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**CONTROL**

GxP PROCESS MANAGEMENT SOFTWARE

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Less Effort.  
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# MasterControl:

What's the Return on Investment?

## Technology Is The Key To Success

It's a well-known fact that pharmaceutical, medical device and other regulated companies are slow in adopting some of the most basic technologies. That this attitude is hurting their bottom line goes without saying. However, what's worse is that a basic misunderstanding of the potential advantages of electronic solutions still pervades these industries, especially among small- to mid-sized companies. In an effort to "save money" many companies are actually spending far more money by not having an electronic solution. In addition, those companies who invest in electronic solutions are getting their products to market much more quickly and efficiently, thus increasing their revenue in meaningful ways.

**Novartis claims that using electronic solutions cut the company's costs by 40 percent and improved cycle times by 70 percent at its site in Suffern, New York.**

As mentioned in the Fall 2004 issue of  
Pharmaceutical Manufacturing

For example, in the Fall 2004 issue of Pharmaceutical Manufacturing, Novartis claims that using electronic solutions cut the company's costs by 40 percent and improved cycle times by 70 percent at its site in Suffern, New York. Novartis further claims that one of the keys to their success involved incorporating these solutions into many aspects of the organization, including the direct labor areas, quality, IT, and maintenance. <sup>1</sup>

Given the obvious tendency toward technology of literally every other industry in the world, it's only a matter of time before the antiquated, paper-based processes currently in use within the life science community will be completely replaced by their far more productive electronic counterparts. In fact, it seems likely that the FDA will demand such changes in the not-too-distant future. Yet, at present, most small- to mid-sized companies are still in the rut of using the same paper-based processes that their predecessors used decades ago. As a result, they are spending more money on internal processes, falling behind in the market and losing literally billions of dollars in unrealized revenue. For example, here are a few statistics that should concern even the most techno-phobic of life science professionals:

*According to an ongoing study at Tufts, the cost and time of bringing a drug to market jumped from \$231 million and 8-10 years in 1990, to \$802 million and 10-12 years in 2001, to the current estimate of more than \$1 billion and 12-14 years. This increase is attributed to the combined effects of increased regulation in the industry and inefficiencies that exist throughout the product development process in areas like clinical development, manufacturing, supply chain, and sales and marketing. Technologies exist today that can eliminate unnecessary delays in literally all of these areas and more. <sup>2</sup>*

These data, as well as many other statistics that could be cited, indicate a clear need among regulated companies to begin adopting technology at a much faster rate. If they don't, costs will continue to rise and delays will continue to occur. It's as simple as that.

## Identifying the Problem

So how do you overcome this technological shortsightedness? How do you convince your management team, your investors, your partners, or even yourself, that investing in some simple document and process management technologies can make a significant difference in reducing costs, getting a product to market sooner, and, in some cases, determining the very success or failure of your company?

**“I would feel pretty certain that we’ve gotten a substantial return [from our investment in MasterControl software].”**

John Pfaff  
VP and General Manager  
for U.S. Operations  
The MedTech Group

The common excuse given by companies for not adopting technology generally focuses on the cost of software applications vs. the perceived return on investment. Generally these companies have the budget to spend, but this budget is allocated to other priorities that are perceived to produce a higher ROI. It’s a simple fact that most regulated companies will spend vast amounts of money and effort in other areas of the product development and manufacturing processes. Yet, they often skimp, postpone, or completely abandon anything to do with new software

that could make their processes many times more efficient. This suggests that budget is seldom the real problem. More than anything else, the real problem seems to be associated with misunderstanding the advantages of technology and a simple fear of change.

Dr. Steve Arlington, who heads the Global Pharmaceutical & Life Sciences Advisory Services at PricewaterhouseCoopers, and is the lead author of the recently released report, “Pharma 2020: The Vision,” (which covers the evolution of the pharmaceutical industry), had this to say about why pharmaceutical companies are so far behind in adopting new technologies:

*“The point of the issue is trying to get technology accepted, and the communication of how good those benefits have to be to a point where you make some sort of change. It’s about emotions. It’s about human intelligence, but emotional intelligence. In essence, a lot of organizations miss the complexity of how to make that happen inside their own environment.”*<sup>3</sup>

Likewise, Jane Clarke, Senior Director of Clinical Trials Operations Support at Wyeth Research, believes one reason regulated companies have been slow to adopt e-solutions is a lack of vision regarding the potential of these applications:

*“Pharma is a highly regulated industry, thus very conservative with non-paper systems... The real leverage [of specialized software applications] is the total integration and flow of data captured at one point and flowing through other systems.”*<sup>4</sup>

Finally, Nora Dyer, Global Head of Clinical Development Operations at Novartis, suggests that a lack of understanding among key decision makers is often the biggest hurdle when trying to adopt an electronic solution.

*“Adoption of e-solutions is hindered when important stakeholders do not clearly understand and support the overall business rationale, and don’t drive towards the change. Therefore, an effective communication strategy using multiple channels to reach the end-user is essential for a successful implementation. In addition, people in key positions need to manage expectations, recognize setbacks, and also highlight achievements.”<sup>5</sup>*

Thus, while the cost and effort associated with implementation are often cited as reasons for delaying the adoption of new technology, more often than not the real reasons have to do with a lack of understanding of the advantages these technologies bring, and a fear of changing the current process to something new and unfamiliar.

### **The Solution**

The reality is that the amount of money, time and effort saved by process and document management software applications greatly outweigh the costs. In addition, software applications that have features specific to the life sciences industry, such as MasterControl, are becoming more and more affordable and new ways are being created to dramatically reduce the cost, amount of time and effort required to implement these systems. Jeff Klein, VP of Global Solutions Sales and Product Development for First Consulting Group, explained the situation this way:

*“We are entering an era in 2008 and 2009 where we’ll actually have content-management solutions available to pretty much all pharma and biotech organizations, from the start-ups to the VC-funded 20-person organizations, all the way up to the large guys...In the last couple years we’ve seen [software applications] mature to the point where there’s a much broader reach. We’ve seen the maturity of software products built specifically to address life sciences’ regulated-content management.”<sup>6</sup>*

A great example of this is MasterControl’s automated validation solutions. Currently, over 90% of our new customers purchase our automated validation products to reduce the cost and effort associated with implementation and validation of their new systems.

With the use of automated tools and other services that accompany our products, MasterControl customers have experienced huge savings and significant ROI, both during the implementation process as well as in their day-to-day production processes. For example, Tom Gosse, Business Analyst at Schiff Nutritional International, said the following about the money, time and effort saved by using MasterControl:

*“It’s hard to quantify, but we have saved a lot of time. Having an automated system has been a life saver ... It used to take us nine months to validate our systems, so being able to do it in a couple of weeks is great!”<sup>7</sup>*

**“Our users come up with new ideas about how to use MasterControl all the time. Everybody is impressed by how fast we can accomplish things now. I’m very happy with it.”**

Gary Jerabek  
Senior Quality Engineer  
Mallinckrodt Baker, Inc.

Likewise, John Pfaff, Vice President and General Manager for U.S. Operations at The MedTech Group, made the following comments about the return on investment they've achieved from MasterControl:

*“Our business has grown probably better than 15% a year for the last couple of years and we've been able to stay on top of the business and utilize document control and handle that growth without any significant new increases in personnel required to do so.*

*“I think [one benefit of MasterControl is] avoidance of hiring more people. One of the goals that we had is to move to a paperless system and that really has helped us ... I think that the efficiencies gained in getting our change notices approved are certainly there. We haven't done a formal ROI check but I would feel pretty certain that we've gotten a substantial return.”<sup>8</sup>*

In addition to saving money, the return on investment from MasterControl in the area of getting your product to market sooner can equate to literally millions of additional dollars for your company. For example, according to Forrester Research, between 2000 and 2005, the pharmaceutical industry lost an estimated \$40 billion dollars because of expired drug patents, including \$15 billion in 2005 alone.<sup>9</sup>

Regarding the role MasterControl plays in getting products to market sooner, Ann Clock, the Director of Document Management at Weider Nutrition (now Schiff Nutrition), explained it best when she said:

*“Being the first to market with an innovative product is crucial in our industry and MasterControl is the key to making this happen.”<sup>10</sup>*

While saving money and helping your company generate more revenue are two of the more obvious advantages of implementing MasterControl, our products and services also offer peace of mind for you, your executive team, and your board of directors or investors. With MasterControl your chances of being compliant with FDA and ISO regulations increases dramatically.

For example, Mallinckrodt Baker, Inc., founded more than 130 years ago, is a relatively new convert to the advantages of using MasterControl software to manage GxP and other processes throughout their organization. According to Gary Jerabek, Senior Quality Engineer at MBI:

**“We have completed [one] inspection since we implemented MasterControl and the inspectors that were there were very positive about how easy the system was to use and how compliant it was.”**

Anne Howell  
Director of Training and Development  
Community Blood Center of the Carolinas

*“We have vastly improved our change control process and this is, in no small measure, because of MasterControl [Process Module]. The auditors gave very favorable comments about our system. They noticed that everything was easily traceable, documents were readily available, and electronic signatures were all there. The fewer hardcopy documents we have, the less chance there is of having obsolete SOPs [on the shop floor]. We can now approve documents globally. Our users come*

*up with new ideas about how to use MasterControl all the time. Everybody is impressed by how fast we can accomplish things now. I'm very happy with it.”<sup>11</sup>*

As alluded to above, MasterControl is also a very versatile tool. Our customers use MasterControl throughout their organizations from development, regulatory and manufacturing to accounting, human resources and marketing. As the following MasterControl customers explain, it is far more than just a document or quality management product.

*“[MasterControl] is used completely – throughout the entire company from receiving, purchasing, shipping, manufacturing, HR – everybody uses it.”<sup>7</sup>*

Tom Gosse  
Business Analyst  
Schiff Nutritional International

*Tom Gosse  
Business Analyst  
Schiff Nutritional International*

*“We are using MasterControl throughout the company. We have about nine different departments. We're also looking to incorporate MasterControl into as many things as possible here in the company. [We're] looking at putting contracts in MasterControl, minutes from meetings – every aspect of anything that we want to capture without having to keep a hardcopy of paper.”<sup>12</sup>*

*Anne Howell  
Director of Training and Development  
Community Blood Center of the Carolinas*

The bottom line is that an investment in MasterControl software is an investment in your company's future. MasterControl will help your company to reduce your overall costs, increase speed to market, and reduce the risk of complying with both FDA and ISO requirements. It is structured enough to enforce compliance with even the strictest of regulations, yet flexible enough to improve the productivity of literally every department in your company.

For highly regulated companies trying to compete in today's high-tech world, adopting new software technologies such as MasterControl is no longer a luxury or superfluous to a company's success—but, rather, an essential key to success in an industry that's becoming increasingly competitive. Those who adopt this view and invest in new technology are far more likely to succeed than those who do not.

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