

# CUSTOMER CASES



Medical Corporation Tesshokai

## Kameda General Hospital

ISO 9001 Quality Management System

Located in the southern part of the Chiba Prefecture, Kameda General Hospital is a world-class hospital with 917 beds. They have been operating an ISO 9001 Quality Management System (QMS) for over eighteen years since first achieving certification in 2000. BSI interviewed Kameda to explore how their QMS enables them to deliver world-class medical quality and safety.

### “Safety” is the ultimate priority in medical quality

**BSI:** Please tell us about when you first certified to ISO 9001.

**Ms. Hara:** In the year 2000, when we achieved our initial certification under the ISO 9001:1994 version, the service operation of our organization was out of the standard's scope. It was very difficult to implement the standards. Since then ISO 9001 has been updated a number of times to become much more relevant to an organization such as ours. Eighteen years ago there were no auditors who were specialists in the healthcare sector, however since we started working with BSI our auditors are healthcare experts and consequently the audit has become much more effective. During this time, we've seen how the concept of quality has evolved and is now much more embedded in our industry.

**Mr. Antonio:** Sometimes it is very difficult to define exactly what we mean by “quality”. I think the ultimate priority for medical quality needs to be “safety” as we cannot provide quality care without safety. Safety for our patients and safety for our staff. The second priority is “control” as we need to control our operations to provide quality care. We cannot be very good one day and very bad the next. The final priority is “improvement” as I believe that in healthcare there is always room for improvement. Recently “efficiency” became another requirement in our industry as medical facilities

worldwide face financial challenges. I am confident that our QMS can help improve our operational efficiency. It's for this reason that a robust QMS should be seen as a good investment.

**BSI:** What is unique about Kameda's QMS activities?

**Ms. Hara:** We train at least one internal auditor in each division so that they can lead the team in taking actions from audit findings. Currently we have approximately eighty internal auditors. They have been trained by our own staff who graduated from BSI's lead auditor training course<sup>\*1</sup>.

<sup>\*1</sup> BSI deliver five-day CQI and IRCA Certified ISO 9001:2015 Lead Auditor Training course.



Mr. ANTONIO SILVA-PÉREZ, Director, Quality Management Department

## BSI Academy ISO 9001 training

BSI delivers a wide range of ISO 9001 Quality Management System training courses.

Visit: [bsigroup.com/ja-JP/training/](https://bsigroup.com/ja-JP/training/) to start your QMS journey.

## We want to be ready for the next patient, not for the next audit

**Mr. Antonio:** It's often the case that people work very hard to prepare for the audit, but once it's over they forget everything and go back to normal. We call it "Matsuri syndrome" and if we behave in this way we won't improve. Here in Kameda, we have annual internal audits in addition to biannual external audits from BSI<sup>\*2</sup>. This framework allows us always be ready, no matter what. We don't work for the next audit, we work for the next patient.

\*2 BSI offer several audit-term options for certification assessment. Clients can choose from biannual, every 9 months or annual audit.

## ISO 9001 is embedded in our organization

### BSI: What are the benefits of an ISO 9001 QMS?

**Ms. Hara:** I realized that an important part of ISO 9001 is to maintain our documentation. If we want to continually improve we need a way to support our colleagues so they continually improve. By maintaining documented manuals of our processes and procedures our colleagues have a way to check they are working to the required standard. We also use our documented manuals in our internal training and by taking this approach we have raised standards across the hospital. Another example is when we achieved JCI accreditation in 2009<sup>\*3</sup>. We needed to set new rules for the JCI requirements and it was easy for us to apply the new rules into our daily operations because we already had the foundations of the Plan-Do-Check-Act (PDCA) methodology which is integral to ISO 9001. This made me realize how deeply ISO 9001 has been embedded into our organization.

\*3 JCI is an international healthcare accreditor for medical quality and safety. In Japan twenty-six hospitals have been accredited by JCI as of August 2018.



L: Ms. YOKO HARA, Quality Management Division, Head Nurse  
R: Ms. MERUMO TOMITA, Quality Management Division

### BSI: Please tell us about Kameda's future plans.

**Mr. Antonio:** We plan to align our ISO 9001 and JCI certification as the two systems complement each other very well and help us to improve quality. The JCI audit gives us an international perspective by allowing us to benchmark ourselves against other hospitals worldwide. However, their audit does not cover the local regulatory requirements. Therefore for us ISO 9001 is an essential framework for continuous improvement and compliance with Japanese regulatory requirements. For example, we conducted an analysis of all findings from our ISO 9001 audits in the last three years and found out that 24% of them were related to legal and reimbursement fees requirements. This helped us to proactively identify areas for improvement which is one of the aims of ISO 9001.

## Go for ISO 9001 first because it is a critical framework

### BSI: There are several third-party assessment schemes for medical facilities. Do you have any recommendations?

**Mr. Antonio:** We have been asked the same question by other hospitals from the Tesshokai group. They wanted JCI certification first, but we recommended they start with ISO 9001 certification. Our ISO 9001 QMS gives us a management system framework from which we can develop processes and procedures and sustain continuous improvement. If you ask us, we would say ISO 9001 should come first. You should consider JCI certification after embedding an ISO 9001 QMS in your organization.

## The "Right" motive for achieving certification

### BSI: What would you say to organizations who are considering ISO 9001 certification.

**Mr. Antonio:** You need to choose ISO 9001 for the right reasons. It shouldn't just be because you want a certificate on your wall. You should choose ISO 9001 certification because of what it stands for - improving quality, controlling operations and creating efficiency. I would also advise organizations to choose their certification provider carefully. We were able to identify areas of improvement and learn how to comply with regulatory requirements because we chose BSI as our partner. BSI consider their customers' success as their own success.

The story of Kameda's journey with ISO 9001 provides many medical facilities with an insight into 'what quality for healthcare industry is.' BSI is honoured to walk this path with Kameda as their partner and excited to witness their prosperous future not only in Japan but in the global healthcare arena.

BSI Healthcare Japan offer wide range of services including ISO 9001 certification and related training courses specialized for medical facilities.

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