



The Digital Transformation of Manufacturing

Harnessing the power of the cloud to drive regulatory compliance

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Introduction

As the Fourth Industrial Revolution sweeps across the globe, it is fundamentally reshaping the way in which organizations everywhere operate and their employees work,¹ and manufacturing is a prime example. The digitization at the core of this revolution—enabled and accelerated by cloud computing and related technologies such as artificial intelligence (AI), the Internet of Things, and machine learning—is empowering manufacturers to use data-driven intelligence to transform their business processes and to enrich their market offerings by combining innovative products with value-added services. To capture part of the \$216 billion in annual additional value that the shift to the cloud is expected to generate by 2020,² leading manufacturers are using this transformation as a springboard to deepen customer engagements, accelerate their productivity and agility, improve safety and sustainability, and reimagine how they operate and generate value.

A key, but sometimes overlooked component of the new opportunities and benefits that the cloud offers is its ability to help manufacturers achieve and streamline regulatory compliance. Manufacturers and their products are and will remain subject to a wide range of regulatory obligations that have existed for years. In many cases, manufacturers are also facing new regulatory obligations, such as the General Data Protection Regulation (GDPR) in Europe.

Fortunately, cloud-based tools and services can help manufacturers monitor and execute on their compliance obligations more effectively. For Microsoft, providing our manufacturing customers with holistic cloud solutions that also help them achieve and maintain regulatory compliance is a top goal. Important benefits include the security and data governance advantages that manufacturers can obtain by running operations in the Microsoft cloud. In this respect, the cloud can place manufacturers in a better position than they are in today on many critical compliance issues.

This paper explores how the cloud and AI can help manufacturers—particularly those in discrete manufacturing, chemical and agrochemical manufacturing, and the energy sectors—thrive within even the most complex compliance environments.

Part II of this paper briefly sketches the transformative effect that the cloud is having on the manufacturing sector.³ **Part III** identifies some of the new compliance issues that manufacturers may face as their operations mature and the regulatory landscape evolves. **Part IV** then explains how cloud solutions can enable manufacturers to more easily track and satisfy their compliance obligations, including in areas such as data protection, cybersecurity, protection of intangible assets, product safety, environmental compliance, and many others.



The promise of digital transformation for manufacturers

Cloud-based platforms, tools, and services—in particular, the trusted cloud offerings provided by Microsoft—give manufacturers new ways to grow,



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innovate, and boost their operational excellence. These technologies are helping manufacturers more effectively engage their customers, empower their employees, optimize their operations, and transform their

products and services. This cloud-driven digital transformation is what is driving the Fourth Industrial Revolution and capturing the benefits of this transformation is essential for manufacturers to sustain and sharpen their competitive strengths in an “Industry 4.0” economy.

Among other benefits, cloud-based services can equip manufacturers to better meet customer needs by integrating data from multiple sources—including customer interactions, product performance monitoring, and social networks—and using that data to provide fresh insights into market behavior and customer activity across the product lifecycle.⁴

These services help manufacturers attain greater visibility into customer buying patterns and preferences, enabling them to develop and deliver value-added products and services that are more closely aligned to customer preferences.⁵ Cloud-based technologies can also increase worker productivity and connectedness and facilitate faster, better decision-making.



Case Study: **ABB**



Switzerland-based ABB makes equipment used in all phases of power generation, distribution, and transmission and relies on a variety of cloud-based tools to capitalize on insights gathered at every level, from device to system, enterprise, and cloud. For instance, the company uses a Microsoft Azure Search-based engine for fast searching through operational data on control room dashboards. It uses the Logic Apps feature of Azure App Services to connect its own workforce management system to other enterprise systems, such as SAP and Maximo. And it uses Azure Application Insights and Azure Log Analytics to monitor system health and provide dashboards and alerts. ([Read more](#))

As an example, cloud-based business intelligence tools can allow employees to view and manage data in a visual and intuitive manner, and in real time—enabling them to take more evidence-based and timely decisions at all levels of production, operations, and sales.⁶ Similarly, cloud analytics tools can reduce the time and expense of analyzing large amounts of product data, and thereby help reduce production costs.⁷

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dynamically realign production to meet changing demands, and increase turn-times for inventory across the value chain—all while reducing energy consumption.⁸

These tools also offer better visibility into product performance, enabling manufacturers to more effectively manage a pipeline of ideas and align them with strategic priorities to bring new and innovative products and services to market quickly, increasing competitiveness and customer value.⁹

As GE’s Chief Information Officer has explained, standardizing around the cloud provides “an entire ecosystem of capabilities that are interoperable, highly secure, and easy to use—providing benefits to both employees and IT.”¹⁰

In addition, cloud-powered data analytics can optimize factory operations by equipping people with the data and tools they need to identify areas of waste, improve cycle times for manufacturing operations, make automation processes faster and easier, maintain equipment more efficiently by more accurately predicting maintenance needs,



Indeed, manufacturers that effectively seize on these opportunities will experience significant benefits. According to recent research, manufacturing enterprises that have adopted these new digital technologies generate an average of \$100 million more in annual operating income than those that have not.¹¹

Recent International Data Corporation (IDC) research likewise predicts that manufacturers that invest in big data and business analytics are likely to double the percentage of their connected products in the next three years, helping them establish new revenue streams that will extend the lifetime value of their customers.¹²

Many manufacturers have already begun to make this shift. A 2015 IDC survey of almost 600 manufacturing enterprises from 17 countries found that 66 percent of respondents reported using a public-cloud implementation for two or more applications and 68 percent were using a private cloud.¹³ The study further found that these manufacturers were expected to increase the cloud-services share of their annual IT budgets by 27 percent between 2015 and 2017.¹⁴

As digital transformation continues to unfold, manufacturers that deploy cloud solutions across their business will have an advantage over their slower-moving competitors in developing new capabilities to drive competitiveness and growth.

New compliance challenges for manufacturers

Although manufacturers and their customers becoming more digitally connected has many benefits, it also means that the regulatory compliance landscape for manufacturers is becoming more complex and multifaceted. As manufacturers digitally transform and their products and services become more multilayered and sophisticated, they are encountering some compliance issues for the first time, along with new dimensions to their existing compliance obligations. Many of these challenges are connected to the exponential growth



Case Study: Tetra Pak

Tetra Pak, a supplier of food processing and packaging solutions to enterprises in more than 175 countries, uses Microsoft Azure to predict machine problems and identify potential breakdowns. As a result, it has been able to reduce plant downtimes and the high costs they carry. In addition, by connecting packaging lines to Azure, Tetra Pak has been able to collect operational data to help predict maintenance timing. Tetra Pak service engineers also use Microsoft HoloLens to diagnose and fix machine issues, even in remote locations where arranging on-site inspections of machinery by technicians can be difficult.

[\(Read more\)](#)

in the generation, collection, and processing of data and revolve principally around data protection, data security, and confidential data.

Data Protection. One reason why the cloud is such a game-changer for manufacturers is because manufacturing generates more data than any other sector of the economy.¹⁵ For many manufacturers, however, the compliance issues involved in collecting and analyzing all of this data can manifest themselves in subtle and unfamiliar ways.

For instance, factory floor sensors used to facilitate and expedite operations may at times capture personal data, and manufacturers must have processes in place to ensure that this data is processed in full compliance with applicable law. Similarly, sales through online portals nearly always

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capture personal data, some of which may even enjoy heightened legal protections (e.g., financial data).

And manufacturers with customers or suppliers located outside the United States (e.g., in the EU), may need to

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untangle and comply with multiple overlapping data protection and privacy laws. For instance, the GDPR—which went into effect on May 25, 2018 and has a more expansive scope than previous EU regulations—introduces new and in some cases more exacting requirements relating to consent, transparency, data re-use, and data subject rights, which may extend to information about employees, subcontractors, customers, and suppliers.¹⁶

Cybersecurity. The trove of data that manufacturers possess also sharpens the need for stronger data security practices, particularly as new laws like the GDPR impose new data security and breach notification requirements. With large volumes of personal or sensitive data, unauthorized access to systems or other forms of data breach could impact consumers, companies, and even governments. For instance, a compromise of a manufacturer’s billing systems could put customer credit card numbers and bank account records at risk. A compromise of real-time smart meter readings could offer insights into whether customers are at home or away, rendering their homes susceptible to burglary. For utilities, a compromise on infrastructure control and supervisory control and acquisition (SCADA) systems could destroy critical infrastructures and shut down power to large geographic areas.¹⁷

More generally, the distributed yet connected nature of manufacturing facilities, and the potential hazards to employees or customers from intrusions into those facilities (whether physical or virtual) may create unique compliance challenges.



Perhaps not surprisingly, the number and severity of cyberattacks targeting manufacturers has increased in recent years, underscoring the critical need to keep safe the ever-growing volume of data generated by and available to manufacturers.

Confidential Data. As manufacturers digitally transform, the locus of their most valuable assets will increasingly migrate from the physical realm (equipment, buildings) to the virtual (customer lists, proprietary know-how, critical business data, etc.).

Given the distributed nature of manufacturing and global supply chains, this increasingly valuable

information is often spread across multiple locations and systems. Keeping track of this data and ensuring it's secure and confidential need to be top priorities. Even a single, discrete data breach would compromise trade secrets or other confidential or proprietary business information, imperiling not only the manufacturer's balance sheet, but potentially its continued viability. Despite the novelty and complexity of these compliance challenges for many manufacturers, cloud solutions can help them meet these requirements, all while enabling manufacturers to harness the enormous value of the data they produce.



Using the cloud to promote compliance

In addition to the many business and operational benefits that cloud-based solutions and AI offer to manufacturers, they can also make it easier for manufacturers to better understand the broad fabric of their compliance requirements—and to help them meet those requirements. This holds true both for general compliance obligations that apply broadly across industries—such as data protection and

privacy, cybersecurity, and protection of intangible assets—as well as those that are of unique importance to manufacturers, such as product safety, environmental compliance and sustainability, export controls, and supply chain integrity.



Case Study: Cummins



Cummins, a manufacturer of diesel and alternative fuel engines and generators is another great example of a company that has seized on the enhanced compliance opportunities that Microsoft cloud services offer, realizing benefits for data security and the protection of its intellectual property. Cummins replaced its existing tools with Microsoft 365, introducing an information management and collaboration framework to anchor a new workplace culture. More than 58,000 employees connect in creative teams across functions and borders to focus on keeping Cummins ahead of competitors. Cummins relies on Microsoft 365 to deliver tight security protocols, tools to manage and deliver critical information, and ensure compliance. ([Read more](#))

Data Protection. Cloud solutions and AI can help manufacturers meet their most complex privacy and data protection requirements.¹⁸ For example, Compliance Manager is a cross-Microsoft Cloud services solution designed to help organizations meet even robust compliance obligations like the EU's General Data Protection Regulation.¹⁹

Compliance Manager performs real-time risk assessments that reflect a company's compliance posture against data protection regulations when using Microsoft Cloud services and provides recommended actions and step-by-step guidance.²⁰ It can thus assist manufacturers in making sure that they handle personal information in ways that are consistent with strict privacy regulations.

Cybersecurity. Manufacturers may be subject to a vast array of unique but overlapping data security requirements, both referring to their own data and their customers' data and maintaining compliance with all of them can be challenging.²¹ Cloud solutions can help manufacturers meet these requirements. Microsoft Azure, for instance, offers manufacturers a broad range of tools and solutions to help protect data in ways that are just as safe—and often safer—than can be achieved through on-premises systems.

Azure's advanced security measures maintain compliance with many leading industry regulations, including ISO/IEC 27018, and offer a host of solutions to protect even extremely sensitive data against unauthorized access or misuse. They enable manufacturers to effectively manage and control user identity and access, encrypt communications and operations processes, secure networks, and manage threats. At the same time, with Azure, manufacturers can maintain complete ownership of their data and gain enhanced visibility into and control over information and application access within their organizations.²²

Intellectual Property. Publicly-traded companies, including manufacturers, face increasingly stringent requirements to protect their core assets against cybersecurity vulnerabilities and related threats.²³ Cloud solutions can help manufacturers protect their most valuable data, including their IP, against these threats. This is particularly true of Microsoft's services, where we have adopted policies to make Azure the leading cloud platform for enterprise innovation and agility.

For instance, the Microsoft Azure IP Advantage program offers our customers comprehensive protection against IP risks, including uncapped indemnification coverage that also covers any open source technology that powers Microsoft Azure services.²⁴ In addition, Microsoft's Shared Innovation Initiative establishes principles designed to give our customers confidence and clarity when they innovate on our platform, including that our customers, rather than Microsoft, will own any patents and industrial design rights that result from our shared innovation work.²⁵ Finally, the open but secure nature of the Azure platform, combined with the options Microsoft provides for public, hybrid, and private cloud computing, make it easy for manufacturers both to innovate and to protect their innovations.

Product Safety. Of paramount importance to many manufacturers—including in the discrete manufacturing sector and in chemical and pharmaceutical manufacturing—is product safety.²⁶

With pharmaceutical manufacturers, for instance, a key element of securing product safety is ensuring that medicines are stored at proper temperatures. Cloud solutions and AI can help achieve this objective. For example, [Liebherr Group's](#) Domestic Appliances division has developed an intelligent, connected refrigerator that monitors and analyzes critical performance data remotely, including the accuracy and stability of the device's temperature and the state of the compressor and door. It features a communication module that collects data and



The innovation cycle moves very quickly today—we want to set the pace by offering our customers advances like wearable technology that deliver value beyond what competitors offer. We can adopt new technology and innovate faster in the cloud.



sends it to the Microsoft Azure cloud platform, where Microsoft Azure Stream Analytics generates real-time insights on temperature and other data.

These tools track performance that indicate future problems, enabling them to be detected and resolved before failure occurs.²⁷

Pharmaceutical manufacturers have also deployed cloud tools to improve product quality control by continuously monitoring conditions within mixing vessels, tablet presses, lyophilizers, and other critical equipment.²⁸

Environmental Compliance and Sustainability.

Another major focus of concern for manufacturers is adhering to environmental regulations²⁹ and supporting environmentally sustainable business practices. Again, the cloud and AI can help meet these objectives. Running business applications in the cloud can reduce energy consumption and carbon emissions by a net 30 percent or more versus running those same applications on on-premise infrastructure.³⁰ Enterprises such as chemical and pharmaceutical manufacturers can also leverage the cloud to develop continuous manufacturing suites with footprints less than half the size of conventional factories. Some have even developed portable factories that can be built in 40-foot trailers.³¹



Export controls. Many manufacturers, particularly those in certain discrete manufacturing sectors (e.g., high tech, aerospace), must adhere to stringent and complex export control regulations such as the International Traffic in Arms Regulations (ITAR).³² Here too, Microsoft's trusted cloud platform can help companies manage their compliances. For instance, Microsoft Azure Government and Microsoft Office 365 U.S. Government for Defense provide support for customers with data that is subject to ITAR controls through additional contractual commitments to customers on the location of stored data, as well as restricting access to such data to U.S. persons.³³

Certain manufacturers also may be subject to the Export Administration Regulations (EAR),³⁴ which impose controls on the export and re-export of certain commercial goods, software, and information.

Managing compliance in relation to data can be particularly challenging under these rules. Microsoft's Office 365 includes features that help mitigate the potential risk that customers could inadvertently fail to comply with U.S. export controls when uploading or downloading controlled technical data.

Supply Chain Integrity. Companies in certain manufacturing sectors, such as aerospace and defense, may need to manage enormously complex supply chains as part of their contractual and/or regulatory obligations to government customers.³⁵ Here again, cloud tools can help manufacturers collaborate faster and more efficiently with their suppliers and manage inventories and supply chains more effectively. Cloud-based services can also offer supply-network management tools to obtain a clearer view of materials and parts flowing through their supply chains, helping improve factory operations and product deliveries while cutting costs.³⁶ For instance, cloud solutions can enable an engine maker to share three-dimensional models of components within its network, and each supplier can share information about price, delivery, and quality. Such information-sharing and transparency not only can help drive compliance with regulatory requirements, it also cuts the level of labor necessary to manage design changes, decreases risks for both the manufacturer and its suppliers, and increases efficiency for all parties involved in production.³⁷



Conclusion

The digital transformation of the manufacturing sector is already underway. Manufacturers that lead this transformation by seizing the opportunities that cloud platforms, AI, and services provide will position themselves well to compete and thrive in this new era. Furthermore, cloud solutions offered by Microsoft, can help manufacturers meet in an effective, reliable way both compliance obligations

that already exist as well as new obligations that are arising as the Fourth Industrial Revolution moves forward and regulatory obligations evolve in response, such as the GDPR. Microsoft is an industry leader in providing tools and services that can help our enterprise customers understand and solve even their most challenging compliance obligations.



“Building trust in technology is crucial... Ensure that there is more trust in technology each day. We have to capture the essence of the timeless value”

SATYA NADELLA
CEO

“We employ and partner with thousands of legal and policy experts, auditors, and privacy specialists to work with you in every region of the world on the complex regulatory challenges you face”

BRAD SMITH
PRESIDENT AND CHIEF LEGAL OFFICER



¹ See Klaus Schwab, *The Fourth Industrial Revolution: what it means, how to respond*, WORLD ECONOMIC FORUM (Jan. 14, 2016), at <https://www.weforum.org/agenda/2016/01/the-fourth-industrial-revolution-what-it-means-and-how-to-respond/>.

² See Stephen Ezell and Bret Swanson, *How Cloud Computing Enables Modern Manufacturing*, at 7, INFORMATION TECHNOLOGY AND INNOVATION FOUNDATION (June 2017), available at <http://www2.itif.org/2017-cloud-computing-enables-manufacturing.pdf>.

³ For a more detailed discussion of this issue, see the Microsoft white paper, *THE NEXT-GENERATION MANUFACTURER: HOW TO TRANSFORM INTO A DIGITAL BUSINESS* (2017), at <https://enterprise.microsoft.com/en-us/articles/industries/discrete-manufacturing/the-next-generation-manufacturer-how-to-transform-into-a-digital-business/> [hereinafter "Next Generation Manufacturer Paper"].

⁴ See *id.*

⁵ See *id.*

⁶ See *id.* at 8.

⁷ See *id.* at 8–10.

⁸ See *id.* at 9; McKinsey & Company, *Digital Manufacturing: The revolution will be virtualized*, at 2 (Aug. 2015), at <https://www.mckinsey.com/business-functions/operations/our-insights/digital-manufacturing-the-revolution-will-be-virtualized> [hereinafter "McKinsey Report"].

⁹ See Next Generation Manufacturer Paper, *supra* note 3, at 11.

¹⁰ *GE leads the way to the digital industrial age with a modern workplace culture*, MICROSOFT CUSTOMER STORIES (Feb. 21, 2018), at <https://customers.microsoft.com/en-us/story/ge-manufacturing-microsoft-365>.

¹¹ See Next Generation Manufacturer Paper, *supra* note 3, at 3.

¹² See *id.*

¹³ See *id.* (citing Jeff Edwards, *IDC Survey: Majority of Manufacturers Use Cloud*, CLOUD SOLUTIONS NEWS, (Apr. 21, 2015), available at <https://solutionsreview.com/cloud-platforms/idc-survey-majority-of-manufacturers-use-cloud/>).

¹⁴ See *id.*

¹⁵ See Next Generation Manufacturer Paper, *supra* note 3, at 1.

¹⁶ See Çağlayan Arkan, *Achieving GDPR compliance in manufacturing*, MICROSOFT BLOG (Dec. 15, 2017), at <https://enterprise.microsoft.com/en-us/articles/blog/caglayan-blog/achieving-gdpr-compliance-in-manufacturing/>.

¹⁷ See Microsoft, *Superior security with cloud infrastructure: How Microsoft Azure can strengthen Utilities' security approach*, at 2 (2016), available at https://msenterprise.global.ssl.fastly.net/vnext/PDFs/A01_AzureSecurityWhitepaper20160415c.pdf [hereinafter "Microsoft Utilities Security Paper"].

¹⁸ See, e.g., the California Confidentiality Of Medical Information Act (CMIA), Cal. Civ. Code § 56, imposing confidentiality obligations on entities including pharmaceutical companies.

¹⁹ See Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC, OJ 2016 L 119/1.

²⁰ See Ron Markezich, *Microsoft 365 helps businesses increase trust and innovation through compliance with Compliance Manager Preview*, MICROSOFT BLOG (Nov. 16, 2017), at <https://www.microsoft.com/en-us/microsoft-365/blog/2017/11/16/microsoft-365-helps-businesses-increase-trust-and-innovation-through-compliance-with-compliance-manager-preview/>.

²¹ See, e.g., 201 CMR § 17.04; Conn. Gen. Stat. § 36A-701b (Massachusetts and California state laws requiring businesses to protect data using security measures including encryption).

²² See Microsoft Utilities Security Paper, *supra* note 18, at 3–4.

²³ See, e.g., Securities and Exchange Commission, *Commission Statement and Guidance on Public Company Cybersecurity Disclosures* (Feb. 26, 2018), at <https://www.sec.gov/rules/interp/2018/33-10459.pdf> (SEC statement and interpretive guidance on cybersecurity risks and incidents).

²⁴ See Brad Smith, *Protecting innovation in the cloud*, MICROSOFT BLOG (Feb. 8, 2017), at <https://blogs.microsoft.com/blog/2017/02/08/protecting-innovation-cloud/>.

²⁵ See Brad Smith, *A new IP strategy for a new era of shared innovation*, MICROSOFT BLOG (Apr. 4, 2018), at <https://blogs.microsoft.com/blog/2018/04/04/a-new-ip-strategy-for-a-new-era-of-shared-innovation/>.

²⁶ See, e.g., 21 C.F.R. § 210.1 *et seq.* (setting forth the Current Good Manufacturing Practice regulations, enforced by the U.S. Food and Drug Administration, regulating the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations).

²⁷ See <https://blogs.microsoft.com/transform/2016/04/24/liebherr-domestic-appliances-collaborates-with-microsoft-to-build-new-smart-fridge-for-medicine/> and Microsoft, *A CLOUD FOR GLOBAL GOOD: THE 2018 UPDATE*, Chapter 3 (2018), at <https://news.microsoft.com/cloudforgood/policy/digital-transformation.html>.

²⁸ See McKinsey Report, *supra* note 8, at 2.

²⁹ See, e.g., the Clean Water Act / Safe Drinking Water Act; Federal Insecticide, Fungicide, and Rodenticide Act; Resource Conservation & Recovery Act; Comprehensive Environmental Response, Compensation, and Liability Act; Clean Air Act; Air Pollution Controls Regulations, 40 C.F.R. § 1027 *et seq.*; Metal Products and Machinery (MP&M) Effluent Guidelines and Standards, 40 C.F.R. Part § 438 *et seq.*

³⁰ See McKinsey Report, *supra* note 8, at 2.

³¹ See *id.*

³² See 22 C.F.R. § 120–30.

³³ See *Microsoft and ITAR*, at <https://www.microsoft.com/en-us/TrustCenter/Compliance/ITAR>.

³⁴ See 15 C.F.R. §§730–77.

³⁵ See, e.g., Federal Acquisition Regulations, 48 C.F.R. § 1.000 *et seq.*; Defense Federal Acquisition Regulations, 48 C.F.R. § 201.101 *et seq.*

³⁶ See McKinsey Report, *supra* note 8, at 2.

³⁷ See *id.* at 3