M MasterControl™

Novelty Becomes Necessity

2021 Analytics Trends

Let's just say what we're all thinking: 2020 was rough. It threw every element of our lives into disarray. We suddenly had to become experts at navigating a new way of working, schooling, and socialising. It was disruptive and it was challenging, but it was also transformative. And while the past 12 months might have felt like 12 years, it's time to look forward to what the future holds. If 2020 was the year of disruption, 2021 will be the year of mastering change.

Of course, it's much easier to master change if you can see it coming. We've been talking a lot about the importance of connected quality data, and this will be just as important in 2021 as in 2020. Your connected data will lay the foundation for powerful analytics that give you complete visibility into every aspect of your business. Predictive analytics powered by machine learning (ML), natural language processing (NLP), and other forms of artificial intelligence (AI), can give you even more information about how you can proactively drive success in your business. In 2020, the pandemic interrupted supply chains, clinical trials, and manufacturing. In 2021 and beyond, insights and information from data and analytics will help companies to adapt more quickly to future disruptions.

1

Managing Quality With Analytics

In the broadest sense of the term, analytics can reveal what's happening, why it's happening, and what you should do about it. Analytics can have a broad impact on an organisation, but that impact starts with small changes. These uses are unlikely to make headlines in tech publications, but they change the lives of quality and manufacturing managers. Life sciences companies are starting to use their quality data to make everyday decisions. Analytics help quality managers to understand, in real-time, where they are running into roadblocks and problems and how they can make a positive impact. From understanding where certain documents are typically getting stuck in the revision process, to understanding which work instructions are associated with the most deviations, or even what defects most commonly occur when a particular testing step in the manufacturing process results in values that are slightly out of range, analytics can help give you instant actionable insights.

Predictive analytics provide even more value, giving you the opportunity to understand what is likely to happen. With predictive analytics, you could predict the best combination of team members for each step in your process in order to achieve maximum efficiency and quality. You could predictively identify that a running batch contains attributes that are likely to result in a particular type of defect, with a recommendation for focused related testing. Predictive analytics often utilise ML, NLP, and other types of AI.

Increasingly, enterprise software solutions are utilising AI to deliver tailored, relevant, and intelligent insights. The goal is to deliver relevant recommendations and predictions that are meaningful and useful to any user, not just to those with a background in analytics. AI and analytics are technologies that are becoming more accessible over time. Companies that are just starting their analytics and AI journeys don't need to immediately search out top-notch data scientists to employ. Instead, they can start on smaller measures using the resources they already have and scale up from there.

❝ **Advanced analytics is the linchpin of transforming the investigation process.'[1]**

–McKinsey & Company

Theoretical to practical:
Data is a tool, not a goal

1 **Align With Overall Strategy:**
Advanced analytics for the sake of advanced analytics isn't the way to go here. Analytics and AI 'will likely be most effective when deployed strategically across the entire enterprise.'[2] You may encounter executives that are interested in doing something with data because it's what everyone else is doing, but the largest ROI comes from having a plan.

2 **Have an Objective:**
Analytics are only meaningful when they help you to solve real business problems. Know what you'd like to measure and understand. What are the KPIs and metrics you want to measure, track, and impact? What are your business problems? What data do your teams need to have in order to perform more effectively? What data will help you to understand your bottlenecks and inefficiencies? What data will help you to complete quality review and ship products more quickly? What data would actually help you to create higher quality products? Start by understanding what data is useful and valuable.

3 **Get Your Data House in Order:**
Clean up your company's data. Data is the foundation of analytics, and analytics is only as good as the data being used. This is especially true when you get into the realm of AI because the data is how the program will learn. The data you focus on and how much of it you need will be largely determined by your company's goals.

4 **Look at Your Vendors and Suppliers:**
Optimising data is admirable but, like it or not, suppliers and vendors are a big part of how that journey will end. These organisations are an extension of your business and, while they don't have to use the exact same technology as you or have the same initiatives, if they still do business by paper or Excel spreadsheets you're in for a bumpy ride.

5 **Be Patient:**
Some investments pay off quickly — this isn't one of them. A company can start seeing small improvements very soon after implementation, but analytics get more effective the more data there is to work with. And it takes time to build up that data. About half of life sciences companies report that it takes longer than expected to realise ROI from AI initiatives, though a comparable percentage have also seen process efficiencies from AI.[4]

90%

reduction in investigation time for deviations and nonconformances in the life sciences with advanced analytics.[3]

2

Shaping and Adapting to Regulations

Regulated industries can get nervous when it comes to using new technology. Since lives are at stake, this is completely understandable. While life sciences companies are racing to use their data, the regulators are taking a slower, more careful approach. That approach does clearly show that they intend to use data and AI to improve public health. The U.S. Food and Drug Administration (FDA) set out its Technology Modernization Action Plan (TMAP) in 2019, followed by the Data Modernization Action Plan (DMAP) in 2020. The FDA's plan for improving its data practices can serve as an indicator of what the agency may eventually require from life sciences companies.

Of course, these are the FDA's plans, not regulations. Regulations are still a work in progress, but they continue to gain momentum. The most recent measures have involved software as a medical device (SaMD) that uses AI. It is very clear that the FDA wants life sciences to use this technology because the agency recognises AI's potential to help patients receive better care. The FDA's action plan indicates that a set of good machine learning practices (GMLPs) will be coming soon. There will also be guidance surrounding a predetermined change control plan for the AI.

A common theme in both DMAP and SaMD guidance is the desire to work with industry. The AI/ML-Based Software as a Medical Device Action Plan was only written after the industry had garnered feedback to its proposed regulatory framework. Considering how quickly the FDA moves, there's still plenty of time for life sciences companies to help shape the new regulations.

❝ The ultimate goal is to see if AI can improve our ability to quickly and efficiently identify products that may pose a threat to public health.'⁵

–Stephen M. Hahn
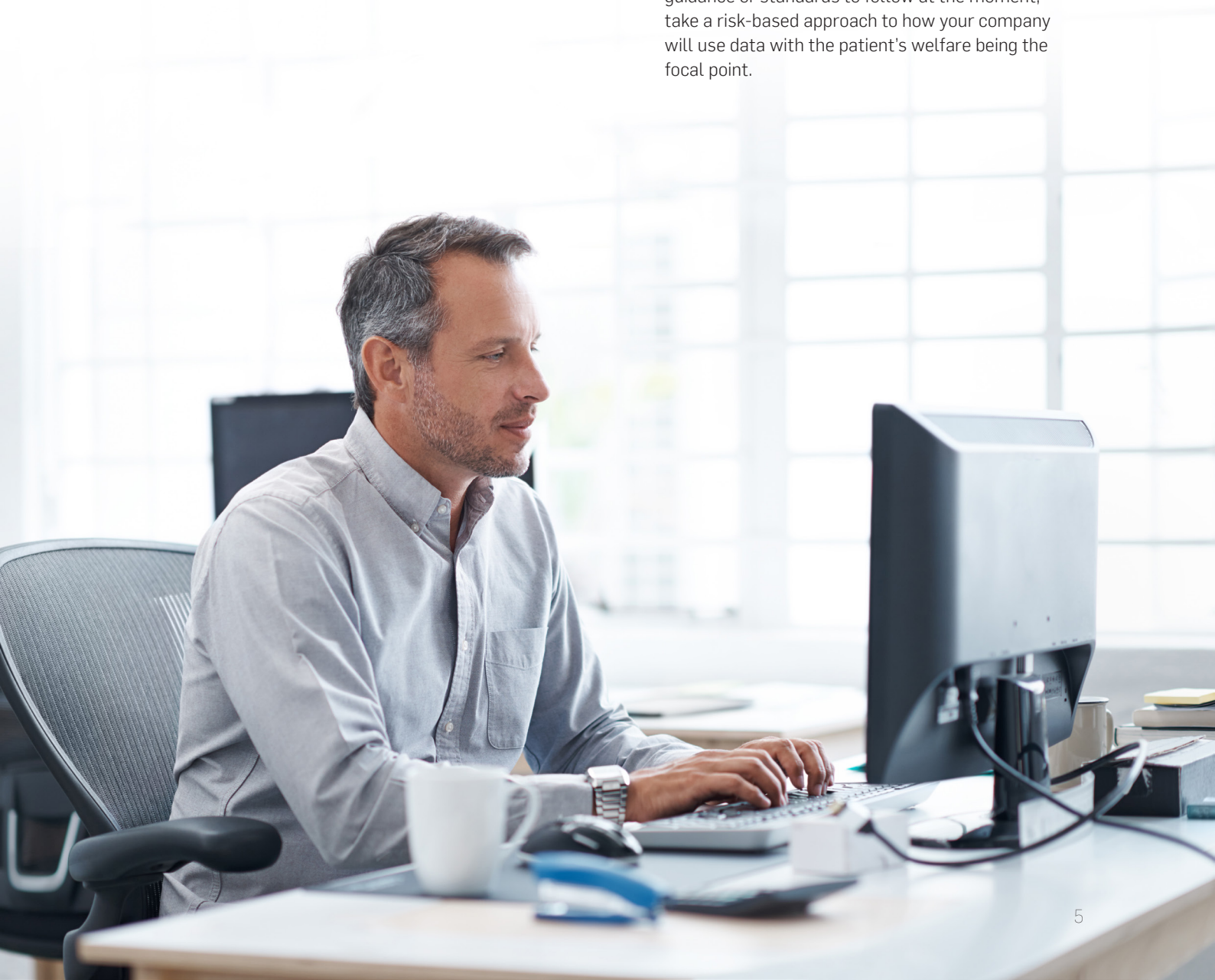*Commissioner of Food and Drugs, FDA*

Theoretical to practical:
Use regulators as a guide

1 **Mirror Their Efforts:**
The FDA's own data modernisation efforts serve as a model for life sciences companies. Their desire to use data and AI in their own work indicates how businesses can also use these tools. One example is the FDA's recent pilot program to use AI in screening imported foods.

2 **Make Your Voice Heard:**
The FDA is actively asking for feedback. This is a chance to voice concerns, ask for clarification, and ensure new regulations protect patients while not imposing too large of a burden on life sciences companies.

3 **Use a Risk-Based Approach:**
Risk has played heavily into other recent FDA guidance (e.g., computer software assurance), and it's clear the agency is primarily concerned with patient safety and product quality. Without specific guidance or standards to follow at the moment, take a risk-based approach to how your company will use data with the patient's welfare being the focal point.

'Public engagement is critical, and we will be seeking input from the public on the deployment of modern technology and data strategies at FDA'[6]

–Amy Abernethy
Principal Deputy Commissioner, FDA

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Responsible Data Practices

You can do a lot with AI and analytics, but there are ethical implications that need to be considered. Data needs to be responsibly used and secured while maintaining the individual's privacy. One of the most promising ways to use analytics in the life sciences is in clinical trials. However, that use requires patient data. Anytime a company handles protected health information (PHI), they don't just need to know that the information's secure, they need to inform patients how that data is going to be used. Along with how their data is used, patients are understandably concerned about security. Data breaches fill the headlines, so most companies know cybersecurity is a risk and most are working to mitigate it, but far fewer are addressing another equally important problem.

Humans aren't impartial, even when they try to be. When it comes to data analytics and AI, it might seem like bias shouldn't be a problem because these are programs, but since their creators are human the risk of bias is very real. Unfortunately, just under a quarter of life sciences companies consider this to be a risk and an even smaller percentage are doing anything to mitigate it. Addressing these problems is important early in an implementation and it's a risk that needs to be constantly monitored and mitigated. There are obvious ethical implications to biased AI, but the bottom line is that biased AI will not be accurate. Just as bias impairs human judgement, it leads to errors in an AI's assumptions and suggestions.
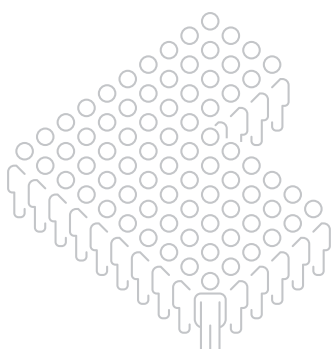
24%
of survey respondents consider equity and fairness to be a relevant AI risk.[7]

14%
are working to mitigate that risk.[7]

Theoretical to practical:
Mitigate risk

1 Give Your Vendor a Security Check:
Software vendors do everything they can to mitigate security threats — but not all vendors are used to working with regulated industries. Doing your due diligence when selecting a software vendor will save you from problems further down the road. Depending on the data your company wants to store in the software, the vendor should also be Health Insurance Portability and Accountability Act (HIPAA) compliant.

2 The Need for Continual Improvement:
Just like other technology, advanced analytics programs need to be monitored and undergo updates. Companies can identify potential bias by continually evaluating the data their algorithms use. In some cases, this may involve setting thresholds for the program's decision-making abilities or requiring human involvement under certain conditions.

3 Ensure Data (E)quality:
When it comes to training AI, historical data is pretty much all companies have to work with. The problem is that some of that data will reflect bias. Unfortunately, bias is a problem in the health care system, which can be present in the data it compiles. Life sciences companies need to determine to what degree bias may affect their data and put effective governance in place to protect against it.

> ❝ Health care delivery … [varies] by … race, ethnicity, and socioeconomic status; therefore, it is possible that biases present in our health care system may be inadvertently introduced into the algorithms.'[8]
>
> –FDA

4

The Rise of the CDO

The chief data officer (CDO) isn't a completely new role, but it's certainly one companies need to consider if they want to use advanced analytics and eventually AI. The CDO is, as expected, in charge of data for the organisation. Since this encompasses or at least touches IT, the responsibilities of a CDO sometimes fall to the chief information officer. The job title isn't what's important here, but the level of the role in the organisational hierarchy is. Any type of digital initiative should span the entire business. That means at least one person in the C-suite or on the executive team needs to be an analytics or AI advocate. The CDO is where much of the high-level analytics to-do list comes in. For example, we've already mentioned the need to align your analytics strategy with your overall business strategy. Doing that effectively requires the direction of someone in a position to affect strategy.

Speedbumps on a digitisation journey don't always involve technology. They frequently involve people. If someone stubbornly set in analog ways is in a position of influence in a company, any kind of digital transformation is an uphill battle. Having someone on the management team to counteract that viewpoint is essential. The turmoil caused by COVID-19 might have some companies thinking that now isn't the time to invest in analytics. On the contrary, now is exactly the time to do so. Data analytics initiatives are an adaptation that will help companies deal with disruption, both now and in the future.

> It's also striking that some of the biggest gaps between AI high performers and other aren't only in technical areas … but also in the human aspects of AI, such as the alignment of senior executives around AI strategy.'[9]

—McKinsey & Company Report

60%

of AI high performers have senior management that is fully aligned and committed to their AI strategy.[10]

52%

of AI high performers systematically track a set of KPIs to measure the impact of AI.[10]

Theoretical to practical:
Establish effective data governance

1 **Convince the C-Suite:**
Change is difficult but showing how automation, analytics, and AI are applicable and beneficial to a business can help. For example, AI can help companies deal with supply chain disruption, implement quality improvement at a lower cost, and improve manufacturing efficiency.

2 **Relate Analytics to KPIs:**
The KPIs you use will depend on what's important to your company. If you want to decrease manufacturing costs, AI can be connected to scrap and rework. If you want to reduce overtime, predictive analytics can tell you how to improve efficiency.

3 **Set Goals:**
The only way to determine if an analytics strategy is working is to define what success will look like in your organisation. Since analytics initiatives should align with the overall company strategy, it makes sense to have your analytics goals be aligned with the company's goals.

4 **Communicate With Employees:**
There's no way around it — AI has been known to replace human employees in the workplace. Analytics in general is less notorious in this regard, but employees will still be nervous if the role of analytics in the organisation isn't well explained. Being transparent with employees and letting them know AI is there to eliminate repetitive tasks and simplify their jobs, is the best way to gain their support for these initiatives.
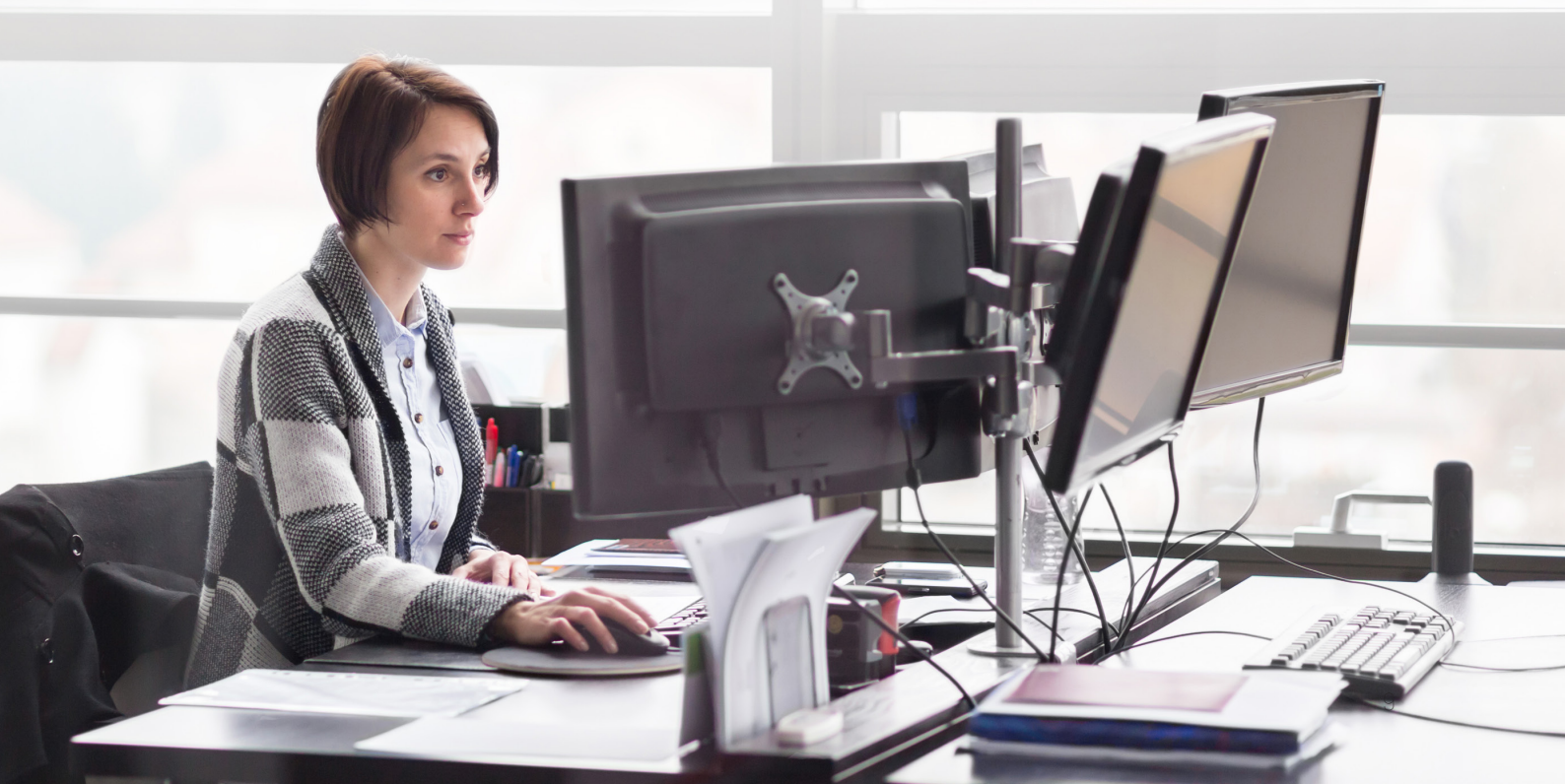
Conclusion

A solid analytics strategy is a necessity moving forward in the life sciences. Companies that haven't already taken steps to consolidate and digitise their data are lagging behind. MasterControl works closely with life sciences companies to accelerate digital transformation. Our cloud-based platform delivers applications that connect the entire product life cycle, from suppliers, to manufacturing, to quality. A connected platform also brings data together and lets it be analysed with no human intervention.

The next generation of MasterControl products offer improved analytics and AI capabilities to users. They'll be able to increase visibility, improve decision-making, and have the operational agility needed to master change in a rapidly evolving and increasingly competitive market.

Insights

MasterControl Insights:
Use data from all enterprise solutions to make everyday decisions. Out-of-the-box reports and visualisations designed specifically for individual roles provide crucial insights. Users can also build their own reports using a simple drag-and-drop interface that visually represents data and allows you to drill down easily.

Mx

Manufacturing

MasterControl Manufacturing Excellence:
Fast, flexible production management and execution for process and discrete manufacturing that connects your shop floor workers and delivers right-first-time results without the cost and complexity of a traditional manufacturing execution system (MES).

Qx

Quality

MasterControl Quality Excellence:
Smart, dynamic enterprise, plant, and supplier quality management that allows organisations to manage product quality, compliance, and risk intelligently.

Sources

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