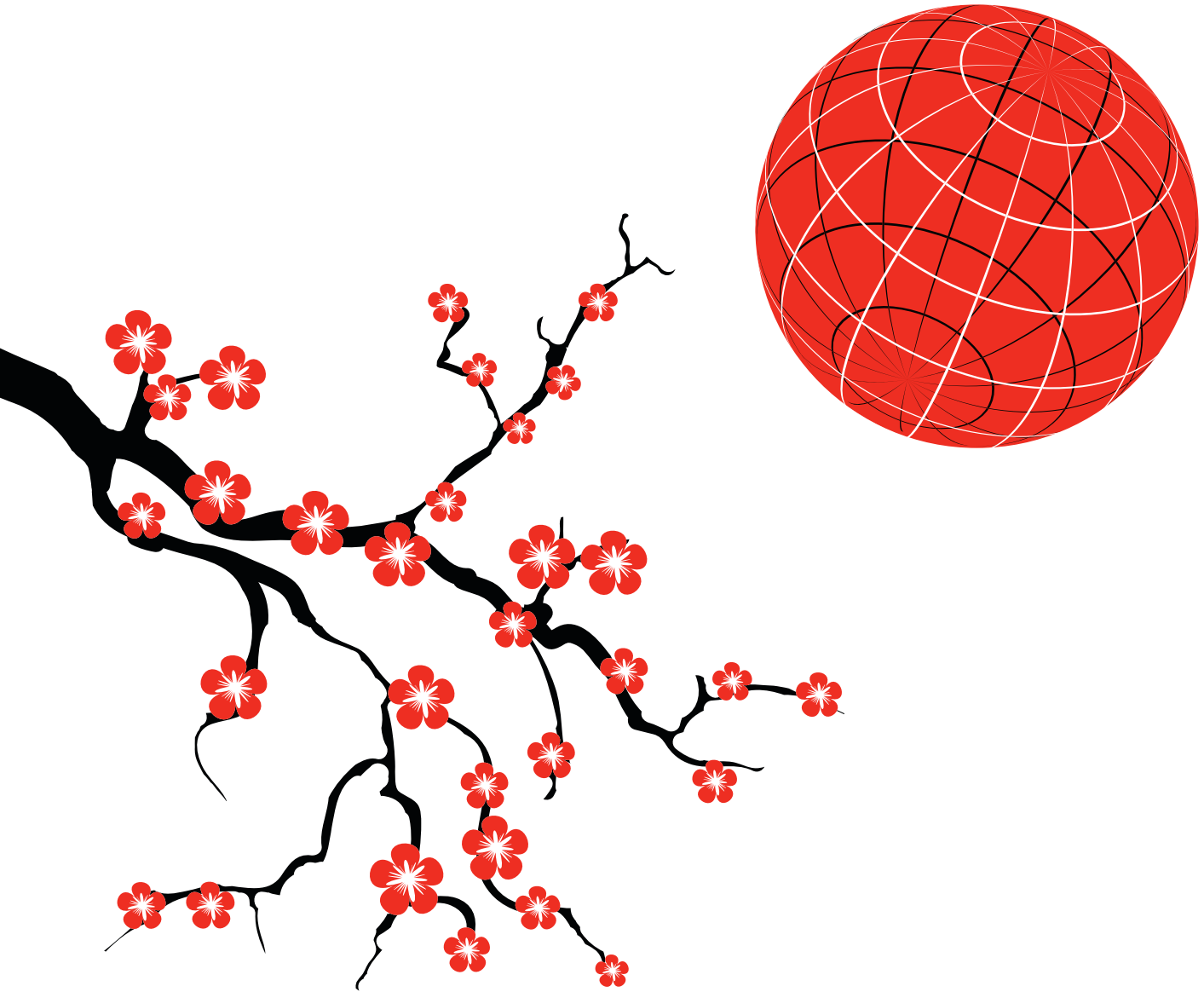


bsi.

...making excellence a habit.™



Maximizing Global **Opportunities**

How international standards can help
your business grow overseas

Foreword

“ BSI is dedicated to promoting excellence. Working with organizations of all sizes in 182 countries worldwide, we improve performance, reduce risk and increase resilience right the way through the supply chain. ”

Howard Kerr, Chief Executive, BSI

84%

of companies say that using standards enhances their reputation

89%

of companies say that standards contribute to the optimization of compliance with regulations such as health and safety legislation

31%

of companies say that using standards increased their capacity to export



Introduction

Japan has the world's fourth largest export economy. In 2017, exports rose by 11.8% to 78.3 trillion yen¹. These figures show that Japanese companies are thriving on the international stage, but it is widely recognized that much needs to be done to maintain this success in an increasingly competitive global marketplace.

In the latter half of the 20th century, Japanese companies were among the first to realize the potential of quality control techniques in increasing productivity. It was these improvements that helped Japanese products to become benchmarks for quality all over the world.

However, a recent OECD report identifying a labour productivity that is "surprisingly low – 25% below the average of the top half of OECD countries"², new ways will need to be found to increase productivity and unlock future growth.

The government is already leading the way, tackling issues such as a diminishing labour pool and relative lack of corporate investment through the third arrow of its revitalization plan. But businesses themselves will also need to be creative. The old ways of doing things will no longer be enough. The leading companies of the 21st century will be centred within the most innovative communities. They will be forward thinking, creating strategic cultures that are capable of embracing new ideas and technologies whilst also ensuring they are part of the most efficient and resilient supply chain networks.

Standards will be an essential tool in this process. They not only ensure compliance, they also maximize intercompatibility and efficiencies within the supply chain. Companies involved in the work of local and international standards bodies like BSI, JSA and ISO will be at the forefront of the latest developments in technology and best practice, with each published standard representing an evolving consensus on the best way of doing things.

But perhaps most importantly, in a rapidly changing world, they provide a catalogue of information that has been shown to play an important role in helping to drive invention and innovation³.

The BSOL (Standards Online) library is a database with over 97,000 international (ISO, EN, BS, IEC and ASTM) standards covering everything from product and material specifications to quality management systems and supply chain resilience.

In this report, we will look at emerging trends in some of Japan's key export markets and discuss some of the key issues facing companies operating on the global stage. Working together, we can make excellence a habit ●

Takashi Kamakari, BSI Sales Director

References

1. http://www.customs.go.jp/toukei/suii/html/nenbet_e.htm
2. <http://www.oecd.org/economy/abonomics-third-arrow-key-to-revitalising-japans-economy.htm>
3. [The Economic Contribution of Standards to the UK Economy](#). Centre for Economics and Business Research Ltd (Cebr), Published in June 2015 by BSI, 389 Chiswick High Road, London W4 4AL

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A History of BSI

“Before the twentieth century there were no standards.”

This may seem like a counter-intuitive statement. After all, society has always been awash with morals and ethics – rules on how to behave and what to do. However, we only need to think of passengers and goods having to be transferred between trains running on different gauges, to be reminded that there was often little consensus in the industrial process.

A growing recognition soon developed that producing materials and components to a standard specification would lead to efficiencies that could both increase competition and open up new markets. This resulted in the very first meeting of the Engineering Standards Committee in 1901.

Convened by Sir John Wolfe-Barry, designer of London’s Tower Bridge, the committee published the first British Standard (BS1) in 1903. It tabulated the standard dimensions of steel angle sections, essential for structural engineers sourcing from different manufacturers.

This was soon followed by standards for the specification of sections and gauges of tramways, copper conductors, telegraph materials and cement. By 1931 the Engineering Standards Committee had been granted a Royal Charter and finally changed its name to The British Standards Institution (BSI).

By the mid 1940s, there was renewed focus on the need for global standards and in 1946 the first Commonwealth Standards Conference took place. This led to the International Organization for Standardization (ISO) of which BSI is a founding member.

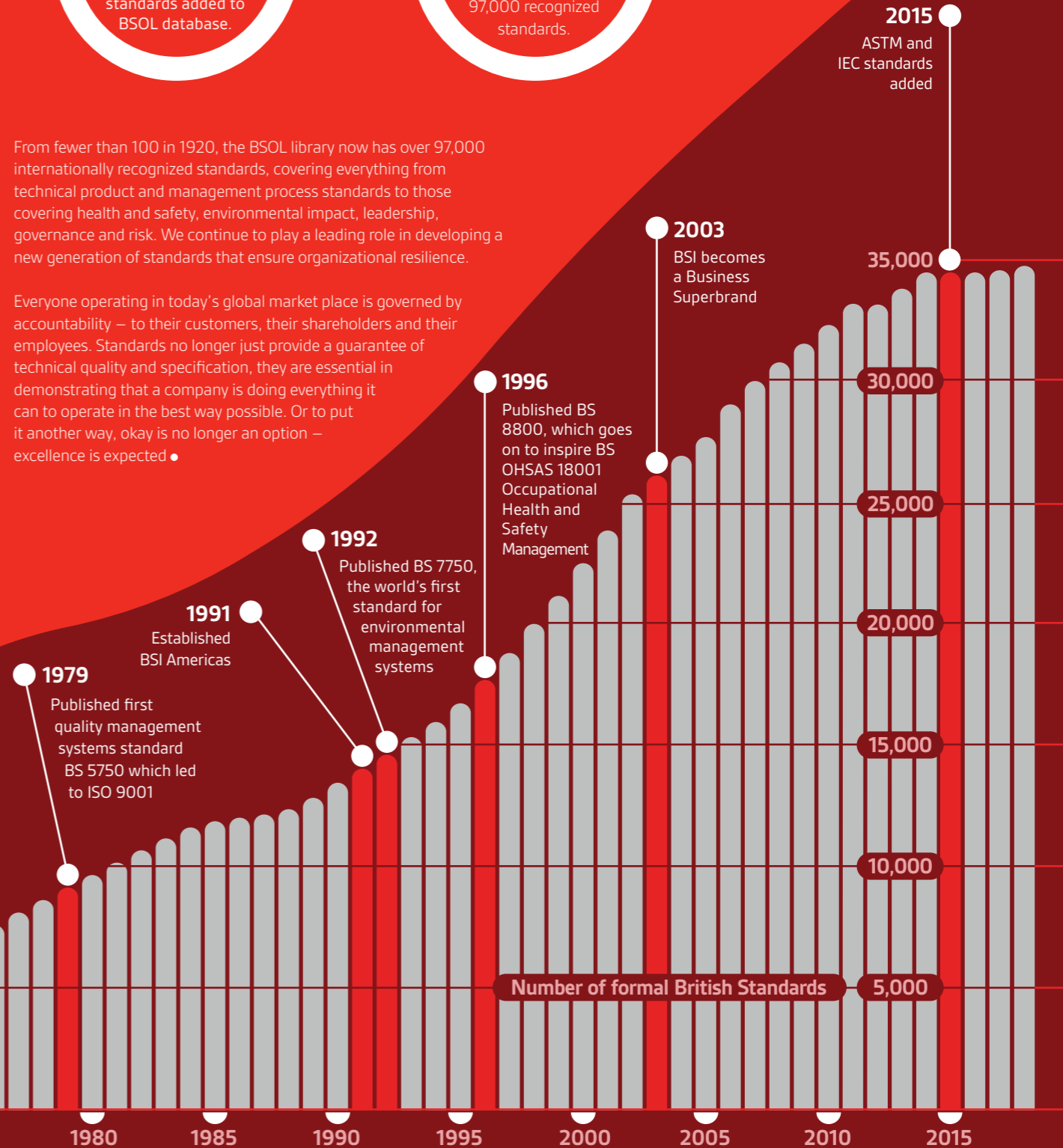
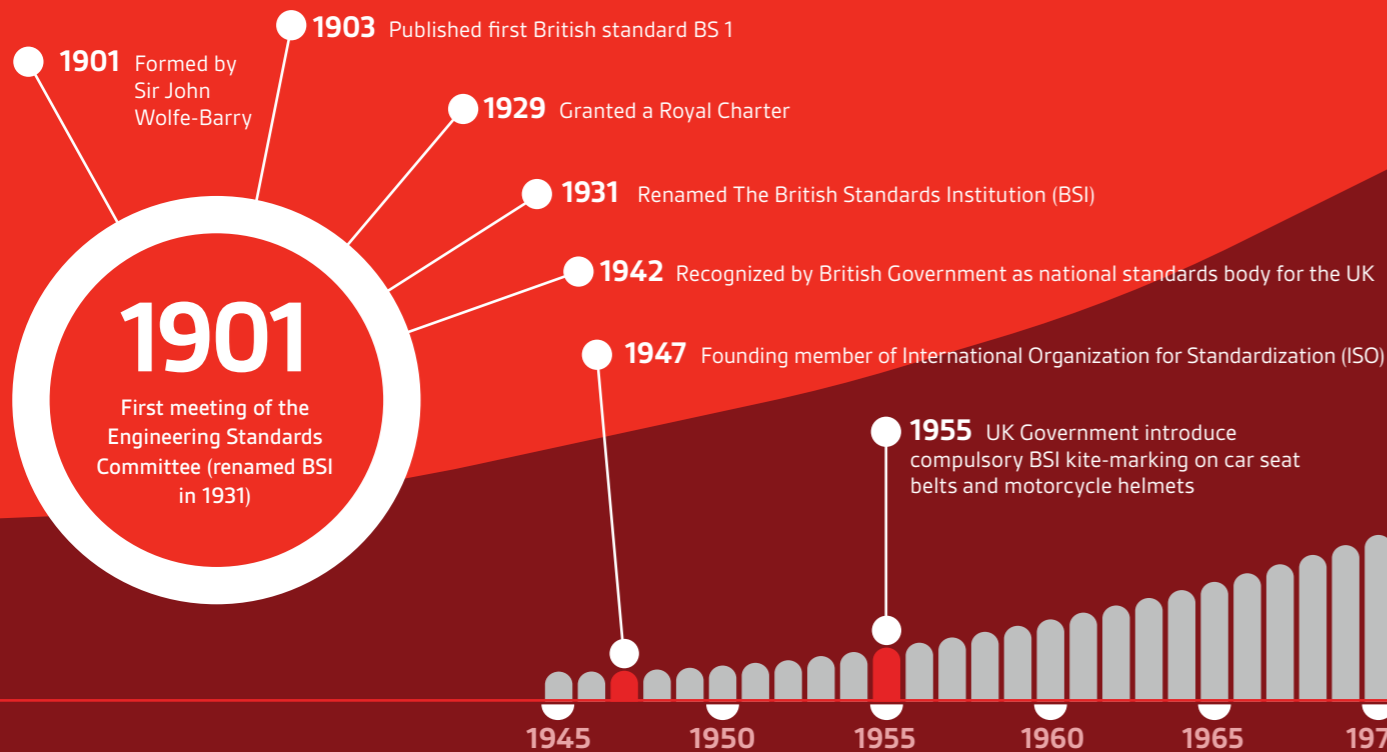
The latter half of the twentieth century saw the emergence of business process standards, as it became increasingly apparent that the quality of a product was directly related to the quality of the process that made it. Many of the world’s most widely used ISO standards, such as the Quality and Environmental Management series (ISO 9001 and ISO 14001), started out life as original British Standards developed by BSI.

2016
5,199 additional standards added to BSOL database.

2018
BSOL now features over 97,000 recognized standards.

From fewer than 100 in 1920, the BSOL library now has over 97,000 internationally recognized standards, covering everything from technical product and management process standards to those covering health and safety, environmental impact, leadership, governance and risk. We continue to play a leading role in developing a new generation of standards that ensure organizational resilience.

Everyone operating in today’s global market place is governed by accountability – to their customers, their shareholders and their employees. Standards no longer just provide a guarantee of technical quality and specification, they are essential in demonstrating that a company is doing everything it can to operate in the best way possible. Or to put it another way, okay is no longer an option – excellence is expected.



Manufacturing: Sector trends

With machines now talking directly to each other, new technologies such as the Internet of Things and 3D printing are set to fundamentally change the relationships that manufacturers have with their customers.

Japan's economic success has been built on the export of high technology manufactured goods, and the value of these exports to the health of the Japanese economy cannot be overstated. The Deloitte Global Manufacturing Competitive Index for 2016 ranked Japan as the world's fourth most competitive manufacturing economy, with products from industrial manufacturing accounting for 87.4% of the total of Japan's exports that year¹.

The survey also identifies talent, cost competitiveness, productivity and supplier network as the four main drivers to maintaining competitiveness in the global marketplace. Maximizing all of these factors will be essential to securing the ongoing success of Japan's manufacturing industry over the coming years.

The government has set a target to double Japan's economic growth from the 1% average of the past 25 years to 2%. To achieve this, it has launched the third arrow of Abenomics², which aims to increase productivity through policies addressing issues such as an ageing population and lack of corporate investment.

Whilst it may be the responsibility of government policy to tackle specific demographic problems and develop the best possible environment for industry to thrive, there is much that businesses can do themselves to secure their long-term health and success.

The opportunities offered by new technologies and the emergence of the Internet of Things (IoT) are set to radically alter the manufacturing landscape. Successful companies will be those that have the imagination to change and adapt their strategic culture, by seeing beyond traditional models to invest in and developing new systems to maximize both efficiency and productivity.

As producer of 50% of the world's industrial robots³, Japan is ideally placed to play an integral role in how the IoT shapes the production line of the future. Autonomous devices are likely to completely revolutionize the shop floor. Through the use of sensors, machines will be able to continually monitor their own performance and communicate with each other to self-diagnose any potential problems.

7,538
standards projects
at BSI

This will allow for ongoing maintenance schedules that can prevent any problems before they arise, with drones or other autonomous machines fetching the correct tools and parts to conduct repairs where necessary and ensuring that every aspect of the production line is operating at the peak of its potential.

Machines that can consistently monitor and improve their own performance will also lead to a fundamental shift in customer relationships and how manufacturers engage in the overall life of their products. The focus is likely to move away from a pay-for-product to a pay-for-performance model. With customers paying more to suppliers who can use real-time data to provide maintenance and upgrades that minimize equipment downtime, improve operating efficiency and maximize productivity.

New technologies are also set to revolutionize global supply chain networks and how replacement parts are supplied. Advances in additive manufacturing (also known as 3D printing) mean that new parts can be produced at a local level, thereby slashing distribution costs and vastly reducing the need to keep huge parts inventories.

Realizing the potential of these new technologies will require investment and innovation. It will also require more openness as products, parts and components have increasingly multi-sector applications. As end products become ever more complex, individual manufacturers will become more reliant on specialist suppliers. Standards have an essential role to play in maximizing the inter-compatibility of these parts which, in turn, secures maximum efficiencies across global supply chains.

But perhaps most importantly, standards have been shown to drive innovation through the dissemination of information. They enable new and existing companies to access not only necessary technical information and specification for product development, but also the cultural processes and behaviours that will ensure the organizational efficiency and resilience that is vital for ongoing success •

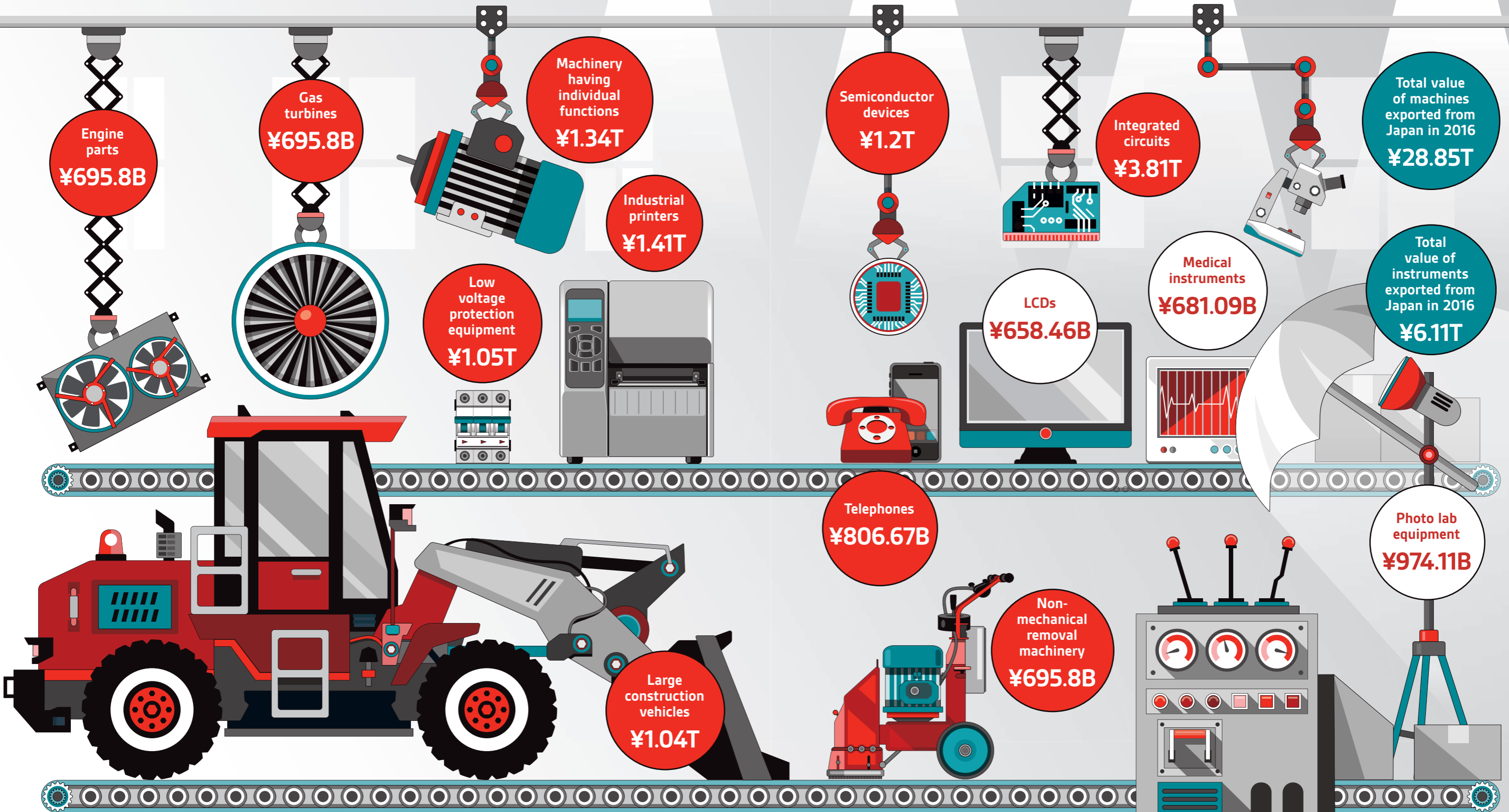
“As producer of 50% of the world's industrial robots, Japan is ideally placed to play an integral role in how the IoT shapes the production line of the future.”

References

- <https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Manufacturing/gx-global-mfg-competitiveness-index-2016.pdf> (export figures for 2016)
- https://www.mofa.go.jp/mofaj/press/iken/pdfs/huffingtonpost_130703_en.pdf
- <https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Manufacturing/gx-global-mfg-competitiveness-index-2016.pdf>

Manufacturing export data

Total Japanese exports for 2016



Automotive: Sector trends

Technological advances have made the autonomous electric vehicle a reality. But with margins remaining tight, the key to profitability will be through maximizing efficiencies in an increasingly complex and diverse supply chain.

Japan continues to be one of the biggest players in the automotive industry. In 2016, it was the world's second largest producer, with four firms, Toyota, Nissan, Honda and Suzuki all in the global top 10 car manufacturers by sales¹. Japanese automotive firms made 9.2 million motor vehicles that year, and nearly 19 million more units in overseas operations.

The sector remains hugely important to the wider economy, bringing in 1.51 trillion yen (almost a quarter of all exports) and providing automobile related employment for 5.34 million people – 8.3% of the total workforce². And worldwide, the overall demand for cars continues to grow. Over the last ten years, global production has increased by 38%, with 73.46 million new cars being built in 2017³.

But beneath all of these reassuring figures, the picture is far more complicated. The industry is about to enter a huge period of upheaval – possibly the biggest it has faced. After a century of the internal combustion engine, new technologies and pressing environmental concerns are driving rapid change. Battery powered cars that can drive themselves are no longer the preserve of science fiction and the world's first fully autonomous vehicles are already making headlines.

Advances in safety technology mean that features such as adaptive headlights, self-parking, lane-keeping assist and collision mitigating braking systems are commonplace on many cars. Utilizing advances in IoT (Internet of Things) technology, the next wave of Intelligent Transport Systems (ITS) aim to improve safety and efficiency by enabling communication between other vehicles and the road network itself.

Navigation systems that can provide real-time traffic information are already in use, as are electronic toll collection systems. The next step is for the vehicle to become fully connected, constantly talking to other cars and the road itself. The challenge of developing standards to ensure this connectivity remains unbroken, wherever a vehicle is being driven, is ongoing and involves several international standards organizations.

Concerns about global warming, as well as pollution in urban areas, are also driving innovation within the industry. Many governments are introducing emission legislation for their towns and cities. Furthermore, countries such as the UK, Norway, the Netherlands, India and France have all set target dates for phasing out petrol and diesel car sales before 2040⁴. The resulting push towards electric vehicles (EVs) will not only require further technological advances to improve the efficiency and range of these vehicles, but also a significant investment in charging infrastructure.

Profit margins for the sector are tight, typically between 5 and 10%, even for the most profitable companies⁵. And with the need for investment in research and development only increasing, the pressure on profit margins is only likely to get bigger. It is now widely recognized within the industry that improving profitability can no longer be met by increasing production. It will instead be delivered through finding efficiencies at every level.

References

- <https://www.drivespark.com/four-wheelers/2017/top-10-car-manufacturers-in-2016-in-the-world-020233.html>
- <http://www.jama-english.jp/publications/MIJ2017.pdf>
- <https://www.statista.com/statistics/262747/worldwide-automobile-production-since-2000/>



3,500
members of staff
at BSI

A number of manufacturers are producing a wider range of derivative vehicles on the same basic platform. By only differentiating the customer-facing elements, they are able to meet the needs of more localized markets whilst minimizing research and development costs. These platforms need to be able to meet the legislative requirements in all global markets and standards are an essential tool in this process.

Other efficiencies can be found through collaboration on shared projects and platforms. Many Japanese companies, for example, are now working together to advance the Suriawase 2.0 initiative⁶. This initiative aims to reinforce international competitiveness with next-generation resource-saving manufacturing. Through the development of a standardized simulation model that can be used by all companies, automobile manufacturers are working to increase the intercompatibility of the supply chain.

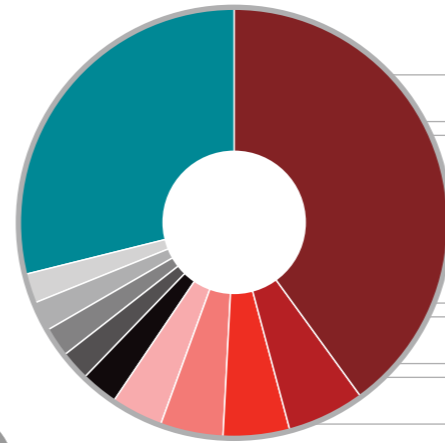
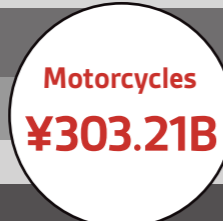
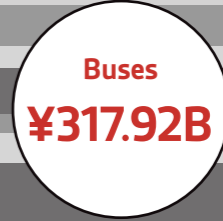
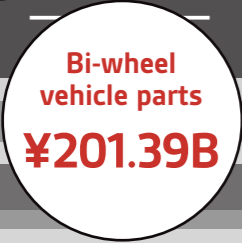
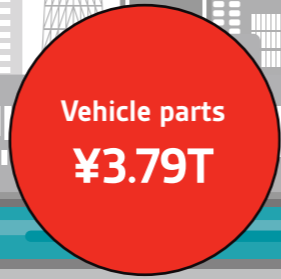
With a new automobile typically composed of 20,000 to 30,000 parts, even the largest manufacturers cannot produce everything themselves and are reliant on specialists. Standardization ensures that highest quality levels are maintained while minimizing costs. Quality management standards, such as ISO 9001 and its application to the automotive industry (IATF 16949, published in 2016), are utilized throughout the industry to achieve these goals.

It is through finding these efficiencies, that companies will remain competitive. Ultimately it is the customer that needs to be reassured that their new vehicle is safe, efficient and built to the highest quality. Standards in the automotive supply chain are responsible for increased customer satisfaction because they directly influence quality, recall frequency and delivery times, enabling consumers to embrace new technology with confidence •

- <http://uk.businessinsider.com/countries-banning-gas-cars-2017-10/#china-has-said-it-will-eventually-only-sell-electric-and-hybrid-vehicles-but-has-yet-to-set-a-concrete-timeline-4>
- <https://www.msn.com/en-in/autos/photos/the-20-most-profitable-car-manufacturers/ss-AAq36pf#image=1>
- http://www.meti.go.jp/english/press/2018/0404_001.html

Automotive export data

Total Japan export values in 2016



Where Japan exported cars to in 2016

| | | | |
|-------------------|-------|--------------|------|
| US | 40% | Canada | 2.8% |
| China | 5.9% | Russia | 2.3% |
| Australia | 5.1% | Germany | 2.2% |
| UAE | 4.7% | Saudi Arabia | 2.2% |
| Belgium | 3.8% | UK | 2.2% |
| Rest of the World | 28.8% | | |

Case Study:

Toshiba Energy Systems & Solutions Corporation

Toshiba Energy Systems & Solutions Corporation is one of Toshiba Group's four business cores. It is a leading supplier of integrated energy solutions delivering innovative, reliable and efficient energy systems across the globe.

Mr. Satoshi Marushima (Toshiba Energy Systems & Solutions Corporation Technology & Production Planning Division, Technology Planning Group) talked to us about the importance of standards and how BSOL helps deliver them across a global business.

Q Tell us about your company.

“Toshiba Energy Systems & Solutions Corporation provides the equipment, systems and services for making electricity, supplying it, and using it efficiently. We aim to harmonize the increasing demand for electric power with the responsibility to preserve the Earth for future generations.”

Q How do you use standards in your business?

“Our customers need to be reassured that our products meet the required specifications as well as any regulatory requirements. We are a global company so we use a large range of international standards including JIS, BS EN, ASME, ASTM, IEC, IEEE, NFPA, ISO, ANSI, ACI, ANS, HI.”

TOSHIBA

Q Why do you use British Standards?

“A lot of ISO and EN standards have been adopted by British Standards. By using BS EN ISO standards we can access these internationally recognized standards in English. We also often refer to some of the older British Standards back catalogue, which can provide invaluable information on how current standard specifications have evolved.”

Q What are the main benefits that the use of standards brings to your business?

“We would not be able to do business without them. Standards help us to meet our customer's requests. They provide a framework for the specifications and regulatory requirements that need to be met. By using standards, we can gain our customers trust and give them peace of mind.”

Q What influence does the use of international standards have on your industry as a whole?

“International standards are increasing the unification of specifications across the energy industry. By working together, we can improve and secure safety through constant use and development of standards.”

Q What are the benefits of using BSOL to supply standards?

“Using the BSOL online catalogue means that the standards we need are available immediately, to be viewed on your computer, at your desk or wherever you are in the world. Multiple standards can be accessed by multiple users simultaneously.”

It is also extremely reassuring to know that BSOL is constantly updated, so we can be sure that we are always using the latest, most up-to-date standards. This means there is absolutely no risk that we could accidentally be designing to old specifications.”

Opinion:

Trading in the EU

John DiMaria, Global Product Champion for Information Security and Business Continuity at BSI Group, describes how standards-based data governance is the best route to regulatory compliance for Japanese organizations operating or trading within the EU.



In 2018, the General Data Protection Regulation (GDPR) superseded the EU data protection directive of 1995, which was no longer able to protect personal data relevant in an age of internet and cloud giants like Google and Facebook.

Japanese organizations processing EU citizens' and residents' data must comply with GDPR or face significant fines, even if they do not maintain a physical presence in Europe. The GDPR unequivocally places responsibility with the organization, giving EU residents and citizens ultimate control over their personal information¹.

GDPR also provides Japanese businesses with more legal clarity and unifies data protection law across the European market. It updated the old legislation in key areas including:

- Consent, which must be actively affirmed by the data subject and recorded by the data controller
- What counts as personal data
- Requests by individuals for information on how personal data is held and used, timeframes for response by organizations, and requests for data to be deleted
- Timeframes and protocol in the result of a data breach

Japan introduced the Act on the Protection of Personal Information (APPI) in 2003, updating it in 2017. Although it was created with similar goals to the GDPR, it is less comprehensive. For example, it does not distinguish between the data processor or controller but holds the

business operator responsible. It also only applies to processing for business purposes, and does not mention regions or territories, while the GDPR is not limited in either of these areas.

Originally, the APPI allowed business operators to transfer personal data to third parties without needing additional consent, as part of an 'opt-out' arrangement. Although the 2017 amendment tightened this system for Japanese businesses, the GDPR does not allow for such opt-out arrangements at all, requiring companies to clearly notify data subjects of all processing activities involving their data².

Although there are over 100 other different territorial data privacy regulations, the GDPR is quickly becoming the de facto international benchmark. Using recognized standards to inform data protection processes helps Japanese companies understand their current, and potential, levels of exposure in relation to GDPR.

For example, BS 10012 provides a pathway for organizations to define their GDPR risks and compliance requirements, and then implement a suitable personal information management system. Once the system is in place, a company can request independent certification to demonstrate compliance.

Certification to recognized data governance standards also helps gain stakeholder and customer trust, reassuring both that their personal data is protected. It increases transparency between supply partners, demonstrating to all parties that appropriate controls are in place and pushing accountability far down the chain •

References

1. www.eugdpr.org
2. <https://blog.focal-point.com/beyond-the-gdpr-what-you-should-know-about-japans-act-on-the-protection-of-personal-information>

The five W's of data and other relevant standards

BS 10012 helps Japanese companies manage the five Ws of data, namely:

- 1 Whose data is it?
- 2 Why are we processing it?
- 3 Where is it kept or transferred to?
- 4 When are we keeping it until?
- 5 What safeguarding mechanisms do we have in place?

Other relevant standards include ISO/IEC 27018 to help protect personally identifiable information in the public cloud, ISO/IEC 29151:2017 for a set of additional controls aligned with ISO/IEC 27001, BS ISO/IEC 38505-1:2017 for data governance and controls over the flow of information and a new emerging standard: ISO/IEC 27552 extension to ISO/IEC 27001 and to ISO/IEC 27002 for privacy management – requirements and guidelines.

Healthcare: Sector trends

As the world's population continues to grow, changes in both local and global demographics are paving the way for new technologies to deliver revolutionary new solutions in healthcare provision.

Figures released by the United Nations in 2017 suggest that there will be another 2.2 billion people living on our planet by 2050. A substantial part of this growth will be fuelled by a rapidly ageing global population, with the number of people over 60 expected to more than double in this time¹. As the proportion of people of working age diminishes, so will the availability of doctors and nurses. The WHO predicts that there will be a shortage of 12.9 million healthcare professionals worldwide by 2035² and the pressure on resources, both human and financial, is only set to increase.

Ultimately, this means that the traditional system of healthcare delivery, through face to face contact with providers, is no longer viable. New value-based systems will need to be developed that use the latest trends and technologies to engage populations in their holistic health and long-term wellness. Advances in areas such as gene therapy and less invasive surgery techniques, as well as exponential technologies like network sensors, AI, robotics, synthetic biology and 3D printing are rapidly changing the possibilities for the delivery of healthcare solutions. But with over two thirds of the world's population having access to a mobile connection³, it is the rise of the smartphone that is set to revolutionize the healthcare sector.

Smartphones provide an access point for data collection and diagnosis. They are already enabling doctors to deliver virtual care to more isolated communities the world over, and developers are utilizing the device's cameras and microphones to create apps that turn them into a diagnostic tool⁴. A number of reports⁵ estimate that the annual global mHealth (mobile health) market could be valued at well over USD 100 billion towards the middle of the next decade. However, it is not only the need to provide increasing value to an expanding and ageing population that is driving this change. By 2030, the global middle class is expected to have more than doubled in size to 4.9 billion⁶, making up 58% of the total population.

These people are active, empowered consumers and they are looking for a healthcare experience that reflects the same levels of convenience offered by other consumer services. They are increasingly open to receiving healthcare in non-traditional settings, particularly in emerging markets, where access to quality care is a prevailing concern, and there are many opportunities for partnerships to be developed with new market participants from the retail, telecommunication and technology sectors.

In Japan, the government has developed new healthcare policy and targets to create 'a new patient-oriented healthcare system through the introduction of data and technological innovations that aims for full-scale operation by 2020'⁷. Some of the key objectives are to increase the use of virtual medicine, so that more medical care can be received at home, give individuals online access to their personal health records, and improve productivity in nursing through the use of robots, sensors and artificial intelligence. Further focus is being given to promoting Japanese capability in medical technology as part of the Third Arrow economic plan and organizations such as MEJ (Medical Excellence Japan) have been set up to promote the globalization of Japan's medical services industry⁸.

Total global healthcare spending is expected to reach USD 8.7 trillion by 2020⁹ and by 2022, one third of all this expenditure is predicted to occur in emerging economies¹⁰. By mobilizing to help meet domestic targets, Japan's healthcare companies will be ideally placed to provide solutions to the rest of the world. However, it is important to remember that the need to ensure quality care and patient safety, along with mitigating fraud and other cyber data threats, means that the global healthcare industry is one of the most heavily regulated in the world. International standards are essential to any business looking to make the most of the opportunities on offer and it is essential that they are integrated right from the beginning of any product development process •

References

1. <https://esa.un.org/unpd/wpp/>
2. <http://www.who.int/mediacentre/news/releases/2013/health-workforce-shortage/en/>
3. <https://venturebeat.com/2017/06/13/5-billion-people-now-have-a-mobile-phone-connection-according-to-gsma-data/>
4. <https://futurism.com/most-significant-innovation-modern-healthcare-isnt-drug-your-cell-phone/>
5. <https://www.grandviewresearch.com/press-release/global-mhealth-app-market> <https://www.psmarketresearch.com/press-release/global-mhealth-market> <https://globenewswire.com/news-release/2016/12/20/899026/0/en/Global-mHealth-Market-will-reach-USD-102-43-Billion-by-2022-Zion-Market-Research.html>

“By mobilizing to help meet domestic targets, Japan's healthcare companies will be ideally placed to provide solutions to the rest of the world.”



6. http://oecdobserver.org/news/fullstory.php/aid/3681/An_emerging_middle_class.html
7. https://www.kantei.go.jp/jp/singi/keizaisaisei/pdf/miraitousi2018_en.pdf
8. <http://www.medical-excellence-japan.org/en/mej/index.html>
9. <https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-2017-health-care-outlook-infographic.pdf>
10. http://www3.weforum.org/docs/WEF_HealthSystem_LeapfroggingEmergingEconomies_ProjectPaper_2014.pdf

Key standards and regulations for the development of medical devices in Japan

1 Concept

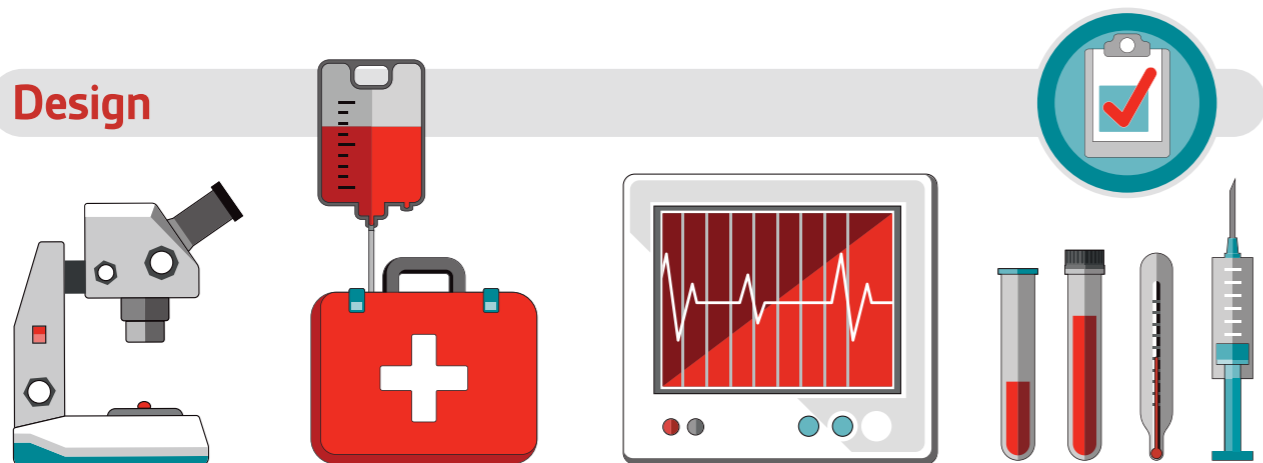


2 Planning

| | |
|----------------------|--|
| ISO 13485 | Medical devices. Quality management systems. Requirements for regulatory purposes. |
| BS EN 60601-1 | Medical electrical equipment. General requirements for basic safety and essential performance. |
| ISO 14971 | Medical devices. Application of risk management to medical devices. |
| ISO 14155 | Clinical investigation of medical devices for human subjects. Good clinical practice. |
| ISO 10993 | Biological evaluation of medical devices. Tests for irritation and skin sensitization. |
| BS EN 62366-1 | Medical devices. Application of usability engineering to medical devices. |
| ISO 15223-1 | Medical devices. Symbols to be used with medical device labels, labeling and information to be supplied. General requirements. |

Note: The above publications are generally referred to as 'horizontal standards', applicable to all types of medical devices. More detailed, product-specific requirements can be found in what are known as 'vertical standards', for example ISO 80601-2-13 Medical Electrical Equipment Particular Requirements for basic safety and essential performance of an anesthetic workstation.

3 Design



4 Validation

Regulations

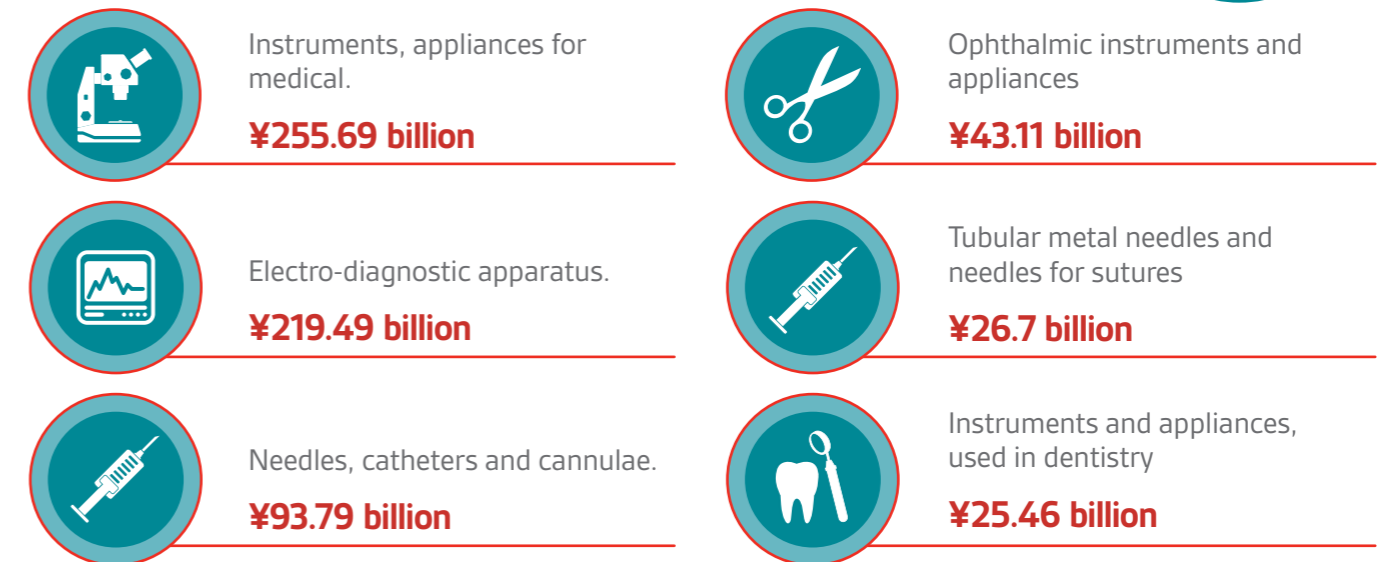
- 1 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EE
- 2 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

5 Launch



Total medical instruments exports
¥681.1B

Medical devices exported by Japan in 2016



Why choose BSOL?

- ✓ A faster, easier way to work with standards.
- ✓ Available 24/7 and revised every single day, BSOL keeps customers/subscribers completely up to date.
- ✓ Using an out of date document could mean product recall or a project failure. BSOL brings peace of mind, because it guarantees everyone has access to the right documents, wherever they are in the world.

BSOL is a comprehensive online standards library giving access to over 97,000 internationally recognized standards including ISO, EN, BS, IEC and ASTM standards in one easily searchable and cost effective solution.

Download standards anywhere in the world

Registered users can find what they are looking for in seconds – searching by number, keyword or phrase, standards can be viewed through the BSOL online viewer or downloaded as a PDF.

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The BSOL database is broken down into 53 standards based modules and 3 book modules. Each module contains all the standards related to a specific subject, and many contain thousands of individual standards.

3 Create a custom collection

Choose from the complete BSOL library to build an easily accessible collection of the standards.

To find out more go to <https://www.bsigroup.com/en-GB/standards/british-standards-online-database/>

Why British standards are best for your business



Formed in 1901, BSI was the first National Standards Body. We create, influence, scrutinize and publish European and international standards. BSI is a founding and permanent member of the ISO and CEN governing councils. We also run 200 international secretariats leading the creation of standards.

British standards are used as the basis for other international standards - ISO 9001, for instance, was originally BSI's BS 5750 standard. BSI provides fast access to the latest standards, as well as documents that will inform future agreements.

We're renowned for stringency. Our prestigious British Kitemark holds great value and the potential to significantly improve your sales and reputation.

A gateway to international trade

British standards help you enter international markets faster. You quickly gain trust from potential customers by showing you're compliant with meticulous British standards.

We publish new European and international standards faster than the 32 other CEN members, so you can see and adapt to them as soon as possible. When a new European or international standard is published, we scrutinize it to assess how you can best apply it as well as highlighting any precautionary measures to take.

Easy to use

Our standards are easy to access and use – wherever you are. You can buy any current British standard online as a download or hard copy. We also provide books, CDs, online tools and training to help you apply them.

When a standard is revised we amend the standard, highlight where the changes are and republish the whole document to save you time and ensure you don't miss anything important.

Even if English isn't your engineers' first language, it's likely to be their second language. Many countries translate standards into English, but the valuable introductory section is still in the native language. Ours are in clear English from start to finish.

For more information go to:

www.bsigroup.com/en-GB/standards/british-standards-online-database/

Training and certification

Why train with BSI?

BSI is one of the world's leading providers of training, information and knowledge on standards.

Expert teams tailor top quality training to organizations of all sizes and for every type of activity – ranging from leading multinationals and innovative start-ups to educational institutions, governments and charities.

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- Determine how standards can help your organization
- Help teams plan and implement
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Certification

For over a century, BSI has led the way in standards. Certifying with BSI sends a clear message to customers, competitors, suppliers, staff and investors that a business is committed to being the best it can be.

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For more information go to:

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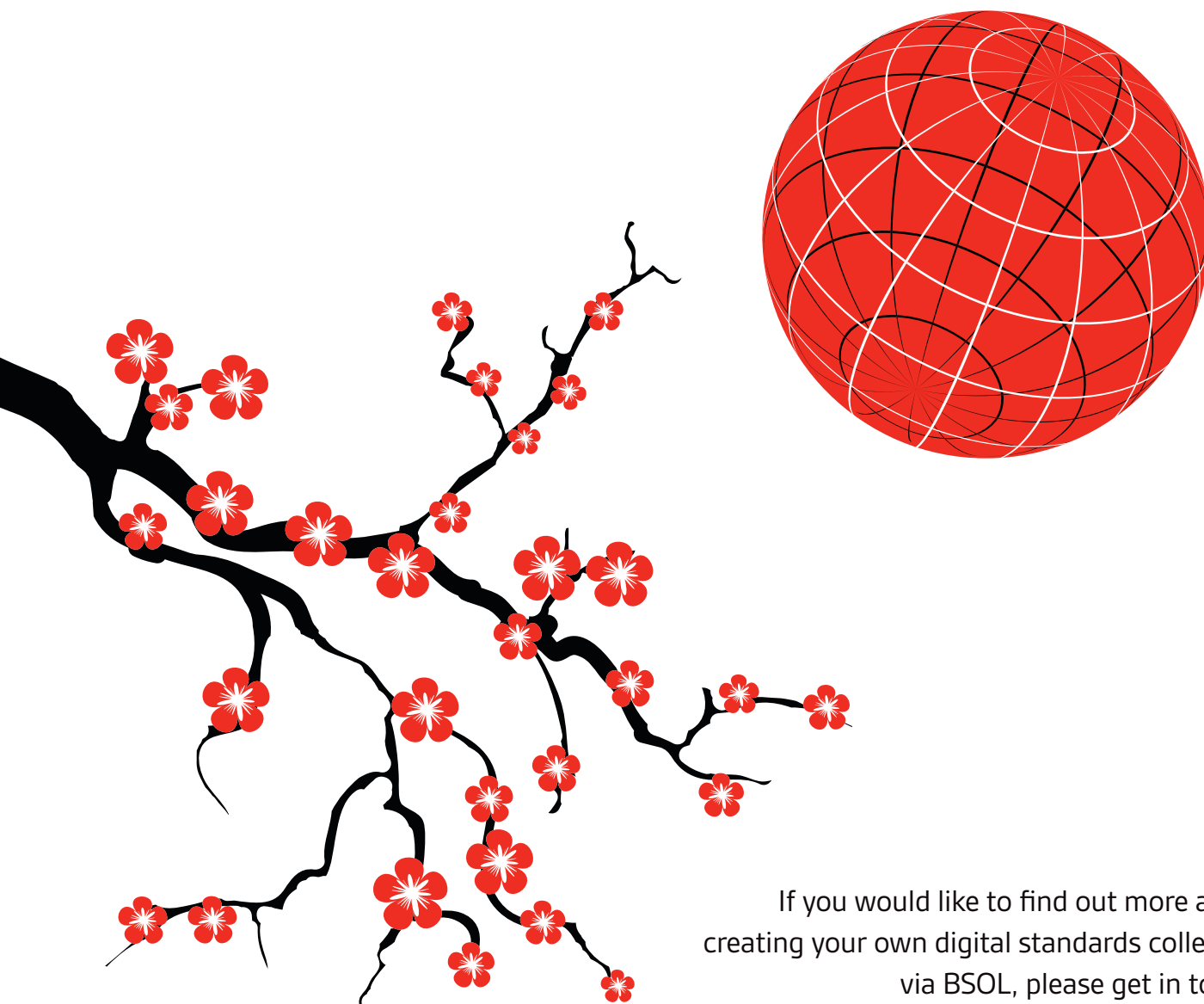
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