Brand Values of Biomedical Calibration Laboratory (BMCL), an Accredited ISO/IEC 17025 Calibration Laboratory

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Abstract

The growing needs of the healthcare industry means the amount of equipment involved is significantly increased along with demands for biomedical equipment calibration services. Accredited testing and calibration laboratories in Malaysia need to comply with ISO/IEC 17025:2005 requirements and national unified laboratory accreditation scheme, known as Skim Akreditasi Makmal Malaysia (SAMM), award by Department of Standard Malaysia. Biomedical Calibration Laboratory (BMCL) of Politeknik Sultan Salahuddin Abdul Aziz Shah is the first biomedical calibration laboratory accredited with ISO/IEC 17025:2005 in Malaysia. This article discusses the most important functional brand value of BMCL from the perspective of academicians, customers and industry experts in medical field in Malaysia. Data collected through focus group semi-structured discussion. Finding reveal that capacity is the most important brand value followed by reliability, quality, after sales service and capabilities.

Key Words: Biomedical, Calibration laboratory, Brand value, Accredited, Focus group, Credibility.
INTRODUCTION

Politeknik Sultan Salahuddin Abdul Aziz Shah (PSA) established its Centre of Excellence in Technology (COT) in the field of Medical Electronics since 2010, and currently recognized nationally as the Centre for Medical Electronic Technology (CMET) by Ministry of Higher Education, Malaysia. CMET operates training, research, innovation and development activities in line with the Malaysian Education Blueprint (Higher Education) 2015-2025.

CMET also established calibration laboratory for medical equipment analyzer known as Biomedical Calibration Laboratory (BMCL). This laboratory is an accredited MS ISO/IEC 17025:2005 calibration laboratory since 2014 awarded by Department of Standard Malaysia. BMCL is the first accredited calibration laboratory for medical analyzer in Malaysia (Department of Standard Malaysia).

Biomedical instrument calibrated under BMCL’s scope of accreditation are Multiparameter/ Electrocardiograph (ECG) /Patient Simulator, Defibrillator/Pacer Analyzer, Electrosurgical Analyzer, Electrical Safety Analyzer, Syringe Pump (Manually operated type), Infusion Pump Analyzer and Non-invasive Blood Pressure (NIBP) Analyzer. Calibration certificate with ILAC-MRA logo will be issued to customer within the lead time.

Demand for Biomedical Equipment Calibration Services

The growing needs of the healthcare industry with the growing numbers of new private and governmental hospitals indicates the number of instruments involved will increased significantly along with the need to operate and maintain them (ETP Annual Report 2014 (Healthcare)). Most of devices are expensive and of high technology that requires routine preventive maintenance and regular calibration services to ensure proper working condition of equipment and applications.

The global medical devices market size by year 2020 is projected to be USD 435.8 billion (ITA, 2016) where Malaysia is contribute to USD 1.2 billion (AMMI, 2013). Based on the medical devices Entry Point Projects (EPPs) in the Economic Transformation Programed (ETP), Malaysia will develop the medical devices industry more profitable. Moreover, with the regulatory for the licensing and registration of medical devices, products which are not registered with Medical Device Authority (MDA) will not be allowed in the market (AMMI, 2013). These will also generate the demand for medical devices calibration services in the market since proper maintenance and calibration of biomedical analyzer ensure safety, quality and performance of the equipment. Moreover patients and consumer’s safety and health are also protected.

Global Medical devices market will continuously grow driven by other factors such as rise in aging population, innovations in medical devices, changing lifestyles and increasing awareness about the medical conditions and available treatments (Deloitte,
In addition, global medical devices market is growing very fast due to its wide-ranging use in hospitals, research and development centers, educational institutions and clinical laboratories (Global Industry Analysis and Opportunity Assessment 2015–2025).

BMCL as the first accredited calibration laboratory for biomedical equipment analyzer in the country, grants BMCL both opportunities and challenges. In order to be competitive locally and globally, BMCL needs to sustain and raise its brand values as the leading player in biomedical equipment’s calibration services provider in Malaysia.

**LITERATURE REVIEW**

**Brand Values in B2B Market:** Supply and demand in industrial market are represented by organizations rather than individual consumers. In general, industrial market transactions are significantly different from consumer market. Previous research acknowledged that brand value management in industrial markets differ from that in consumer market (Dull & Piotroski, 2011), (Keller, Parameswaran & Jacob, 2011) and (Kotler & Pfoertsch, 2007). Furthermore, transactions in industrial market often involve high risk on the part of the buyer due to significant cost, scale of transactions and complexity of buying decision process. However, the number of customer in B2B market is fewer compared to consumer market (Kotler & Pfoertsch, 2006).

Brand values benefits companies in two ways. It may increase loyalty hence it help build and establish customer-firm relationships. Secondly brand values may generate a price premium for the company (Leischnig & Enke, 2011). Marketing studies can examine brand values from two perspectives either the customer or the firm. Majority research such as Pappu, Quester & Cooksey (2005), Yoo & Donthu (2001) and Christopher (1996), explore brand values in consumer market. Previous researchers which explore brand values in industrial market or B2B market for example are Cretu & Brodie (2007), Biedenbach & Marell (2010) and Mudambi, Doyle & Wong (1997).

Based on Leek & Christodoulides (2012) studies, functional and emotional values are the core brand values of business market. Functional value refers to quality, technology, capacity, infrastructure, after sales service, capabilities, reliabilities, innovation and price. Emotional quality refers to risk reduction, reassurance, trust and credibility.
Figure 1. The B2B Brand Value framework (Leek & Christodoulides, 2012)

Figure 1 shows how brand values and company characteristics can be theorized as leading to relationship value. This framework also considers situational and environmental factors which affect the influence of branding in purchases decision. In this research, functional values emerged as the primary factors considered by buyers in the decision making process. Among the functional brand values, quality was perceived as the most important functional attributes of the brand (Leek & Christodoulides, 2012).

Others researcher agrees with quality significantly influence firm reputation (Cretu & Brodie, 2007). Quality experience of services has direct impact on behavioural intentions (Chen, & Chen, 2010). Others indicate that the quality and trust has a positive impact on the anticipation of future interaction (Crosby, Evans & Cowles, 1990), (Loureiro & González, 2008) and (Chenet et.al, 2010). However Babaeian Jelodar, Yiu & Wilkinson (2016), Keller, (2003), Herbig & Milewicz, (2012) and Erdem & Swait (1998) stress that others attributes such as performance satisfaction, commitment, credibility and teamwork were attributes to brand values.
Quality and accreditation: Basically, companies need to deliver the quality they assured to customers. There are many different definitions of quality across research field. In business, engineering and manufacturing, quality has a pragmatic interpretation as the non-inferiority or superiority of something; it's also defined as fitness for purpose. Quality is a perceptual, conditional, and somewhat subjective attribute and may be understood differently by different field. ISO 8402-1986 standard defines quality as "the totality of features and characteristics of a product or service that bears its ability to satisfy stated or implied needs".

Public sector and business entity have known to the culture of quality which often associated with ISO or international organization for standardization (ISO) according to Kang’a et.al. (2017), Nisipeanu, Chiurtu & Darabont (2017), Nasser, Tijane, & El Bouazzi (2017), Psomas, Pantouvakis & Kafetzopoulos (2013) and Gilvin, Gibbens & Baker (2016). Accreditation of ISO/IEC 17025 is a voluntary, third party assessments where the laboratory's quality management system is thoroughly evaluated on a regular basis to ensure continued technical competence and compliance with ISO/IEC 17025, granted by an accreditation body. International Laboratory Accreditation Cooperation (ILAC) - Mutual Recognition Arrangement (MRA) agreement ensure members recognizes other members' accredited laboratory (International Organization For Standardization).

ISO/IEC 17025 is the global quality standard for testing and calibration laboratories. Laboratory need to implemented and demonstrate quality management and quality assurance under accreditation of ISO/IEC 17025 (Tsimillis & Michael, 2014). The quality standard consist of 15 Management requirements and 10 Technical Requirements. Management requirements are primarily related to the operation and effectiveness of the quality management system within the laboratory. Technical requirements includes factors which determines the correctness and reliability of the tests and calibrations performed in laboratory. According to Al-mijrab, Elgharib & Ahmed (2016), implementing a successful ISO/IEC 17025 increased market share, improved service provision, increased productivity and streamlined procedures. The practical benefits of these technical and management quality improvements are seen on a daily basis in the laboratory. Faster identification and resolution of issues regarding methods, personnel or equipment, improved customer satisfaction and overall increased laboratory business are all the outcome of implementing an effective quality system (Honsa & McIntyre, 2003).

After Sales Services: After sales service refers to numerous processes which make sure customers are pleased with the products and services of the organization. With reference to business dictionary, after sales service are periodic or as-required maintenance or repair of equipment by its manufacturer or supplier, during and after a warranty period. After-sales service includes what organizations do at the point of sale, follow up after the customer has left and effectively dealing with complaints. Providing
good after-sales service shows organization’s mission to build a long-term relationship with their customers earn their loyalty and keep their business. The needs and demands of the customers must be fulfilled for them to blowout a positive word of mouth. After-sales service has a strategic relevance in its potential contribution to company profitability (Saccani, Johansson & Perona, 2007). In line with this, according to Gaiardelli, Saccani & Songini (2006), after-sales cannot be considered simply a set of operative activities but it plays a strategic role as major profit source. However, Bendixen, Bukasa & Abratt (2004) argue that price and delivery were more important in business-to-business market. Other researchers stress that after-sales service quality affect satisfaction, which in turn affects behavioral intentions. Therefore, after-sales services affect the whole offering and consequently, the quality of the relationship with customers (Rigopoulou et.al., 2008).

**Price:** The fundamental rule of pricing tells us that the price charged for a product or service offered must match the value consumers perceive when they acquire that product or service. According to Dodds, Monroe, & Grewal (1991), price had a positive effect perceived quality, but a negative effect on perceived value and willingness to buy. A price premium can be obtained when a company has high brand equity (Gaiardelli, Saccani & Songini, 2006). Customer feels satisfied and is fully committed to pay the product price against the quality delivered (Ghafoor et.al., 2016).

**Reliability:** Reliability in normal understanding is the quality of being trustworthy or of performing consistently well. In calibration services, reliability means the degree to which the result of a measurement, calculation, or specification can be depended on to be accurate. The purpose of calibration is to ensure readings from an instrument are consistent with other measurement, to determine the accuracy of the instrument readings and establish the reliability of the instrument i.e. that it can be trusted (Measurement Standards Laboratory of New Zealand). In business to business market, there is a need for reliability which as service providers, we deliver what we promised for example meet the lead time of calibration service. According to Gunasekaran, Patel, & McGaughey (2004), good supply chain management increase delivery performance through a reduction in lead time. Reliability has a more profound impact on your business (Bendixen, Bukasa & Abratt, 2004) since customer earn trust when business always deliver service in shorter time, lower cost and efficient procedure or system.

**Capabilities:** Capability describes a unique, collective ability that can be applied to achieve a specific outcome. A capability describes the complete set of capabilities an organization requires to execute its business model or fulfill its mission. An easy way to grasp the concept is to think about capabilities as organizational level skills imbedded in people, process, and/or technology. Capability provides a common language for change, create a common link between executive intent and operational activities and provide a foundation for assessment and prioritization (Scott, 2014). Capabilities are complex bundles of skills and knowledge embedded in organizational processes (Krasnikov & Jayachandran, 2008).
The scope of accreditation is transcribed for a specific International System (SI) unit at a particular level of measurement, with its corresponding uncertainty. Accredited calibration laboratories provide a calibration within their scope of capabilities that reports whether or not an electronic instrument meets its specification. The challenge for the customer of calibration services is to choose the laboratory which has the necessary capabilities to provide a statement of conformance to specifications. However, there is value in purchasing from an accredited laboratory. Even if their accredited uncertainties are too large to verify an instrument's performance against its published specification, the fact that they have undergone a rigorous evaluation emphasizes their commitment to quality and technical proficiency of their measurement services (Abell, 2001).

A study on industrial global brand leadership conducted by Beverland, Napoli & Lindgreen, (2007), five capabilities identified are relational support, coordinating network players, leveraging brand architecture, adding value, and quantifying the intangible. Supporting these distinctiveness capacities were five organizational level supportive capabilities: entrepreneurial, reflexive, innovative, brand supportive dominant logic, and executional capabilities. Theoretical and practical issues associated with organizational capabilities have been a major research focus in marketing but little research on industry environment and internal competitive capability development. According to O'Cass & Weerawardena (2010), industry environment and internal competitive capabilities may lead to higher brand performance. Others study the relative impact of firm's functional capabilities and diversification strategy on financial performance (Nath, Nachiappan & Ramanathan, 2010).

**Capacity:** Capacity is the power to hold, receive or accommodate. Capacity is really about “amount” or “volume.” The relevant question related to capacity is “Do we have enough?” and the related question, “How much is needed?” Recent discussions with a large consumer products manufacturer revealed that while they had internal competencies in certain essential technologies, and even some capabilities, their years of buying it on the outside had left their internal capacity very thin. They were constrained less by what they knew and more by their inability to get their skills and know-how to enough of the places where it was needed (Vincent, 2008).

Consequently a definition of capacity as the ability to work off an existing demand makes for a more dynamic measure. Once capacity is expressed in these terms it becomes apparent that it is related to an output quantity from the service delivery system. Consequently capacity has a time dimension and is influenced by all input elements to the system. So a variable mix of product and service packages will give rise to variations in the input and demand placed on the service delivery system. This variation will, in turn, mean the capacity of the system will alter as the balance of the resources required alters with changes in the product produced (Armistead & Clark 1991).
METHODOLOGY

This study used focus group approach. Focus group is a form of qualitative research that is used often in social science research (Silverman, 2016) and (Stewart & Shamdasani, 2014). Before the focus group meeting, a semi-structured question was prepared as guidance during focus group discussion. The researcher adopted the B2B brand values framework from Leek & Christodoulides (2012). A semi-structured discussion format with either an individual or group can take between 30 minutes and several hours to complete (Cheong, Bhatnagar & Graves, 2007). In this study, the focus group discussions took 2 hours to complete.

The participants of the focus group are selected based on their position and relevance to the topic under study. All participants were informed by formal letter through email about the purpose of the study and time range allocation. The arrangement of focus group meeting took place once participant volunteered to participate. Among 12 selected respondents, 9 respondents agreed to participate. They are four academicians, three industry expert and two customers from biomedical field. Some were directors in their field and willing to share. According to (Stewart & Shamdasani, 2014), a focus group discussion is a group of individuals around 10 people is brought together in a room to engage in a guided discussion of some topics.

During this focus group discussion, a moderator was appointed to ensure discussion was in line with research objectives and data was recorded using video recorder, tape recorder and manually record by appointed staff. Subsequently all data were transcribed and compared. The final transcript prepared and analysed using content analysis.

The following section presents the findings regarding accreditation and brand values from the focus group discussion.

RESULTS AND DISCUSSION

Table 1 shows academician’s, customers and industry expert’s responses about brand values for BMCL. There were five functional brand values identified from the focus group discussion.

<table>
<thead>
<tr>
<th>Brand Values</th>
<th>Frequency</th>
<th>Sample Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capacity</td>
<td>33</td>
<td>“How to lessen the load, with extra load to promote...with extra work to do marketing and to deliver very good service” - Respondent 8</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“as centre of technology.. industry will park their personel as reference point and give”</td>
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<tr>
<td>Brand Values</td>
<td>Frequency</td>
<td>Sample Responses</td>
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<tr>
<td></td>
<td></td>
<td>consultation job”</td>
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<tr>
<td></td>
<td></td>
<td>- Respondent 3</td>
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<tr>
<td></td>
<td></td>
<td>“You need more technician than calibration engineer if you insist to run this accredited laboratory like a business entity” - Respondent 5</td>
</tr>
<tr>
<td>Reliability</td>
<td>17</td>
<td>“Looking at the accreditation certificate, we respect”</td>
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<tr>
<td></td>
<td></td>
<td>- Respondent 6</td>
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<tr>
<td></td>
<td></td>
<td>“I can see your staff commitment, very high”</td>
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<td></td>
<td></td>
<td>- Respondent 4</td>
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<tr>
<td></td>
<td></td>
<td>“if you sent overseas, equipment may damaged even if properly pack” - Respondent 5</td>
</tr>
<tr>
<td>Quality</td>
<td>11</td>
<td>“Accredited 17025, once you awarded you strong” - Respondent 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“You are recognized overseas with the ILAC-MRA mark” – Respondent 7</td>
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<tr>
<td></td>
<td></td>
<td>“Since you are pioneer, industry will remember you”</td>
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<td></td>
<td></td>
<td>– Respondent 5</td>
</tr>
<tr>
<td>After Sales Services</td>
<td>5</td>
<td>“insert the repair element in your services because industry like company that supported with maintenance service..”</td>
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<tr>
<td></td>
<td></td>
<td>- Respondent 7</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“When come to calibration, they will return to us back..either we sent back to manufacture or we have to correct.” - Respondent 4</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“customers they want one stop centre.”- Respondent 5</td>
</tr>
<tr>
<td>Capabilities</td>
<td>4</td>
<td>Your strength... The turnaround... The lead time is faster. If sent here..Within a week get back... - Respondent 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“The turnaround time is good” - Respondent 5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“If you don’t have the facilities, outsource.” - Respondent 9</td>
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</tbody>
</table>
Even many researchers agree that quality or accreditation significantly benefits company’s brand value, from research finding reveal that the most important brand value for BMCL was capacity with highest frequency (33), followed by reliability (17), quality (11), after sales service (5) and capabilities (4). Capacity are the most crucial brand value to achieve but BMCL can improve the laboratory capacity by strategically allocate manpower across department. As mention by respondent 5, BMCL need more technicians than calibration engineer.

BMCL have the capabilities to meet the lead time and fulfill customer satisfaction. According to Peter et.al., (2010), laboratory capacity can be improved by increased resources. Laboratories that achieve accreditation are recognized for superior test reliability, operational performance, quality management, and competence. Furthermore, accreditation promotes trust in laboratories and confidence among authorities, health care providers, and patients that laboratories and the results they produce are accurate and reliable. Successful laboratories can rationalize the resources they need to maintain quality for example number of staff and organization structure.

Functional brand value is positively related with customer satisfaction (Candi & Kahn, 2016). However emotional relationship help industrial firm differentiate themselves effectively in business market (Coleman, Chernatony & Christodoulides, 2015). Findings also identified emotional brand values with concern to BMCL such as trust. Trust is confidence or belief in the competence and integrity of the other party. Reliable and trustful in B2B relationship help organization minimize perceived risk (Bendixen, Bukasa & Abratt, 2004). Like most transactions, it is important to establish a level of trust and evaluate the reputation of the calibration provider (Abell, 2001). Respondent 5 and 9 mentioned:

“ You need industry linkages through Memorandum of Understanding (MOU) or Memorandum of Agreement (MOA) in order to gain trust in this industry”
- Respondent 5.

“BMCL should strategically carry outreach programmes in order to promote BMCL locally and globally”
- Respondent 9.

Outreach programs are the facet of marketing in which a company representative aggressively seeks out potential customer by meeting with local businesses or the public, speaking at local events, or getting involved with the local chamber of commerce. Thus to dramatically informed potential customer either locally or globally, awareness programs about BMCL should be carried out. Outreach can range at the least from simple exhibits, tours, and curatorial, talks to more sophisticated activity, including multilevel conferences, traveling exhibits, workshops and courses based activities (Freivogel, 1978). Others outreach programs such as written materials including news releases, newsletter articles, emails, business cards, and flyers.
A study on collaboration and industry linkages (Santoro, 2000) stresses that industry–university alliances can be instrumental in facilitating the industrial firm's advancement of both knowledge and new technologies. Collaboration in the Business-to-Business (B2B) ensuring reliability of workflows underlying inter-organizational business processes (Demirkan et. al., 2012). Trust is shown to have a positive influence in building behaviors (social interaction, open communications, customer orientation) and service outcomes (technical, functional and economic quality) on trust formation (Doney, Barry, & Abratt, 2007). Thus to gain trust from other parties especially potential customers from overseas, BMCL need to execute outreach programs and initiate more collaboration among players in biomedical industry.

CONCLUSION

Findings of the study demonstrated that functional brand values such as capacity, quality, capabilities, reliability and price were found to be of importance to BMCL. Accreditation of ISO/IEC significantly benefits BMCL in terms of quality management, quality assurance and trust. In order to sustain the accreditation, BMCL as a public sector organization, should be given appropriate level of autonomy in making decision to be able to operate as legal business entity and properly strengthen the organization structure. Laboratory accreditation is a challenging process and the commitment of top management and staff involvement will support the success of its implementation.

The study however did not cover environmental factors and situational factors which contribute to the brand values. Further research considering these factors could enhance the brand values of an accredited laboratory.

REFERENCES

2016 Global health care outlook, Deloitte.


ETP Annual Report 2014 (Healthcare)


Gobal Scenario and Medical Devices Industry in Malaysia (2013), Association of Malaysian Medical Industries (AMMI).


International Organization For Standardization (www.iso.org)
International Trade Administration (ITA) Medical Devices Top Markets Statistics (2016)
Department of Commerce, United States of America


Website Standard Malaysia Department : www.standardsmalaysia.gov.my