

Guidelines on Selection of a Consultant

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AGENDA

- Introduction.
- Definition - Consultant vs Contractor.
- Identify Your Scope / Services Required.
- Selection Criteria.

Introduction

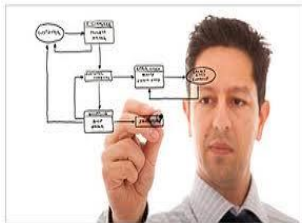
- Most companies pursuing certification (i.e. ISO, GDPMD, etc.) frequently begin the process by hiring consultants.
- Although certification bodies (i.e. conformity bodies /registrars) must meet certain accreditation requirements, consultants do not have overseeing bodies to qualify their competence.



Consultant Vs Contractor



Consultant



- A consultant, on the other hand, acts as an adviser who help lay out a strategic project plan. Knowledgeable and capable consultants have worked with several companies and have learned first-hand some of the typical pitfalls companies face when pursuing certification.

Identify Your Scope / Service Required

Type	Scope
1. Type of Certification	GDPMD, ISO 9001, ISO 13485



Medical Device Authority
Ministry of Health Malaysia



Scope & Application

2 (1): This document, “Good Distribution Practice for Medical Devices (GDPMD)”, is made pursuant to Appendix 4 of Schedule 3 of the Medical Device Regulation 2012 and is applicable to all parties involved in the supply-chain of medical device covering authorized representatives of foreign manufacturers, importers or distributors of medical devices in Malaysia. The scope of this document does not cover manufacturers and retailers of medical devices.

Note: (i) GDPMD specifies the requirements for a quality management system to be established, implemented and maintained by an establishment in carrying out activities in medical device supply-chain to comply with Malaysian medical device regulatory requirements as stipulated in Medical Device Act 2012 (Act 737).

Note: (ii) The certification to GDPMD is to be conducted by a registered conformity assessment body

Identify Your Scope / Service Required

Type	Scope
1. Type of Process	<p>The objective of GDPMD is to ensure the quality, safety and performance of medical devices during all aspects of the medical device supply-chain, which includes, but not limited to:</p> <ul style="list-style-type: none"> ✓ <u>product sourcing & procurement;</u> ✓ <u>transportation & delivery;</u> ✓ <u>storage;</u> ✓ <u>installation, commissioning, service & maintenance,</u> ✓ <u>calibration & after sales service;</u> ✓ <u>tracking, documentation & record-keeping practices.</u>

Identify Your Scope / Service Required

Type	Scope
1. Type of Business Model	Main Sales Office, & Branches (Regional) Sub-Distributor / Sub-Wholesaler / Dealer Distribution Center (Warehouse) & Depot Technical Support / Repair Centre Repackaging

Note: (i) If any requirement in GDPMD is not applicable due to the nature and the range of the medical device and supply chain activities, a justification has to be provided for exclusion from fulfillment of that particular requirement.

Note: (ii) Establishment shall ensure control over outsourced processes - does not absolve the establishment of the responsibility of conformity to GDPMD, statutory and regulatory requirements.

Note: (iii) Ensure, for outsourced activities, the supplier of outsourced activities is audited as part of the establishment's system unless the supplier is already certified to GDPMD covering the scope of the outsourced activities

Identify Your Scope / Service Required

Type	Scope
<p>1. Type of Documentation</p>	<p>GDPMD Point 6 : Documentation</p> <p>(1) The establishment shall establish and maintain a <u>Regulatory Compliance Manual</u> which shall include the following information—</p> <p>(v) documents needed by the establishment to ensure the effective planning, operation and control of processes for compliance; and</p> <p>(vi) records required by the GDPMD regulatory compliance system;</p>

Identify Your Scope / Service Required

Type	Scope
<p>1. Type of Documentation</p>	<p>GDPMD Point 7 : Document Control (ii) establish a documented procedure for the control of documents.</p> <p>7 (2) All documents shall be prepared, approved, signed and dated by an authorized person.</p> <p>7 (3) The establishment shall give appropriate authorization on any change on authorized person permitted to carry out the task in sub-clause (2)</p> <p>7 (5) The establishment shall - (iii) retain the records for a period of time</p>

Identify Your Scope / Service Required

Example of a simple and basic establishment :

- Scope of Establishment: *Importer & Distributor . Employees: ~10*
- Type of Business Model: *One main head office with a medium sized store.*
- Type of Documentation: *No Quality Manual/Policy, some basic SOPs on procurement, pick/pack, trade returns and product recall. Records retention – invoice for income tax purposes.*
- Type of Certification: *None*
- Note: *Keen to comply with GDP but Busy, Inadequate internal expertise and time constraint.*

Propose service required:

- *To build and establish : GDP Regulatory Compliance Manual (Quality Management System)*
- *To build and implement: Process SOPs/ WIs/Checklist Templates*
- *To train and upgrade internal expertise: QMS Awareness & Compliance Mind-Set.*
- *To secure GDP Certification and apply for Establishment License.*

Selection Criteria

Once the decision is made to use a consultant/contractor, and the proposed services are defined, the following criteria would be considered best practices:

- *Credentials*
- *Experience*
- *Availability*
- *Attribute / Inspiration*

Selection Criteria	Details
1. Credentials	<ul style="list-style-type: none"> • Brand Recognition • Number of Employees (team of qualified/experience auditors/trainers) • Clients portfolio and/or references (at least two or three).

Selection Criteria

Selection Criteria	Details
2. Experience	<ul style="list-style-type: none">• Academic credentials and practical experience.• Have they worked in different business categories ?• Have they worked for small and large businesses ?• Success Stories.

Selection Criteria	Details
3. Availability	<ul style="list-style-type: none">• Availability when work need to be done.• Responsiveness to your needs. Does the consultant promptly respond to your email messages and return telephone calls?• Focus on result.• Training needs.

Selection Criteria

Selection Criteria	Details
4. Attribute / Inspiration	<ul style="list-style-type: none"><li data-bbox="788 329 1837 601">• The communication skills of your consultant are extremely important. You want someone who is easily understood and relates well with you and all levels of the organization.<li data-bbox="788 672 1837 1058">• The consultant should be open-minded and flexible. Being perceptive and practical are also valuable attributes. You want a consultant that is able to adapt to different circumstances, since your organization may have unique traits

Summary

- Your primary consideration when hiring a consultant should be value creation.
- Establishing what you want from your project and what you need from a consultant to help you reach your goals should be the basis of your decision.
- Thinking through these issues will help you establish a mutually satisfying and productive relationship with your consultant.

THANK YOU