“ONE OF THE GREATEST DISCOVERIES A MAN MAKES,ONE OF HIS GREAT SURPRISES, IS TO FIND HE CAN DO WHAT HE WAS AFRAID HE COULDN'T DO”

HENRY FORD

Automsoft®

ENABLING PROCESS IMPROVEMENT
USING BREAKTHROUGH TECHNOLOGY

Breakthrough technology as an enabler of manufacturing transformation was probably first applied in the mid-1800's as part of the industrial revolution. There is probably an argument that it was much earlier, in the first millennium with the development of water mills but for conventional manufacturing as we know it, the industrial revolution heralded the development of new paradigms or 'views on the world' in terms of manufacturing and production. Over a fifty-year period, the development of the steam engine, automated looms, the cotton jenny and other elements of new technology transformed manufacturing in enabling breathtaking increases in volumes of production whilst driving down the unit costs.

THE LANDSCAPE OF INNOVATION_

Fast forward to the early 1900's in the United States and Henry Ford, an Irish immigrant, began to apply technology to support a substantial shift in thinking – assembly line production – to transform the manufacture of automobiles thus bringing them into the reach of ordinary people. In fact, the consistent driver of such shifts in manufacturing is generally driven by a view that creating greater efficiency in the process inevitably leads to lower costs of production, lower prices and access to a larger market. These innovations in discrete manufacturing continue to the present day where the Dell model of production to order with almost zero inventories is enabled by information technology and innovative thinking.

So what happened to process manufacturing? Perhaps it would be useful at this point to establish a broad definition of process manufacturing for the purposes of this paper. Process manufacturing, in the context of this paper, refers to industries where the manufacturing process is a continuous flow – oil & gas, utilities – or a process where the product is grown or cooked – pharmaceuticals, chemicals, cement manufacture, food, brewing, biotech/biopharma. It does appear that, in terms of the optimization of the production process, particularly through the application of technology, very little progress has been made in the last 30 years, certainly in comparison with discrete manufacture.

30 years ago, a picture of process manufacturing (take pharmaceutical as an example) was of lots of people in white coats with clipboards taking readings from clocks and dials in a sterile environment and making changes to the devices as a result of aggregated readings. Programmable Logic Controllers (PLCs) replaced the clocks and Supervisory Control and Data Acquisition systems (SCADA) emerged as summary monitoring systems, Manufacturing Execution Systems monitored materials usage and the production process and Distributed Control Systems helped to manage various activities across the plant at a time when other industries were undergoing fundamental shifts in their thinking about their manufacturing processes. Whilst these technologies added a great deal to the sophistication of the manufacturing process, they are largely associated with the automation of existing activities.

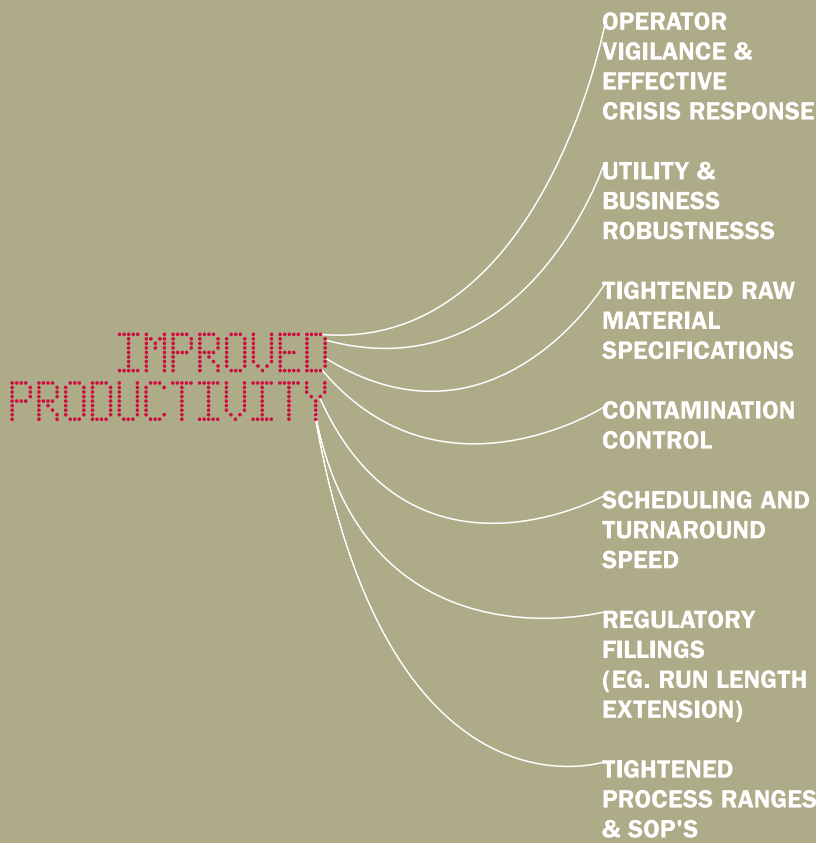


FIGURE 1.1

MANY WAYS TO INCREMENTALLY IMPROVE OVERALL PLANT PRODUCTIVITY

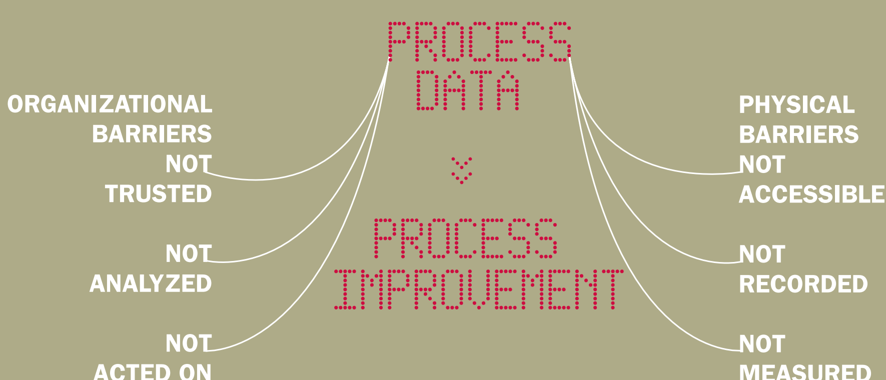


FIGURE 1.2

PROCESS INFORMATION YIELD LOSSES

What hinders process improvement most in your system?

Notwithstanding the limited application of technology to process optimization in this sector, there have as always been some notable pioneers. Genzyme Corporation is a biotechnology company that develops and markets innovative products and services designed to address significant unmet medical needs. It employs 5,500 people in facilities around the world and is recognized as one of the leaders in biotechnology globally. It is headquartered in Massachusetts, USA.

THE GENZYME EXPERIENCE_

Dr. Jack Prior is head of Therapeutics Manufacturing Support with Genzyme Corporation and responsible in particular for 'monitoring, understanding and reducing process variability' in Genzyme. In his Allston MA facility, Jack and his team initiated process improvements resulting in improvements in some bioprocesses of 50% to 100%. The core business benefit was enabling the plant to increase production to keep pace with sales without having to extend the facility.

His blueprint for process productivity improvement, identifies the levers that can be influenced to deliver sustainable outcomes. See figure 1.1.

In the specific case of the Allston facility, he describes the challenges and the approach.

As the Allston facility moved into commercial production, manufacturing management recognized the potential value of large amounts of online and offline data being generated by the process. They enthusiastically supported efforts by the newly formed Manufacturing Technical Support group to leverage this data for process improvement and variability reduction.

When approaching a data driven process improvement effort, it can be useful to assess the situation at hand using the paradigm of the process information pathway, see figure 1.2. Of all the data potentially available from a process, the vast majority is usually not leveraged for one of the six reasons represented. The right side streams represent physical barriers of data not being measured, not being recorded or not being readily accessible. The left side streams represent barriers of perception, focus or decision-making processes of an organization. In particular, data usefulness can be limited if it is perceived as inaccurate, not analyzed or if the resulting conclusions of an analysis are not acted on appropriately. The key rate-limiting losses and bottlenecks will vary for any given manufacturing or development organization depending on their physical capabilities and culture. The approach taken by Genzyme in Allston has been to try to identify the key limitation at any given time and address them.

As one progresses in understanding and reducing variability in a bioprocess, it is important to remember that new sources of variability can and will emerge during routine manufacturing due to the process having unanticipated sensitivities to variations in raw materials attributes or the timing of manufacturing steps. Unrecognized, this can confuse and confound data interpretation.

Amongst the lessons learnt are ensuring apples to apples comparisons – ensuring that sufficient granularity of the data is present so that distortion of the results doesn't occur as a result of, for example, non-optimum conditions late in a run. In addition, they ensured involvement of the manufacturing people as well as Technical Support. The long-term day-to-day process involvement of manufacturing operators and supervisors provides them with valuable insights on process troubleshooting and improvement. Genzyme's Technical Support Group worked hand in glove with Manufacturing and achieved many successes that neither group could achieve independently. In one instance, they were facing nagging specification failures at one process step that appeared to occur randomly. A supervisor observed that the failures seemed more frequent on days after certain sequences of manipulations had occurred. When this hypothesis was tested statistically, the phenomenon was found to be 8 times more likely to occur after the particular operations described and 42 times more likely after a more specific set of circumstances. Corrective actions were taken immediately and the problem was eliminated.

In another situation, one reactor was found to have slight differences in performance versus the others over time. Working with the MTS group and using their experience, two operators were able to identify a mechanical design problem that occasionally hindered the smooth operation of an automated step early in the process. This was subsequently corrected in all reactors and improved performance and consistency.

Finally, Jack Prior's team developed a methodology to tighten control thus enabling the ability to recreate the common aspects of the best runs. This trending approach allowed each variable to be quickly interpreted and conclusions to be drawn as to whether process performance was sensitive to that variable and if the optimum is in the high, middle or low range.

Dr. Prior summarises thus: "The ramp up at the Allston facility to meeting growing market demand required ongoing efforts to improve the robustness, consistency and performance of process operations. Data driven process improvement played an important role in this successful effort, which has improved overall performance, several fold. Data driven process improvement requires the elimination of key bottlenecks, which we have described here using the process information pathway paradigm."

The ability to process data quickly can be the most important factor in effective process improvement and variability reduction. Although all recorded data is 'always' available somewhere, Dr. Prior proposes that the likelihood of its use goes down inversely to the square of the amount of time or effort required to retrieve it. Often the discovery of a process improvement of the correct diagnosis of a process problem will depend on the individuals being able to analyze the right data.

MEASURING PERFORMANCE

The Genzyme experience was driven by looking at existing data that was collected in a disparate group of systems, collating as fast as possible and applying substantial brainpower to identify opportunities for improvement. The challenge in terms of creating sustainable long-term process change relates to the diagnosis of issues and then the design and embedding of those revised or changed processes such that they become integral to the fabric of the business.

TOM REYNOLDS,

a Director of the consulting firm BSM, specializes in process optimization consulting. In his role leading this practice in BSM, he has worked with major global corporations such as Pfizer, Baxter Millipore and Intel. Tom is now at the forefront of the development of combined software and consulting solutions around the optimization of equipment productivity via implementation of operational Key Performance Indicators such as OEE (Overall Equipment Effectiveness) and the application of TPM (Total Productivity Management) best practices.

WHAT IS OEE?

See figure 1.3

OEE is a KPI, which expresses equipment productivity as a percentage. Its real value is that it effectively captures all productivity losses including many that are hidden by more traditional equipment measures such as Utilization or Downtime.

The rationale for a specialization in Operating Equipment Effectiveness is that in most process industries the focus has traditionally been on the integrity of the core chemical reactions and on yield rather than on how the equipment itself is managed and utilized. As opportunities for yield improvement are exhausted, companies are turning to the optimization of equipment productivity in order to generate further improvements.

Measuring OEE is sometimes referred to as 'revealing the hidden factory' and when it is first measured, many companies are genuinely shocked by how low their OEE actually is. The major components of OEE are availability, performance and quality and below that are the 'losses' which can be anything but usually include the so called 'Big Seven' of breakdowns, set-up's & adjustments, minor stoppages, reduced speed (or reaction rate), yield, defects and losses from poor planning.

WHAT IS TPM?

The management of equipment has evolved over the years from simple breakdown recovery through preventative maintenance (PM) and eventually to TPM. TPM still includes all the elements of preventative maintenance but where as PM only aims to ensure that equipment is kept available for production, TPM goes much further by also focusing on how well the equipment is used when it is available. Its aim is not just to prevent breakdowns but also to proactively work to maximize equipment performance and utilization. Also unlike preventative maintenance, which is centered in the maintenance department, TPM is a team-based methodology, which involves different levels and functions within manufacturing. A TPM team will normally include operators, technicians, engineers, managers and increasingly equipment suppliers. They work to improve & maintain the OEE measure.

ITS ALL ABOUT DATA

TPM and OEE are highly data driven methodologies. More and better data allows more accurate, identification and quantification of losses and therefore more effective improvement initiatives. The availability of such data is also critical to enable the effective ongoing management of performance following the initial optimization activity. The development of breakthrough technology, which can collect, store and analyze massive volumes of production data in real time transforms the outcomes possible from the implementation of Key Performance Indicators such as OEE.

BSM previously applied a consulting-only model, which often involved highly experienced manufacturing professionals in tedious manual data collection or re-entering equipment 'events and alarm data' into spread sheets for processing. Very often the non-availability of data or the difficulty in manually collating data proved to be a significant constraint in the identification of opportunities for optimization. Obviously the availability of technology, which can connect directly to equipment and collect and process this data, has made the application of TPM and OEE much more accessible and cost effective.

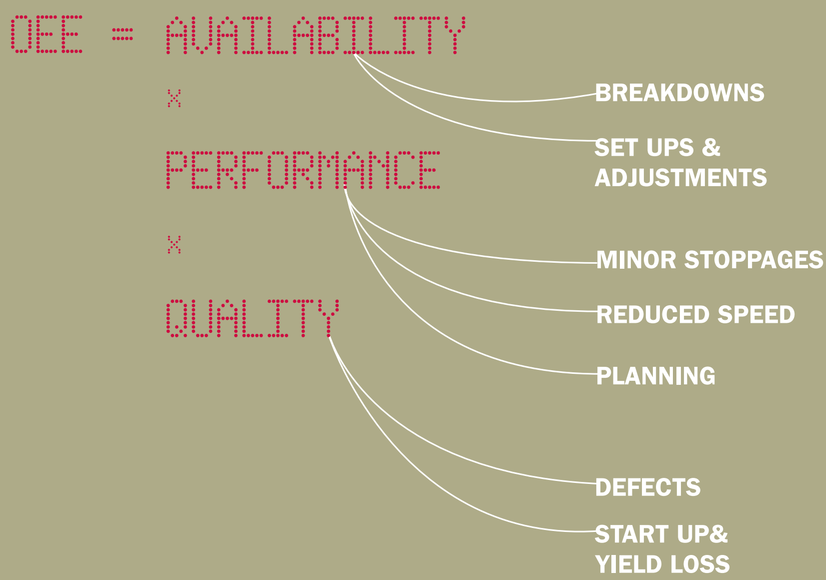
Tom Reynolds contends that improving OEE is all about being accurately able to measure OEE and its components and being able to drill down to the losses. One has to be able to examine trends over time, by shift, by product, by overall process and by individual equipment. Having such data readily available allows more accurate identification of root causes and therefore more effective improvement activity. A well-implemented OEE improvement program can significantly increase productivity and plant capacity and / or defer capital expenditure. It will also directly impact on key financial measures such as ROA (Return on Assets).

The evolution of thinking from preventative maintenance to performance management and finally to Operating Equipment Effectiveness is stimulated by the emergence of breakthrough data management technologies such as Automsoft's RAPID technology. What this means is that it is now possible to undertake a diagnosis, based on real-time data, identify the opportunities for change and design new processes which combine people, process and technology to create a new way of doing things.

FIGURE 1.3

OEE

Also calculated as Actual Good Output / Maximum Theoretical Output and expressed as a percentage



Drawing on the perspectives above, and the experience of a range of other industries that adopted and developed models for operational excellence, a clear methodological structure emerges. It has long been accepted that there are four key elements to effecting sustained change – people, process, organization and technology. Successful process optimization is that which delivers not only reduced cost of operation, increased or maintained quality and increased velocity of production but achieves it on a sustained basis. It is this final element, which presents the major challenge, and that which the emergence of breakthrough technologies enables.

PROCESS OPTIMIZATION MODEL_

Each of the major players in this sector, as consulting firms, applies their own methodology model. However, there is at a high level a standard set of steps as mapped on figure 2.1.

DIAGNOSTIC OR ANALYSIS PHASE

This is the stage when information gathering takes place. The purpose of this phase is to gather all the relevant data, analyze it and develop a picture of the opportunities for immediate and longer-term improvement of the processes. The frequent approach involves structured interviews with all of the relevant people (those managing and operating the process), collection of all the relevant data from SCADA, PLCs and other devices over a limited time period and observation over a period of time by highly experienced engineers. Through interviews and observation, an experienced engineer who has completed a large number of assignments will usually be in a position to develop pointers to areas of opportunity. This, however, is the point at which diagnosis becomes challenging.

At this point, the collection and analysis of data from the production environment takes place. The object is to provide a statistical base for the analysis activity, which achieves two objectives – validating that sub-optimal activities are being undertaken and quantifying the scale of opportunity for improvement. Because of limitations of current technology, the best that typically can be achieved is a snapshot of the operation at a point in time. Current technologies for the collection and storage of production data have a range of limitations – they hold very limited amounts of data history, they hold limited data types (alarm and event data is typically not associated with the core production data), and what data exists is held in disparate systems in disparate locations – MES, DCS, LIMS, SCADA, Historians. As a result, a substantial amount of engineer's cost and time is spent in a low value activity – collecting data and subsequent manual data entry into analysis systems.

Automsoft's RAPID technology is a database system specifically designed to manage production data for process industries in a secure environment. It manages time series data, batch data, flow data, alarm and event data as well as connecting to all of the systems, both shop floor and enterprise, that manage production activity. It explodes previous limitations on volumes of data managed as well as response rates. Built on object oriented architectures, RAPID manages terabytes of online data and can collect and retrieve hundreds of thousands of point changes per second. Delivery of this performance is achieved using patented zero loss data compression technology (hierarchical compression) and a distributed component architecture. It is typically used as an information management system for the plant, as well as a process diagnostic tool.

The technological breakthrough represented by RAPID enables a diagnostic process to review real-time as well as historic data from all elements relevant to production activity, resulting in truly sustained improvement opportunities. Jack Prior in Genzyme, as well as Tom Reynolds in BSM identified the core data as both the key to unlocking improvements and the obstacle to detailed understanding of opportunities. Now, with this breakthrough, it is possible to support an experiential and observational analysis with solid data, with minimal effort, enabling more detailed analysis to take place.

DESIGN PHASE

Having identified improvement opportunities, they are typically divided into quick wins and change opportunities. Quick wins typically are immediate opportunities for substantial payback requiring minimal implementation. Change opportunities typically require detailed design in all four dimensions – people organization process and technology – and a migration plan to the new model. Designing process is not simply a question of a newly mapped flow diagram but must take account of current state in each dimension, future state (what skills will be required, will retraining be necessary, what organizational structure will be necessary (team, hierarchy, departmental, network), how will the new process be mapped (obstacles, measures, touch points) and what technology can be implemented to enable the change.

Since this is about breakthrough technology, it is appropriate to concentrate on the technology dimension. The other three factors are generally addressed in current process optimization programs. However, we are back to the recurring theme of the major challenge being the creation of sustainability in change.

Breakthrough technology enables the design of new processes built on constant performance analysis and modification. In process industries, more than anywhere else, this is key. Process industries have, as a key dimension of their production processes, unpredictability. Freezing a new process and set of activities still requires constant evaluation and modification. In stark contrast to the robotic (in all senses of the word) aspect of discrete manufacturing, a process which involves chemical reactions as part of the production process delivers a constant challenge to managers and operators to deliver predictable, quality output.

In this case, data management technology like Automsoft's RAPID delivers real time data on the activities across the entirety of the production environment. It enables real-time and historic data, collected and stored in one location to be reported on as part of a newly designed activity management process. With previous technologies, it was possible to undertake historic analysis using data historians, albeit with a limited amount of data, or to do real-time analysis utilizing individual control systems but the capability to view real-time and historic data, on all elements of the process, facility or multiple facilities is truly breakthrough. In effect, the level of granularity available means that predictability in process manufacturing becomes a reality.

IMPLEMENTATION PHASE

Implementation is, of course, where the ‘rubber hits the road’. Academic analysis is all very well but process which looks very good in consultants reports but don’t translate to the real world are useless. Implementation typically involves two stages – pilot and rollout. The pilot is usually applied to one process or a step in a process to validate that the design is workable. Pilot implementation involves ensuring that a designed retraining program works, team structures for ongoing management are realistic, key indicators and measures that underpin the operation of new processes are reflective of the real world and in effect that the process works.

Most seasoned optimization professionals recognize that a changed process, based on new behaviors or activities, rarely survives more than six months at the most. This is because people will revert to the old, comfortable way of doing things. Irrespective of the educational or professional background of the person, implementing a sustained change is very difficult to achieve because of the natural human comfort of the familiar.

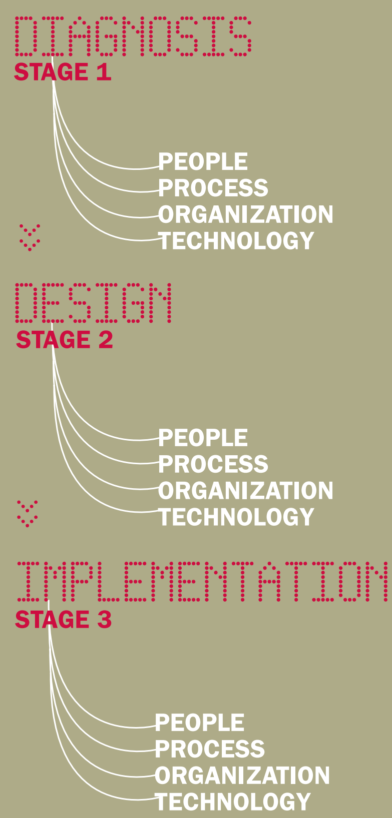
This is the primary reason behind the development of the multi-dimensional approach addressing all elements of the execution of a process – people, process, organization and technology. In this case, the changed process needs to generate a level of ownership in the new environment, enthusiasm and commitment and ongoing measures of success to ensure that the new process becomes part of the familiar.

Previously, in attempting to achieve this, the technology dimension, whilst essential to implementing measurable change, mitigated against successful implementation. This is because the implementation schedule for new technology in production environments was enormously costly, not in terms of the software itself, but in terms of implementation services, disruption, lost production, validation in the case of regulated industries and commissioning.

The aspect of the breakthrough technology which addresses these issues, enabling successful implementation of change is standards based architectures. Automsoft’s RAPID technology utilizes industry standards such as OPC (OLE for process control), DCOM (Distributed Component Object Model) and XML (Extensible Markup Language) to produce software that can be installed in a network and be operational in a matter of a number of weeks. In some cases, it has been operational in 24 hours. Whilst validation for the regulated sectors is determined by the extent of the process, partnerships between software product firms and validation consulting firms is leading the way in offering solutions to business problems rather than products to customers.

FIGURE 2.1

PROCESS OPTIMIZATION METHODOLOGY



DEFINITION 01 _ OPC

The OPC Foundation is dedicated to ensuring interoperability by creating and maintaining open specifications that standardize the communication of acquired process data, alarm and event records, historical data, and batch data to multi-vendor enterprise systems and between production devices. The foundation produces the OPC (OLE for Process Control) specifications implemented by RAPID.

DEFINITION 02 _ DCOM

The Distributed Component Object Model (DCOM) is a protocol that enables software components to communicate directly over a network in a reliable, secure, and efficient manner. DCOM is designed for use across multiple network transports, including Internet protocols such as HTTP.

DEFINITION 03 _ XML

Extensible Markup Language (XML) is a simple, very flexible text format derived from SGML Originally designed to meet the challenges of large-scale electronic publishing, XML is also playing an increasingly important role in the exchange of a wide variety of data on the Web and elsewhere. It is fast becoming the lingua franca of information interchange.

Process optimization in process industries is becoming a real opportunity for companies, following on from the efforts of pioneers such as Jack Prior and Tom Reynolds. In creating visibility of optimization opportunities, they have paved the way for companies like Automsoft to add the technology dimension and complete the picture. Process Optimization services has remained the preserve of a small number of specialists who have invested their effort and experience in driving to create approaches to identify optimization opportunities. This in turn, has created the scope for firms like Automsoft to identify the technology opportunity and apply innovation and creativity to provide data management and analysis software that acts as what we term: **"THE INFORMATION HEARTBEAT™"** of the Plant.

SUMMARY AND CONCLUSIONS_

RAPID, from Automsoft, enables the immediate implementation, collection and analysis of all production data in processes, plants and multiples of plants across geography, giving a true picture of production activity both real-time and historic. It provides the ability to analyze production activity, patterns and flows across all types of production data. Breakthrough technology, the application of leading edge architectural approaches coupled with design input from the industry has taken process optimization opportunities a substantial step ahead.

In essence, all through history, landscape change in industries has come about through the development and adoption of breakthrough technology. From the development of the cotton jenny, through Babbage's analytical engine to Henry Ford's production line techniques and even Microsoft's desktop computing, breakthrough technology has stimulated revolutions in the way we think about our world. In process manufacture, we are finally beginning to see technology, particularly software, being developed which is designed to reflect and focus on the specific nature of the process production environment.

Automsoft is only the first in what will be a number of firms developing technology to complete the picture, delivering true visibility of plant operations. We are already seeing firms emerging in the software analysis tools arena, particularly in the pharmaceutical sector. Inevitably, competitors to Automsoft will emerge to challenge in what is now the next generation of data management software for process industries. We in Automsoft welcome the challenge, and continue to blaze a trail of innovation. And whatever happens, the customer will be the winner.

AS IT SHOULD BE.

Automsoft is a leading global provider of advanced manufacturing intelligence systems for process industries across a range of sectors, utilizing advanced database software to collect and store, consolidate and analyze production data and bridge islands of data within the plant and the enterprise. Its core product suite RAPID™ has been configured for the requirements of different industries while from an early stage its specialist RAPID-Pharma™ system has been focused on the specific needs of the life sciences sector. In recent years that has notably involved the compliance requirements of FDA 21 CFR Part 11 while more recent development involves supporting the new Process Analytical Technology (PAT) approach to manufacturing sponsored by the FDA.

ABOUT AUTOMSOFT_

The experienced development and support team of automation professionals has earned an international reputation for its expertise. At the same time the leading edge development of Automsoft RAPID software has been to a great degree in collaboration with industry partners, addressing real manufacturing challenges and anticipating trends in manufacturing technology.

Founded in 1997, Automsoft has its United States of America head office in New York and its European Union head office in Dublin, Ireland. Automsoft has customers in the United States and Canada, in the EU, Norway and Switzerland.

Automsoft is a member of the OPC Foundation and International Society for Pharmaceutical Engineering (ISPE) and is quality certified to ISO 9001:2000.

For further information, please visit www.automsoft.com

AUTOMSOFT

NORTH AMERICA
SALES, NORTH AMERICA
330 SOUTH SERVICE ROAD, SUITE 120,
MELVILLE, NY 11747, USA
TELEPHONE: +1.631.574.4922
FACSIMILE: +1.631.574.4923

PROFESSIONAL SERVICES
5 INDEPENDENCE WAY, SUITE 170
PRINCETON, NJ 08540, USA
TELEPHONE: +1.609.919.6010
FACSIMILE: +1.609.720.9000

EUROPE
SALES, EUROPE
18 LANSDOWNE ROAD
DUBLIN 4, IRELAND
TELEPHONE: +353.1.449.1100
FACSIMILE: +353.1.449.1199

EMAIL: INFO@AUTOMSOFT.COM
WEB: WWW.AUTOMSOFT.COM