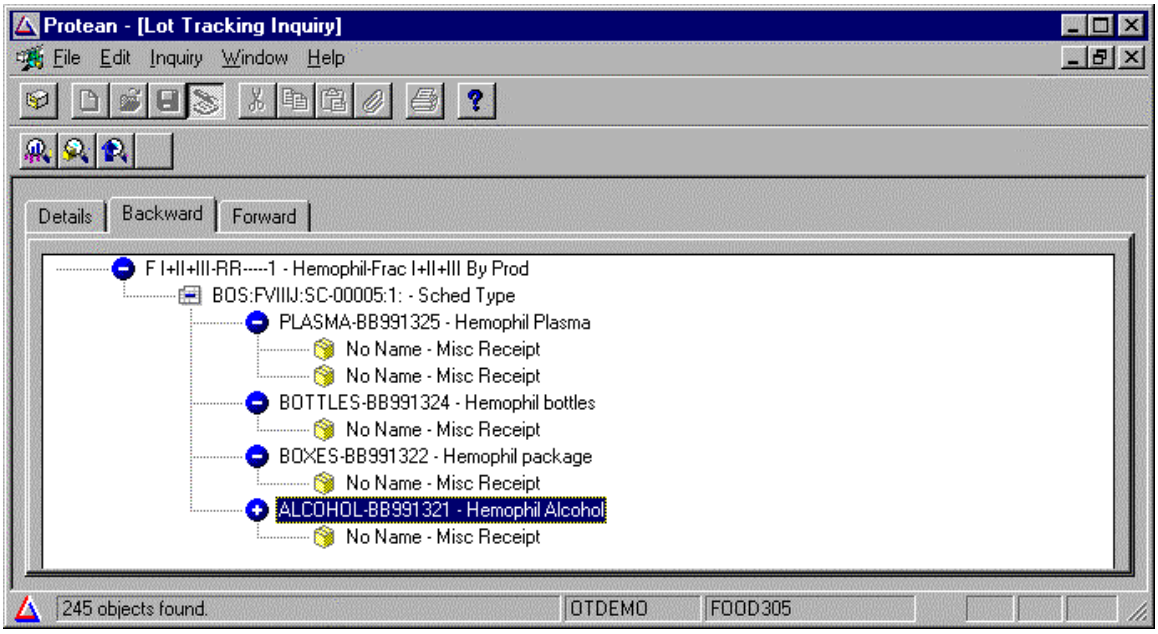


Fig. 6 Lot Tracking Inquiry

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Lot/Sub-lot Dating

Lot Dating is tracked by pharmaceutical manufacturers to determine if a lot can be used in the production process, and to satisfy customer orders. The software you select should provide the option to track multiple dates at the lot and sub-lot level, including:

- Expiration Dates
- Manufactured Date
- Shelf Life Date
- Re-test
- User-Defined Lot Aging Dates.

Lot Number Generation

A unique asset of any plant-level software is the ability to automatically generate lot number's based on specific numbering rules and criteria. The pharmaceutical industry tracks lots to a level that requires unique and specific lot numbers to identify specific products, product groups and/or production sites. And at times, requires the option to pre-assign a lot number to a product prior to it being received from the production process or incoming inventory receipt to insure integrity.

Lot Numbers and Customer Service

The importance of providing inventory availability inquiries and reservations by lot number insures that specific lots requested by customers are properly shipped. Selecting software that can fully support your Customer Service and Logistics

requirements is critical to maintaining customer satisfaction and an efficient manufacturing process.

Process Control & Data Capture

Rapid innovations over the past few years and developments in automation and control have resulted in a drastic reduction in labor, and the widespread use of process control instruments. These developments have increased information flow between the shop floor, laboratories and the ERP system.

In the more integrated scenario, the real-time, plant floor information should be the controlling information in a manufacturing environment and it should flow upward into the business enterprise systems.

Wonderware is the only company to provide industrial strength software to enable the immediate response needed—**from sensor to supply chain.** This enables the real-time, plant floor information to be the controlling in formation in a manufacturing environment, flowing upward into the business enterprise systems.

The focus is on the factory floor, specifically, the operator, who is the most intelligent agent in a manufacturing environment. Automatic data capture provides real-time updates to your inventory, improving the speed, ease and accuracy of data capture. Each operator is connected to all the information systems, to everyone else in the plant floor and to all plant floors within the organization worldwide. This operations-centric manufacturing environment—where information is shared within and between plants and planning in real-time – is a truly efficient supply chain.

It is critical that you consider production systems that can easily integrate to automatic data collection devices, a system that is agile, adaptable and easy to link.

Sales Order Processing and Constantly-Changing Demand

Retailers are increasingly influencing the entire supply chain. The growth of superstores, changes in trading partner organizations and networks, retailer demands, the SKU explosion, sales order processing, and more, all mean that you have to continually evolve to stay competitive.

Retailers continue to gain power (consolidation of the number of retailers mean fewer customers with more power), and are leveraging it to make demands on their suppliers. Pharmaceutical manufacturers need to be able to react to these demands, which means the systems pharmaceutical companies employ must be able to react quickly to changing demands. Order processing capabilities, in particular, must be flexible and agile. Customer Relationship Management is increasingly becoming an important part of the whole system and the ability to segregate each individual customer's requirements determines customer satisfaction and ultimately profitability.

Protean addresses customer satisfaction requirements by exploiting it's "characteristics" tracking features, which allow your customer service organization to distinguish the needs of one customer from another. Protean's "Customer Order Management" application utilizes product "characteristics" to ensure that each customer's unique needs (e.g., product specifications) are being satisfied. Here are just some of the advantages of using Protean's characteristics features:

- Customers can order product with precise specifications.
- Customer specific product specifications can be recorded into the Sales Catalog function
- Pricing and discounting are based on ordering characteristics and specifications.
- Confirm ATP using product and ordering
- Reserve inventory using specific characteristic values.

Quality Assurance

The nature of you're the pharmaceutical business requires individual products to be tracked, monitored, tested and controlled in different ways. **FDA regulations** impose process level requirements to track, control and trace down to the individual lot, sub-lot and even pallet level.

The software you select should provide you with this basic function, although most standard application software does not. Because requirements vary from one category to another, one company to another, and even one product line to another, most standard application software has to develop methods to resolve this issue, which may impact data integrity.

Quality assurance works best using real-time data in an environment that easily accesses this data. The pharmaceutical industry specifically leverages the tracking of sample and process testing to assure the integrity of their products. Software that supports product testing at the levels and frequency dictated by either customer expectations or regulatory guidelines, expands manufacturing control and improves profitability.

Quality assurance is another area to consider production systems that can easily integrate to automatic data collection devices to increase the integrity of information.

Conclusion

Companies in the pharmaceutical industry share similar information system requirements. Systems designed for this industry are increasingly required to overcome the industry's challenges in a cost-effective and reliable manner.

Wonderware Corporation

The industry trend is toward integrated software solutions that support the flow of information from plant floor operators and equipment to the business planning systems in real-time. In this scenario, operators are empowered knowledge workers, using handheld devices and real-time control and process information to do their own tracking, scheduling, yield, control and optimization strategy monitoring and requests. The informed and empowered operators can make real-time decisions which save valuable time and increase productivity significantly.

The operations-centric systems which connect the plant floor and the planning functions can improve the operational efficiency of the plant by minimizing waste, eliminating process variability, aiding on-time delivery, enabling compliance, and maximizing use of resources

Wonderware's Factory Suite, Protean, Avantis and PRISM products offer a vision of industrial automation that eliminates the information gaps in the plant's business processes to build a foundation for truly optimized supply chain and E-commerce. Wonderware provides process manufacturing companies in the pharmaceutical, food and chemical industries with specialized, agile business solutions that enable them to continuously improve their operations while realizing low total cost of ownership. With our solutions for real-time data integration, customers realize unprecedented improvements in productivity and efficiency.

Pioneering Solutions for the Process Industry

Wonderware specializes in providing manufacturing software for process industries. Having pioneered the creation of factory floor automation and of process-focused Manufacturing Resource Planning (MRP) software, Wonderware continues to distinguish itself with process industry expertise, proven mission-critical solutions for operations and key components that easily integrate with core applications from leading ERP providers, including SAP and PeopleSoft.

Wonderware provides its business solutions to multi-site, multinational enterprises as well as single-site, midrange customers in the pharmaceutical industry. Representative clients include:

- Abbott Laboratories
- Ares-Serono
- Bausch & Lomb Pharmaceuticals
- Bayer Corporation
- Douglas Pharmaceuticals Ltd.
- Medimmune
- Oxford Glycosicences Plc.
- Novo Nordisk A/S
- Rhone-Poulenc Rorer
- Saitama Daiichi
- Schering Corporation
- Searle & Co.
- Smithkline Beecham
- Warner Lambert Company
- Wyeth Ayerst International, Inc.

Wonderware & Pharmaceutical

Wonderware has an unequaled success record in supplying pharmaceutical companies with solutions. It also has an unparalleled customer base. These two advantages give Wonderware exceptional insights into the needs and requirements of the pharmaceutical industry.

Wonderware's products provide:

- Best fit
- Lowest total cost of ownership
- Continuous Improvement

Wonderware teams are:

- The proven pharmaceutical experts.
- The proven industry experts.
- The provider of unique components to the pharmaceutical supply chain.

Product Family

FactorySuite 2000™ is the first fully integrated suite of software for industrial automation. It is a component-based MMI system that gives users access to a full package of automation tools including:

- Visualization (InTouch®)
- Factory Database (IndustrialSQL Server™)
- Resource and WIP Tracking (InTrack™)
- Flexible Batch Management (InBatch™)
- Pure Windows NT-based Control (InControl™)
- Internet/Intranet Visualization (FactorySuite Web Server)
- Connectivity

FactorySuite 2000 is applicable in continuous, discrete and batch manufacturing environments. Each component of FactorySuite 2000 is a robust, best-of-breed software module. These components can be used to collect and manage production information, visualize and analyze the process; track and improve production operations; control machines and processes and manage batches. FactorySuite 2000's domain spans every level of the enterprise, from control to business systems. With FactorySuite 2000, you have access to all the information you need to run your plant and increase your productivity.
Four versions of the suite are available for developing applications in different manufacturing environments. FactorySuite 2000 runs on the Microsoft Windows NT 4.0 SP5 operating system. InTouch and IndustrialSQL Server clients also run on Windows 95/98 SE.

Protean® is Wonderware's operations-centric ERP solution for process companies. Built on a foundation of leading edge, object-oriented technology, the product contains a full suite of advanced functionality that addresses all aspects of running and managing process operations. This functionality is contained in powerful modules that support production, formula management, inventory management, procurement, planning, scheduling, product costing, asset management, customer order management, and financials.

Protean is designed to leverage industry standards such as Microsoft's DNA for Manufacturing architecture, and operates on leading databases such as Oracle, SQL Server, and DB2. Seamlessly integrated, the Protean modules easily link with legacy systems, third-party software and process control systems. Designed to operate on Microsoft's Windows® platform, Protean takes full advantage of Windows' rich capabilities. Up-to-date support for Object Linking and Embedding (OLE) provides integration with other applications such as word processing, spreadsheet, e-mail, imaging, and workflow products. Built-in, user-definable report generator provides reports in the format you want.

Note: All screenshots presented in this white paper are from Wonderware's 's Protean product.

Avantis is the Company's application suite designed to meet the asset management requirements of capital-intensive industries. These asset applications (Avantis.XA and Avantis.Pro) are available as an integrated component of the PRISM or Protean application software suites or can be supplied as stand-alone applications under the brand name of Avantis. Objects within the applications seamlessly integrate with industry-leading solutions for workflow, document management and imaging.

PRISM, a comprehensive product line consisting of 35 integrated applications, is Wonderware's application suite for process manufacturing companies using the IBM AS/400. PRISM incorporates design features, such as the patented Production Model, that differentiate it from traditional process manufacturing application software. It helps enterprises to increase operational efficiency, shorten delivery cycles, bring new products to market more quickly, integrate the plant floor, document quality assurance, improve inventory control, improve planning and scheduling, measure performance and streamline warehouse operations.

Services

By providing customer-focused services for its enterprise applications, Wonderware enables customers to implement their solution quickly, add value on an ongoing basis and maximize return on their application investment. The Company has a comprehensive set of expert services to support all phases of the customer's Wonderware technology investment life cycle—from startup and initial implementation, through ongoing application management, enhancements and continuous improvement. Wonderware provides implementation, customer support, training, optimization, customization and technical services. The Company's global support and services teams are staffed with industry professionals from the manufacturing industry who understand the work customers need to accomplish every day. Wonderware has a heritage of implementation success that translates into rapid return on investment and low total cost of ownership for its customers around the world.

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