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REDUCE SUPPLIER RISK, REDUCE ORGANIZATIONAL RISK

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INTRODUCTION

If the Medical Device industry wants to improve patient outcomes, then it has to manage risk. One of the largest sources of risk is dependence on third-party suppliers.

Risk is a major focus in most businesses today, regardless of industry. In the past few years, the Life Sciences have seen a steady rise in supply chain issues resulting in lost market caps, recalls, regulatory fines, and other financial impacts valued in the billions of dollars.

The Medical Device Industry is no exception to this reality; if the industry wants to improve patient outcomes, then it has to manage risk. One of the largest sources of organizational risk is dependence on third-party suppliers. Today's global economy has added complexity to supply chains, and longer supply chains are making it increasingly difficult to manage our suppliers, and in many cases our suppliers' suppliers, thereby increasing overall risk. The plethora of regulatory requirements placed on Medical Device organizations, including the updates to ISO 13485:2016, reflect this new reality.

How can supplier risk be reduced and what is the role of Quality in that process?

SUPPLIER RISK AND ITS IMPACT ON CORPORATE RISK

Minimizing business and operational risk, as well as legal and regulatory compliance, is on every executive's mind, and for good reason.

Supplier risk, put simply, is the probability associated with a supplier causing an interruption in an organization's supply chain and to the availability of products and services within that supply chain. Suppliers impact, at a minimum, two legs of the three-legged Governance, Risk and Compliance (GRC) stool: Risk and Compliance. It is safe to say then, that the impact of suppliers on an enterprise is significant.

Supplier risk, put simply, is the probability associated with a supplier causing an interruption in an organization's supply chain and to the availability of products and services within that supply chain.

Governance: Strategic business planning and alignment within the organization, typically addressed through policies and vision setting.

Risk: Addresses threats to the organization and management objectives.

Compliance: Adherence to the laws and regulations of the regions in which the organization operates.

When you couple the global nature and length of supply chains with operational strategies such as lean manufacturing, just-in-time manufacturing, zero inventory, outsourcing, and subcontracting, supply chain risks are increased as even minor supplier disruptions will have a cascading effect on supply. There is little to no safety net to prevent these effects. While lean, just-in-time, off-shoring, and outsourcing strategies have allowed companies to reduce overall costs while improving efficiencies and expand more quickly into new markets, they also expose companies to risk. These risks include the potential of a supplier suddenly going bankrupt, closing operations, taking short-cuts in quality, experiencing capacity issues, regulatory compliance pressure, a data breach, or even being acquired.

It's been said that one risk leads to another. While the source of that phrase is unknown, its truth is readily apparent. Supply chain disruptions, product and service shortages, and quality issues can result in poor financial performance, drops in stock prices, brand reputation issues, and most importantly, an organization's ability to serve patients, thereby impacting public health.

The cost of a major recall in a medical device organization has been as high as $600 million. Penalties and fines of $900 million have been recorded, and that figure doesn't include losses of goodwill and market share.

One McKinsey study of medical products companies claims that supply chain risk events are the second leading contributors to large monthly declines in share price, "resulting in drops of 10 percent or more." The cost of a major recall in a medical device organization has been as high as $600 million. Penalties and fines of $900 million have been recorded, and that figure doesn't include losses of goodwill and market share.

There are many types of supply chain disruptions that can occur and they can be very expensive; expenses that go well beyond the loss of a sale. Ironically, the risk circumstances that have a relatively low probability of occurrence, typically result in the greatest severity of impact, because when they do occur, they have a cascading risk impact throughout the organization. Although such risks cannot be completely eliminated, their impact can and should be reduced. Regulatory bodies around the globe recognize this as well, and have implemented regulations and guidances around supplier controls to manage this risk and its potential fallout on organizations and the public.

THE MEDICAL DEVICE REGULATORY LANDSCAPE IS IMPACTING SUPPLIER CONTROL

Regulatory bodies around the globe have increased their oversight of organizational supply chains, and they've increased the penalties for corporate noncompliance. This oversight has been evident in the FDA's Quality System Regulation (QSR), 21 CFR Part 820, which defines the requirements for purchasing controls applicable to manufacturers of medical devices for United States domestic use. Regardless of the location of its corporate headquarters, if a manufacturer is selling into the U.S. this regulation applies.

21 CFR Part 820

§820.50 states that each manufacturer shall ensure that all purchased or otherwise received product and services conform to specified requirements. This is accomplished by:

- Conducting an evaluation of suppliers, contractors and consultants, establishing and maintaining the requirements, including quality requirements that must be met by suppliers, contractors and consultants.
  - Evaluations must be documented.
  - Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants based on the evaluation results.
  - Maintain records of acceptable suppliers, contractors, and consultants.

- Ensuring purchasing data clearly specifies requirements, including quality requirements, for purchased or otherwise received product and services, and includes an agreement that requests, at a minimum, that suppliers, contractors, and consultants will notify the manufacturer of changes in the product or service, allowing the manufacturer to determine whether the changes may affect the quality of a finished device.

Scrutiny of supplier controls is not relegated only to the FDA.

ISO 13485:2016

The scrutiny of suppliers is also reflected in ISO 13485:2016 (7.4) which has been updated extensively for Supplier Oversight. ISO 13485:2016 defines the requirements for purchasing controls applicable to manufacturers of medical devices that are selling into the European Union (EU) and most other countries around the globe.

§7.4 Purchasing - requires that the organization shall establish documented procedures to ensure purchased product conforms to specified purchase information. Several steps are used to achieve this:

- Evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for evaluation and re-evaluation shall be established
- Establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements, including specifications, product acceptance, supplier personnel qualifications, and quality system requirements.

MDSAP

The Medical Device Single Audit Program (MDSAP) requires adherence to ISO 13485:2016. At a high level, Chapter 7 of MDSAP requires that the purchasing process covers the regulatory needs for supplier management for all the participating countries (USA, Canada, Brazil, Japan, and Australia), and therefore, covers the evaluation, selection, and re-evaluation of suppliers, outsourcers, and service suppliers. Supplier controls and monitoring are to be established based on the type and significance of the purchase as well as its impact on subsequent product realization. Additionally, country-specific requirements are detailed. For example, Chapter 7 Clause 5 clearly denotes the Australian (TGA) country-specific requirement that 1) in-country sponsors or representatives are to be dealt with as suppliers, and 2) they should be subject to the entire process, from qualification to monitoring.

EU Medical Device Regulation (MDR)

Like MDSAP, the new European Medical Device Regulation (MDR) requires adherence to ISO 13485:2016. However, it too adds its own declarations. Article 10.8 (d) & 10.12-14 Supplier Controls and Corrective Action respectively, and for Market Surveillance, Article 88.3 (b) call for announced and unannounced inspections of suppliers and subcontractors, and the facilities of professional users.

The audit of the manufacturer's suppliers and/or subcontractors is called out again in Annex IX Chapter 1.2.3 and Chapter 1.3.3; and the unannounced audits on the site of the manufacturer, and where appropriate, on the site of the suppliers and/or subcontractors, is documented in Annex IX Chapter 1.3.4. Based on the regulations just reviewed, which are only a representative example of the major regulations addressing supplier management, it is clear that regulators understand that at the root of many quality issues are the materials and services delivered by an organization's suppliers. The regulatory observations support that. In the Life Sciences space (excluding veterinary, food, and Parts 1240 and 1250), medical devices account for 47 percent of the FDA observations that were made in the period ending September 30, 2017.

Number of 483s Issued from the System*

Inspections ending between 10/1/2016 and 9/30/2017

Center Name	483s Issued
Biologics	115
Bioresearch Monitoring	243
Devices	1030
Drugs	694
Foods	2662
Human Tissue for Transplantation	61
Parts 1240 and 1250	75
Radiological Health	31
Veterinary Medicine	244
Sum Product Area 483s from System*	**5155**
Actual Total in System 483s**	**5045**

*This table does not represent the complete set of 483's issued during the fiscal year as some 483's were manually prepared and not available in this format. The sum of 483's for all Product Areas will be greater than the actual Total 483's issued during the fiscal year since a 483 may include citations related to multiple product areas, and counted more than once, under each relevant product center.

** This is the Actual Total number of 483's issued from this system, and that are represented in this spreadsheet.

Looking further at the details of the medical device observations, it becomes apparent that supplier and purchasing controls account for a large percentage of those observations -- 240 of them to be exact -- which is 24 percent of all medical device observations. (source: Office of Regulatory Affairs. Inspection References - Inspection Observations. Retrieved from https://www.fda.gov/iceci/inspections/ucm250720.htm)

SUPPLIER MANAGEMENT PROCESSES

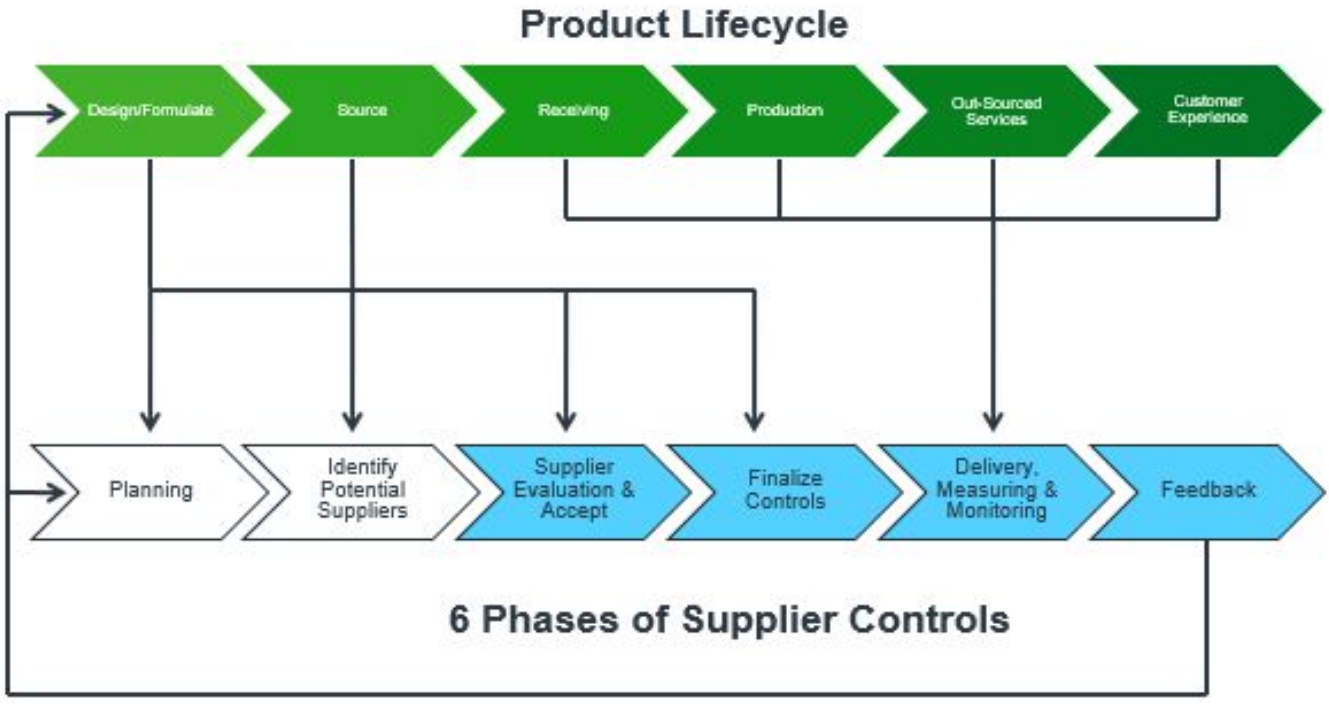
With the significance of supplier management to managing risk in the supply chain, which impacts risk in the overall organization, it's fair at this point to ask: What do supplier management processes look like? How does my organization effectively manage suppliers? How does this minimize risk? Finally, you might also be asking, what is quality management's role in all of this, particularly considering that suppliers are traditionally managed by purchasing?

To start, it is important to understand that supplier management is a component within the larger ecosystem of Supplier Quality Management. While this may seem to be a play on words, there is an important distinction between the two disciplines. Supplier quality management is the multi-departmental process of managing the supplier throughout their lifecycle: evaluation, selection, monitoring, and decommissioning (end of life).

It is important to understand that supplier management is a component within the larger ecosystem of supplier quality management.

Controls

An important element in supplier management are supplier controls. They form the basis for supplier monitoring. For maximum effectiveness, supplier controls, should be connected to the product lifecycle.

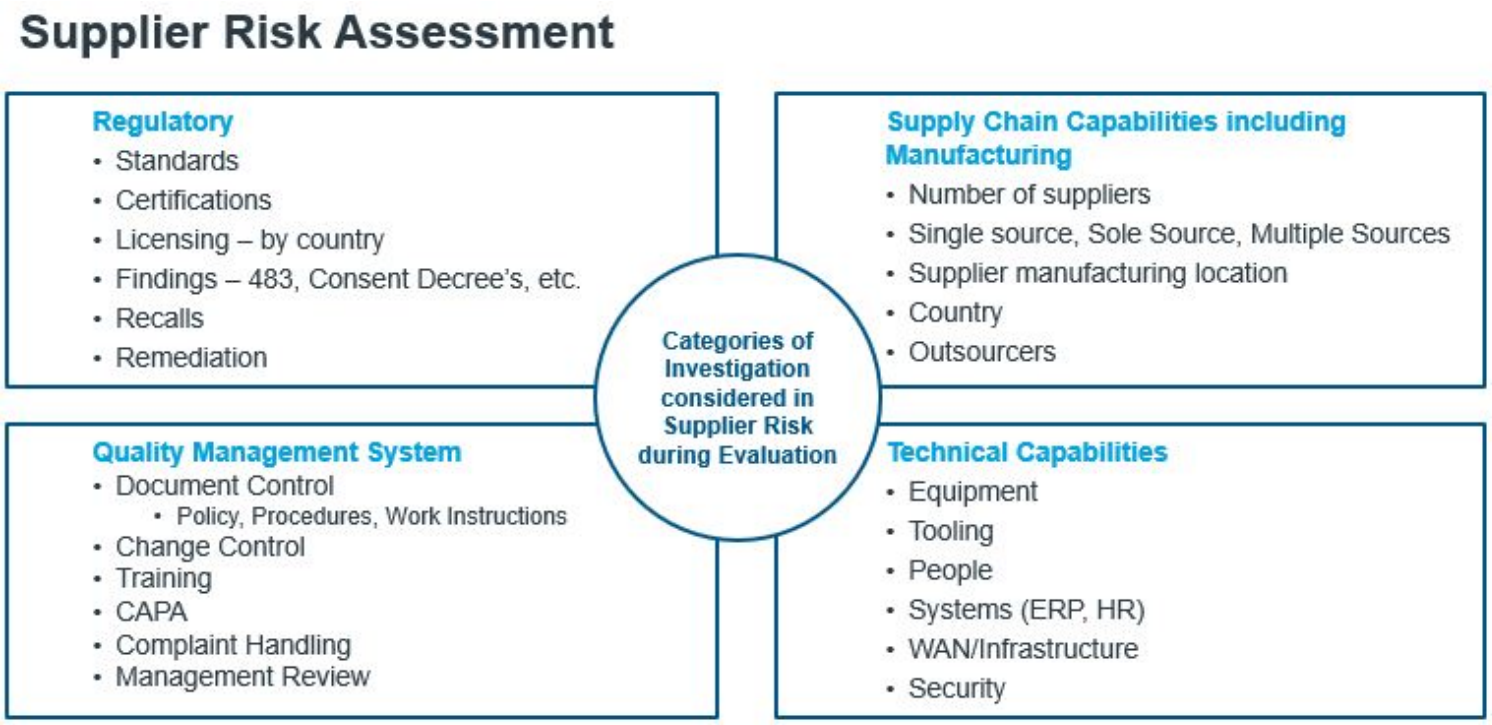


Planning for supplier controls begins with the design/formulation of a product where product requirements and specifications are created. As the product come to fruition and prepares to enter production, sourcing for materials must occur. This includes the identification of potential suppliers, their subsequent evaluation (including risk assessment), and acceptance or rejection. During this process, supplier controls must be finalized and put in place.

Once the purchasing process commences, the organization begins receiving materials and the products go into production or are out-sourced (a purchase as well); the supplier delivery, measurement, and monitoring process must begin. Supplier monitoring is key to successful risk management, key to the management of an organization's suppliers, and key to continuous improvement sought after by all organizations. Monitoring serves as the mechanism for feeding into the design/formulation process, supplier monitoring, and re-evaluation called for in the aforementioned regulations.

Evaluation

Another critical element of supplier management is supplier evaluation. The key areas that need to be evaluated to minimize risk include regulatory assessments, and assessments of supply chain capabilities (capacity), the Quality Management System, and the supplier's technical capabilities. These areas of supplier oversight will minimize the risk of material or service shortages due to supplier shut downs, distractions due to regulatory compliance findings, non-compliant deliveries due to lack of process control, and/or lack of capacity or lack of control over their own suppliers. T

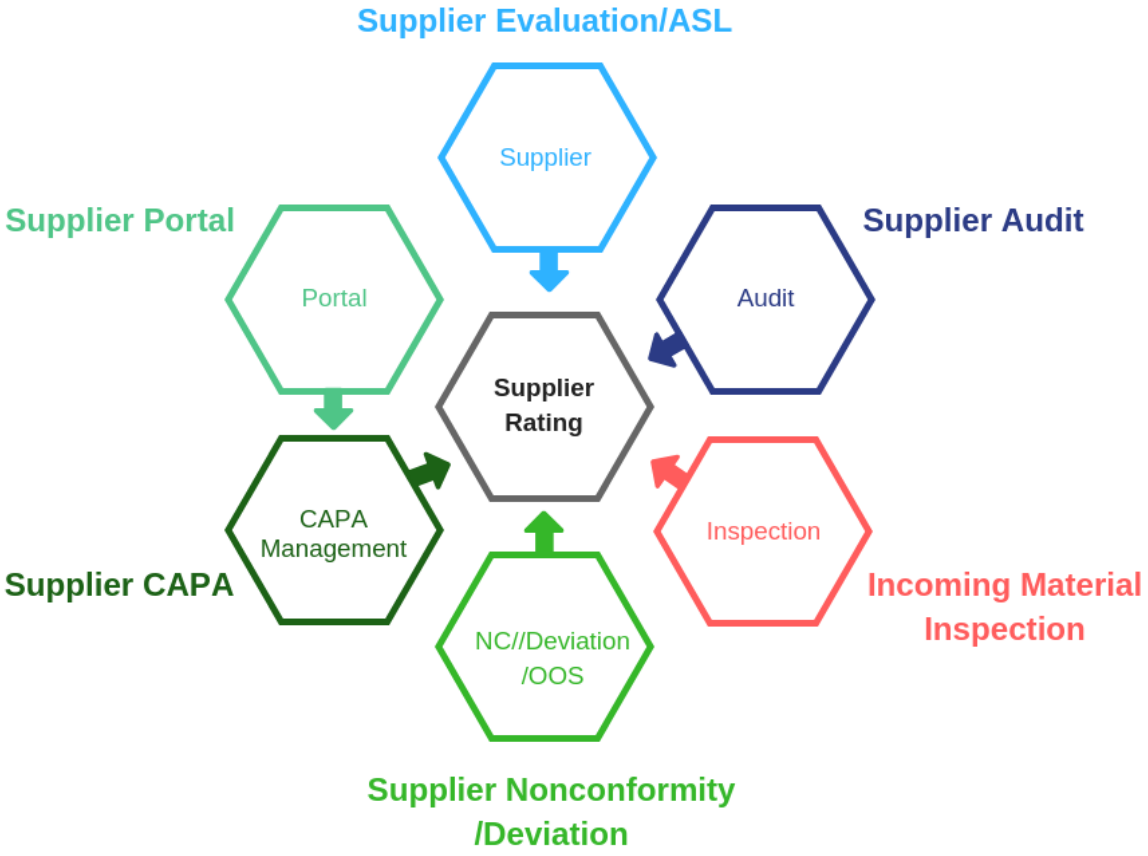


To ensure supplier longevity, and therefore minimize risk to the supply chain, organizations should also assess a supplier's financial stability, reputation, and the processes they use to manage their suppliers. A supplier's financial breakdown can shut down a supply chain in very short order.

The assessments performed during a supplier evaluation are the building blocks needed to monitor and measure supplier performance. All assessments should result in an objective scoring (preferably numerical) that results in the assignment of the supplier risk rating and the supplier's inclusion in the organization's Approved Supplier List (ASL). The supplier risk rating will also dictate the level of control/monitoring required for a supplier; some of these controls include audit frequency and the level of incoming material inspections.

Monitoring and Measurement

Setting supplier controls based on the supplier evaluation performed is not a one-and-done process. Supplier rating and supplier inclusion on the ASL must be an on-going activity that is continuously monitored and measured. Doing so will minimize the risk of supply chain interruptions due to supplier quality issues which include supply availability. These monitors are most effective when established within the integrated supplier quality ecosystem mentioned earlier. Supplier ratings (supplier scorecards) should be updated regularly based on supplier execution results. In other words, the results of incoming material inspections, supplier nonconformance or deviations, supplier CAPAs (SCARs) and supplier audits should be updating the supplier's scorecard (rating), at a minimum, on a monthly basis. Without the conversion of supplier data into information, appropriate corrective and preventive actions cannot be taken, and risk is added into the supply chain.



The purpose of supplier scorecards is to raise the objectivity level of not only the initial supplier review and acceptance process, but the on-going assessment of supplier performance. Criteria and measures within the scorecard must be pre-defined with specific calculations that are applied to the evaluation of all suppliers. This is one way to ensure objectivity during the supplier re-evaluation process, and serves as the foundation for early warnings that a supplier is not performing as it should. Without dynamic and objective supplier scorecards, supplier risk cannot be managed effectively. Even more important, however, is the role that supplier scorecards play in promoting continuous improvement by facilitating communication between an organization and its suppliers' organization.

Analytics are additional tools for the transforming supplier data into supplier information that promotes quality through the effective monitoring of supplier performance, and thereby reducing organizational risk. Each organization should develop supplier analytics that can be used to demonstrate the compliance of their suppliers.

Without dynamic and objective supplier scorecards, supplier risk cannot be managed effectively.

Supplier quality analytics should demonstrate:

- Timeliness
  - On time delivery of goods or services
  - Response times
- Completeness
  - Fill Rate
  - Order Completion
- Productivity
  - Yield
  - Process Efficiency
  - Utilization
- Regulatory/Compliance
  - Regulatory Findings
  - Compliance Penalties
- Quality
  - Complaint Rate
  - Products in Compliance
  - Supplier Defect Rate
  - Supplier Return Rate
  - Successful NPI (New Product Introductions)
  - Defects per Million Opportunities (DPMO)
  - Number of Nonconformances
  - Number of CAPAs
- Trends
  - SCAR Trend
  - Deviation/Nonconformance Trend
  - Charge Back Trend

The above analytics are just a representative example of key supplier metrics. Regularly updated and monitored supplier ratings and metrics, that are harmonized across the organization, and can be deployed at all levels within the organization, allow supply chain constituents to be an integrated component of the organization's extended value chain. They aid in the equitable comparison of suppliers, minimizing supplier risk, and therefore, supply chain risk.

BENEFITS OF SUPPLIER MANAGEMENT

Supply chain risks grow as an organization's suppliers expand geographically and companies increase offshoring and outsourcing activities. The increasing sophistication in technology, and ever-increasing regulatory oversight, are additional factors in the increased supply chain risk. Resulting supply chain issues are impacting medical device and pharmaceutical manufacturers around the globe, costing billions of dollars in market devaluations, recalls, regulatory fines, and settlements. But supplier management is a viable tool in the arsenal to minimize the risk of those outcomes.

In an article by Dan Jacob, LNS Research Analyst, it's noted that organizations need a supplier quality management initiative as it is a high-impact, low-maturity discipline within most organizations that will deliver results. Effective, harmonized, enterprise-grade Supplier Quality Management will not only improve the metrics mentioned above, it will result in:

- Improved customer satisfaction and loyalty
- Improved patient safety
- Improved organizational goodwill
- Improved brand reputation
- Increased profitability and shareholder value
- Improved visibility across the enterprise and its value chain
- Collaboration and the interchange of best practice processes

Business leaders are focused on risk in an effort to eliminate undesirable disruptions within their business operations. Supplier quality management is one way to accomplish this. Effective supplier management results in improved collaboration between an organization and its suppliers, and can drive continuous improvement of products, processes, and technologies, while driving innovation.

RESOURCES

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